NAP5

5th National Audit Project of
The Royal College of Anaesthetists and the
Association of Anaesthetists of Great Britain and Ireland

Accidental Awareness during General Anaesthesia in the United Kingdom and Ireland

Report and findings

September 2014

Editors

Professor Jaideep J Pandit

Professor Tim M Cook

The Royal College of Anaesthetists

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- Pandit JJ, Andrade J, Bogod DG, et al. The 5th National Audit Project (NAP5) on accidental awareness during general anaesthesia: protocol, methods and analysis of data. *Anaesthesia* 2014;**69**: doi: 10.1111/anae.12811.
- Pandit JJ, Andrade J, Bogod DG, et al. The 5th National Audit Project (NAP5) on accidental awareness during general anaesthesia: protocol, methods and analysis of data. *British Journal of Anaesthesia* 2014; doi: aeu312.
- Pandit JJ, Andrade J, Bogod DG, et al. The 5th National Audit Project (NAP5) on accidental awareness during general anaesthesia: summary of main findings and risk factors. *Anaesthesia* 2014;**69**: doi: 10.1111/anae.12826.
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- Jonker WR, Hanumanthiah D, Ryan T, et al. Who operates when, where and on whom? A survey of anaesthetic-surgical activity in Ireland as denominator of NAP5. *Anaesthesia* 2014;**69**:961–8. doi: 10.1111/anae.12763 [In Press].

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- Sury MRJ, Palmer JHMacG, Cook TM, and Pandit JJ. The state of UK anaesthesia: a survey of National Health Service activity in 2013. *British Journal of Anaesthesia* 2014; doi: 10.1093/bja/aeu292.

Contents

List of standard abbreviations

AAGA	accidental awareness during general anaesthesia
AAGBI	Association of Anaesthetists of Great Britain and Ireland
AIMS	Australian Incident Monitoring System
ANZCA	Australian and New Zealand College of Anaesthetists
AoMRC	Association of Medical Royal Colleges
ASA	American Society of Anesthesiologists' physical status classification system (1-5)
BIS	Bispectral Index
BMI	Body Mass Index
CABG	coronary artery bypass graft
CAI	College of Anaesthetists of Ireland
CO_2	carbon dioxide
CPB	cardio-pulmonary bypass
CS	Caesarean section
CT1,2,3	Core Trainee (anaesthetist or other doctor)
DAS	Difficult Airway Society
DOA	Depth of anaesthesia (monitor)
DoH	Department of Health
ECG	electrocardiogram
ED	Emergency department
EEG	electroencephalogram
ET	endotracheal
$ETCO_2$, ETO_2, etc	end-tidal carbon dioxide, oxygen, etc
fMRI	functional magnetic resonance imaging
GMC	General Medical Council
HF	Human factors
ICU	Intensive care unit
IFT	isolated forearm technique
ILMA	intubating laryngeal mask airway
ITU	Intensive therapy unit
IV	intravenous
LC	Local Co-ordinator
LMA	laryngeal mask airway
LSCS	Lower segment Caesarean section

MAC	minimum alveolar concentration
MRI	magnetic resonance imaging
NAP	National Audit Project
NAP5	5th National Audit Project (Accidental Awareness during General Anaesthesia)
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NICE	National Institute for Health and Care Excellence
NMB	neuromuscular blocking drug
O_2	oxygen
ODA	Operating Department Assistant
ODP	Operating Department Practitioner
PCO_2, PO_2	partial pressure of carbon dioxide, oxygen,
pEEG	processed EEG
PTSD	post-traumatic stress disorder
RCoA	Royal College of Anaesthetists
RCT	randomised controlled trial
RSI	rapid sequence induction
SAD	supraglottic airway device
SALG	Safe Anaesthesia Liaison Group
SAS	Staff or Associate Specialist grade of doctor
SD	standard deviation
SEM	standard error of mean
ST3, 4, etc	Specialist Trainee (anaesthetist or other doctor)
SUI	Serious Untoward Investigation
TCI	target controlled infusion (of anaesthetic, usually propofol and/or remifentanil)
TIVA	total intravenous anaesthesia
ToF	train of four
WHO	World Health Organisation
UK	United Kingdom

Notes on publications and referencing of this report

The preferred style of referencing material in this Report is to refer to the specific papers that have arisen from it, namely:

- Pandit JJ, Cook TM, Jonker WR, O'Sullivan E. A national survey of anaesthetists (NAP5 Baseline) to estimate an annual incidence of accidental awareness during general anaesthesia in the UK. *Anaesthesia* 2013;**68**:343–53.
- Pandit JJ, Cook TM, Jonker WR, O'Sullivan E. A national survey of anaesthetists (NAP5 Baseline) to estimate an annual incidence of accidental awareness during general anaesthesia in the UK. *British Journal of Anaesthesia* 2013;**110**:501-509.
- Pandit JJ, Andrade J, Bogod DG, et al. The 5th National Audit Project (NAP5) on accidental awareness during general anaesthesia: protocol, methods and analysis of data. *Anaesthesia* 2014;**69**: doi: 10.1111/anae.12811.
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- Pandit JJ, Andrade J, Bogod DG, et al. The 5th National Audit Project (NAP5) on accidental awareness during general anaesthesia: summary of main findings and risk factors. *Anaesthesia* 2014;**69**: doi: 10.1111/anae.12826.
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- Jonker WR, Hanumanthiah D, O'Sullivan EP, et al. A national survey (NAP5-Ireland baseline) to estimate an annual incidence of accidental awareness during general anaesthesia in Ireland. *Anaesthesia* 2014;**69**:969-76. doi: 10.1111/anae.12776 [In Press].
- Jonker WR, Hanumanthiah D, Ryan T, et al. Who operates when, where and on whom? A survey of anaesthetic-surgical activity in Ireland as denominator of NAP5. *Anaesthesia* 2014;**69**:961-8. doi: 10.1111/anae.12763 [In Press].

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- Sury MRJ, Palmer JHMacG, Cook TM, and Pandit JJ. The state of UK anaesthesia: a survey of National Health Service activity in 2013. *British Journal of Anaesthesia* 2014; 10.1093/bja/aeu292.

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Throughout this Report, the NAP5 Activity Survey is referred to, but not always listed in the reference lists. The reference for this is: Sury MRJ, Palmer JHMacG, Cook TM, and Pandit JJ. The state of UK anaesthesia: a survey of National Health Service activity in 2013. *British Journal of Anaesthesia* 2014; doi: 10.1093/bja/aeu292.

CHAPTER
1

Foreword

J-P van Besouw
President, RCoA

William Harrop-Griffiths
President, AAGBI

Ellen P O'Sullivan
President, CAI

We are pleased to be able to present this report of the 5th National Audit Project (NAP5) on Accidental Awareness During General Anaesthesia, jointly funded by the Royal College of Anaesthetists (RCoA) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI).

A key recommendation of the Francis Inquiry and the Berwick report has been a requirement for increased candour from individuals and organisations when things go wrong. It is therefore heartening to see the specialty undertake a study that acknowledges the seriousness of accidental awareness during general anaesthesia, providing important new data on its frequency, seeking to understand why it occurs, and informing the profession to help further decrease its occurrence.

Accidental awareness during general anaesthesia (AAGA) is an intra-operative complication greatly feared by patients, and is a concern frequently raised during pre-operative visits. Although AAGA is not a common event, its impact on patients is such that it must not be ignored or trivialised. It is therefore important that we understand the factors that make its occurrence more likely, so that our practice can be improved and its incidence minimised. As with previous National Audit Projects, while the quantitative data derived from the project are important and may create headlines, it is arguably the qualitative information – that derived from numerous individual patient stories and the themes that emerge from them – that can teach us most.

NAP5 is perhaps the most 'patient facing' of these projects to date, and studies the largest number of individual patient stories: more than 400. The methodology of NAP5 offers a standardised approach to the investigation and analysis of cases of AAGA, and will continue to inform clinical and medicolegal practice in the future. It is our hope that NAP5, with support from anaesthetic and patient safety organisations, will result in the incorporation of new questions into surgical checklists to help prevent AAGA, and the adoption of standardised pathways for psychological support should AAGA occur.

We were delighted to have the endorsement of all four Chief Medical Officers of the UK at the start of the project, and we are pleased to welcome the expansion of a National Audit Project into Ireland for the first time, making this a truly international endeavour.

This study is the culmination of almost four years' work by a large number of multidisciplinary contributors, including specialist anaesthetic societies, psychologists, patients and medicolegal experts. A nationwide network of local co-ordinators across all UK NHS and Irish public hospitals have worked tirelessly to ensure that all new cases of AAGA were promptly reported, and we have achieved 100% participation across five countries, a truly remarkable achievement.

Our special thanks go to the NAP5 Clinical Lead, Professor Jaideep Pandit, and to Professor Tim Cook, RCoA NAP Advisor. Their leadership in the development and delivery of this project has been exemplary.

CHAPTER 2

A patient's story of AAGA

Sandra

At the age of twelve, I thought I was about to die.

I was wheeled into a fairly routine orthodontic operation, not expecting anything untoward to happen. I was quite a grown up twelve-year-old, the size of a small adult, but I was aware the medical professionals were treating me like a much younger child, so played along with them, for the sake of an easy life. I counted down from ten, as you do, and presumably fell asleep.

Suddenly, I was aware something had gone very wrong. I could hear what was going on around me, and I realised with horror that I had woken up in the middle of the operation, but couldn't move a muscle. I heard the banal chatter of the surgeons, and I was aware of many people in the room bustling about, doing their everyday clinical jobs and minding their own business, with absolutely no idea of the cataclysmic event that was unfolding from my point of view. While they fiddled, I lay there, frantically trying to decide whether I was about to die, and what options were open to me.

I rapidly audited each part of my body, to see if anything worked at all. I had seen films about this sort of thing, I thought to myself. People are paralysed for their whole lives and sobbing relatives congregate by the bedside for years at a time until the damaged person finally manages to blink. Good! I said to myself. Let's try the eyes first. No result. Let's try the toes, I thought. No result. Oh dear, I thought. This is a very serious situation. Systematically I went through each body part again, muscle by muscle, nerve by nerve, sinew by sinew, willing something, anything to react. At first, it felt as though nothing would ever work again, as though the anaesthetist had removed everything from me apart from my soul. On the next full body audit, suddenly my arm was free, with a mind of its own, and I successfully punched the surgeon in the face to get his attention. "Oh dear!" he said, in a rather flat, uninterested voice, "We have a fighter." Then the pace of work sped up and finally I was taken to recovery. Once I had gathered my wits a little, and worked out how to speak with a huge plate in my mouth; I said, "I woke up in there! I woke up during the operation!"

This would be something I would continue to say for the rest of my time in hospital, and each time I said it, I was told this couldn't be true, that it was my imagination, that I was mistaken. When I related surgically-related conversations to the theatre team, they went a little white, but continued to deny what had happened. They denied it to my mother, and in doing so, left me alone to deal with the decades-long fallout of my putative near death experience.

There was no internet or Childline then, so when something dramatic and terrifying happened, children were more or less on their own. Slowly, over the years, I tried to make sense of events. Each time I needed an operation subsequently, I would tell the anaesthetists of the chain of events, and they would reveal a little more of what might have gone wrong, and promise profusely that I would be safe in their hands. This helped on an intellectual level, and for that I am very grateful. However, they could not help with the recurrent nightmare, where a 'Dr Who' style monster leapt on me and paralysed me. That went on for fifteen years or so, until I suddenly made the connection with feeling paralysed during the operation. After that I was freed of the nightmare and finally liberated from the more stressful aspects of the event.

What of the longer term consequences? I went on to develop a research interest in professional standards and accreditation, and I now work with doctors, teachers and lawyers to ensure that each of their fields aspires to the highest possible ideals with regard to their professional practice. This was one positive outcome, as was the realisation that I was more resilient than most people and had proved that to myself at a very early age. However I am left feeling that all those years ago, it would not have been difficult for the surgical team to show a human face and apologise. That won't happen now, but this NAP5 Report, and the reflective practice that will be engendered by it, goes a long way to making up for any lack of an apology at the time.

CHAPTER
3

Introduction

Jaideep J Pandit

Tim M Cook

The nature of human consciousness is one of the fundamental questions of biology. Anaesthetists have long had the means to suspend, or temporarily abolish consciousness and restore it safely. But the means have been empirical, discovered by chance. Hence when those means fail, as they do in the phenomenon of 'accidental awareness during general anaesthesia' (AAGA), the cause of that failure is not readily understood, as there is no generalised 'theory of anaesthesia' underpinning understanding of the whole process. This is perhaps why historically, when faced with a report of AAGA, there was a tendency to disbelieve the patient's account.

Nevertheless the process of general anaesthesia *can and does fail* and AAGA *can and does arise*, as is compellingly demonstrated in the words of Sandra in Chapter 2 of this NAP5 Report. Its long term consequences can be most dreadful, as later pages of this Report describe. The staff response of disbelief exacerbates the adverse impact as experienced by Sandra and still seen in some NAP5 vignettes. A form of 'collective denial' is perhaps reflected in our finding in the NAP5 Baseline Survey (Chapter 26) that only 12 of ~360 hospitals in the UK have any specific guidelines to manage AAGA if it arises.

All this must change, and – as Sandra has hoped in Chapter 2 – part of the purpose of this NAP5 Report is to present an apology on behalf of the profession to all those patients who have hitherto been let down by a collective failure to understand or accept the condition of AAGA. We hope and anticipate that this is historic, and one of the key elements of this Report is to disseminate knowledge of what we have now learned, in a systematic way, about patient experiences, and offer a more standardised support pathway for those who report AAGA.

In addition to constructive patient support, the NAP5 project has interrogated several hundred reports of AAGA, enabling us to gain a clearer understanding of how it might arise. From first principles, AAGA could arise because of either:

(a) Failure to deliver sufficient anaesthetic agent to the body.

(b) Individual patient resistance to an otherwise sufficient dose of anaesthetic agent.

Discussion of the first group of causes forms the bulk of this Report. This encompasses 'technical failures' during the conduct of anaesthesia, including interruptions in supply of agent, drug errors, low-dosing regimens, etc. In turn, these have more fundamental causes in 'human factors' issues, including pressures of poorly organised or overbooked surgical lists, distractions, and issues of education and training. It is perhaps disappointing to discover that, even in the 21st century, at least 75% and possibly 90% of all the AAGA cases we examined were probably preventable by the application of existing knowledge and experience. Taking our cue from the 'timeout' of the WHO Safer Surgery checklist (now standard in all UK and Irish hospitals), we propose adoption of a very simple anaesthesia-specific checklist as an *aide memoire* that we anticipate will help prevent a significant proportion of AAGA cases, namely those arising from a natural 'gap' in delivery of anaesthesia during transfer or movement of a patient (notably from anaesthetic room to theatre).

It is apparent that reminders are needed to reinforce good practice in some areas. Chief amongst these is the proper management and monitoring of neuromuscular

It is apparent that reminders are needed to reinforce good practice in some areas. Chief amongst these is the proper management and monitoring of neuromuscular blockade. Monitoring is not really required to always ensure profound muscle relaxation for surgery, but is essential to ensure complete recovery from blockade *before* the return of consciousness. We also emphasise the need to continue anaesthesia during attempts to manage an unexpectedly difficult airway, and we offer the reminder that an 'awake' tracheal extubation *primarily* requires the patient to be completely reversed from neuromuscular blockade, and only *secondarily* requires the patient to be 'awake'. These are not new suggestions for relatively common scenarios – for example, they were in part the subject of NAP4 – but reinforcement of good practice seems necessary.

The second group of potential causes of AAGA – inherent resistance to anaesthetic – is intriguing and should be considered seriously. Although some resistance may be temporary 'physiological' resistance to general anaesthesia (e.g. due to anxiety) or 'pharmacological (e.g. due to concomitant drugs that increase anaesthetic requirement or metabolism) there is also the intriguing possibility of intrinsic, perhaps genetic, resistance.

Historically, it was proposed that anaesthetic agents, unlike other drugs acting on specific protein channel receptors, exerted their action by rather non-specific bulk physico-chemical effects on the lipid in cell membranes. It has also been generally assumed that 'general anaesthesia' is a binary phenomenon (i.e. awake/anaesthetised), and that therefore, the mechanism of anaesthetic drugs is like 'flicking a switch' between the two brain states. The first concept perhaps constrained anaesthetists into developing unique models for how anaesthetic drugs work, set apart from the rest of pharmacology. The second perhaps promoted the lazy assumption that all that was required to understand 'anaesthesia' (and, by implication, be a complete anaesthetist), was to learn how to 'flick the switch', rather than 'understand the machine'. Over time we are moving away from both these concepts and NAP5 may contribute.

NAP5 is, we believe, the largest ever prospective study on the topic of AAGA in the world. Some who read this Report may focus particularly on quoted incidences of patient reports of AAGA and the discrepancy between these and incidences derived from Brice questionnaires. While this numerical analysis (and the inevitable discussion) is important, we hope that readers will also see beyond this and explore the comparative data and qualitative learning within the report. More perhaps than any previous National Audit Project, NAP5 is a patient-focused project, dealing as it does entirely with patient reports of AAGA. These are our starting point and our currency throughout the project. We hope the numerous patient stories – captured both by data and in vignettes – will provide a focus on this important topic for anaesthetists, patients and administrators.

It is our intention that the NAP5 Report leads to changes in anaesthetic practice, that it stimulates research and that it generates discussion. The NAP5 report therefore contains important and pragmatic practice recommendations. However, readers will also sense an encouragement to challenge many established 'tenets of anaesthesia' especially in the research implications we have made. For instance, what is the place of thiopental in modern practice? What are the non-essential components of a rapid-sequence induction? Anaesthesia *might* work primarily through binding to protein channel receptors, rather than on lipid membranes (proteins, susceptible to influence by genetic factors). Anaesthesia *might* be a group of diverse brain states, all compatible with the patient undergoing surgery, each created by different drug combinations. It is worth, even briefly, considering these notions, if only as drivers for research. Other research implications are provided to encourage discussion and debate and to illustrate the huge gaps in knowledge that remain. We hope others will be inspired to formulate research proposals that we have not considered. We especially hope that colleagues will take forward our proposals in their own work: they are not our exclusive domain.

Together with 64 explicit recommendations for clinical practice (directed at national organisations, healthcare institutions and individual anaesthetists), we hope this NAP5 Report will greatly reduce the incidence of AAGA and also, importantly, provide processes and strategies to help mitigate any adverse consequences for patients who experience it. We believe the increased knowledge about AAGA derived from NAP5 will be of benefit to patients and anaesthestists when addressing the topic as part of the consent process.

Finally, we thank all those who have contributed to this report: most especially the patients who reported their experiences and the individual anaesthetists and Local Co-ordinators who brought those stories, sometimes vividly, to our attention. We commend this Report to the specialty.

CHAPTER
4

NAP5 Executive Summary and Recommendations

Jaideep J Pandit

Tim M Cook

INTRODUCTION

3.1 In a 2007 *British Medical Journal* poll, general anaesthesia was voted the third greatest advance in medicine (after sanitation and antibiotics; see www.bmj.com/content/334/7585/111.2. Before the discovery of general anaesthesia, submitting to surgery was greatly feared, so was often avoided; indeed much surgery was technically impossible. General anaesthesia changed that, facilitating unconsciousness during peak surgical stimulus, and comprehensively and safely, advancing surgery.

3.2 This NAP5 Report focuses on failure of general anaesthesia – that is when general anaesthesia is intended yet the patient remains conscious. Accidental awareness during general anaesthesia (AAGA) ranks high among concerns of both patients and anaesthetists. It is one of the most common concerns for patients to discuss before surgery, and both patients and anaesthetists rank it high in outcomes to avoid during anaesthesia, to the point that, after death, 'awareness with pain' is the outcome anaesthetists most wish to avoid.

3.3 The NAP5 study is, by a considerable margin, the largest ever study of the topic in the world. We believe its findings are robust as a result of its size (capturing data from every public hospital in the UK and Ireland) and depth (involving detailed prospectively acquired reports and multidisciplinary structured analysis of their content and themes). First and foremost, NAP5 is a report *for patients* as it is based entirely on patients' reports of their experiences. Yet our aim is also that it will have an impact on national, institutional and individual practice of anaesthesia, so that the incidence of AAGA can be significantly reduced, and where it occurs it can be recognised and managed in such a way as to mitigate any longer term effects on patients.

3.4 This Executive Summary can only scratch the surface of the details contained within the full Report and is intentionally brief. We hope those responsible for procuring or organising anaesthetic services will take serious note of its contents and recommendations.

OBJECTIVES OF NAP5

3.5 In many ways, NAP5, like the preceding National Audit Projects, aims simply to shine a bright light on the topic of AAGA and explore it in greater depth than has hitherto been possible. There was an expectation that at least the following might be explored:

- How many patients (in a defined national population) spontaneously report AAGA?
- How do these patients present: when, to whom and how?
- To what extent can risk factors be identified (including but not limited to those suggested in the literature)?
- What do patient stories tell us about patients' experiences and expectations soon after an episode of AAGA (and do these change with time)?
- Is specific depth of anaesthesia monitoring used and does it alter incidence of AAGA?

3.6 The overarching purpose of addressing these questions was:

- To develop strategies for prevention of AAGA.
- To identify an optimal process for managing cases of explicit awareness.
- To acquire further knowledge of AAGA that can be used by anaesthetists when informing patients and consenting for anaesthesia.

The main findings and recommendations are summarised below.

NAP5 METHODOLOGY

3.7 NAP5 is the 5th in a series of National Audit Projects, managed by the Royal College of Anaesthetists (RCoA), which study important complications of anaesthesia over a period of several years. The topic of AAGA was selected for NAP5 after an open call for proposals, peer review and shortlisting. For NAP5, the RCoA was joined by the Association of Anaesthetists of Great Britain and Ireland (AAGBI), meaning that for the first time the two largest organisations in the specialty in the UK worked together on such a project. The project has also, for the first time, expanded into Ireland with the support of the AAGBI and the College of Anaesthetists in Ireland. The project was endorsed by all four Chief Medical Officers.

3.8 A nationwide network of local co-ordinators across all the UK National Health Service hospitals (and separately in Ireland) anonymously reported all new patient reports of AAGA to a central secure on-line database over a calendar year. The database collected detailed information about the event, the anaesthetic and surgical techniques and any sequelae. These reports were then categorised by a multidisciplinary panel, using a formalised process of analysis. The main (mutually exclusive) categories included Certain/probable (Class A), Possible (B), Sedation (C), ICU (D), Unassessable (E), Unlikely (F), Drug Errors (G) and Statement Only (SO). The structured analysis also classified patient experience and sequelae. The large number of reports collected and analysed in this manner enabled a detailed and unique exploration of quantitative and qualitative themes within the dataset. The NAP5 methodology is proposed as an important means to assess new reports of AAGA in a standardised manner. Parallel censuses of UK and Irish anaesthetic activity enabled us to calculate the incidence of patient reports of AAGA overall (in each country separately), in various anaesthetic subspecialties and to determine risk factors for AAGA.

OVERVIEW OF NAP5 RESULTS

Reports

3.9 NAP5 received more than 400 contacts from individuals wishing to report cases of AAGA. Delay in reporting ranged from none to up to 62 years after the event. After sifting and exclusions 300 reports were reviewed in full: these included 141 Certain/probable or Possible cases of AAGA; 17 cases of awake paralysis due to drug error; 7 cases of AAGA in ICU and 32 reports of AAGA after sedation. The 141 Certain/probable and Possible reports were the basis of our most in-depth analysis. Other categories were analysed separately.

Incidence

3.10 The estimated incidence of patient reports of AAGA was ~1:19,000 anaesthetics. However, this incidence varied considerably in different settings. The incidence was ~1:8,000 when neuromuscular blockade was used and ~1:136,000 without it. Two high risk surgical specialties were cardiothoracic anaesthesia (1:8,600) and Caesarean section (~1:670).

Psychological experiences of AAGA

3.11 There was a wide range of patient experiences (from the trivial to something akin to feelings of torture) and a wide range of psychological consequences (from none to life-changing). Most reports were short in duration, the vast majority lasting <5 minutes. While almost half the reports described recall in a neutral way, focussing on a few isolated aspects of the experience, the other half experienced distress at the time of the experience. In some cases, distress was overwhelming and described in terms of dying. Distress was particularly likely when patients experienced paralysis.

Longer-term psychological effects

3.12 Longer-term psychological effects were identified in approximately half of patients reporting AAGA. Overall, 41% of patients reporting AAGA experienced moderate or severe longer term sequelae. The experience most strongly associated with subsequent psychological sequelae was distress at the time of the event. This in turn was strongly associated with a sensation of paralysis. The majority of patients reporting paralysis developed moderate or severe longer term sequelae. Conversely, understanding what was happening, or what had happened, seemed to mitigate immediate and longer-term psychological distress.

3.13 Cases of early reassurance during an episode of AAGA, or of early support, were often followed by good outcomes. In a minority of cases denial of events by clinicians or unsympathetic early management was seen, and this was associated with psychological sequelae. Active early support may offer the best prospect of mitigating the impact of AAGA, and a structured pathway to achieve this is proposed.

Phase of anaesthesia

3.14 In contrast to previous case reports and series, NAP5 identified almost two-thirds of AAGA experiences arising in the dynamic phases of anaesthesia (induction and emergence).

Induction

3.15 Induction accounted for half of all reports. Half of these involved urgent or emergency anaesthesia. Contributory factors included the use of thiopental, rapid-sequence induction, obesity, neuromuscular blockade, difficulties with airway management, and interruption in anaesthetic delivery when transferring the patient from anaesthetic room to theatre (termed the 'gap'). Despite often brief patient experiences in this phase, distress was common. Simple changes in practice and a checklist to prevent interruption of anaesthetic delivery would eliminate many of these events.

3.16 We recommend the use of an 'anaesthetic checklist' (easily integrated with the World Health Organisation Safer Surgery checklist) to be used after transfer of the patient, to prevent incidents of AAGA arising from human error, monitoring problems, circuit disconnections and other 'gaps' in delivery of anaesthetic agent.

Maintenance

3.17 This accounted for one-third of reports, though many were caused by problems that arose at induction or towards the end of anaesthesia (e.g. a 'gap', or too early cessation of anaesthetic). Pain was more often experienced in this phase than at induction or emergence. In 25% of maintenance cases, no cause could be determined, and in this group resistance to anaesthetic drugs is a plausible explanation.

Emergence

3.18 Almost a fifth of the reports occurred at emergence. In almost all cases patients experienced residual paralysis and found this distressing. This was commonly caused by poor management of neuromuscular blockade combined with failure to ensure full return of motor capacity before turning off anaesthetic agents. Failure to use a nerve stimulator was judged causal or contributory in half of the reports. Improved knowledge of drug action and better monitoring of neuromuscular function would likely eliminate the majority of such events.

Risk factors

3.19 Risk factors were determined by comparing distributions in the reported cases with distributions in the NAP5 national census of anaesthetic activity (Activity Survey). The following were identified:

- Drug factors: neuromuscular blockade, thiopental, total intravenous anaesthesia techniques.
- Patient factors: female gender, age (younger adults but not children); obesity, previous AAGA and possibly difficult airway management.
- Subspecialties: obstetric, cardiac, thoracic, neurosurgical.
- Organisational factors: emergencies, out of hours operating, junior anaesthetists.

3.20 The following were not risk factors for AAGA: ASA physical status, race, nitrous oxide.

Total intravenous anaesthesia (TIVA)

3.21 AAGA was approximately twice as likely during TIVA as during volatile anaesthesia, but this 'headline figure' hides important detail. TIVA in the operating theatre was usually administered by target controlled infusion (TCI), but this was rare outside theatres. In-theatre failure to deliver the intended dose of propofol (disconnection, tissued drip, etc) was an important cause of AAGA. Many AAGA cases during TIVA involved use of non-TCI techniques (e.g. manual infusions, fixed rate infusions, intermittent boluses). High risk situations were conversion of a volatile anaesthetic to TIVA and transfer of paralysed patients outside theatres; inadequate dosing using non-TCI regimens was common. Three quarters of cases were considered preventable. All anaesthetists are likely to need to use TIVA, particularly in sites/circumstances when a volatile cannot be administered, and need to be skilled in its administration: these results suggest that is not currently the case.

Neuromuscular blockade (NMB)

3.22 Use of neuromuscular blockade was a highly significant risk factor for AAGA, and its use was associated with sensations of paralysis and distress, and those in turn with longer term psychological sequelae. Fewer than half of UK general anaesthetics include an NMB but 93% of reports to NAP5 concerned patients who had received an NMB.

3.23 The cases of 'AAGA' reported to NAP5 were overwhelmingly cases of unintended awareness in patients who were unable to move because of the effects of a neuromuscular blocking drug but who had received inadequate anaesthetic agent to produce loss of consciousness. It is worth reconsidering the problem of AAGA as one of 'unintended awareness during neuromuscular blockade'.

Depth of anaesthesia monitoring

3.24 Specific depth of anaesthesia (DOA) monitors are rarely used during general anaesthesia in UK practice (processed EEG in 2.8% of general anaesthetics and isolated forearm technique in 0.03%). Although DOA monitoring was over-represented in the AAGA cases (4.3%), it appears to be used in a 'targeted fashion': in the Activity Survey DOA monitoring was used in ~1% of cases of volatile without NMB and in ~23% of cases with TIVA and NMB. Only one report of AAGA in association with DOA monitoring was followed by adverse psychological sequelae. The overall findings are supportive of the use of DOA monitoring during TIVA with NMB (including cases where TIVA is used for transfer).

3.25 End-tidal anaesthetic gas monitoring is an alternative to DOA monitoring, but in ~75% of reports to NAP5 it would likely have been impractical or ineffective at preventing AAGA.

Obstetric anaesthesia

3.26 Obstetric cases account for 0.8% of general anaesthetics in the NAP5 Activity Survey but ~10% of NAP5 reports of AAGA, making it the most markedly over-represented of all surgical specialties. Almost all reports occurred after Caesarean section and at induction or early during surgery. Obstetric general anaesthesia includes most of the risk factors for AAGA including use of thiopental, rapid sequence induction, neuromuscular blockade, in a population with a relatively high incidence of obesity and difficult airway management, and high rates of emergency surgery. Surgery starting almost immediately after induction of anaesthesia requires special care to avoid AAGA. There was some evidence that obstetric patients more readily report AAGA when it occurs than in those other settings and this merits further investigation.

Cardiothoracic anaesthesia

3.27 The incidence of reports of AAGA after cardiothoracic anaesthesia was higher than for other specialties at 1 in 8,600. Most reports involved either brief interruption of drug delivery (caused by human error or technical problems), or use of intentionally low anaesthetic doses in high risk patients. These specialties should continue to be considered higher risk for AAGA.

Paediatric anaesthesia

3.28 The incidence of reports of AAGA in children in NAP5 is significantly lower than the previously reported incidence in prospective studies which used a Brice-type questionnaire (~1:60,000 versus ~1:135 respectively). Reports of AAGA in children were often delayed for many years until adulthood. These may be received earlier by parents but not transmitted further, though the reasons for this are unclear. Serious long term psychological harm and anxiety states are rare, but do occur after AAGA in children. Children should be believed and treated sympathetically.

Intensive Care (ICU)

3.29 A small number of cases of AAGA were reported during intended general anaesthesia in critically ill patients in ICU. Themes included underestimating anaesthetic requirements in sick, obtunded or hypotensive patients. Problems also arose when low dose propofol infusions were used to maintain anaesthesia for procedures or transfers. All patients were paralysed during their AAGA and experienced distress or psychological harm. Most cases were judged to be preventable.

Drug error

3.30 Cases of brief awake paralysis as a result of drug errors accounted for approximately 10% of reports to NAP5. These led to a neuromuscular blocking drug being administered without prior anaesthesia. The types of experiences and the consequences for the patient are indistinguishable from AAGA. It is notable that the distress during the patient experiences and the subsequent psychological distress were greater in this group than in any other class of reports: all were judged preventable.

3.31 These cases were rich in organisational and individual latent factors that made such events more likely. These included ill considered policies for drug management, similar looking ampoules, poorly organised operating lists, high workload, distraction and hurriedness. Prevention of such events requires action from national organisations (e.g. to improve drug labelling and packaging), organisations (e.g. to ensure safe management of operating lists) and individuals (e.g. to develop

clear personal strategies for drug preparation – particularly neuromuscular blockers).

'AAGA' and sedation

3.32 Approximately 20% of reports of AAGA to NAP5 followed intended sedation rather than general anaesthesia. The rate of 'reports of AAGA' following sedation by anaesthetists (~1:15,000) appears to be as high as after general anaesthesia. In reports of AAGA after sedation, the experiences and the psychological sequelae were similar in nature, though perhaps less in severity than AAGA after general anaesthesia. Reports of AAGA after sedation represent a failure of communication between anaesthetist and patient and should be readily reduced or eliminated by improved communication, management of expectations and consent processes.

Consent

3.33 NAP5 has implications for obtaining informed consent for anaesthesia and sedation. Pre-operative consent for anaesthesia was rarely documented and AAGA rarely discussed. The data from NAP5 provide a wealth of information about the nature of AAGA, the relative risk of different types of anaesthesia, and its consequences. Anaesthetists can use this data to inform their approach to consent. Whether anaesthetists wish to use incidences from NAP5 or elsewhere in the literature to describe the risk of AAGA is a professional decision, and is discussed in depth in the Report.

3.34 Pre-operative information should include details about AAGA risk and potential experiences. For sedation, consent should clearly distinguish sedation from general anaesthesia, and should indicate that amnesia is more a side effect than an aim of sedation and therefore is not guaranteed.

Medicolegal issues

3.35 Only a small minority of reports of AAGA to NAP5 were associated with a complaint (~10%) or initiation of litigation (~5%), though because of delayed claims this may be an underestimate. However, in only 22% of reports were judged to have received 'wholly good' care both during and after anaesthesia. In 78% of cases where intra-operative care was considered less than good, the AAGA was judged preventable, indicating considerable potential for litigation.

3.36 Anaesthetists defending a claim will rely on a careful record of rational and justifiable conduct. The NAP5 methodology provides a template, which might usefully inform the investigation of claims or serious incidents related to AAGA.

Human Factors (HF)

3.37 NAP5 identified Human Factor contributors in the majority of reports of AAGA, even though the NAP process is not well suited to robust analysis of such factors. Preventing awareness by addressing human factors goes beyond simply examining the final 'action error' that leads to relative under-dosing of drugs, and should consider the many latent factors that impact on this. This is particularly so for AAGA caused by drug errors.

NAP5 in Ireland

3.38 NAP5 ran as a linked but parallel project in Ireland. The number and type of reports of AAGA in Ireland has remarkable similarities to the UK. The Irish experience, in a country with different organisation of public and private healthcare and notable differences in the adoption of DOA monitoring, is a useful comparison to the UK. The outputs of NAP5 in Ireland and their similarity both numerically and qualitatively to the outputs from the UK can be seen as a form of validation of the UK project.

RECOMMENDATIONS

Recommendations appear at the end of most of the chapters in this Report. Below they are re-ordered to provide guidance broadly at national, institutional and personal level (acknowledging there is overlap of these responsibilities and a need for co-ordinated action to achieve them).

NATIONAL

Recommendation 1

The relevant anaesthetic organisations should work with the NHS and other public bodies to develop an ongoing database of AAGA reports (using processes similar to those of NAP5) to encourage the process of learning from events, and as an essential basis for further investigation of research questions emanating from NAP5.

Recommendation 2

The relevant anaesthetic organisations should consider including nerve stimulators as 'essential' in monitoring guidelines whenever neuromuscular blocking drugs are used.

Recommendation 3

The relevant anaesthetic organisations should engage with industry to seek solutions to the problem of similar drug packaging and presentation.

Recommendation 4
All anaesthetists should be trained in the maintenance of anaesthesia with intravenous infusions.

Recommendation 5
The relevant anaesthetic organisations should establish a set of standards and recommendations for best practice in the use of TIVA.

Recommendation 6
Anaesthetists should be familiar with the principles, use and interpretation of specific depth of anaesthesia monitoring techniques (i.e. the available EEG-based monitors and the isolated forearm technique). Relevant anaesthetic organisations should include this monitoring in their core training programs.

Recommendation 7
In regard to monitoring depth of anaesthesia, the relevant anaesthetic organisations should develop pragmatic protocols or algorithms for the use of all available information about depth of anaesthesia (including information from pEEG monitors) to guide anaesthetic dosing.

INSTITUTIONAL

Recommendation 8
All reports of AAGA should be treated seriously, even when sparse or delayed, as they may have, or have had, serious psychological impact. If reported to someone else, every attempt should be made to refer the case to the anaesthetist responsible.

Recommendation 9
Healthcare or managerial staff receiving a report of AAGA should (a) inform the anaesthetist who provided the care; (b) institute the NAP5 Awareness Support Pathway (or similar system) to provide patient follow up and support. Anaesthetic departments should have a policy to manage reports of AAGA, and a named professional should be assigned to manage each case.

Recommendation 10
Anaesthetists and organisations should ensure that operating lists are planned in an objective manner that explicitly includes adequate time to ensure safe conduct of anaesthesia, and that will reduce pressures and scope for distractions.

Recommendation 11
Hospitals should take ampoule appearance into account to avoid multiple drugs of similar appearance. Hospital policies should direct how this risk is managed. This may require sourcing from different suppliers.

Recommendation 12
An anaesthetic checklist should be conducted before the start of surgery to confirm (amongst other things) delivery of adequate anaesthesia. This might usefully be incorporated into the WHO checklist.

Recommendation 13
The surgical team should formally confirm with the anaesthetist that it is appropriate to start surgery, before doing so.

Recommendation 14
Patients should be provided with information about risks of anaesthesia and this should include risks of AAGA (which can be written information provided before anaesthesia).

Recommendation 15
Patients should be informed of the possibility of brief experience of paralysis, especially where neuromuscular blockade is used, on induction and emergence. Although desirable to avoid these symptoms, a warning would prepare the patient for a relatively common experience in the context of AAGA.

Recommendation 16
There should be documentation that the risks and benefits of the anaesthetic technique have been discussed, including appropriate information about the risk of AAGA. Pre-operative written material may be an efficient way to achieve this.

Recommendation 17
All reports of AAGA should be carefully assessed mapping details of the patient report against the conduct of anaesthetic care, using a process like that outlined in NAP5.

Recommendation 18
All anaesthetists should be educated in human factors so they can understand their potential impact on patient care and how environments, equipment and systems of work might impact on the risk of, amongst other things, AAGA.

Recommendation 19
Investigation of and responses to episodes of AAGA – especially those involving drug error – should consider not only action errors but also the broader threats and latent factors that made such an event more or less likely.

PERSONAL

Recommendation 20
If AAGA is suspected intra- or peri-operatively, anaesthetists should speak to patients at the time of AAGA to reassure them that they know of their predicament and are doing something about it.

Recommendation 21
Conversation and behaviour in theatres should remain professional, especially where there is a situation where or concern, that AAGA is a risk (e.g. RSI, prolonged intubation, transfer). Adverse impact of any recall may be mitigated where the patient is reassured by memories of high quality care.

Recommendation 22
The anaesthetist who provided the anaesthesia care at the time of a report of AAGA should respond promptly and sympathetically to the patient, to help mitigate adverse impacts.

Recommendation 23
Standard induction doses for intravenous agents should be used as a reference in dosing. Deviating greatly from these requires justification and where appropriate, explanation to the patient.

Recommendation 24
During routine induction, loss of consciousness after induction should be verified by loss of response to verbal command and simple airway manipulation (e.g. jaw thrust) before undertaking further anaesthetic interventions, including the administration of neuromuscular blocking drugs.

Recommendation 25
Formal airway assessment is a mandatory component of anaesthesia. If a difficult airway is anticipated, a clear management strategy must be communicated to anaesthesia assistants and to the surgical team. A patient with a difficult airway must also be considered to be at higher risk of AAGA at the time of induction, and (unless it is planned to secure the airway awake or sedated) this risk should generally be communicated to the patient as part of the process of consent.

Recommendation 26
When airway management difficulties become prolonged the anaesthetist should decide whether to awaken the patient or to continue to try to secure the airway; if the latter, general anaesthesia must be continued. This is more logically done by administration of an intravenous agent.

Recommendation 27
Anaesthetists should exercise caution when using thiopental for RSI. This caution should include appreciation of the need to have additional doses of induction agent for possibly prolonged airway management.

Recommendation 28
Obesity should be considered a risk factor for AAGA at induction, especially if RSI is planned. Care is required to ensure adequate but not excessive dosing.

Recommendation 29
Intentional underdosing of anaesthetic drugs at induction to avoid cardiovascular instability is appropriate in some circumstances, but the risk of AAGA should be considered and where it is unavoidable:

(a) The higher risk of AAGA should be communicated to the patient.
(b) Invasive monitoring should be considered to allow accurate early use of vasopressor drugs to enable adequate doses of anaesthetic agents to be administered safely.
(c) Specific depth of anaesthesia monitoring should be considered.

Recommendation 30
Anaesthetists should regard transferring an anaesthetised patient from anaesthetic room to theatre (and by logical extension all patient transfers) as a period of risk for AAGA. There are several interventions that can mitigate this risk; among these is the use of a suitable checklist as proposed by NAP5.

Recommendation 31
If AAGA is suspected during maintenance, then prompt attention should be paid to increasing analgesia, as well as deepening the level of unconsciousness. As recommended elsewhere, verbal reassurance should be given to the patient during this time.

Recommendation 32
Anaesthetists should exercise great caution in interpreting the outputs of pEEG- based depth of anaesthesia monitoring as indicating adequate anaesthesia, in the face of unexpectedly low administered anaesthetic concentrations.

Recommendation 33
In addition to communication throughout surgery, there should be formal confirmation from the surgeon to the anaesthetist and other theatre staff that surgery has finished. This point should be at the actual completion of all interventional procedures (including dressings, post-surgical examinations, etc) and could be usefully linked to the sign-out section of the WHO checklist.

Recommendation 34
Anaesthetists should recognise that residual paralysis at emergence is interpreted by patients as AAGA. When recognised, it should be managed using the same Recommendations in this Report as apply to AAGA arising in other phases of anaesthesia, with the same level of psychological support.

Recommendation 35
When planning an awake extubation, this should be explained to the patient as part of the consent process, including the possibility of recall of the tube in the airway and difficulty in moving or breathing at this time.

Recommendation 36
The nerve stimulator should be used to establish motor capacity. An adequate response to nerve stimulation (e.g. return of a 'train of four' ratio of >0.9, or other suitable measures) is a minimum criterion of motor capacity. Anaesthetists should use additional signs such as spontaneous breathing and motor response to command before full motor capacity is judged restored.

Recommendation 37
All patients who have less than full motor capacity as a result of pharmacological neuromuscular blockade should remain anaesthetised.

Recommendation 38
Anaesthetists should regard an 'awake extubation' (as stressed in the DAS Extubation Guidelines) as an undertaking in a patient who primarily has full motor capacity, and secondarily is co-operative to command. Being 'awake' alone does not fulfil any safe conditions for tracheal extubation.

Recommendation 39
The possibility of pseudocholinesterase deficiency should be considered whenever using mivacurium or suxamethonium. Where suspected, anaesthesia should be maintained until full recovery from neuromuscular blockade is confirmed. Genetic testing should be arranged.

Recommendation 40
During emergence, speaking to patients to explain what is happening provides important reassurance about potentially unusual sensations such as tracheal intubation or partial paralysis.

Recommendation 41
Given the potentially serious consequences of paralysis unopposed by general anaesthesia even for brief periods, anaesthetists should plan the use of neuromuscular blockade very carefully assessing whether it is needed at all, and if so then whether needed throughout surgery, and to what depth of blockade.

Recommendation 42
Care should be exercised in the handling of syringes of neuromuscular blocking drugs prepared 'in case' of need: inadvertent administration may have catastrophic results.

Recommendation 43
If neuromuscular blockade is planned, then anaesthetists should ensure consent and explanation outlines the possibility of feeling weak or unable to move, for example at the start or end of the anaesthetic.

Recommendation 44
Anaesthetists should develop clear personal strategies in the preparation of drugs that minimise or avoid scope for drug error. This includes the recognition that preparation of drugs for use is a potentially high-risk activity, during which distractions should be avoided. This applies particularly to neuromuscular blocking drugs.

Recommendation 45
Where a drug error leading to accidental paralysis has occurred, then at all times, verbal reassurance to the patient should be provided, explaining that the team knows what has happened, that any paralysis is self-limiting and that the patient is safe. Then the first priority is to induce anaesthesia promptly. It is difficult to conceive of any justification for keeping a paralysed patient conscious. The next priority is to reverse the paralysis as soon as is practicable.

Recommendation 46
Anaesthetists should regard obstetric patients, particularly those undergoing caesarean section, as being at increased risk for AAGA. This risk should be communicated appropriately to patients as part of the consent process.

Recommendation 47
Consideration should be given to reducing the risk of AAGA in healthy parturients by:

(a) The use of increased doses of induction agents.
(b) Rapidly attaining adequate end-tidal volatile levels after induction without delay.
(c) Use of nitrous oxide in adequate concentrations.
(d) Appropriate use of opiates.
(e) Maintaining uterine tone with uterotonic agents to allow adequate concentrations of volatile agents to be used.

Recommendation 48
Before induction of the obstetric patient, the anaesthetist should have decided what steps to take if airway management proves difficult, with maternal wellbeing being the paramount consideration, notwithstanding the presence of fetal compromise. An additional syringe of intravenous hypnotic agent should be immediately available to maintain anaesthesia in the event of airway difficulties, when it is in the mother's interest to continue with delivery rather to allow return of consciousness.

Recommendation 49
Anaesthetists should regard failed regional technique leading to the need for general anaesthesia for obstetric surgery to be an additional risk (for AAGA and other complications).

Recommendation 50
Anaesthetists should regard the presence of antibiotic syringes during obstetric induction as a latent risk for drug error leading to AAGA. The risk can be mitigated by physical separation, labelling or administration of antibiotics by non-anaesthetists. Using propofol for induction mitigates the risk of this drug error.

Recommendation 51
When using total intravenous anaesthesia, wherever practical, anaesthetists should ensure that the cannula used for drug delivery is visible and patient at all times.

Recommendation 52
Depth of anaesthesia monitoring should be considered in circumstances where patients undergoing TIVA may be at higher risk of AAGA. These include use of neuromuscular blockade, at conversion of volatile anaesthesia to TIVA and during use of TIVA for transfer of patients.

Recommendation 53
If AAGA is suspected, immediate verbal reassurance should be given to the patient during the episode to minimise adverse consequences, as well as additional anaesthetic to limit the duration of the experience.

Recommendation 54
Anaesthetists should minimise the risk of any period of neuromuscular blockade without anaesthesia by the appropriate use of a nerve stimulator coupled with end-tidal volatile agent monitoring. Where the latter is absent or irrelevant (such as in TIVA), then specific depth of anaesthesia monitoring may be necessary.

Recommendation 55
Anaesthetists should recognise that neuromuscular blockade constitutes a particular risk for AAGA. Use of a specific form of depth of anaesthesia monitor (e.g. pEEG or IFT) is logical to reduce risk of AAGA in patients who are judged to have high risk of AAGA for other reasons, and in whom neuromuscular blockade is then used.

Recommendation 56
If specific depth of anaesthesia monitoring is to be used (e.g. pEEG or IFT) then it should logically commence, if feasible, before/at induction of anaesthesia and continue until it is known that the effect of the neuromuscular blocking drug has been reversed sufficiently.

Recommendation 57
Anaesthetists should ascertain the degree of information that is required by a patient about the risks of AAGA, over and above that contained in information leaflets. An explanation of risks should be coupled with information about how those risks will be mitigated.

Recommendation 58
Anaesthetists should form an opinion on the magnitude of risks of AAGA to quote, based on the evidence available in the literature, making clear how any estimate quoted was obtained (e.g. spontaneous report vs active questioning).

Recommendation 59
Anaesthetists should provide a clear indication that a pre-operative visit has taken place, identifying themselves and documenting that a discussion has taken place.

Recommendation 60
Sedationists should make efforts to ensure that the patient understands the information they are given about sedation, specifying that sedation may not guarantee unawareness for events or guarantee amnesia.

Recommendation 61
Patients undergoing elective procedures under sedation should be provided with written information well in advance of the procedure. This should emphasise that during sedation the patient is likely to be aware, and may have recall, but that the intention is to improve comfort and reduce anxiety. It should be stressed that sedation is not general anaesthesia.

Recommendation 62
On the day of the procedure, sedation should be described again from the patient's perspective, using terminology such as that suggested in NAP5 as a guide.

Recommendation 63
The anaesthetist(s) who provided the anaesthesia care at the time of a report of AAGA should respond promptly and sympathetically to the patient, to help mitigate adverse impacts.

Recommendation 64
Anaesthetists should keep clear, accurate anaesthetic records, which will help provide a defence to a claim of negligence. Equally, where a lapse has occurred, the accuracy of record-keeping in documenting the lapse should mitigate further adverse outcomes for the anaesthetist, hospital and patients, as it will serve as a focus for learning.

CHAPTER
5

Protocol and methods of NAP5


Jaideep J Pandit


Tim M Cook

HEADLINE

5.1 NAP5 employed a novel methodology to approach the problem of AAGA: a nationwide network of local co-ordinators across all the UK National Health Service hospitals (and separately in Ireland) reported all new patient reports of AAGA to a central database using a system of monthly anonymised reporting over a calendar year. The database collected the details of the reported event, anaesthetic and surgical technique and any sequelae. These reports were categorised into mutually exclusive groups by a multidisciplinary panel, using a formalised process of analysis. The main categories were those reports judged Certain/probable (Class A), Possible (B), Sedation (C), ICU (D), Unassessable (E), Unlikely (F), Drug Errors (G) and Statement Only (SO). The degree of evidence to support the categorisation was also defined for each report. Patient experience and sequelae were categorised using current tools or modifications of such. This methodology is compared with previous methods used to address the problem of AAGA, and its potential strengths and limitations discussed. The NAP5 methodology should form an important means to assess new reports of AAGA in a standardised manner, especially for the development on an ongoing database of case reporting.

BACKGROUND

5.2 Several studies into AAGA use the methodology of a Brice questionnaire (Brice et al., 1970) and consistently establish an incidence for AAGA of 1–2:1,000 (e.g. Avidan et al., 2008 & 2011). It is also suggested that there is a potentially severe impact, with high rates of post-traumatic stress disorder (PTSD) reported (Bruchas et al., 2011).

5.3 However, it is apparent that the methodology used to study AAGA influences the results that can be obtained. For example, a method that uses Brice questioning of patients, but administered twice over a 48-hour period (as in a study by Pollard et al. as part of a quality improvement program) yields a much lower incidence of 1:14,500 (Pollard et al., 2007). Mashour et al. (2013) reported that different methodologies can yield different incidences for AAGA.

5.4 There are, overall, several methodologies employed in studying the problem of AAGA or, the differences in large part related to the specific research question being addressed. Amongst these are: case series, randomised or non-randomised controlled trials, and data registries.

5.5 An example of a *case series* is the paper of Blussé van Oud-Alblas et al. (2009) who questioned 928 consecutive paediatric patients for AAGA using a Brice questionnaire repeated three times over a month. Their aim was to ascertain an incidence and look for common patterns that may emerge in the elicited reports. Other types of case series examine only the patients reporting AAGA, to focus on common themes or on the psychological impact (Moerman et al., 1993; Samuelsson et al., 2007).

5.6 *Non-randomised* studies usually seek to establish the incidence of AAGA or ascertain influential factors. For example, Sebel et al., (2004) reports on a prospective cohort study in just under 20,000 patients that sought to establish an incidence (using Brice interview repeated twice over a week) and used multivariate logistic regression to identify possible contributory factors.

5.7 *Randomised* study designs usually seek to assess the impact of an intervention (such as preventative treatment or monitoring) to reduce incidence of AAGA (Avidan et al., 2009). For example the impact of BIS monitoring was examined by the B-Aware trial of Myles et al. (2004). An example of a randomised study examining the impact of a prophylactic treatment is that of Wang et al. (2013).

5.8 *Data registries* are, at the simplest level, a collection of case details stored and then analysed by later interrogation (Klein et al., 2014). Small scale registries may be assembled by referral from colleagues (Moerman et al., 1993) or advertisement (Schwender et al., 1998). The ASA Awareness Registry (http://depts.washington.edu/asaccp/projects/anesthesia-awareness-registry) was hitherto probably the largest database. Started in October 2007, it is a system of direct access, self-registration by patients. To date, in seven years, it has collected ~278 subjects (~40 per year), about one-third of whom in fact received sedation and not general anaesthesia (Kent et al., 2013). By definition, this methodology is self-selected (or colleague-selected) and so subject to biases.

5.9 Mapped against these previous methodologies, that of NAP5 seems unique.

METHODS

5.10 The methodology of NAP5 is similar to, and builds upon, that used for NAP3 and NAP4 (Cook et al., 2009 & 2011a and b).

5.11 The NAP5 project was approved by the National Information Governance Board (NIGB) in England and Wales, and Patient Advisory Groups in Scotland and Northern Ireland. The National Research Ethics Service (NRES) confirmed it to be a service evaluation and waived the requirement for formal ethical approval. The project has the endorsement of all four Chief Medical Officers of the UK. In March 2013, NIGB was abolished and its functions taken over by the Confidentiality Advisory Committee of the NHS Health Research Authority (HRA). This deals with approvals for the handling of patient-identifiable information across the NHS. If such information is required, then approvals are required under Section 251 of its governance procedures. NAP5 re-submitted the relevant information to the HRA and the latter confirmed that, since no patient-identifiable information was used, no section 251 application was necessary.

5.12 Each of 329 UK hospital centres volunteered a Local Co-ordinator (LC), a consultant anaesthetist who provided the main link between the central NAP5 team and their hospital. Because some LCs covered more than one hospital as part of an NHS Trust (or Board in Scotland) there were 269 LCs.

5.13 In parallel, in Ireland 41 Local Co-ordinators volunteered to provide the link between the NAP5 team and all the 46 public hospitals. The NAP5 project in Ireland has received approval from the Department of Health and was endorsed by the Health Service Executive (HSE) National Quality and Patient Safety Directorate. The requirement for ethical approval in Ireland was waived.

5.14 There were three phases to NAP5:

(a) A Baseline Survey conducted in early 2012 and relating to the calendar year 2011, to ascertain anaesthetist knowledge of reports of AAGA, and certain baseline data related to anaesthetic practice (monitoring) and staffing.

(b) The core project which ran from 1 June 2012 to 31 May 2013.

(c) An Activity Survey to provide denominator data for the key findings of interest, conducted between 26 November and 3 December 2012 in Ireland and 9 and 16 Sept 2013 in the UK.

5.15 The UK and Irish Baseline Surveys have been published in full (Pandit et al., 2013a and b). The UK and Irish Activity Surveys are also published (Jonker et al., 2014a and b).

5.16 LCs were provided with detailed information which can be viewed at www.nationalauditprojects.org.uk/NAP5_home . In brief, they were asked to develop local multidisciplinary networks across their centres, encompassing all surgical and medical specialties, nursing and paramedical services, and psychiatric and psychology units. On a monthly basis each LC was required to provide the central NAP5 team with a 'return' indicating the number of reports of AAGA received that month. Where no reports were received the LCs returned a 'nil' report; this was based on the UK obstetric surveillance system (Knight, 2007).

5.17 Information about the project was also disseminated at intervals to their members by the Royal College of General Practitioners, the Royal

College of Psychiatrists and national societies of psychological practitioners. Publications in general medical journals also helped highlights the project to professionals (Pandit & Cook, 2013).

5.18 Initially, no public announcement or media exposure was actively sought, in case this altered the normal manner in which patients made reports of AAGA. However, publication of the Baseline papers in April 2013 was accompanied by widespread media attention (see www.bbc.co.uk/news/health-21742306 and www.dailymail.co.uk/news/article-2292532/Study-reveals-153-patients-wake-anaesthesia.html as examples).

5.19 Any person wishing to file a report of AAGA on behalf of themselves or another person could do so, or could contact an LC using an online list. Equally, LCs could contact each other to exchange information securely (e.g. if a patient presented to one hospital having had an experience of AAGA at another). The architecture of the secure website (see http://nap5.org/) meant that the NAP5 Panel had no knowledge of these exchanges, or who was filing the report.

5.20 In order to file a report of AAGA, the LC (or other person) needed login details to the secure site provided by the administrative arm of the NAP5 central team. A short set of screening questions was used to filter inadmissible reports, and later on review, some reports that had been filed were deemed inadmissible. To be reportable, a report of AAGA had to:

(a) Be a situation where the patient (or their representative or carer) made a statement that they had been *aware for a period of time when they expected to be unconscious*. Thus, a complaint of 'pain' or 'anxiety' alone was inadmissible, as was a desire to have been less conscious (as opposed to unconscious) during a procedure.

(b) Be a *first report* of AAGA made to the healthcare system.

(c) Be a first report made between 00.00hrs on 1 June 2012 and 23.59.59hrs on 31 May 2013; regardless of when the actual event occurred. Thus an operation that led to AAGA many years ago, but was not reported until, say, October 2012 was potentially admissible. A report made on 1 June 2013 about an operation that occurred on 31 May 2013 was, however, inadmissible.

(d) Be a report that related to a specific surgical or medical intervention in which anaesthesia care was provided. 'Anaesthesia care' is interpreted in the broadest sense, ranging from monitored anaesthesia care (i.e. where the anaesthetist is on standby for purposes of resuscitation) through sedation to general anaesthesia, given by any type of practitioner.

(e) Relate to care undertaken in a public hospital.

We therefore aimed to capture all new patient reports of AAGA irrespective of whether the patient's perception of the event was accurate.

5.21 For cases deemed to meet inclusion criteria, login details and a password were issued. The reporter was required to change this password on first accessing the website. Once access information was released to an individual, the NAP5 team had no access to information during report submission but merely received notification of when the website was first accessed and when the form was completed, to enable progress to be monitored. The website was secure and encrypted.

5.22 Where there was uncertainty as to whether a case met the inclusion criteria, the reporter was directed to discuss this with the NAP5 Moderator, Dr David Smith, a consultant anaesthetist with expertise in the topic and clear knowledge of the inclusion criteria. The NAP5 moderator was entirely independent of the NAP5 project team and had no contact with the review Panel throughout the project.

5.23 The secure reporting site asked for details of the case and the conduct of anaesthesia, so LCs were advised to file the report after reviewing the case notes. No patient identifiable data was requested and prompts on the secure site ensured that all potentially identifiable data were removed. Once completed and closed, the website forwarded the report electronically to the NAP5 Clinical Lead. A demonstration of all the questions asked can be viewed as a demonstration at http://nap5.org/. To further guarantee anonymity the NAP5 Clinical Lead had no link indicating who had originally filed the report, and no method of determining this.

5.24 On a monthly basis, the NAP5 Panel met for a full day to review and discuss all submitted reports. The Panel had access to several types of information in performing the review: first, the full patient report on the secure website. Second, a case summary prepared by the NAP5 Clinical Lead. The Panel used these to review cases in a structured manner (see below). The Panel also created a standardised output form to help provide a summary of categorisation, and spreadsheet output combining

data from all submitted reports for quantitative analysis of the dataset (e.g. age range, weight, agents used, etc).

5.25 Each report was first reviewed by a minimum of four Panel members. These first review groups populated the structured review output form. Definitions of all classifications were available to all Panel members at each meeting. Several small groups reviewed simultaneously in this way. The report then underwent second review by a larger group formed of the combined small groups, typically 12-16 members. Each report and its output were presented and this was further reviewed and moderated. At each meeting some reports were intentionally reviewed by pairs of small groups before large group review as a form of 'internal control'.

5.26 In performing reviews the Panel was repeatedly cautioned about 'outcome bias' (where knowledge of the poor outcome can lead to a retrospective harsh judgement) (Caplan et al., 1991); 'hindsight bias' (an exaggerated belief that a poor outcome would have been predicted) (Henriksen et al., 2003); and 'groupthink' (where groups make irrational decisions given a subconscious desire to agree with others) (Turner & Pratkanis, 1998). The two stage review process was specifically designed to address the latter bias.

Small group review by a minimum of four reviewers was the first phase of review

5.27 Reports were classified by *type of report* (Table 5.1) and separately classified by *degree of evidence* (Table 5.2). Reports were given only one classification of type and evidence (i.e. all were mutually exclusive).

Table 5.1. Classification into types of report

Class A: Certain/probable AAGA. A report of AAGA in a 'surgical setting' in which the detail of the patient story was judged consistent with AAGA, especially where supported by case notes or where report detail was verified independently.

Class B: Possible AAGA. A report of AAGA in a 'surgical setting' in which details were judged to be consistent with AAGA or the circumstances might have reasonably led to AAGA, but where otherwise the report lacked a degree of verifiability or detail. Where the panel was uncertain whether a report described AAGA, the case was more likely to be classified as Possible rather than excluded.

(For the purpose of the final numerical analysis, it was decided to group Certain/probable and Possible cases together; numerical analysis showed this did not change the overall conclusions of the report).

Class C: Sedation. A report of AAGA where the intended level of consciousness was sedation.

Class D: ICU: A report of AAGA from a patient in, or under the care of an intensive care unit, who underwent a specific procedure during which general anaesthesia was intended.

Class E: Unassessable. A report, where there was simply too little detail submitted to make any classification possible.

Class F: Unlikely. Details of the patient story were deemed unlikely, or judged to have occurred outside of the period of anaesthesia or sedation.

Glass G: Drug error and miscellaneous. This was originally used as a miscellaneous category to be reviewed at the end of the data collection period. In fact, this class rapidly filled with syringe swaps and drug errors, with only three remaining other cases.

Statement Only. A patient statement describing AAGA, but for which there were no case notes available to verify, refute or examine that claim further. This was often because the case was historical.

Table 5.2 Classification by degree of evidence

Evidence A: high. Where the report was (or could easily be) confirmed – or refuted – by other evidence.

Evidence B: circumstantial. Where the report was supported only by clinical suspicion or circumstance. For example, poor record keeping or chaotic, rapidly changing clinical scenarios may have led the Panel to conclude that there were circumstances that could have led to AAGA.

Evidence C: plausible. Where other evidence (e.g. case notes) were available, but this did not shed further light on the matter.

Evidence D: unconfirmed/unconfirmable. This was generally applied to the Statement Only cases where there was no evidence other than the patient report.

Evidence E: implausible. This was generally applied to Statement Only reports where there was no evidence other than the patient story and where this was judged implausible.

5.28 The *phase of anaesthesia/surgery* when the AAGA event occurred was recorded:

(d) **Pre-induction** (drug errors occurring before intended anaesthesia).

(b) **Induction** at or after induction, before surgery.

(c) **Maintenance** during surgery.

(d) **Emergence** after surgery was complete but before full emergence.

(e) **Other** (uncertain time).

5.29 Induction was defined as from the start of induction of anaesthesia; maintenance from the start of incision or procedure, and emergence from when the last dressing, intervention or examination took place. Emergence reports extended to any time after the end of surgery, where the patient reported they were awake when they felt they should have been unconscious. Emergence therefore included cases where drug errors or failure to reverse neuromuscular blockade caused paralysis (and hence perceptions of AAGA) in the recovery period.

5.30 We classified *causality (contributory factors)* and *preventability*. Table 5.3 indicates the categories of causal/contributory factors considered. This is based on the NPSA contributory factors framework (at: www.nrls.npsa.nhs.uk/resources/?entryid45=75605).

Table 5.3. Contributory, causal or mitigating factors considered

Factors
Communication
Education and Training
Equipment/ resource factors
Medication
Organisation and strategic
Patient
Task
Team and social
Work and environment
Other
Unknown

5.31 We judged quality of care (i) leading up the reported event, and (ii) after the reported event. This was classified as 'good', 'poor', 'good and poor' or 'unassessable' based on consensus of the Panel, where possible making the judgement relevant to standards effective at the time of the report for historical cases.

5.32 The preventability of each case was classified as 'yes', 'no', or 'uncertain'. In one sense, all cases of AAGA are by definition preventable simply by the administration of 'more anaesthetic' but this is of little value in judging practice. Preventability was therefore defined as where '*had one or more avoidable actions or omissions outwith standard practice not occurred, AAGA would unlikely have arisen*'.

5.33 The impact on the patient was classified in three ways:

(a) Patient experience during the episode using the Michigan Awareness Classification Instrument (Mashour et al., 2010) (Table 5.4).

(b) Intra-operative cognitive state and the later psychological impact on the patient using the Wang classification (Wang et al., 2012) (Table 5.5).

(c) Severity of patient outcome, using a modification of the NPSA tool (NPSA, 2008) adapted specifically for NAP5 to be suitable for the predominantly psychological harm related to AAGA (Table 5.6). This was used to estimate the 'longer term' impact on the patient (i.e. as judged at the time they made the report).

Table 5.4. Michigan Awareness Classification Instrument (from Mashour et al. 2010). An additional designation of D is applied where the report described distress during the experience (e.g. fear, suffocation, sense of impending death, etc)

	Class A cases (%)
Class 0	No AAGA
Class 1	Isolated auditory perceptions
Class 2	Tactile perceptions (with or without auditory)
Class 3	Pain (with or without tactile or auditory)
Class 4	Paralysis (with or without tactile or auditory)
Class 5	Paralysis and pain (with or without tactile or auditory)

Table 5.5. Wang classification of intra-operative cognitive states (Wang et al., 2012)

Grade	Intra-operative state		Immediate post-operative state	Late post-operative state (>1 month)	Descriptor
0	Unconscious	No signs; no response to command	No recall	No recall	Adequate anaesthesia
1	Conscious	Signs/response to command	No recall	No recall or emotional sequelae	Intra-operative wakefulness with obliterated explicit and implicit memory
2	Conscious; word stimuli presented	Signs/response to command	No explicit recall, implicit memory for word stimuli	No explicit recall; implicit memory for word stimuli but no emotional sequelae	Intra-operative wakefulness with subsequent *implicit memory*
3	Conscious	Signs/response to command	No recall	PTSD/nightmares but no explicit recall	Intra-operative wakefulness with implicit emotional memory
4	Conscious	Signs/response to command	Explicit recall with or without pain	Explicit recall but no emotional sequelae	Awareness but resilient patient
5	Conscious	Signs/response to command	Explicit recall with distress and/or pain	PTSD/nightmares with explicit recall	Awareness with emotional sequelae

Table 5.6. Original NPSA classification of harm caused by a patient safety incident (from www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787) (column 2), and the modified NPSA classification including psychological impact on the patient devised for use in NAP5

Severity	NPSA – original definitions of harm (NPSA, 2008)	Revised definitions for NAP5
0	No harm occurred	No harm occurred
1	Required extra observation or minor treatment and caused minimal harm	Resolved (or likely to resolve) with no or minimal professional intervention. No consequences for daily living, minimal or no continuing anxiety about future healthcare
2	Resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused short term harm	Moderate anxiety about future anaesthesia or related healthcare. Symptoms may have some impact on daily living. Patient has sought or would likely benefit from professional intervention
3	Caused permanent or long term harm	Striking or long term psychological effects that have required, or might benefit from professional intervention or treatment: severe anxiety about future healthcare and/or impact on daily living. Recurrent nightmares or adverse thoughts or ideations about events. This may also result in formal complaint or legal action (but these alone may not be signs of severity)
4	Caused death	Caused death

(Modification by Ms Helen Torevell, NAP5 Panel member)

Small group review was followed by second review in a large group to moderate output from the first review

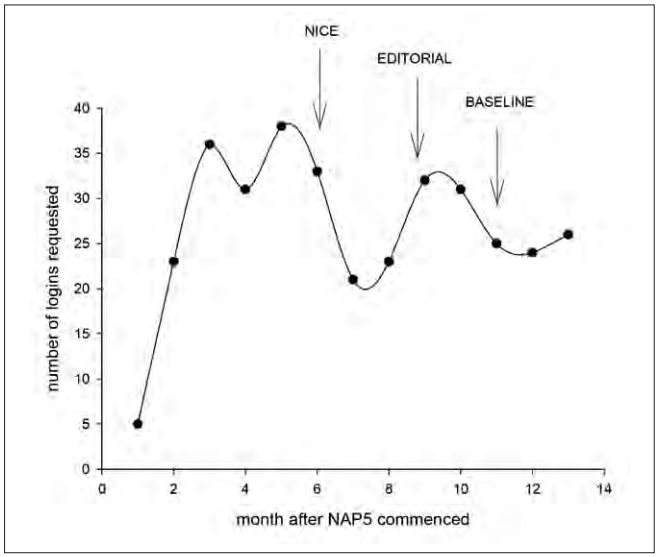
NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

5.34 The results and analysis of reports of AAGA is presented in the remainder of this Report. This chapter presents only the results relating to the methodology itself.

5.35 Regular responses were received from all 269 UK LCs on a monthly basis (100% response rate). Of these, 108 LCs consistently filed zero returns for the whole data collection period (i.e. the hospitals covered by 108 LCs received no reports of AAGA in the year). There were no security breaches of the website, de-anonymisation of patient reports, or technical problems related to data collection. In Ireland, regular responses were received from each of 41 Irish LCs, 31 of whom submitted a nil return for the whole period.

5.36 A total of 471 requests from both UK and Ireland were received by the NAP5 team for login details to access the website. After screening, including consultation with the NAP5 Moderator where indicated, 341 were judged admissible and logins issued. However, 20 LCs did not use their logins, leaving 321 reports filed. Guidelines from the National Institute for Health and Care Excellence (NICE) on electronic depth of anaesthesia monitoring and criticisms thereof (Pandit & Cook, 2013b) were published in November 2012 and February 2013 respectively; the Baseline Survey (Phase 1) of NAP5 was published, with considerable media attention, in March 2013 (Pandit et al., 2013a and b). None of these appeared to influence the request rate for logins to the website (Figure 5.1).

Figure 5.1. The monthly request rate for logins to secure website per month. NAP5 commenced on 1 June 2012; the arrows show the times when relevant NICE guidance (NICE, 2012) and an associated editorial (Pandit & Cook, 2013b) and the NAP5 Baseline Survey (Pandit et al., 2013a and b) were published

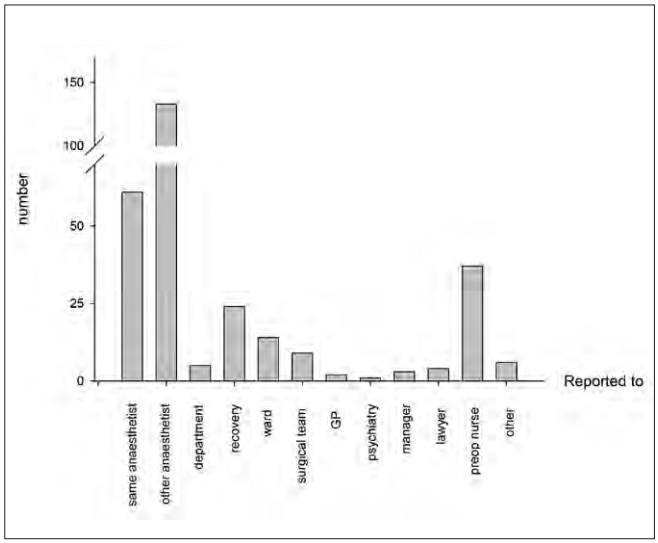


5.37 In the majority (98%) of reports, an LC was involved in submission to the NAP5 website, either alone or with another anaesthetist. In 7 reports, an anaesthetist who was not an LC filed the report alone.

5.38 A majority (95%) of reports were made spontaneously by the patient. Otherwise, reports were made by the patient to a friend, who reported it to an anaesthetist (one case), in a legal letter of claim (one case), where the anaesthetist suspected AAGA and initiated the discussion with the patient (six cases), by a carer or relative (eight cases).

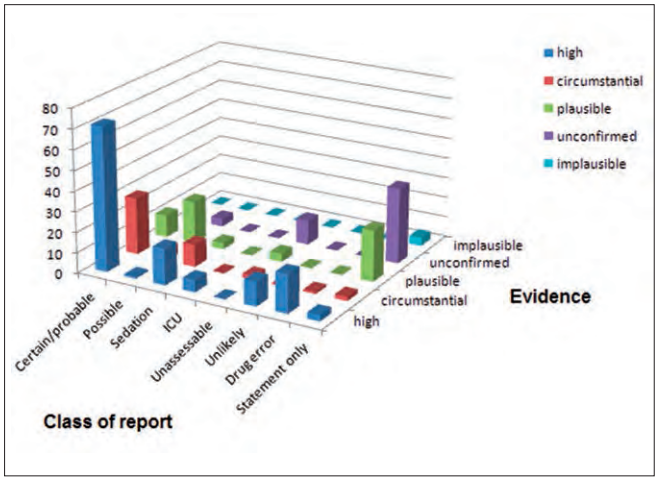
5.39 Figure 5.2 shows to whom the report was first made. In the majority of cases (66%) the same anaesthetist who provided care, another anaesthetist, or the anaesthetic department received the report. It was also common for pre-operative nurses to receive a first report of AAGA (i.e. before a subsequent operation; 21%). Statement Only cases were generally reported to another anaesthetist or to the pre-operative nursing staff (presumably because most of these were historical cases, there was unlikely opportunity to report to the same anaesthetist that administered care).

Figure 5.2. Bar chart of to whom the report of AAGA was made. Department = anaesthetic department (e.g. by letter or telephone); GP = General Practitioner; Pre-op nurse = pre-operative nurse)



5.40 Most of the Certain/probable reports, the Sedation and the Drug Error cases were associated with a strong level of evidence. Conversely the Unlikely and Statement Only cases with a weaker evidence base. For Possible cases the degree of evidence was variable see Figure 5.3.

Figure 5.3. Distribution of evidence base by class of report



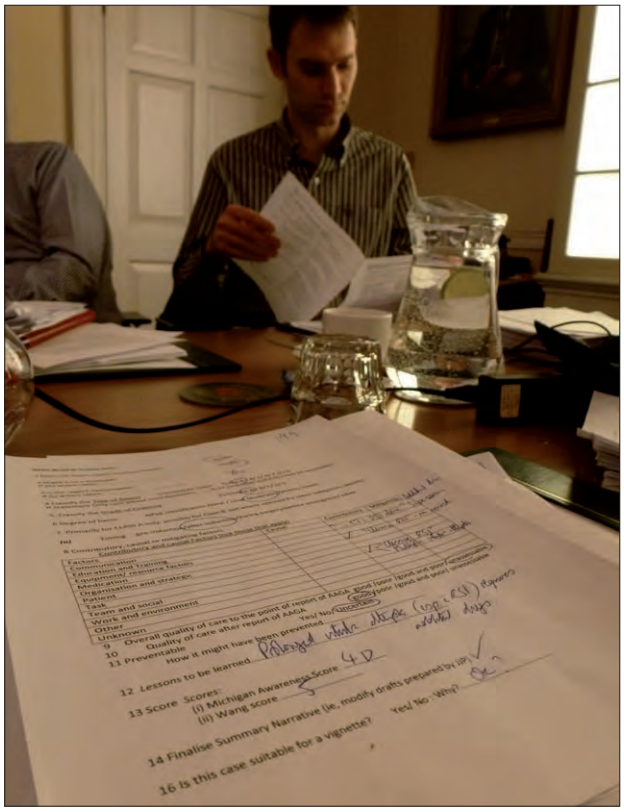
5.41 The Certain/probable and Possible reports (and those relating to Sedation, ICU or Drug Error) are discussed in later chapters, as are inadmissible reports, Unlikely reports and Statement Only reports.

DISCUSSION

5.42 The study architecture of NAP5 conforms to a registry, but one that is nationwide (separately for the UK and Ireland): NAP5 is therefore probably the first national survey of AAGA ever undertaken. Our method of assembling registry cases through LCs at each hospital appears unique to this topic (though identical to two previous NAPs). Several other features are important. It is a registry of *first reports* of AAGA and great care was taken to exclude reports made previously to the healthcare system. No active questioning of patients was required, but naturally, sometimes anaesthetists did question patients whom they suspected of having been aware. Reports elicited in this manner (6; 1.9%) were accepted as being part of routine clinical care rather than excluded as protocol-based interrogation.

5.43 It was the intention of the project that the AAGA reports remained anonymous, and the regulatory requirements imposed on NAP5 reinforced this necessity. Hence, the NAP5 Panel do not know the geographical source of the report, the identity of the LC who filed the report, or any patient, hospital or clinician identifiable details. If despite this case details provided in this Report appear recognisable to some readers, it is likely because they are very representative of not-infrequent occurrences (i.e. very few, if any, reports we received appeared unique).

All reports were reviewed in a structured manner with structured outputs



5.44 By relying on spontaneous reports we hoped to receive the most 'robust' reports; that is, those reports unprovoked by active questioning. We were confident that our team of LCs diligently scanned their hospitals on a regular basis, across departments actively searching for reports. The 100% response rate (including zero response) provides some evidence that this worked, and indeed reports were received from a variety of sources (Figure 5.2). Although we did obtain some reports from GPs and psychiatrists/psychologists, we cannot be certain that we did not miss any. The use of strictly defined categories of report was important in the project. We believe our methodology improved the likelihood of correct inclusion and exclusion of reports and made the nature of reports more explicit, adding to the robustness of the project. We have described those cases judged inadmissible or Unassessable here and in the Report to enable others to judge this. The relatively high proportion of Statement Only cases, and the strikingly long time intervals for their reporting, might also suggest a diligence of the system in detecting these otherwise long-unreported cases.

5.45 However, the accuracy of our method in detecting all cases of AAGA relies upon the ability of the healthcare system to transmit the report to anaesthetists: as Avidan and Mashour (2013a and b) previously commented, we may be 'under the rate, or under the radar'. The fact that the majority of reports were made to anaesthetists (Figure 5.2) does not exclude the possibility that reports were made to others but not transmitted to anaesthetists' and therefore, not detected by LCs. The type of report we obtained was at several removes from the source. That is, details were not obtained from the patient direct but rather mostly from an LC, who in turn had obtained information from a mixture of case notes and colleagues involved in the case. Furthermore, we did not have access to the medical records, but rather, the LC's version of what those records were. There was thus some inevitable loss of detail. On first principles, this potential loss of detail may have affected the reporting of sophisticated outcomes such as psychological detail more than it did objective details such as drugs administered, etc.

5.46 The alternative to a reliance on spontaneous reporting is to use active questioning. Although the Brice interview is commonly used in research, we cannot find any previous critique of it; its possible weaknesses appear to have gone unchallenged. It is often described as 'modified', but seems identically used in respect of its key questions to that originally described. For example it is not known if different questions, or an alternative sequence of questions, will elicit a different response rate. Studies using the Brice questionnaire often lack detail as to how the output of the questionnaire is interpreted, what (if any) other investigation of possible cases is undertaken and what criteria are used to confirm or refute AAGA. Therefore for any given group of patients administered the Brice instrument, it is not known what proportion of those initially indicating AAGA are (or would be) later judged by a review panel *not* to have Certain or Possible AAGA (and whether this proportion is consistent across studies). While it seems that up to three Brice interviews up to a month post-operatively yields the highest positive response rate for AAGA, it is not known if even more questioning yields higher (or lower) rates. Indeed, it would appear likely that several cases classified as 'Unassessable' or 'Unlikely' in NAP5 might in fact have been deemed as admissible AAGA if a Brice method alone had been used. Therefore, although methods relying on spontaneous reporting have their limitations, it is far from certain that Brice questioning should be regarded as the 'gold standard'.

5.47 The issue of what causes AAGA is important, but our methodology did not robustly address this: AAGA could be avoided or prevented by knowing its causes. However, the analysis of causality is complex. In one sense, it implies that one action (or inaction) directly leads to another event. This simplistic view does not always accommodate a need for several conditions to exist (no one of them alone sufficient) so that one event can lead to another. Nor does it encompass causality as a probabilistic analysis (i.e. as an event more or less likely to occur given certain conditions). In the analysis of medical practice in particular, the notion of 'contributory factors' is perhaps more meaningful than 'cause' (Pearl, 2000; Green, 2003) and we have adopted this in our analysis.

5.48 *The immediate cause* of AAGA is always 'inadequate anaesthesia'. However, the *root cause* (the event initiating the causal chain) can be something quite different (e.g., distraction, ignorance, etc) (Mashour, 2013). In a more pragmatic sense, causes of AAGA might be broadly summarised as:

(a) a failure or interruption of delivery of suitable concentrations of anaesthetic (e.g. through root causes of mechanical failure, human error or misjudgement); or

(b) an inherent patient resistance to anaesthetic drugs (which may involve root causes of 'physiological' resistance such as due to anxiety or pain; or 'pharmacological' resistance, such as the presence of other drugs that increase anaesthetic dose requirements; or possibly genetic factors that make the patient less susceptible to anaesthetic effects).

5.49 If possibilities like this are to be investigated then an ongoing database of AAGA cases becomes necessary, as large cumulative databases are the only means to study relatively rare diseases or syndromes with a genetic basis (DoH, 2013). Moreover, a more direct clinical relevance of our methodology is that it offers a standardised means to investigate or analyse cases of AAGA as they arise in practice. Use of the classification scheme in the Tables would help standardise some of the terminology. The relevant anaesthetic organisations, working together with the appropriate national patient safety organisations should consider developing a means by which all incidents of AAGA are properly recorded and entered onto a permanent database, to allow for ongoing learning.

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CHAPTER
6

NAP5 summary of main findings and incidences


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HEADLINE

6.1 The estimated incidence of patient reports of AAGA (using a parallel national anaesthetic Activity Survey to provide denominator data) for Certain/probable and Possible cases of AAGA was ~1:20,000 anaesthetics. However, there was considerable variation in this incidence when subtypes of anaesthetic techniques or subspecialties were taken into account. Thus, whereas the incidence of reports of AAGA when neuromuscular blockade was used was ~1:8,000, when no paralysis was involved this was ~1:136,000. The cases of 'AAGA' reported to NAP5 were overwhelmingly, cases of unintended awareness during neuromuscular blockade. The incidence of reports from cardiothoracic anaesthesia (~1:8,600) closely resembled that for neuromuscular blockade. The incidence of reports of AAGA after general anaesthetic Caesarean section was much higher, ~1:670. Almost two-thirds of AAGA experiences arose in the dynamic phases of anaesthesia (at induction and emergence). One third of AAGA events arose during the maintenance phase of anaesthesia. There was an over-representation in AAGA cases (versus the population of general anaesthetics as estimated by the Activity Survey) of: neuromuscular blockade (associated with under-representation of use of a nerve stimulator or reversal of blockade), thiopental, rapid-sequence induction, total intravenous anaesthesia techniques, female patients, early middle age adults, out of hours operating, junior anaesthetists, previous episodes of AAGA and specific depth of anaesthesia monitoring. Many of these warrant further detailed exploration. Paediatric cases, trauma and orthopaedics and plastics were under-represented.

BACKGROUND

6.2 NAP5 is probably the largest and most comprehensive study AAGA and its risk factors ever undertaken.

6.3 Perhaps the most common tool used to establish the incidence of AAGA has been the Brice interview, conducted immediately after surgery and often repeated up to three times over up to a month (Brice et al., 1970). Over several decades, the incidence appears to have been consistently reported to be ~1–2 :1,000 general anaesthetics (Sandin et al., 2000; Wennerrvirta et al., 2002; Myles et al., 2004; Sebel et al., 2004; Avidan et al., 2008 & 2011). It has been reported as higher in obstetric (1:384; Paech et al., 2008), cardiac (~1:43; Ranta et al., 2002) and paediatric (1:135; Davidson et al., 2011) anaesthesia. However, some studies do report a much lower incidence (1:14,560; Pollard et al., 2007) but have been criticised for using a modified Brice interview confined to within 48-hour of surgery (Leslie, 2007).

6.4 Interestingly, the NAP5 Baseline Survey also reported an 'incidence' for (patient reports of) AAGA of ~1: 15,000 (similar to the findings of Pollard et al., 2007). This was a national survey of

>8,000 senior anaesthetists in the UK and they were simply asked to state how many new cases of AAGA they had experienced in the calendar year 2011 (Pandit et al., 2013a and b). A similar survey conducted in Ireland (using as denominator an estimate of anaesthetic activity that was conducted in parallel (Jonker et al., 2014a) has also established an incidence for AAGA as reported to anaesthetists of ~1:23,000 (Jonker et al., 2014b). These surveys suffer from various limitations (as discussed in the relevant papers) including failure of patients to report the event, memory of the anaesthetist for the incident, biasing (i.e. anaesthetists perhaps failing to report) and also possible systems failures that prevent transmission of a patient report made to another practitioner back to the anaesthetist (Avidan & Mashour, 2013a and b).

6.5 Incidence apart, previous studies have also addressed factors which may be associated with AAGA. The possible influence of types of surgery (notably obstetric, cardiac and paediatric) has been mentioned above, and these may be related to specific anaesthetic practices (some of them arguably historical) that predisposed to AAGA. Anecdotally, risks may be conferred by the (historic) technique of avoiding volatile agent before (or perhaps more recently, after) delivery in obstetrics, or the use of cardiac bypass and largely opioid-based techniques for cardiac surgery.

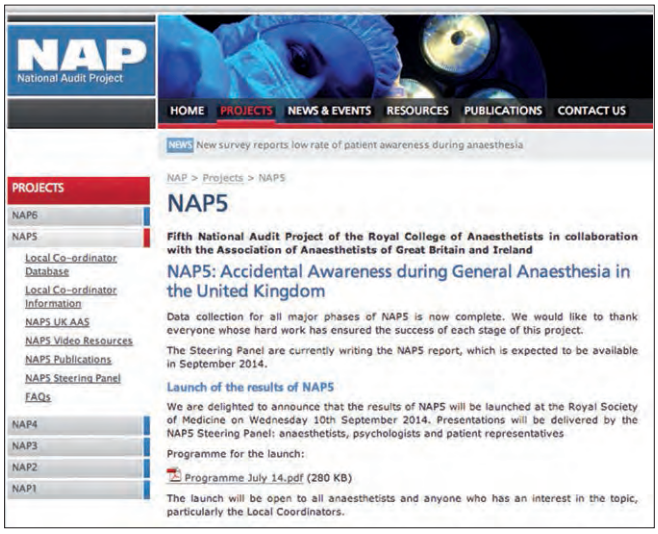
6.6 The obstetric influence may overall make AAGA commoner in women. Analyses of case series in medicolegal settings of awareness in the UK and the USA have demonstrated that a higher proportion of claims come from women. Domino et al., (1999) reported 77% of US claims were from women. Mihai et al., (2009) reported that 74% of UK claims were from women, and that 29% of claims arose in obstetric general anaesthesia. This may indicate that gender influences reporting rates as well as susceptibility to AAGA.

6.7 Some studies have reported that patients with a higher ASA score, are at increased risk of AAGA (Bogetz & Katz, 1984; Domino et al., 1999). Intentionally reduced doses of anaesthetic drugs because of concerns over cardiovascular and other effects may contribute to this. However, others find the converse; i.e. that patients with higher ASA scores are more susceptible to anaesthetic effects with lower AAGA incidence (Ranta et al., 1997).

6.8 There are several reasons why obesity is implicated in AAGA (Aranake et al., 2013). Inadequate drug dosing may arise because of the altered pharmacokinetics due to changes in body fat content, lean body mass, blood volume, cardiac output, total body water and alterations in plasma protein binding (Ingrande & Lemmens, 2010). However, some studies fail to find an association (Ranta et al., 1997; Ghoneim et al., 2009). Obesity is possibly associated with a difficult airway, which could potentially increase risk of AAGA, but Ghoneim et al., (2009) did not report this as a risk.

6.9 The notion of an intrinsic (possibly genetic) resistance to anaesthesia has been raised over the years in the literature. Ghoneim et al. (2007) reported that 1.6% of patients reporting AAGA described a previous history of AAGA. In the BAG-RECALL study, 11% of patients with AAGA had a previous history (Avidan et al., 2011). In most epidemiological studies of AAGA, cases are reported with no apparent cause (Errando et al., 2008; Sandin et al., 2000). Most recently Aranake et al., (2013) reported a secondary analysis of 26,490 patients enrolled in three major trials (B-Unaware, BAG-RECALL and MACS), and found that patients with a history of AAGA had a 5-fold greater incidence of AAGA. The Australian and New Zealand College of Anaesthetists has begun a collaborative trial to examine a possible genetic link to AAGA (see: (www.med.monash.edu.au/sphpm/anzca/research.html).

NAP website



NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

6.10 Table 6.1 shows that by class of report, Certain/probable (Class A) were the commonest. Together with Possible (Class B), Sedation cases (Class C), ICU cases (Class D) and Drug Errors (Class G) this meant that the vast majority of reports likely had a genuine basis that was potentially confirmable.

Table 6.1. Numbers of reports by class

Class	Number of reports (%)
Certain/probable (A)	110 (37)
Possible (B)	31 (10)
Sedation (C)	32 (11)
ICU (D)	6 (2)
Unassessable (E)	19 (6)
Unlikely (F)	12 (4)
Swaps/drug error (G)	20 (7)
Statement Only (SO)	70 (23)
Total	300

6.11 Most of the data that are presented in this chapter focus on the 141 Certain/probable and Possible cases (Class A and B) combined.

Patient characteristics

6.12 Figure 6.1 shows the main patient characteristics in the Certain/probable or Possible cases, namely age distribution, body habitus and ASA grade, and their comparison with the distributions from the NAP5 Activity Survey. There appeared a marked under-representation of children (a 4.6-fold difference) and a slight over-representation of younger/middle-aged adults in AAGA reports, and an under-representation of the elderly. There was a preponderance of females reporting AAGA (65% vs 35% males) exceeding that in the Activity Survey (53% vs 47% males undergoing general anaesthesia). There is an over-representation of the obese in cases of AAGA in this category, with proportionately more than three times as many obese patients experiencing AAGA as undergo anaesthesia. The distribution of ASA grades in this category was in proportion with the numbers of patients undergoing general anaesthesia in the Activity Survey, with the majority of cases being ASA 1 and 2.

6.13 Tables 6.2 and 6.3 show some of the data used for Figure 6.1.

Figure 6.1. (A) Age distribution (The x-axis is in deciles, with the smallest value <5yrs and the largest >90 yrs); (B) ASA grades distribution; (C) body habitus distribution. Where a bar extends above the line that feature is relatively over-represented in the reported cases relative to Activity Survey activity – and vice versa

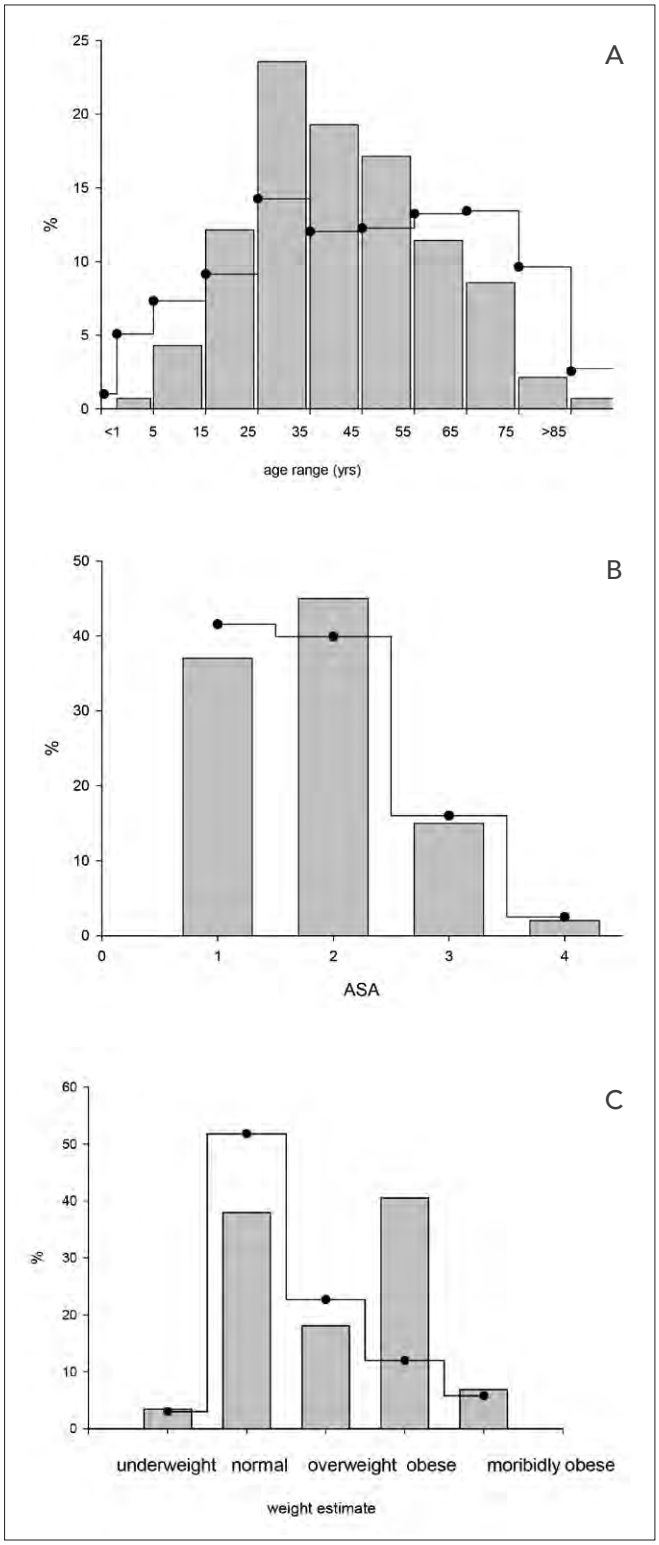


Table 6.2. Data used in Figure 6.1C for body habitus. A ratio >1 indicates the feature is over-represented in the cases relative to Activity Survey activity

Body habitus	% in Activity Survey	% in AAGA cohort	Ratio of % in AAGA cohort: Activity Survey
Underweight	3.00	3.4	1.15
Normal	51.8	37.9	0.73
Overweight	22.7	18.1	0.80
Obese	12.0	40.5	3.38
Morbidly obese	5.8	6.9	1.18

Table 6.3. Data used in Figure 6.1B for ASA distributions. A ratio >1 indicates the feature is over-represented in the cases relative to Activity Survey activity

ASA	% in Activity Survey	% in AAGA cohort	Ratio of % in AAGA cohort: Activity Survey
1	40.6	37.0	0.91
2	39.0	45.0	1.15
3	16.1	15.0	0.93
4	2.6	2.0	0.77

AAGA by specialty

6.14 By specialty (Figure 6.2), the striking result is the marked over-representation in AAGA cases of obstetrics (a 10-fold difference) and of cardiothoracic (2.5-fold difference). Two specialties appear 'under-represented' in AAGA cases: orthopaedics/ trauma/ spine (~1.5 fold difference) and plastics (a 5-fold difference).

6.15 Table 6.4 shows the data for Figure 6.2.

Figure 6.2. Distribution by specialty of Certain/probable and Possible AAGA cases (bars) and in the Activity Survey (dots and line). Three AAGA cases in bariatric and transplant surgery have been omitted as they were not sought in the Activity Survey. (ENT – ear, nose, throat and dental and maxillofacial surgery; ortho/ spine includes orthopaedics, trauma and spinal surgery; eye is ophthalmology; X-ray is radiology). General surgery includes urology and other specialties not listed

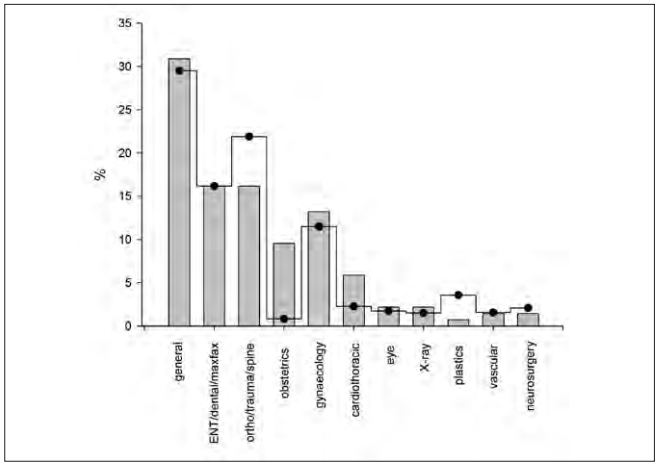


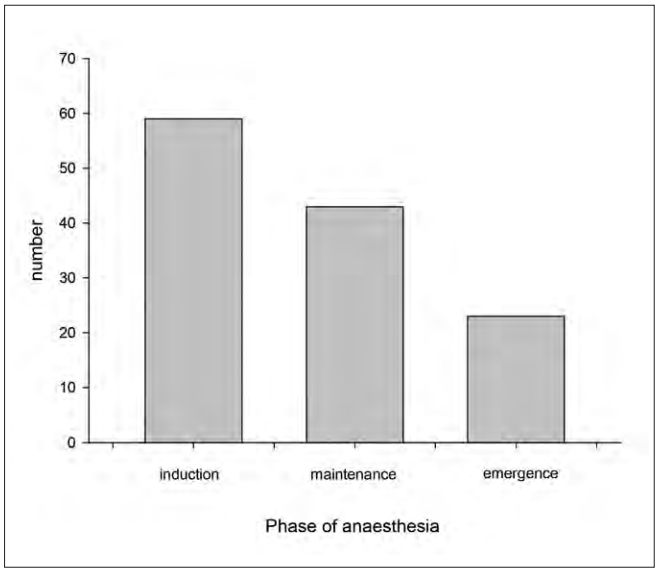
Table 6.4. Data used in Figure 6.2 for AAGA cases by specialty. A ratio >1 indicates the feature is over-represented in the cases relative to Activity Survey activity

Specialty	% cases in Activity Survey	% cases in AAGA cohort	Ratio of % cases in AAGA cohort: Activity Survey
General	29.5	30.9	1.04
ENT	16.2	16.2	1.00
Orthopaedic	22.0	16.2	0.74
Obstetrics	0.83	9.6	11.51
Gynaecology	11.5	13.2	1.15
Cardiothoraciic	2.29	5.9	2.57
Ophthalmology	1.75	2.2	1.26
Radiology	1.53	2.2	1.44
Plastics	3.59	0.7	0.20
Vascular	1.59	1.5	0.92
Neurosurgery	2.1	1.5	0.70

AAGA by phase of anaesthesia

6.16 Two-thirds of Certain/probable and Possible reports were related to the dynamic phases of anaesthesia (induction n = 59 (47%) and emergence n = 23 (18%); Figure 6.3) compared with during maintenance n = 43 (34%). In nine cases AAGA was judged to occur during multiple phases and in seven cases the Panel was not able to judge a phase of occurrence.

Figure 6.3. Distribution of the cases by phase of anaesthesia (AAGA more common at induction > surgery > emergence)



Elements of anaesthesia practice and AAGA

6.17 The main features of anaesthetic practice in the AAGA cases compared with those in the Activity Survey are shown in Figure 6.4 and the corresponding ratios of occurrence of those variables in the AAGA cohort versus those in the Activity Survey in Figure 6.5.

6.18 Table 6.5 shows the data for Figures 6.4 and 6.5.

Figure 6.4. The representation of some components of anaesthesia practice in Certain/probable and Possible AAGA reports (bars) and in the Activity Survey (dots and lines). 'Propofol' in first bar refers to its use as an induction agent, as distinct from a later bar (TIVA/TCI) where its use is referred to for maintenance. N2O, nitrous oxide; NMB, neuromuscular blockade, RSI rapid sequence induction, DOA, specific depth of anaesthesia monitor

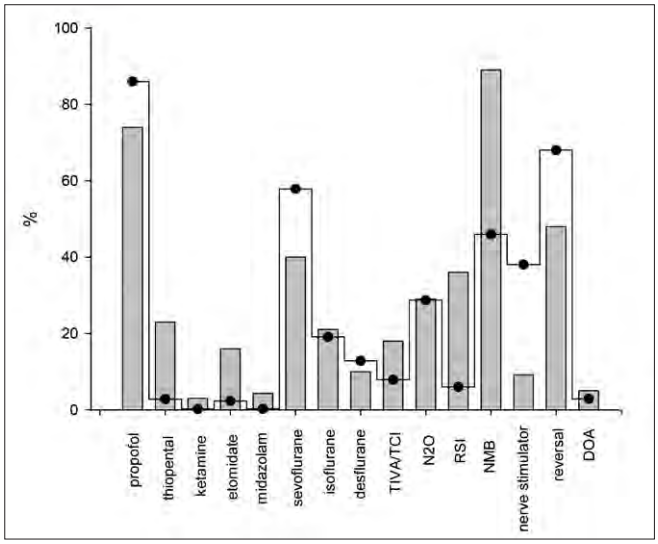


Figure 6.5. Ratio of the proportions from Figure 6.4 for each aspect of anaesthesia care. The horizontal dotted line at unity indicates the proportions being equal. The larger the bar, the greater is the feature represented in AAGA report; the smaller the bar, the less is the feature represented in the AAGA reports

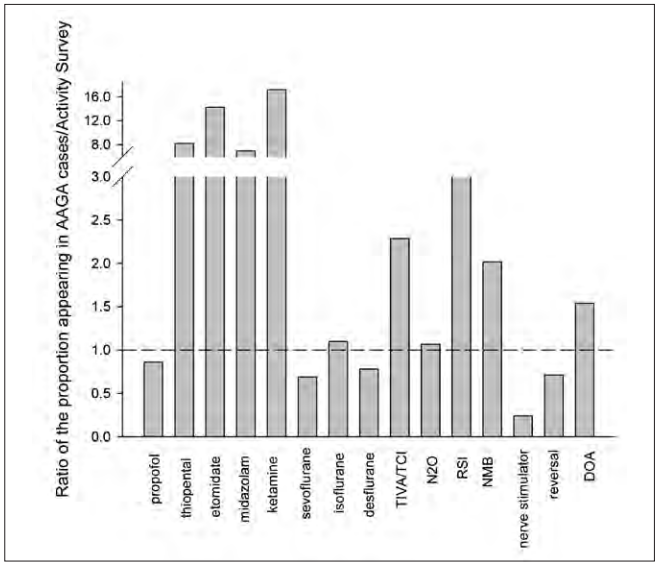


Table 6.5. Data used in Figures 6.4 and Figure 6.5. *for those cases in which non-depolarizing NMB used. A ratio >1 indicates the feature is over-represented in the cases relative to Activity Survey activity

Anaesthetic variable	% use in Activity Survey	% use in AAGA cohort	Ratio of use in AAGA cohort: Activity Survey
Propofol	86.0	74.0	0.9
Thiopental	2.8	23.0	8.2
Etomidate	0.2	3.0	14.3
Midazolam	2.3	16.0	7.0
Ketamine	0.3	4.3	17.2
Sevoflurane	57.9	40.0	0.7
Isoflurane	19.1	21.0	1.1
Desflurane	12.8	10.0	0.8
TIVA	7.9	18.0	2.3
N2O	28.7	29.0	1.1
RSI	36.0	6.0	6.0
NMB	46.0	93.0	2.0
Nerve stimulator*	38.0	9.2	0.5
Reversal of NMB*	68.0	48.0	1.7
DOA	2.8	4.3	1.5

6.19 Strikingly, neuromuscular blockade (NMB) appears far more commonly in the AAGA reports (93% of reports) than its use in general anaesthesia (in 46% of anaesthetics). Additionally, a nerve stimulator was used after a non-depolarising NMB much less frequently in AAGA cases (9%) compared with the Activity Survey (38%). Similarly, reversal of non-depolarising NMB was less common in AAGA cases (48%) than in the Activity Survey (68%). Thus the combination of using NMB, not monitoring its effect, and not reversing it together seemed to incur a risk for AAGA.

6.20 Of induction agents, thiopental, etomidate, midazolam and ketamine are over-represented in AAGA cases. Thiopental is used in only 3% of inductions in the Activity Survey, but features in 23% of AAGA reports – an almost 8-fold difference. Fewer cases overall were conducted with the other three agents, making them subject to greater variation in estimates (and the Activity Survey did not differentiate between co-inductions or use of midazolam or ketamine), so these data should be interpreted with caution.

6.21 Of the maintenance agents, the volatiles appeared in AAGA cases in broad proportion to their general use (although sevoflurane is somewhat under-

represented). Total intravenous anaesthesia (TIVA) when including all methods (i.e. target controlled infusions, manually varied infusions, fixed rate infusions and boluses) appears over-represented (18% in AAGA cases, but 8% overall; a greater than two-fold difference). Nitrous oxide is no less frequently used in AAGA cases than in cases overall.

6.22 Specific (EEG-based) depth of anaesthesia monitoring was used sparsely, but more commonly in the AAGA reports (4.3%) than in the general population of anaesthetics (2.8%). This is discussed in more detail in Chapter 20.

Incidence of AAGA reports

6.23 The Activity Survey indicates there were ~2,800,000 cases of general anaesthesia annually. The overall headline incidence of patient reports of AAGA can be estimated. Several incidences can be calculated depending on which cases of AAGA are included or excluded – for completeness and clarity we describe several. Discounting the Sedation cases, Unassessable and Unlikely reports, and the Statement Only cases (but including the Drug Error and ICU cases) leaves 167 cases; yielding an incidence of patient reports of AAGA ~1: 17,000 (0.006%) general anaesthetics.

6.24 If drug swaps are excluded (as they are really examples of unintended paralysis rather than accidental awareness) this leaves 147 cases and an incidence of patient reports of 1:19,000 (0.005%). Both the number and the estimated incidence is remarkably close to the estimate from the Baseline Survey of 153 cases and ~1:15,000, respectively. The incidence using only Certain/probable and Possible reports is 1 in 20,000.

6.25 Assuming that all unassessable and statement only cases are also accurate reports of AAGA gives a 'pessimistic incidence' of ~1 in 12,000 (0.008%).

6.26 The most pessimistic incidence of 'patient reports of suspected AAGA' can be estimated assuming that all 471 original requests for logins were made on some positive grounds, or that the Panel methodology erroneously categorised reports as inadmissible, Unassessable, Unlikely, etc. The overall incidence of patient reports of suspected AAGA is therefore no higher than ~1:6,000 (~0.02%).

6.27 The summary of the different incidences are presented in Table 6.6.

6.28 There is a striking difference between the incidence of AAGA when no NMB is used (~ 1: 135,900) versus when an NMB is used (~1:8,200). The latter figure.

Table 6.6. Estimated 'incidences' for reported AAGA arising out of reports to NAP5. The first column shows the number of reports in that category (n) from NAP5 (Poisson confidence intervals are given in square brackets); the second column shows the number in this category in the Activity Survey from the Activity Survey. *includes all login requests to NAP5 (i.e. an artificially inflated estimate); ** includes all Certain/probable and Possible cases, ICU cases, and cases of drug error

	Activity Survey estimate, n	Incidence	%
Incidence of any report of AAGA made by a patient (n=471)* [429–515]	2,766,600	1: 6,500	0.015
Incidence of AAGA Certain/probable (n = 111) [91–133]	2,766,600	1: 25,000	0.004
Incidence of AAGA Certain/probable or Possible (n = 141) [118–166]	2,766,600	1: 19,600	0.005
IIncidence of AAGA when NMB used** (n = 155) [131-181]	1,272,700	1: 8,200	0.012
Incidence of AAGA when no NMB used** (n = 11) [5–19]	1,494,00	1:135,900	0.001
Incidence of AAGA reports after sedation by anaesthetists (n = 20) [12–30]	308,800	1: 15,500	0.006
Incidence of AAGA with Caesarean section (n = 12) [6–20]	8,000	1: 670	0.150
Incidence of AAGA in cardiothoracic anaesthesia (n = 8) [3–15]	68,600	1: 8,600	0.012
Incidence of AAGA in paediatric anaesthesia (n = 8) [3–15]	488,500	1: 61,100	0.002

is very similar to the incidence for cardiothoracic surgery, where NMB use is commonplace, which might explain over-representation of this specialty in AAGA cases. Another subgroup where NMBs are commonly used with notably high incidence is obstetrics (~1:670). The estimate for AAGA in children (where NMB is used less often) is, on the other hand, very low.

DISCUSSION

Incidence

6.29 A striking finding is that, similar to that of the NAP5 Baseline Surveys (Pandit et al., 2013a and b; Jonker et al., 2014b), the overall incidence of patient reports of AAGA is very low, occurring in approximately 1 in 19,000 general anaesthetics. Even the most pessimistic estimate is <1 in 6000. We believe this is important new information for anaesthetists and patients.

6.30 Of note: these figures are several orders of magnitude less common than the incidence consistently ascertained using the Brice interview (ie ~1:20,000 vs ~1:600). If we assume the Brice method to reveal the 'correct' incidence, then it means that for every ~40 patients who experience AAGA (by Brice) just one will make a report (by NAP5). The reasons for this marked disparity need fuller discussion. Methodological differences may be relevant (including inherent weaknesses in the Brice interview, versus weaknesses in the process of NAP5 data collection).

6.31 The differences may also relate to the possible impact the AAGA has had on the patient. The theoretical reasons for not reporting an experience are diametrically opposed: either because it was so trivial that it simply does not warrant a report; or because the event was so traumatic that it is difficult or impossible to make a report. Some support for the first interpretation may lie in the fact that the incidence of distress at the time of the event or psychological sequelae afterwards did not differ between early and late reported cases (see Chapter 7, Patient Experience). Also in studies using the Brice interview, about one-third of patients reporting pain or distress associated with their AAGA experience (Avidan et al., 2008 & 2011) indicating that the majority are neutral events. This is similar to the proportion reporting distress in the NAP5 Baseline Survey (Pandit et al., 2013a & b), but (consistent with the first proposition), lower than the ~50% we now report. Furthermore, Villafranca et al. (2013) describe a patient who responded positively to a Brice interview, but maintained that the experience was so trivial that he did not wish to discuss it further.

6.32 Yet in some support of the second interpretation, our data for Statement Only cases reveals several patients who clearly exhibited forms of phobic avoidance for decades after AAGA (see Chapter 30).

The relative proportions of 'too trivial' versus 'too traumatic' experiences in a 'Brice-positive' cohort are unknown and this warrants formal investigation. Nevertheless, it would appear that the Brice interview in its current form is uncovering a memory that was (as a result of either triviality or trauma) previously inarticulated.

Specific depth of anaesthesia monitoring

6.33 In contrast to the overwhelming prominence of neuromuscular blockade and its (lack of) monitoring, DOA monitors feature little in our results. NAP5 is not a project about DOA monitoring: if for no other reason, this is because DOA monitors are very rarely used as a guide to anaesthesia in the UK. The Activity Survey estimates just 2.8% of all general anaesthetics involve the use of any form of DOA monitoring. This is despite guidance from the National Institute for Health and Care Excellence a full year before the activity survey was conducted, notwithstanding some criticism (Pandit & Cook 2013). The isolated forearm technique (IFT) is even less frequently employed (just ~0.03% of all general anaesthetics (Sury et al., 2014). The use of DOA monitors in Ireland is somewhat higher (~9% of all general anaesthetics) but hardly commonplace (and the IFT is not used) (Jonker et al., 2014a & b). It is unknown if this pattern is mirrored in other countries.

6.34 There was an over-representation of use of depth of anaesthesia monitors in AAGA cases by ~50%, superficially suggesting lack of the benefit from them. However we do not know if they were used appropriately in cases where AAGA occurred. Furthermore, these monitors appeared to be used selectively. The details of DOA monitoring are further explored in Chapter 20.

Inherent resistance to anaesthetic agents

6.35 There was some evidence from our data of differential risk of AAGA with different anaesthetic agents: increased with thiopental and lower for sevoflurane compared with other volatiles. Variation

in the risk of AAGA with different anaesthetic agents and the potential for heterogeneity in coding for protein channels on which anaesthetic agents likely act provides some support for the idea of a genetic role in patients' susceptibility to anaesthetic agents or conversely risk of AAGA.

6.36 In this regard, the NAP5 data contain two potentially relevant results. First, is the finding that within the AAGA reports arising in the maintenance phase of anaesthesia, the causality for 25% was unexplained. Second is the finding that there were six possible cases of previous AAGA and one possible family history of AAGA in our Certain/probable or Possible AAGA reports (i.e. in 5% of cases overall there was some family history). This is not an insignificant proportion. Aranake et al. (2013) have reported that AAGA is up to five times more likely in patients with a previous history of AAGA (an incidence of 1.7%, ~1:60 using Brice questionnaire), which suggests an influence of inherent patient factors. However, NAP5 methodology does not allow us to explore these intriguing speculations further.

Summary

6.37 The detailed analysis of discrete sections of this data (e.g. relating to phases of anaesthesia, subspecialties and monitoring) are discussed in later chapters of this Report.

6.38 The overview of the NAP5 data, especially the data on incidence, make one conclusion compelling. If sustained learning through data collection for a relatively uncommon but important condition is to occur, then an ongoing national database of cases is necessary, modelled on the process used by NAP5.

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CHAPTER
7

Patient experiences and psychological consequences of AAGA


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HEADLINE

7.1 AAGA encompasses a wide range of experiences (from the trivial to something akin to feelings of torture) and a wide range of psychological consequences (from none to life-changing). In NAP5 recall was, in about half the cases, expressed in a neutral way, focused on a few isolated aspects of the experience. In about half of cases there was distress at the time of the experience; distress was particularly likely with sensations of paralysis or pain, but could also occur when only isolated sounds or tactile sensations were experienced. Distress during AAGA was strongly associated with subsequent psychological sequelae. Understanding what was happening, or what had happened, seemed to mitigate immediate and longer-term psychological distress. Active early support may offer the best prospect of mitigating the impact of AAGA, and a structured pathway to achieve this is proposed.

BACKGROUND

7.2 At its worst, accidental awareness during general anaesthesia (AAGA) can be terrifying. Common experiences include: hearing voices or noise of equipment; trying to move to alert staff and being unable to; feeling anxious that something has gone wrong with the operation and powerless to do anything, or feeling frightened that things are going to get worse (Aaen & Møller 2010; Moerman et al., 1993; Sebel et al., 2004; Ghoneim et al., 2009, Samuelsson et al., 2007; Schwender et al., 1998).

7.3 In Samuelsson et al.'s (2007) study of 46 AAGA cases, auditory (70% of AAGA reports) and tactile (72%) were the most common sensory experiences. Forty six percent of patients experienced pain during AAGA and 65% experienced an acute emotional reaction including helplessness (57%), fear (54%) or panic (43%). Thirty-seven (80%) of the 46 patients felt they understood what was happening, and most (67%) tried to communicate.

7.4 In Sebel et al.'s (2004) study of 25 AAGA cases, around half included auditory perceptions and paralysis, 32% tracheal intubation, and 28% pain. Helplessness, fear and panic were again prevalent (36% of cases), with patients thinking "*I'm going to die*" or "*…it is one of the worst scares I've had…*". Visual perceptions, for example seeing silhouettes, are also reported (Sandin et al 2000; Schwender et al., 2008). Specific auditory memories usually involve salient information, for example: "*It's a boy*" (Samuelsson et al., 2007); "*how can a man be so fat*" (Schwender et al., 1998; "*This woman is lost anyhow*" (Schwender et al., 1998). Commonly, patients find the experience of paralysis particularly disturbing and traumatic, may not appreciate its reversible nature, and have catastrophic appraisals about its cause and meaning.

7.5 Concern about AAGA is an important contributor to pre-operative anxiety (McCleane & Cooper, 1990).

As it is not discussed in routine consent procedures (Chapter 21, Consent), lack of understanding may cause patients to interpret an experience of awareness catastrophically, thinking that they must be dying. There are also patients who experience AAGA but are relatively unconcerned by it (Sebel et al., 2004).

7.6 In a large analysis of patient satisfaction, Myles et al. (2000) reported that although overall patient satisfaction with anaesthesia is very high (97%), dissatisfaction was most strongly associated with an experience of intra-operative awareness (odds ratio 54). Even moderate to severe post-operative pain resulted in much lower odds ratios for dissatisfaction of ~4.

7.7 As well as dissatisfaction, AAGA can lead to serious psychological disorder. Distress at the time of AAGA appears to be an important risk factor for long-term sequelae (Samuelsson et al., 2007).

7.8 It is not yet known if early response to, and sensitive handling of, AAGA reports at the time they are made by the patient can reduce the risk of long-term sequelae, although it seems intuitive that this would be beneficial.

7.9 Management of the response to reports of AAGA is complicated by the fact that patients do not always report awareness to medical staff. In Samuelsson et al.'s (2007) study, 85% of patients reported their AAGA experience to someone but only half to hospital staff. One-third of patients reporting their experiences to staff or family received sceptical responses. It is not well understood what triggers patients to report or withhold a report of AAGA, or how they decide to whom to report. Delayed emergence of AAGA memories may determine who receives the report, as patients may have a fear of medical staff resulting from the experience – both discussed below.

7.10 Patients may interpret experiences during emergence or conscious sedation as AAGA. Samuelsson et al. (2007) interviewed more than 2000 patients of whom 3.7% reported previous AAGA, but 42% of these were excluded as either having had surgery performed under regional anaesthesia or having reports not consistent with AAGA. Of patients in the ASA Awareness Registry whose medical notes were examined, one-third had not received general anaesthesia (Kent et al., 2013). Mashour et al. (2009) reported that patients who had received anaesthetic interventions that did not include general anaesthesia reported AAGA with the same incidence as those who had received general anaesthesia.

Anaesthesia and memory

7.11 NAP5 is a study of *patient reports* of AAGA. The patient must recall AAGA to be able to report it. Because not all episodes of conscious awareness during intended general anaesthesia are subsequently recalled, it is inevitable that they will not all be reported. Studies with volunteers show that post-sedation recall is prevented by doses of anaesthetic agents low enough to permit conversation, voluntary responses and short-term memory functions. In other words, someone who is sedated might be able to recognise a word that was presented a few minutes earlier, but be unable to recall it later when fully conscious again (Andrade et al., 1994; Andrade, 1996). Similar findings have been reported in patients receiving sedation (Andrade et al., 2001).

7.12 It is not known how long a period of awareness must last in order to produce a memory that can be recalled on recovery, but these sedation studies illustrate the fact that memory formation is a complex process that does not happen instantly and completely the moment someone becomes conscious. Studies using the isolated forearm technique during general anaesthesia show that patients can be sufficiently conscious to respond to a complex conditional command intra-operatively but have no explicit post-operative memory of such events (Russell, 1989; Russell & Wang, 1997; Zand et al., 2014).

7.13 Questioning of patients about their possible experiences during anaesthesia is therefore a test of memory. Prospective studies of the incidence of AAGA use versions of the Brice interview (Brice et al., 1970) post-operatively for this purpose. There is good agreement that in studies using this methodology the incidence is between 1–2 cases per 1000 general anaesthetics, an estimate that has remained stable over more than a decade (Sandin et al., 2000; Wennervirta et al., 2002; Myles et al., 2004; Sebel et al., 2004; Avidan et al., 2008; Avidan et al., 2011).

7.14 However, estimates still vary considerably. Errando (2008) used repeated structured interviews and reported an incidence of 1% (1:100) of patients 'stating at interview or spontaneously reporting awareness' whereas Mashour et al., 2013) found an incidence of only 0.02% (1:6,279) when patients were asked generally, one day after surgery, if they had had any problems with the anaesthetic. Pollard et al. (2007) found an even lower incidence of 0.0068% (1:14,705) using a modified Brice questionnaire as part of a quality control program.

7.15 A critique of the Brice interview is offered in Chapter 5 (Methods), but it is clear that the role of memory is important to any interpretation of the data.

7.16 Recall of a period of awareness, whether spontaneously reported or elicited through questioning, is an example of *explicit or declarative memory*. The person has an experience of remembering something and can articulate the content of their memory. People are generally much better at recalling meaningful or well-organised material (Bransford & Johnson, 1972). The realisation of what is happening during AAGA may help the patient to form a memory that is recalled in its entirety rather than as a series of disjointed events or sensations. On the other hand, lack of comprehension of what is happening may lead to greater distress and formation of a *trauma memory*.

7.17 *Trauma memory* is a type of explicit memory with some special characteristics. Normally, memories are stripped of much of their sensory detail as they are encoded, so it is the general gist of events and information that is recalled. Very strong levels of fear and distress can alter this encoding process, leaving memories that are rich in sensory detail and hard to control (Brewin, 2011). Recall of these trauma memories is distressing because it feels like reliving the traumatic event, rather than simply remembering it. AAGA might be expected to lead to rich sensory descriptions from patients who were distressed during their experience.

7.18 *Implicit memory* is very different. This is a memory that is not accompanied by an experience of remembering, but can be revealed by changes in mood or behaviour. It results from 'priming', which is temporary activation of existing representations in memory. On tasks that notionally involve guessing, people's responses are biased towards items they have recently seen or heard because representations of those items remain active in memory. Patients who were played words like 'tractor' during general anaesthesia were biased towards responding with those words when asked to say the first word that comes to mind beginning with 'tra-' (Deeprose et al., 2004), even when bispectral index remained <60 during anaesthesia and they could not explicitly recall hearing 'tractor' during surgery (Deeprose et al., 2005). As these findings show, there is evidence for implicit memory after general anaesthesia, but it is unknown if this has any adverse impact (Deeprose & Andrade, 2006; Andrade & Deeprose, 2007).

7.19 Memory recall is a process of reconstructing rather than replaying a past event. There is therefore a risk of memories becoming distorted and it is a challenge for anaesthetists to know whether a report of AAGA represents a true recollection or a false memory (Pryor & Root, 2013; Pryor & Hemmings, 2013). False memories can be created by inserting false information into the reconstruction process or by encouraging people to generate that information themselves. In a classic study illustrating how people are susceptible to leading questions, participants watched a film of a car crash. Those who were then asked how fast the cars were going when they *smashed* into each other gave higher estimates of speed than those asked how fast the cars were travelling when they *hit* each other, and recalled, incorrectly, that they had seen broken glass at the crash scene (Loftus & Palmer, 1974). Children who had never been to hospital but were repeatedly encouraged to answer questions about a hospital visit later believed it had happened (Principe et al., 2006), and adults shown fabricated photos of themselves enjoying a hot-air balloon ride as children later 'remembered' the event even though it had never happened (Wade et al., 2002).

7.20 These examples of false memories are alike in that people are encouraged to reconstruct an event that is plausible and about which they have been offered false information. Spontaneous reports of AAGA are unlikely to be false memories, because patients are not given the detailed sensory information of anaesthetic and surgical procedures that they would need to construct a false account that felt like a genuine memory.

7.21 It is unknown, however, whether Brice interviewing ever induces false memories (discussed in Chapter 5, Methods).

7.22 *Source memory* refers to our ability to recall where, when or in what format we did something or learned something, i.e. the context in which the learning occurred. Source memory often fails, so we might remember a witty remark but not who said it or when we heard it. An episode of awareness during an otherwise effective general anaesthetic cuts off the memory of AAGA from its sources, so the patient might recall intra-operative events but not be able to place when they occurred. The difficulty in placing a memory is likely to be compounded if a patient does not understand what is happening during AAGA. In a compelling personal account of AAGA, Aaen vividly describes how she forgot that she was having a Caesarean section and thought instead that she was being raped. She only recalled her experience gradually in the months that followed (Aaen & Møller, 2010).

7.23 Without source memory, it is conceivable that some patients might interpret AAGA as a memory of a dream rather than a real event, but there is little evidence that this is the case. Although recall of peri-operative dreaming is common (6% in Sebel et al., 2004; 22% in Leslie et al., 2007; 50% in Errando et al., 2008), it does not seem to be related to depth of anaesthesia or intra-operative events (Leslie et al., 2007). In contrast to most reports of AAGA, peri-operative dreams tend to have pleasant content (Errando et al., 2008; Leslie et al., 2007) and to be reported close to emergence from anaesthesia. Leslie et al (2007) therefore argued that post-operative recall of dreams reflects dreaming during recovery rather than misinterpreted AAGA.

7.24 Memories of AAGA can emerge gradually. In a review of 271 reports of AAGA, 49% were identified on the day of surgery, but 37% were not identified until more than a week after surgery (Ghoneim et al., 2009). In Sandin et al.'s (2000) study using Brice interviewing, only six cases of AAGA were identified during the interview in the immediate post-anaesthesia care unit; seven more emerged at the second interview 1–3 days after surgery, and a further five at the last interview 7–14 days after surgery. Similar findings are reported in children (Davidson et al., 2005). It appears that, even if they experience AAGA, patients may not develop a clear memory of this until some time after they have left hospital. Reports such as Aaen's indicate that recall of AAGA may even be delayed for months.

7.25 Gradual emergence, or spontaneous recovery of memories, is not unique to AAGA (Sara, 2000). The literature on 'hypermnesia' explains how memories can be overwritten by later events and retrieval is impaired until those later memories fade or become less salient (Wheeler, 1995). In the case of AAGA, it is important to remember that the patient regains consciousness at least twice – at least once during anaesthesia and then again on recovery. Recovery may initially be remembered better, because it is more comprehensible. When that memory fades, it becomes easier to retrieve the AAGA memory. Repeated questioning may aid this process (e.g. as in Brice questioning – see Kelley & Nairne, 2003).

7.26 There is also a theory that memories of very traumatic events (e.g. childhood sexual abuse) can be repressed, to be uncovered much later, but this hypothesis is very controversial (Loftus, 1993; Patihis et al., 2013) and does not explain the finding that delayed recall of AAGA often involves a neutral recollection of events (Sandin et al., 2000).

7.27 The relationship of memory and AAGA (or no AAGA) is represented by Figure 7.1.

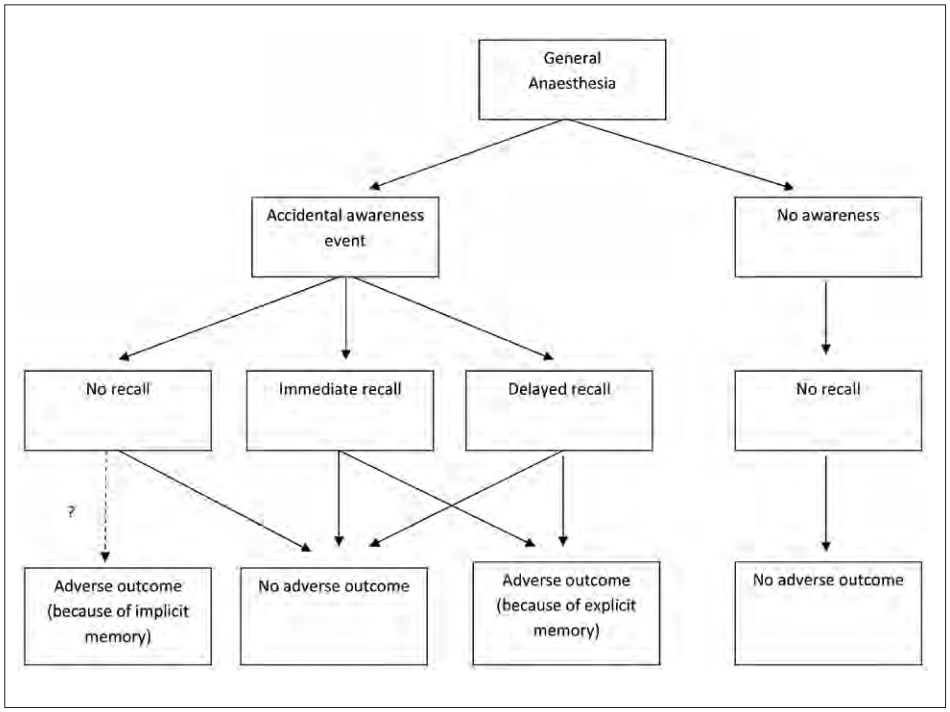


Figure 7.1. General anaesthesia most commonly involves no AAGA and there is no explicit recall or adverse psychological outcome (notwithstanding the possibility of adverse outcome due to implicit memory despite adequate general anaesthesia). An accidental awareness event might lead to no recall, immediate recall or delayed recall. Where there is no recall, the outcome from anaesthesia itself might be expected to be neutral, but there remains a possibility that implicit memories lead to adverse outcome. Recall of AAGA can lead to a neutral or adverse outcome

Post-traumatic stress disorder (PTSD)

7.28 Much of the literature on AAGA stresses that it is a traumatic event. It is not therefore surprising that individuals who experience AAGA may develop post-traumatic stress disorder (PTSD), but it is not known what proportion of patients does so. Aceto et al. (2013) systematically reviewed existing research and reported a range of PTSD rate across all studies (which included cohorts of medicolegal cases, self-reporters and prospective studies) of 0–70%. The highest rate was reported by Leslie et al. (2010) in a high risk surgical group but a very small cohort (just 5 of 7 patients). They calculated an aggregate rate of ~15%. This compares well with Mashour's estimate (in an accompanying editorial; Mashour 2010a) of 13%. It is not known if the likelihood of developing PTSD is influenced by early intervention, or by time delay in reporting AAGA, or whether there is a difference in incidence between self-reported AAGA and that revealed after Brice interview.

7.29 Hospital admission, surgery and anaesthesia may include numerous events and patient experiences that can later lead to adverse psychological impact. AAGA is only one of these. However, it seems probable that AAGA is a risk factor for developing PTSD over and above other aspects of surgery and hospitalization. Leslie et al. (2010) found 5 of 7 patients (71%) reporting AAGA developed PTSD whereas only 3 of 25 matched controls (12%) without AAGA did so. Avidan, Whitlock et al. (2014; personal communication, unpublished results) using a symptoms checklist rather than a formal diagnosis of PTSD, have found symptoms of post-operative PTSD in ~16% of elective surgery cases without awareness and 43% in matched cases with AAGA.

7.30 PTSD is a very serious outcome that can last many years and greatly impair function and quality of life (National Collaborating Centre for Mental Health, 2005). It is associated with increased risk of suicide (e.g. Hendin & Haas, 1991). Classically, PTSD comprises three categories of psychopathology: hyperarousal, re-experience and avoidance. Hyperarousal refers to persistent anxiety-related symptoms such as tachycardia, hypertension, sweating and hypervigilance. Re-experience includes flashbacks in which the patient experiences an unexpected return to the traumatic situation with associated perceptions, such as the sound, smell and sight of the operating theatre, along with extreme distress. The flashbacks may be so intense that they interrupt routine activity such as driving or work tasks. Understandably, patients tend to avoid behaviours and stimuli that might trigger a flashback, so in the case of PTSD triggered by AAGA, the patient will exhibit behavioural avoidance (phobia) of aspects of the medical environment associated with the trauma, e.g. hospitals, anaesthetists, doctors, medical settings on television. In Samuelsson et al.'s (2007) study, 41% of patients who had experienced AAGA reported a lack of trust of medical staff, though for most this resolved over time.

7.31 These disturbances are variable in duration. Some may only be troubled by PTSD symptoms for a matter of weeks. Others will be disabled for many years, possibly for the rest of their lives. Generally the intensity and frequency of disturbance will decline with time. The general trauma literature includes descriptions of late onset PTSD in which symptoms only emerge more than six months following the initial incident. This can take the form of 'anniversary' reactions in which symptoms begin exactly one or more years after the initial incident (Ehlers & Clark, 2000). With AAGA, PTSD symptoms may be precipitated by the need for further surgery after a significant interval (Ostermann, 2000).

7.32 There are effective treatments, such as exposure-based cognitive behavioural therapy or Eye Movement Desensitisation and Reprocessing (NICE, 2005), and these should be made available to those PTSD cases caused by AAGA as much as to those triggered by other causes.

7.33 It is important to note that there may be a range of psychological harm following AAGA. Patients may experience a sub-set of PTSD symptoms that is insufficient for a formal diagnosis of PTSD yet sufficient to cause lasting distress and change in behaviour (e.g. avoidance of medical settings). For example, in Avidan & Whitlock et al.'s unpublished (2014 – personal communication) study of psychological sequelae of surgery, 15 of 35 AAGA patients experiencing AAGA exceeded the screening cut-off for PTSD symptoms but only 5 of those patients had the full range of symptoms consistent with a diagnosis of PTSD. Some AAGA patients develop clinical depression shortly after the AAGA experience, while others may suffer acute PTSD followed by a period of depression. Some may develop acute *de novo* anxiety states such as complex phobia, the content of which may not obviously relate to the AAGA experience (Jones & Wang, 2004).

7.34 Individuals vary in terms of psychological resilience. Previous psychiatric history or previous trauma increase vulnerability to developing PTSD after a traumatic event (Ehlers & Clark, 2000), as do

personality variables such as introversion and neuroticism (McFarlane, 1989). An important element is that the person perceived a threat to their life and responded with fear or helplessness. This is a critical point to consider in the case of AAGA, for two reasons. First, the perceived threat to life depends on the patient's understanding and interpretation of what is happening. Second, neuromuscular paralysis prevents the patient from moving (leading to 'helplessness') and this is predicted to be influential in catastrophic interpretations of what is happening.

7.35 Patient experience during AAGA is usefully classified using the Michigan Awareness Classification Instrument (Mashour et al., 2010b)

- Class 0: No awareness
- Class 1: Isolated auditory perceptions
- Class 2: Tactile perceptions (e.g. surgical manipulation or tracheal tube)
- Class 3: Pain
- Class 4: Paralysis (e.g. feeling one cannot move, speak, or breathe)
- Class 5: Paralysis and pain

An additional designation of 'D' is used for patients who experience distress during AAGA, so a classification of '1D' means the patient reported hearing voices and feeling distressed (e.g. scared that something has gone wrong or anxious that they will start to feel pain).

7.36 Severity of sequelae after AAGA in NAP5 was categorised using a modification (specifically for this project by Ms Helen Torrevell, Panel member) of the NPSA severity outcome scale (NPSA 2008) in order to include psychological harm.

- None – 0. No harm occurred.
- Low – 1. Resolved (or likely to resolve) with no or minimal professional intervention. No consequences for daily living, minimal or no continuing anxiety about future healthcare.
- Moderate – 2. Moderate anxiety about future anaesthesia or related healthcare. Symptoms may have some impact on daily living. Patient has sought or would likely benefit from professional intervention.
- Severe – 3. Striking or long term psychological effects that have required or might benefit from professional intervention or treatment: severe anxiety about future healthcare and/or impact on daily living. Recurrent nightmares or adverse thoughts or ideations about events. This may also result in formal complaint or legal action (but these alone may not be signs of severity).
- Death – 4. Caused death.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

7.37 There were 141 Class A and B cases (i.e. Certain/probable or Possible respectively). Reports varied considerably, from recall of isolated sensory experiences, to detailed recall of pain and paralysis with catastrophic interpretations of the experience. Distress was particularly likely with paralysis, but all forms of distress were strongly associated with longer-term psychological impact, which included nightmares, flashbacks, insomnia and fear of future surgery. Data supporting these findings is presented below.

7.38 Figure 7.2 shows to whom the report was first made, for all categories of report. Generally, in all case types, reports were made to the same anaesthetist that administered care, or to another anaesthetist, and occasionally to the ward staff. Statement Only cases (largely historical cases) were generally reported to another anaesthetist or to pre-operative nursing staff (presumably because in these historical cases, there was unlikely to be any opportunity to report to the same anaesthetist that administered care).

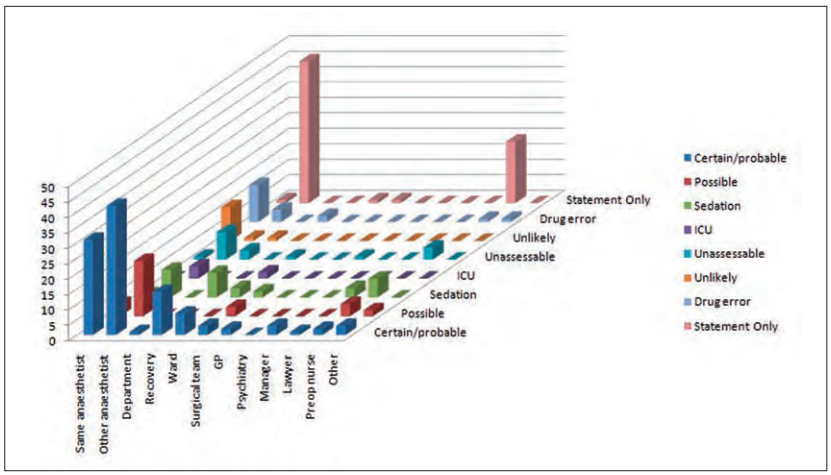


Figure 7.2. Histogram of to whom the report of AAGA was made. Data from all Classes of reports of AAGA. Department = anaesthetic department (e.g. by letter or telephone); GP = general practitioner; Pre-op nurse = pre-operative nurse)

7.39 For (Certain/probable and Possible) cases, the majority were first reported to another anaesthetist (most often during assessment for a subsequent procedure; 60; 43%), followed by reports to the anaesthetist who provided care (36; 26%). Other routes of reporting were recovery nurses (14; 10%), ward nurses (7; 5%), pre-operative nurses (6; ~4%) or surgical team (6; ~4%), Very rarely, reports were to a hospital manager or anaesthetic department (e.g. as part of a complaint 4); General Practitioners (2), a lawyer (1); and other staff groups such as ODPs, pharmacists, or the pain team (5, collectively). No Certain/probable or Possible reports were received via a psychologist or psychiatrist.

7.40 For Certain/probable and Possible reports, the commonest time to report AAGA was on the day it occurred (34% of reports). Another 11% of reports were made the day after surgery. Altogether, 52% were made within a week of surgery. There were also some very long delays in reporting (See Chapter 6, Results), with 35 (25%) of cases reported after a year or more. Reasons for delay were generally not given, although one patient reported being reluctant to report the incident earlier due to fear of ridicule and not wanting to re-live the incident.

7.41 Although it might be expected that experiences that were distressing would be reported immediately, this was not always the case. There was no clear association between reporting delay and distress during AAGA (captured by Michigan score D) (Figure 7.3) or between reporting delay and longer-term sequelae (Figure 7.4).

Word cloud based on responses to question 'illustrate the patient experience' for class A and B reports. Size and colour vary with count as reported in NAP5 results. Created at worditout.com

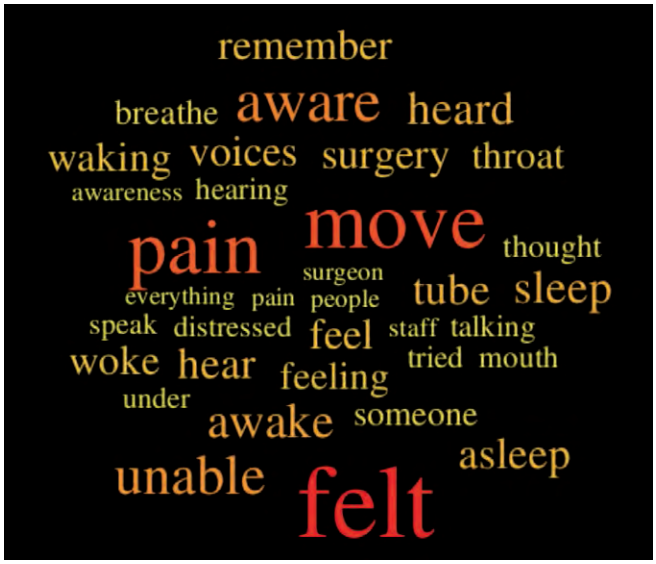


Figure 7.3. Boxplot showing the lack of an association in Certain/probable and Possible reports between the distress at the time of AAGA. Michigan score with distress (grey bars, no distress (white bars) and delay in reporting

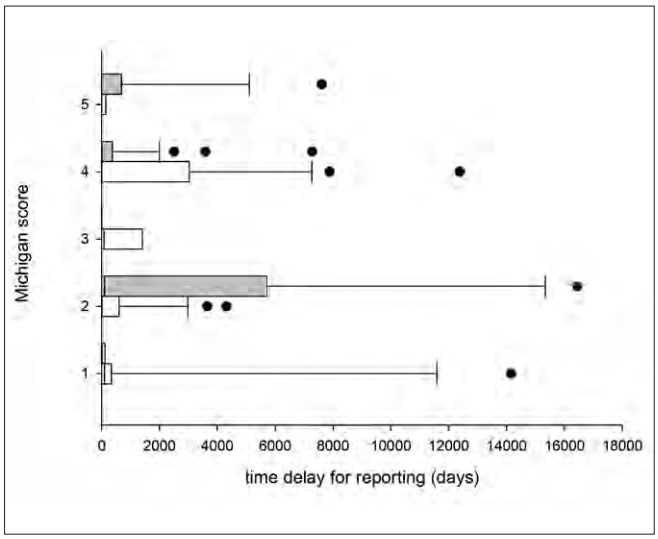
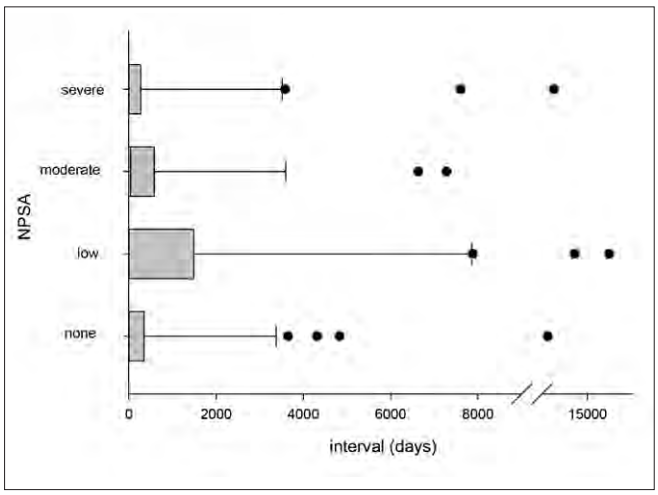


Figure 7.4. Boxplot showing lack of any clear relationship in Certain/probable and Possible reports between psychological impact at the time of the report (i.e. modified NPSA score) (grey bars) and delay in reporting



7.42 Experiences reported in the 141 Certain/probable and Possible cases included (*indicates symptoms consistent with paralysis):

- inability to move (42%)*
- inability to communicate (41%)*
- hearing noise/voices (37%)
- touch without pain (21%)
- awareness of tracheal intubation (21%)
- pain (18%)
- inability to breathe or suffocation (11%)*
- movement or being moved (9%)
- visual sensations (3%)
- dreamlike experiences (5%)

Patients reported between 0 (a report of simply 'being awake' with no further detail) and eight of these experiences (median 2). Although patients sometimes interpreted AAGA as a dream, there was only one assessable case (Class F – judged Unlikely) where the patient seemed to interpret a vivid dream as AAGA.

7.43 Tactile sensations and paralysis were common at induction, paralysis most common on emergence, and pain and paralysis most common during surgery.

7.44 Sixty five (47%) of 138 Certain/probable and Possible cases with known Michigan scores were judged not to be associated with distress, including some cases where the patient experienced pain and paralysis. There was a range of such neutral reports, with occasional positive reports where the patient felt thankful for the efforts of staff or had had a dreamlike experience.

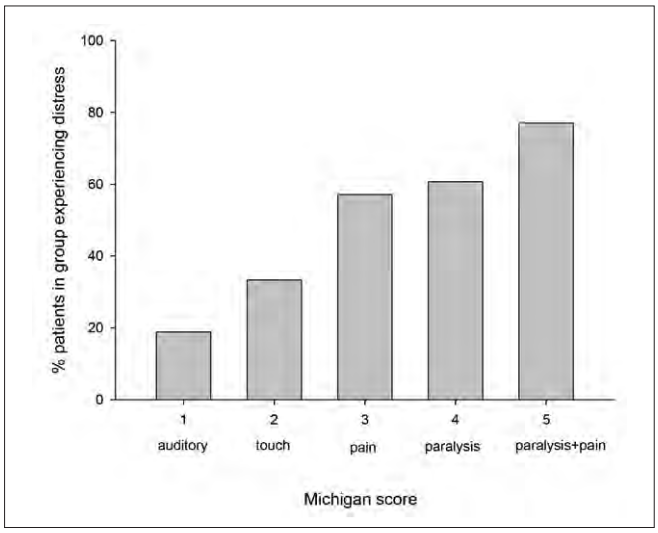
A patient mentioned to the surgeon overhearing a conversation between surgeons regarding the position of incision, and quoted exactly what had been discussed. The conversation had taken place in the middle of surgery, for a few seconds. The patient was interested rather than concerned.

A patient whose trachea was difficult to intubate recalled anaesthetists trying to "get the tube down and struggling" but was reassured by their care and thanked them. The patient was not distressed and thanked the anaesthetists for their care and attention.

A patient reported dreaming that they had felt paralysed and unable to communicate during surgery for a few minutes, but they had been comfortable and not in pain. The vaporisor had not been turned on during the procedure, for a time approximating to the patient's dream recollection.

7.45 The proportion of patients judged to have experienced distress at the time of the AAGA increased with Michigan score (Figure 7.5): distress was most common when pain and paralysis were experienced together, with 17 of 22 patients reporting distress (77%).

Figure 7.5. Percentage of Class A and B patients experiencing distress in each Michigan category



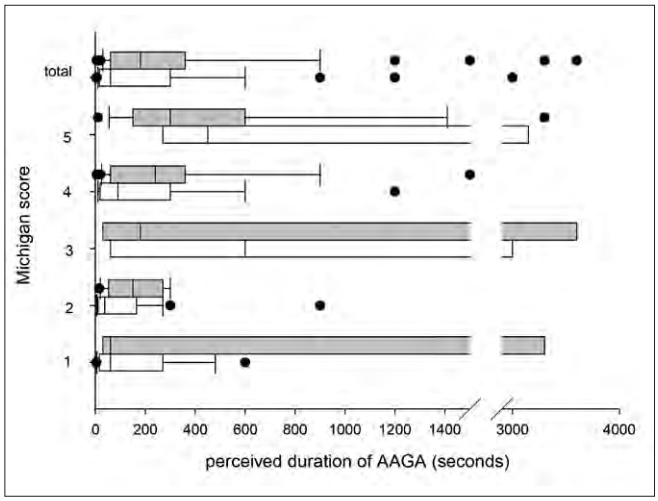
7.46 For the majority of those in distress, this was primarily because of the experience of paralysis (67%), but a few more reported pain first, followed by paralysis as upsetting (6%). Some patients were particularly troubled by breathing difficulty (15%) and four specifically mentioned they feared they were going to die. Two patients thought they were actually dead at the time of the intra-operative awareness episode because of the experience of paralysis. Chapter 19, Neuromuscular Blockade, highlights the experience of 'awake paralysis' as being the common central feature of traumatic AAGA. Of those reporting intra-operative distress, only 11% identified pain alone as the problem and did not report paralysis.

A patient reported auditory and tactile recall of laryngoscopy and intubation and the start of surgery. The patient wanted to scream but could not move or speak. The patient developed nightmares, waking up crying in a cold sweat recalling events repeatedly. The patient described feeling imprisoned in their own body.

A patient reported neither pain nor the experience of being paralysed (even on direct questioning), but did report severe distress at "being alive only in the head". The patient felt as if just their brain and ears were still working. "It felt like being in a crypt". The patient could hear everything (and reported conversations) but felt no pain, only some touch when somebody lifted their leg, and something being drawn along the leg with a pencil (as did happen), some humming, and then with no pain, an incision. This case was associated with a psychotic episode post-operatively and PTSD.

7.47 There was no clear association between distress and perceived duration of AAGA, i.e. it was not the case that the longer the perceived experience, the greater the distress, across any of the Michigan scores (Figure 7.6). For all Michigan scores combined, the median duration for no distress was 60 (15–300 [3 – 10,800]) and for distress was 180 (60–360 [5 – 3,600]) sec (p = 0.405, factorial analysis of variance).

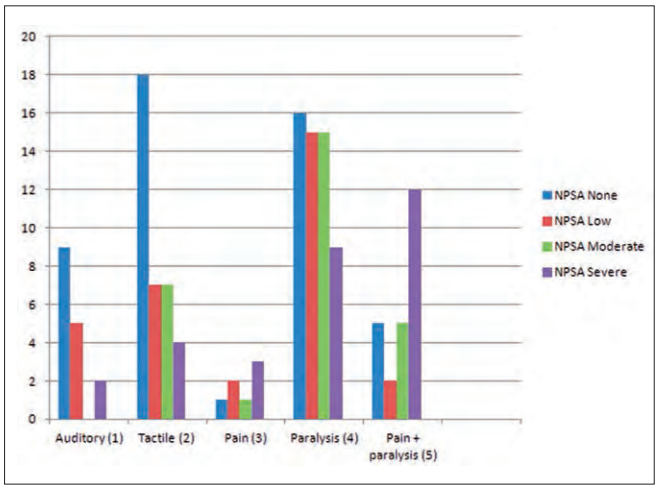
Figure 7.6. Boxplot of duration of perceived AAGA vs Michigan score: no distress (white bar); distress (shaded bar)



7.48 Overall, 41% of cases were judged to have moderate to severe longer-term harm, and this was more common in patients experiencing pain and/or paralysis: 51% of these patients reported moderate to severe harm compared with 25% of those reporting only auditory or tactile sensations. Of note: the methodology of NAP5 meant that psychological impact was usually measured at the time of reporting the AAGA event and as a result of early reporting some episodes of longer term harm may have been missed. Equally, early reports may have indicated psychological impact that did not continue into the longer term.

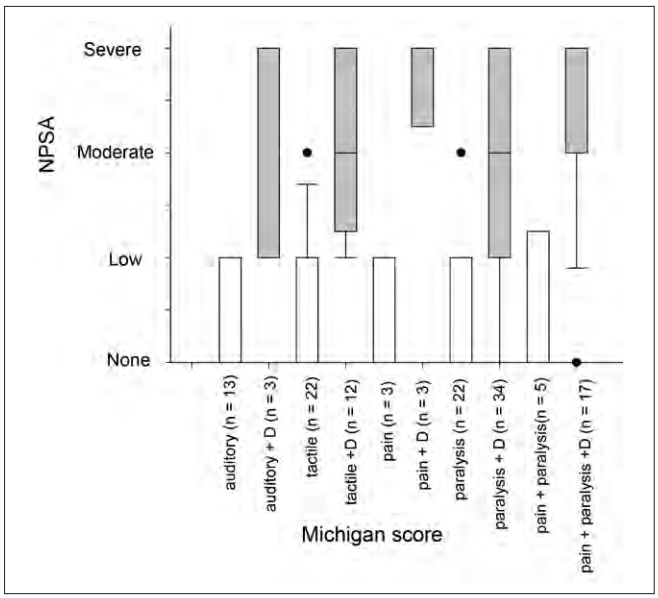
7.49 Importantly however, severe longer-term harm was not restricted to those experiencing pain or paralysis. It also occurred in patients experiencing only auditory or tactile symptoms (Figure 7.7)

Figure 7.7. Relative proportions (n) of modified NPSA scores (none to severe) by Michigan score



7.50 Distress during AAGA was strongly associated with longer-term sequelae (Figure 7.8). Fifty-five of 70 (79%) patients reporting distress had moderate to severe longer-term impact, compared with only 2 of 68 (3%) of patients without distress during AAGA, giving an odds-ratio for developing longer-term sequelae following distress during AAGA of 121.

Figure 7.8 Boxplots of NPSA score vs Michigan score: no distress (white bars); distress (shaded bars) for those Certain/probable and Possible cases where both NPSA and Michigan scores were assessable. Distress during AAGA is notably associated with longer-term poor outcome



7.51 Severe reactions to the episode of AAGA were characterised by re-experiencing the event through 'flashbacks' and nightmares, hyperarousal (increased anxiety, sleep disturbance) and avoidance (e.g. of lying flat, future anaesthetics). The process of cognitive appraisal *at the time of the trauma* (i.e. during the episode of awareness) is thought to be central to the development of PTSD

and there were several examples of catastrophic interpretation, where the patient thought they were going to die or be permanently paralysed.

A patient recalled talk about hallucinations associated with ketamine, and then having their neck extended, a plugging sensation of something in the mouth and a suffocating feeling. The patient tried to cry so that they could show people that they were awake. The patient recalled being positioned on the operating table and pain of the start of surgery. The patient did not think they would survive. The patient developed PTSD with flashbacks, panic attacks, fear of the dark (seeing the anaesthetist's face when asleep), an inability to lie flat and was referred to a psychologist.

On waking in recovery an elderly patient reported having heard voices and feeling some pain. The following day the description became clearer and the patient described a sharp agonising pain of a knife slicing into skin and of flesh pulled apart. The patient tried to move but was unable to and was terrified of "enduring the torment". The patient experienced flashbacks, re-living experiences and felt traumatised.

After incomplete reversal of neuromuscular blockade a patient reported being unable to talk or to move, the feeling of a tight chest "I was very scared, I thought I will be paralysed and unable to move. It was really a bad experience." The patient developed anxiety and fear about anaesthesia, needing psychological support.

A patient felt a tube in their throat and could not breathe. They panicked and thought they were going to die. Then they 'passed out' but then heard a voice reading from the notes "saying I was a smoker; this is when I realized I was alive". The patient developed a fear of anaesthetics and sleep disturbance.

7.52 In counterpoint to the catastrophic interpretations, there were cases where the patient's own understanding of anaesthesia, spontaneous benign interpretation, or explanations provided by staff during the experience, appeared to reduce the impact of AAGA.

A patient reported for a few minutes hearing voices, and experiencing paralysis and abdominal pain. The patient wanted to ask theatre staff to give painkillers but could not speak. The pain was unpleasant; but the paralysis was not a great worry because the patient knew "you were supposed to be paralysed during the operation". The patient was later not worried about having another anaesthetic.

Inadvertently a patient was given suxamethonium before induction The anaesthetist immediately recognised the error and induced anaesthesia. The patient experienced paralysis, was afraid they were dying from a stroke and had flashbacks for 2–3 days afterwards. However the patient was very reassured by the anaesthetist's immediate explanation, "I know what's happening and I can fix it", during the critical event and had minimal long-term sequelae.

A patient recalled hearing voices, seeing bright lights, not being able to move or communicate and being terrified, thinking they were going to die. The patient went home and mentioned it to their family and was reassured when they all apparently had a report of awareness "…it happens to all my family – we all wake up. Please can you give me a bit more?"

7.53 In several cases, early support and empathy after the occurrence of AAGA appeared to influence the nature of longer-term reactions. This is also highlighted in Chapter 22, Medicolegal. In contrast, in a minority of cases patients were reported to have become angry or upset by an apparently unsupportive reaction by staff and in some cases this engendered greater unhappiness than the actual experience.

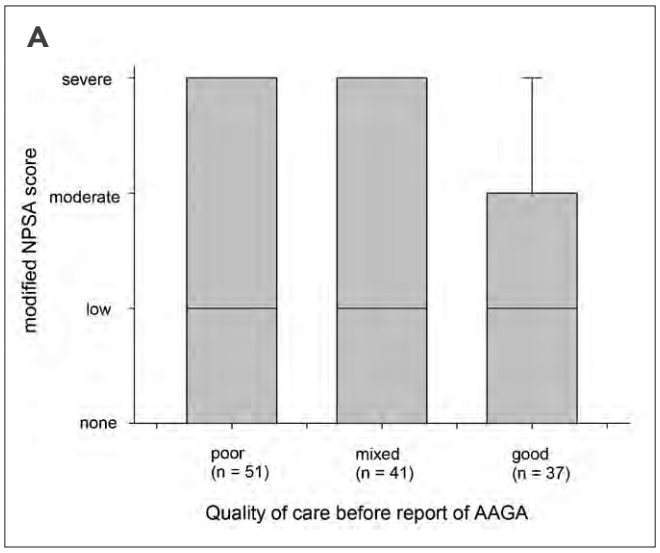
A young patient was panicky in recovery and reported that they heard people talking, felt stitching and a choking sensation. The patient was very upset as they could not speak or do anything until they managed to move a little. In recovery they felt they were re-experiencing the events. The patient was upset that they did not get support from the nursing staff in recovery or on the ward, who told the patient it was a bad dream and there was nothing to worry about. It was only when the patient spoke to the anaesthetist and recounted what happened that they felt they were believed.

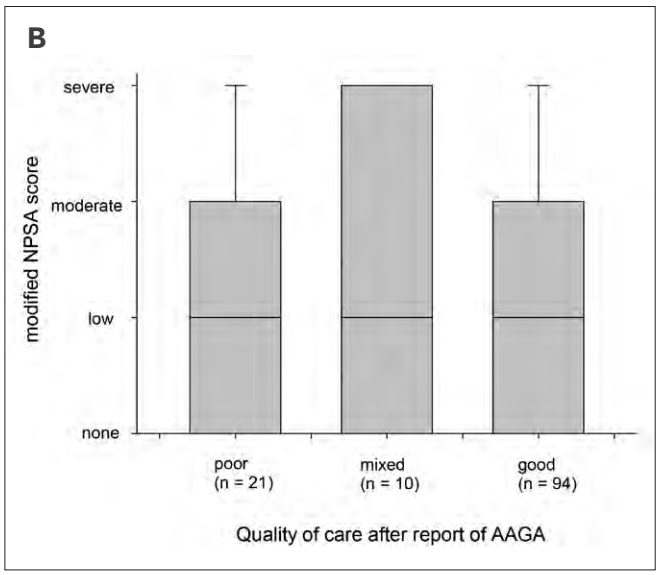
A patient became aware of intubation during a difficult rapid-sequence induction intubation. The anaesthetist later explained the need for rapid-sequence induction. The patient was not distressed and thanked the anaesthetist for their care and attention.

7.54 However, there was no relationship demonstrable between the quality of care and the longer-term outcome as judged by modified NPSA score, in a quantitative manner, either for clinical care leading up to the report of AAGA, or for care after report of AAGA Figures 7.9 and 7.10.

7.55 The adverse impact of a report of AAGA on anaesthetists should not be overlooked. Two reports indicated that AAGA could be as much a surprise to them as it was to the patient. One confessed to changing their anaesthetic techniques after an episode and one judged themself very harshly: "*I simply screwed up. Fortunately it was brief and the patient forgiving*".

Figure 7.9. Boxplots of modified NPSA score and Panel judgement on quality of care, in Certain/probable and Possible cases, for: Panel A (top) care up to the point of report of AAGA and Panel B (bottom) care after report of AAGA





DISCUSSION

7.56 Experiences of AAGA varied widely, from isolated and sometimes vague sensory experiences of sounds, touch, or movement, to full and clear awareness including pain and paralysis. The range of experiences was comparable to that reported in literature using the modified Brice interview.

7.57 Consistent with previous literature (Ghoneim et al., 2009), only a third of the reports were made on the day AAGA occurred and fewer than half within the first 24 hours. Only a quarter were received by the anaesthetist who provided the care. It was common for AAGA to be reported for the first time during preparation for a subsequent procedure, and in some cases psychological sequelae only emerged at this time, when the patient became anxious about AAGA happening again. There was no clear relationship between the perceived duration of AAGA (which was generally brief) and psychological impact, or between reporting delay and impact. Brief experiences could be severely distressing and experiences reported after a delay were no less distressing or harming than those reported immediately.

7.58 In about half the cases, recall was expressed in a neutral way, focused on just a few seemingly isolated aspects of the experience.

7.59 However, in about half of cases there was distress at the time of AAGA, and this distress was strongly associated with longer-term psychological impact. Distress generally led to longer-term harm, even if it occurred during a 'patchy' experience of AAGA where the patient heard voices or felt sensations without pain or paralysis. Not surprisingly, distress was particularly likely to accompany paralysis and pain, and complaints of being unable to alert staff by moving or speaking were common.

7.60 Although patients sometimes interpreted AAGA experiences as dreams or described them as dreamlike, we only received one report of a patient interpreting dreams as AAGA (however, other dream reports may not have reached NAP5). There were rare descriptions of disembodied experiences that may be interpreted in several ways: (a) as attempts to interpret the sensation of paralysis (and hence distressing); (b) a misinterpretation of the unusual experiences as dreams (perhaps because the patient cannot see where they are and what is happening, so the experience lacks full context); (c) a representation of what has been variously termed 'dysanaesthesia' (Pandit, 2014), 'disconnectedness' (Sanders et al., 2012), or 'cognitive unbinding' (Mashour, 2004).

7.61 All reports described here in the Certain/probable and Possible category were supported by anaesthetic notes. Reports classed as Unassessable or Unlikely were typically confused about the timing of peri-operative events or were too vague and sparse to be interpretable (Chapter 25). This uninterpretability on the part of the Panel assessors may in turn relate to the difficulty the patients themselves had in making sense of events, as alluded to above, so these may still represent genuine AAGA events: it is impossible to know. The Panel judged that there were no malicious reports.

7.62 The fact that a minority (25%) of Certain/probable and Possible reports of AAGA were first made to the anaesthetist responsible for the case might reflect a difficulty of following up every case (e.g. if patients are discharged or transferred, etc) or an early opportunity for the patient to report to another healthcare worker. It could also reflect delayed recall, with the memory not emerging until other staff had taken over responsibility for the patient's care. Avoidance on the part of the patient due to fear or concern is a possibility, though we note that the majority of the cohort with the greatest distress (the cases of accidental paralysis due to drug error or syringe swap – see Chapter 13, Drug Errors) reported to the original anaesthetist. There was no evidence that reports made to someone other than the anaesthetist were less trustworthy or serious.

7.63 The disparity between the 'incidence' reported using Brice questionnaire (~1:600) and NAP5 methodology (~1:20,000) is striking. It is discussed in full elsewhere in the Report. The number of cases of AAGA that were reported for the first time after considerable delays suggests that some patients may be reluctant to report AAGA when they first recall their experiences. Practice implications depend on discovering the reasons for this and why it apparently seems to be overcome by Brice interviewing. It would seem that routine active questioning could help elicit earlier reports of AAGA that would allow earlier and more effective intervention, but it is not yet known whether this could risk eliciting false but still distressing memories of AAGA, as well as improving recall of genuine memories.

7.64 Longer-term sequelae included symptoms associated with PTSD, including nightmares, flashbacks and anxiety. Anxiety sometimes emerged only when the patient needed a subsequent anaesthetic.

7.65 As in other types of traumatic experience, catastrophic interpretations of awareness experiences (e.g. the patient believing they are dead, dying or permanently paralysed) at the time of the trauma, were strongly associated with serious longer-term sequelae. Conversely, understanding what was happening seemed to be protective. Hearing staff explain the problem while it was happening appeared helpful. Consistent with this conclusion, studies with informed volunteers have shown that paralysis per se need not be distressing if it is expected and understood, though associated sensations of being unable to breathe do tend to cause distress (Heier et al., 2001; Topulos, Lansing & Banzet, 1993). Therefore, anaesthetists suspecting inadequate anaesthesia should focus on talking to the patient in reassuring ways, indicating an understanding of their predicament. This is likely more important than attempting to abolish memory retrospectively using drugs.

7.66 Quantitatively, there was no apparent association between quality of care and longer-term impact of AAGA. This null result should be interpreted with caution because (a) the Panel judgement of care quality was highly dependent upon the sometimes scant information provided; (b) overall more than half of events led to no or low impact; (c) the large majority of cases were associated with good care after AAGA, so true impact of poor care was difficult to assess (Figure 7.9, 7.10). Our data do not differentiate cause and effect in terms of good care and outcomes. Thus, good care could have been offered after registering that the impact of AAGA had been severe, in which case it is misleading to imply lack of association.

7.67 There were cases where a sympathetic response to the report of AAGA seemed to mitigate the impact of the experience, and cases where unsympathetic responses seemed to exacerbate the adverse impact. Around 15% of cases were judged to have received poor care, where no attempt was made to follow up reports of AAGA to ensure patients had access to psychological treatment if they needed it. We suggest that there should be a plan for supporting patients who indicate an experience of AAGA. The Appendix to this chapter provides a suggested response pathway. We propose that the efficacy of this pathway should be tested formally to enable any suitable modifications over time.

IMPLICATIONS FOR RESEARCH

Research Implication 7.1
Research is needed into whether and what type of early and supportive response at the time of and after a report of AAGA mitigates longer-term psychological sequelae. In particular, the efficacy of the proposed NAP5 Awareness Support Pathway warrants investigation.

Research Implication 7.2
The observation that many cases of AAGA are reported only after considerable delay warrants further investigation. Is there a delay in consolidating the memory? Do memories of recovery interfere with the AAGA memory? Is AAGA hard to recall because source memory is poor and there may only be partial sensory information (e.g. a memory of voices but not of tactile sensations?)? Or does it take time for patients to come to terms with their experience and feel able to discuss it?

Research Implication 7.3
Building upon existing work, research is needed to establish if implicit memories for anaesthesia have consequences for patients' wellbeing on recovery.

Research Implication 7.4
It would be important to assess if the method of Brice interview (i.e. repeated questioning over several occasions) might lead to the creation of any false memories of AAGA, or conversely help patients to retrieve genuine AAGA memories.

Research Implication 7.5
Research is needed to ascertain the incidence of PTSD or other adverse psychological impact arising from AAGA. It needs to be established if the evolution of these is influenced by the nature of the AAGA experience at the time, by early response and intervention, by any delays in reporting, or if there is a difference between incidence of psychological harm with spontaneous reporting of AAGA versus that ascertained after Brice interview.

Research Implication 7.6
It would be interesting to explore patients' interpretations of the sensation of paralysis during AAGA, and the extent to which catastrophic interpretations of being dead or permanently paralysed may be prevented through pre-operative information or the impacts ameliorated by post-operative explanation.

Research Implications 7.7
Comparative research into psychological responses to paralysis at the time of a cerebrovascular accident or other acute neurological disorders, versus the paralysis of AAGA would be important to ascertain if the response to the latter has a unique basis.

Research Implication 7.8
Cross-cultural research to ascertain if patient attitudes to AAGA are similar across countries and cultures would be illuminating, perhaps encompassing the interaction of religious beliefs, societal influences, acceptance of regional anaesthesia, etc, in attitudes to notions of suffering, 'consciousness' or 'self'.

Research Implication 7.9
Research is needed into individual risk factors for developing long-term sequelae following AAGA. It is not known if a patient's personality or levels of anxiety influence the experience of AAGA and its aftermath, nor whether previous traumatic experiences increase vulnerability.

Research Implication 7.10
Little is known about the precise symptomatology of PTSD following AAGA. A comparison of NAP5 findings with estimates of AAGA from Brice studies suggests that many experiences of AAGA go unreported. They may nonetheless have psychological impact, therefore it would be useful for psychologists and psychiatrists to know if AAGA-induced harm has a signature pattern of symptoms.

RECOMMENDATIONS

RECOMMENDATION 7.1
If AAGA is suspected intra- or peri-operatively, anaesthetists should speak to patients to reassure them that they know of their predicament and are doing something about it.

RECOMMENDATION 7.2
Conversation and behaviour in theatres should remain professional, especially where there is a situation or concern that AAGA is a risk (e.g. RSI, prolonged intubation, transfer). Adverse impact of any recall may be mitigated where the patient is reassured by memories of high quality care.

RECOMMENDATION 7.3
All reports of AAGA should be treated seriously, even when sparse or delayed, as they may have serious psychological impact. If reported to someone else, every attempt should be made to refer the case to the anaesthetist responsible.

RECOMMENDATION 7.4
The anaesthetist who provided the anaesthesia care at the time of a report of AAGA should respond promptly and sympathetically to the patient, to help mitigate adverse impacts.

RECOMMENDATION 7.5
Healthcare or managerial staff receiving a report of AAGA should (a) inform the anaesthetist who provided the care; (b) institute the NAP5 Psychological Support Pathway (or similar system) to provide patient follow up and support.

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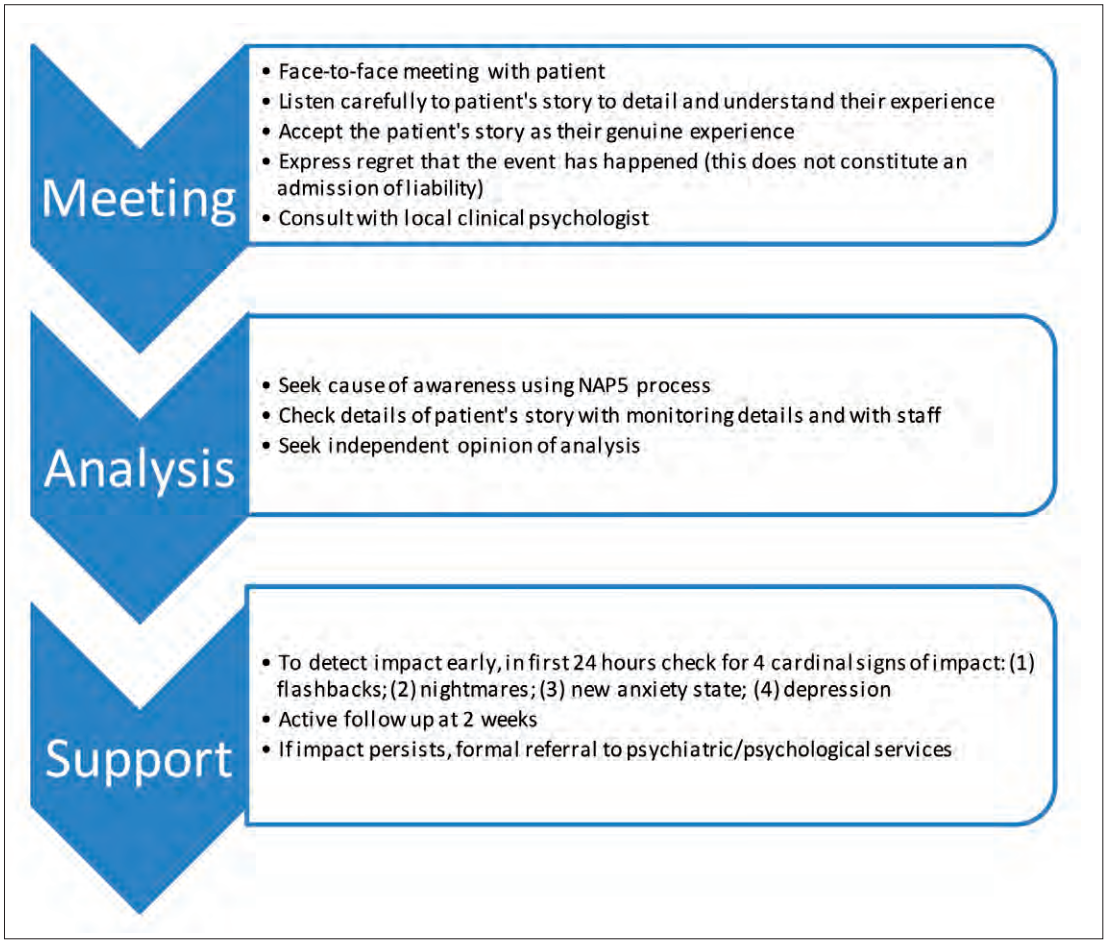
NAP5 Awareness Support Pathway for AAGA

NAP5 Awareness Support Pathway

This pathway is created on the assumption that psychological trauma of AAGA is compounded bylack of or insensitive post-operative management. Thiscan compound the long-term severity of psychiatric consequences which if untreated become progressivelymore difficult to ameliorate. Early identification, monitoringand psychological intervention (where necessary) of AAGA are known to be likely to reduce psychological morbidityand costs. NAP5 revealed many cases of AAGA where patients were minimally distressed with little need for psychological support; typically where simple support had been offered promptly. This is a basis for the meeting stage of our Psychological Pathway, emphasising the value of empathetic communication. The second stage, analysis, seeks to identify causes of AAGA to inform continuing dialogue and prevent recurrence. The third stage, support, stems from evidence that psychological sequelae of AAGA, including memories, increase in the weeks following anaesthesia and are amenable to treatment (NICE PTSD Guidelines).

NAP5 Awareness Support Pathway for AAGA



Accompanying notes

Meeting stage

1. **Face-to-face meeting with patient**. Ideally this should include the anaesthetist who provided the anaesthesia care and where this is a trainee, a suitably senior colleague. Where this is not possible or desirable, a senior colleague should take their place.
2. **Listen to patient story and experience**. Blatant fabrication by the patient is extremely rare; however, careful note should be taken of all details provided by the patient. Particular attention should be devoted to the type of experience (e.g. from auditory sensations only, to touch, or pain and/or paralysis). This enables classification according to the Michigan scale. An attempt should also be made to classify the patient's situation according to the modified NPSA guidelines as a measure of severity of medium to long-term impact. Careful account of information that could be corroborated, or refuted, is very important to establish the veracity of the report.
3. **Accept the patient's story as their genuine experience**. This means listening carefully and empathically to the patient's account, without interruption or contradiction (even if there are inconsistencies) and take verbatim notes of the patient's account.
4. Express regret. This can be done using words like "I am sorry to hear of your experience; we need to establish what has happened". This is not an admission of error or medicolegal culpability.

Analysis

1. **Seek cause of awareness using NAP5 process**. In addition to establishing the Michigan and modified NPSA score, this involves classifying the report as Certain (or refuted) or Probable (Class A); Possible (Class B); a case where sedation was intended (Class C); a case in the ITU (Class D); Unassesseable (Class E); Unlikely AAGA (Class F) or Unintentional paralysis due to drug error (Class G). A Class H may be used for cases not fitting any of these classifications. The purpose is to help create a common terminology for later group analysis.
2. **Check details of patient's story.** For cases that are Certain/probable or Possible (Class A/B) causality can be determined by careful analysis of the anaesthetic chart and anaesthetist's report. Note, as confirmed by NAP5, that some cases have no apparent cause and may be due to insensitivity to anaesthetic drugs. As NAP5 and other studies have shown, patients may be mistaken in several ways. They may not have had an anaesthetic at all, or may have experienced an unpleasant dream not involving specific surgical events. Events during the immediate post-operative or pre-operative period may be incorrectly attributed as intra-operative. Therefore proper analysis is important and any such confusion should be addressed gently, with care and understanding.
3. **Seek independent opinion**. The Analysis process may be undertaken by a small group with appropriate skills and knowledge (independent of the hospital if necessary), who can provide an unbiased opinion as to the classification, impact and likely causality, in much the same way as NAP5 has done.

Support

1. **Detect impact early**. Inpatient review or follow up telephone consultation for day-cases is essential within 24 hours to establish if there are flashbacks, nightmares, any new anxiety state or symptoms of depression. If early symptoms cause concern, early referral to an appropriate psychologist or psychiatrist is advised.
2. **Two-week review**. The same follow-up should be conducted at two weeks. Even where true AAGA is unlikely, NAP5 has shown that the patient interpretation is of such importance that the impact of peri-operative unpleasant experiences may be severe and psychological support may still be needed.
3. **Support for impact**. If impact persists, a formal psychological review is needed. Once referral to a psychologist or psychiatrist is found necessary, in accordance with NICE Guidance, PTSD-type reactions should be treated with either trauma-focussed Cognitive Behavioural Therapy or Eye-Movement Desensitisation and Reprocessing. If there are none of the four cardinal signs of impact (flashbacks, nightmares, a new anxiety state or symptoms of depression), then the patient can be encouraged to make contact if they later have concerns. However, there is a need for an ongoing national case registry (as recommended by the NAP5 Report), so that the longer term evolution of any symptoms in those judged not to need specific support after two weeks can be assessed.

   Ideally, each geographical area or Trust should have access to a psychologist or psychiatrist who has expertise in PTSD and can be 'on call' for unintended incidents.

SUPPORTING REFERENCES TO APPENDIX

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CHAPTER
8

AAGA during induction of anaesthesia and transfer into theatre


James H MacG Palmer


Jaideep J Pandit

HEADLINE

8.1 This chapter discusses reports of AAGA between the start of induction of anaesthesia and the start of the surgical intervention. This includes induction of anaesthesia and transfer of the anaesthetised patient into theatre. We refer to this entire period as 'induction' except where aspects of the transfer are discussed. We do not discuss reports of 'syringe swaps' or drug errors, which are discussed in Chapter 13. Half of Certain/probable reports to NAP5 were in this phase of anaesthesia, and half the reports involved patients categorised as NCEPOD urgent or emergency. Over half were obese, a third of reports involved RSI, and in 92% of these, induction was with thiopental. In over a third of reports no opioid was used at induction, notably in cases conducted by trainees working alone. In about a third of cases there was difficult airway management, and failing to continue anaesthesia was judged contributory to AAGA. Despite the brevity of patient experience in this phase, distress was common.

BACKGROUND

Induction

8.2 Induction of anaesthesia in a dedicated anaesthesia room and transfer to the operating theatre (perhaps a UK-specific phenomenon, as discussed below) is a complex process that is readily understood by anaesthetists but, for reasons that are self-evident, less well by patients. Gas induction (used frequently for children and rarely in adults) takes several minutes, so that patients who have undergone this process sometimes recall 'being given a gas to breathe to fall asleep'. For most modern anaesthetics, intravenous drugs are used to produce unconsciousness in the short time it takes for the drug injected into the vein to reach the brain (the 'arm-brain circulation time').

8.3 Despite its rapid nature, induction of anaesthesia is a *process* rather than an *event* and, even for those carefully observing the patient, it is difficult or impossible to know the exact moment when consciousness is 'lost'.

8.4 Clinical assessment of induction uses end points that rely on absence of some form of *response*, e.g. to calling the patient's name (a relatively weak stimulus so the patient may not respond to sound, but may move or awaken with painful stimulation); the eyelash reflex (a reliable sign of loss of consciousness with thiopental but less so with propofol), and releasing an object held in the hand. All of these have variously been used in trials (Wilder-Smith et al., 1999). Lack of movement in response to airway manoeuvres (a reasonably strong stimulus) can be used to signify adequate depth of anaesthesia, at least for instrumenting the airway (Figure 8.1).

8.5 However, concomitant use of neuromuscular blocking drugs during induction blunts or eliminates motor response, thus making all these tests invalid.

8.6 AAGA at induction is not widely described in the literature, if at all. Use of depth of anaesthesia (DOA) monitors during induction appears uncommon but there is a paucity of data confirming this. Although 62% of hospitals in the UK have access to DOA monitors only ~1.8% of anaesthetists report routinely using DOA monitors at any point during general anaesthesia (Pandit et al., 2013 a and b).

8.7 Studies using DOA monitors at induction focus on dose-sparing effects rather than utility in preventing AAGA at induction (Gürses et al., 2004), and in large trials such as the BAG-RECALL trial, although the DOA monitor was applied before induction and data collected to ensure stable recordings, it is not clear if AAGA at induction was included in the reports (Avidan et al., 2009; Avidan et al., 2011). Processing time is acceptable for routine use, but is too slow for rapid induction and monitor output is displayed only up to 30 sec later (Nishiyama et al., 2004).

8.8 After induction using intravenous agents, the maintenance of anaesthesia relies on either introduction of a volatile agent or continued, uninterrupted administration of intravenous anaesthetic. As the brain concentration of the intravenous induction agent declines, the brain concentration of the maintenance agent gradually increases. Thus there may be a period where the overall concentration of anaesthetic agents is lower than desirable. Patient stimulation during this 'gap' may lead to AAGA. Any delay in starting administration of the maintenance agent, or an interruption, will compound this gap. The Panel called this type of AAGA report 'Mind the Gap', and found that it could occur for a variety of reasons which are discussed below (Figure 8.2).

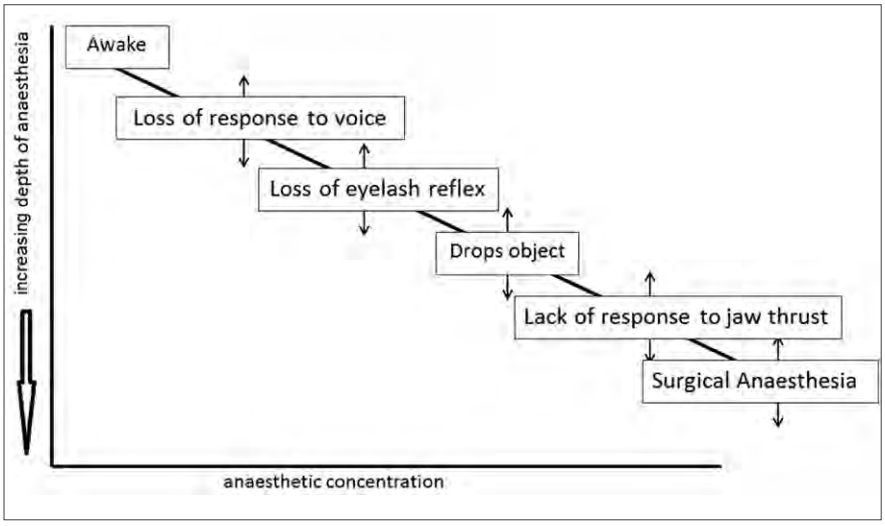


Figure 8.1.
Diagrammatic representation of how tests of patient response might vary with anaesthetic depth. Arrow lengths are illustrative only and vary with drugs used

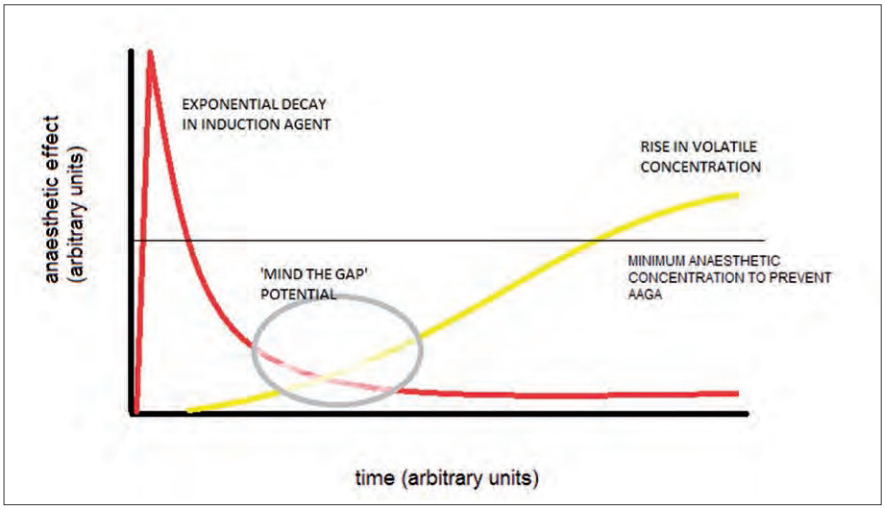


Figure 8.2.
Diagramatic representation of a 'gap' in delivery of anaesthetic when the volatile agent is turned on a little too late, at too low a rate or is interrupted, as the effect of the initial intravenous bolus is in decline. The thin line represents the minimum agent concentration required to prevent AAGA

Anaesthetic rooms and transfer into theatre

8.9 In the UK induction is usually in a dedicated anaesthetic room (Bromhead & Jones, 2002). Anaesthetic rooms are rare in Australasia, the United States or Europe. (Masters & Harper, 1990). Perceived advantages of anaesthetic rooms are privacy for the patient, teaching, line insertion or regional blocks, but patients do not seem to mind where they are anaesthetised (Soni & Thomas, 1989). There may be benefits, but the practice involves interruption in the delivery of anaesthetic during transfer from anaesthetic room to operating theatre and is therefore a systemic risk.

8.10 Transfer from the anaesthetic room to theatre takes on average ~51 sec (Riley et al., 1988), but can take > 3 min (Broom et al., 2006). Once re-connected to a breathing circuit there will be further delay in delivering anaesthetic to the patient, as this circuit needs to first fill with vapour.

8.11 The transfer process can create distractions that increase the possibility of AAGA from task fixation errors (see Chapter 23; Human Factors). Airway and intravenous access events during transfer are, unsurprisingly, common and demand immediate attention. Even minor problems such as lead tangles, sticking brakes, table/trolley height differences or lack of available staff can add delays of up to 30 sec in reconnection to the breathing system or monitoring (Broom et al., 2006). Such distractions may lead to errors of omission so that the maintenance volatile is not turned on. These risks and advantages of anaesthetic rooms must be balanced.

8.12 Ghoneim & Block (1992) summarised the then known methods for avoiding AAGA in this phase of anaesthesia:

(a) Premedication with 'amnesic' agents.

(b) Use more than the minimum dose of intravenous agent to induce unconsciousness (especially when the plan is to immediately follow this with neuromuscular blockade) and administer even more induction agent if intubation is prolonged.

(c) Avoid neuromuscular blockade wherever possible and if used, avoid complete paralysis.

(d) Use volatile agents at >0.6 MAC (end-tidal) with nitrous oxide, or >0.8 MAC if used alone.

8.13 In summary, existing literature includes not only evidence that anaesthetic induction and transfer are situations in which events can conspire to produce a relatively high risk of AAGA, but also sensible advice for reducing these risks.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

8.14 The Activity Survey reported that 71% of all general anaesthetic inductions took place in anaesthetic rooms; 92% of inductions were intravenous and 8% gaseous. In adults the figures are 98% and 1% respectively. After induction a volatile agent was used in 92% of UK general anaesthetics and TIVA (in a variety of forms) in 8% (Activity Survey, 2014).

8.15 A specific DOA monitor was used, 2.8% of GAs in the Activity Survey, two thirds being processed EEG. However, the Activity Survey did not establish how many anaesthetists use DOA monitoring during induction.

8.16 Of the 141 'Certain/probable' or 'Possible' (Class A and B) reports, half (72) involved the induction phase (five of these involved both induction and maintenance; two both induction and emergence, and in six cases there was some uncertainty about the exact phase, but induction was likely involved). Of these, 58 occurred at induction and 12 on transfer into theatre (in two not specified). There was a preponderance of women, 47 (65%) in line with the overall data. A bolus induction agent and volatile maintenance were used in the majority 62 (86%) of cases, with 10 (14%) using TIVA throughout (these proportions being broadly in line with data in the Activity Survey). Nitrous oxide featured in 21% of reports consistent with the Activity Survey (27%).

8.17 Half (37, 51%) of cases at induction, were in elective patients and half were in NCEPOD urgent or emergency cases. Fifty seven (79%) patients were ASA 1 and 2. A consultant or non-consultant career grade anaesthetist cared for 46 (64%) of patients, a senior trainee for eight (11%), and a CT1 or CT2 (i.e. a junior trainee) for 5 (7%) of patients. Grade was unknown in seven (10%).

8.18 Body habitus was known in 62 of the 72 patients: 25 (35%) were overweight, obese, or morbidly obese. In the Activity Survey, 22% of all surgical patients were overweight, obese or morbidly obese.

8.19 In 67 (93%) of cases, neuromuscular blockade was used at induction (vs 45% of cases in the Activity Survey).

Underdosing and patient weight

8.20 In 23 (32%) of cases reported during induction, the Panel judged the induction agent dose inappropriately low and identified it as a contributory factor to AAGA.

A very obese adult underwent orthopaedic surgery and reported AAGA after induction. There was recall of being transferred onto the operating table and people talking. The patient could not move. The patient remembered trying to cry in an attempt to alert the anaesthetist. The period lasted an estimated three minutes before consciousness was lost. The patient is scared of future anaesthesia. A consultant anaesthetist undertook RSI with thiopental 250mg, suxamethonium 150mg and maintenance with remifentanil by infusion, sevoflurane, nitrous oxide and atracurium. The anaesthetic chart first recorded sevoflurane ten minutes after induction.

A very obese patient underwent emergency abdominal surgery and later reported AAGA to another anaesthetist saying they felt something inserted into their mouth. "It was as if there was no anaesthetic at all. I saw a man at my head, he kept pushing the thing in my mouth and I heard him say: "This has been a really busy day and there's still more to come'. I tried to lift my hand up but someone at my side held my arm down. I felt everyone was rushing". The patient felt paralysed and was fearful of dying. Two trainee anaesthetists induced anaesthesia with 500mg of thiopental and 100mg of suxamethonium. There was minor difficulty with laryngoscopy and intubation. No opioids were used at induction.

Opioids and thiopental

8.21 It was striking that RSI was over-represented in the cases occurring at induction. Whereas RSI was used in only 7.4% of general anaesthetics in the Activity Survey, it was the induction technique in 26 (36%) of all Certain/probable AAGA cases.

8.22 In the Activity Survey, more than two-thirds of patients received opioids during RSI, but of AAGA cases involving RSI, only one-third received opioids.

8.23 Thiopental was disproportionately the induction agent in cases of RSI-related AAGA. In the Activity Survey 33% of RSIs used thiopental, while 92% of cases of AAGA during RSI involved thiopental. The Activity survey indicates that thiopental is predominantly used for RSI: it is used for <3% of all inductions of which 87% of uses are for RSI.

8.24 In 28 (39%) reports no opioids were used at induction and their omission, including during RSI, was either highlighted by the Local Co-ordinator or judged by the Panel as contributory to AAGA on several occasions. Although traditional teaching suggests they should be omitted from an RSI, in fact RSI without opioids is a rare technique (Morris & Cook, 2001), and in the Activity Survey opioids were used in over two-thirds of RSIs.

Opioids were used at induction in 96% of cases when career grade anaesthetists were involved, but in only 31% of cases when trainees were managing the patient, either solo or accompanied by another trainee.

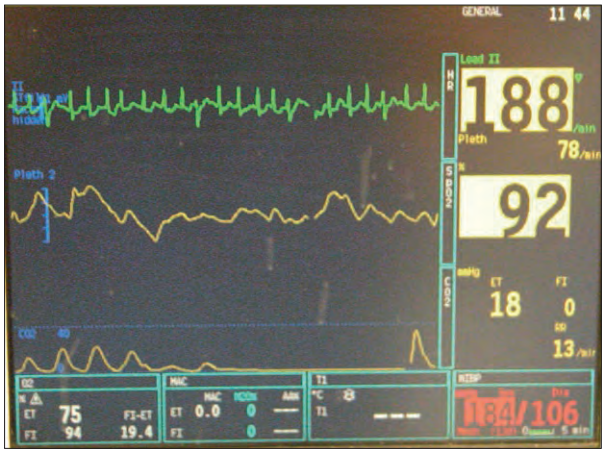
A middle-aged, slim, healthy patient underwent urgent abdominal surgery. There was unexpected difficulty with intubation during an RSI undertaken by a trainee anaesthetist, and the patient reported AAGA to an anaesthetist at a later procedure saying: "Next time you try to put the tube down could you please make sure that I'm asleep. I could feel some pressure on my neck, some poking around in my throat and then something larger coming down". Only thiopental and suxamethonium were used at induction.

8.25 It is uncertain if RSI was required in all cases where it was used, or if better pre-operative preparation would have avoided it. In obese patients there is often justification for tracheal intubation (Cook et al., 2011), but the reasons for choosing formal RSI were unclear from the reports.

Difficult airway management

8.26 Twenty-one (30%) reports at induction occurred during protracted or 'difficult' airway management; 12 during RSI. The overall incidence of difficult airway management is unclear, in part due to issues of definition: difficult bag mask ventilation occurs in approximately 1–5%, difficult or failed supraglottic airway insertion in 1–2%, a grade 3 view at laryngoscopy in approximately 6% (Cook & MacDougall-Davis, 2012), and difficult intubation (three or more attempts) in up to ~4% (Crosby et al., 1998). Based on these figures, NAP5 confirms that the risk from difficult airway management is to some extent coupled with a risk of AAGA.

Difficult airway management is a risk factor for AAGA



8.27 In several cases of AAGA during airway difficulty, it was unclear whether the anaesthetic team intended to persist with attempts at intubation or to cease anaesthesia and awaken the patient.

A middle-aged very obese patient underwent urgent surgery at night. Induction was with fentanyl 100µg, thiopental 500mg and suxamethonium 100mg. There was unexpected difficulty with intubation and after repeated intubation attempts, during which no further drugs were administered, the case was abandoned and the patient awoken. The patient heard discussion about intubation difficulty, felt instruments in his mouth and was unable to move.

An elderly overweight patient underwent general anaesthesia for major orthopaedic surgery. There was unexpected airway difficulty and the vaporiser was turned off to avoid 'pollution' during intubation. Induction was with propofol, midazolam, fentanyl and atracurium then sevoflurane for maintenance. Bag and mask ventilation was easy but laryngoscopy was difficult and help was summoned. The lack of volatile was recognised when the blood pressure was noticed to be elevated during ILMA insertion. Airway management lasted 45 minutes. It was unclear whether the plan was to wake the patient up, or to continue with attempts to secure the airway. The patient told recovery staff of recall of voices, the sensation of being ventilated with a mask and a description consistent with insertion of a supraglottic airway.

8.28 In numerous cases where AAGA occurred during airway difficulty, no additional intravenous anaesthetic agent was administered. Anaesthesia relied on volatile administration during either difficult/failed mask ventilation or repeated attempts at instrumenting the airway. The Panel judged that this contributed or caused AAGA which was preventable.

A very obese unfit middle-aged patient reported hearing the consultant tell the trainee to "…get out of the way!" during her operation. There was a high quality record showing the trainee had difficulty with tracheal intubation and handed over to the consultant. Induction was with fentanyl 100µg, propofol 200mg and rocuronium 45mg. The anaesthetic record showed elevated blood pressure and heart rate during airway management.

8.29 In some reports the Panel judged that the dose of neuromuscular blocking drug was low by weight and may have itself contributed to difficult or prolonged intubation.

Vaporisers: prolonged 'gap' in administration of anaesthetic on transfer ('mind the gap')

8.30 Six cases (8%) occurred as a consequence of failing to turn on the vaporiser either after induction (n= 3) or on arrival in theatre.

8.31 In other cases the Panel judged that actions including starting volatile agents at too low a level, at too low fresh gas flow or using an unchecked (and faulty) vaporiser were causal in cases of AAGA. The rapid and appropriate action of the anaesthetists when AAGA was recognised and subsequent management of cases demonstrate an appropriate 'rescue' mechanism if AAGA is suspected.

A young healthy patient underwent urgent abdominal surgery. While the senior trainee anaesthetist was waiting for the patient the theatre co-ordinator changed the vaporiser for a new 'trial vaporiser' without informing the anaesthetist. Meanwhile the anaesthetist was called to an emergency. On returning, anaesthesia was induced without a further machine check. Following uneventful induction a regional block was performed and the heart rate and blood pressure were observed to be elevated so more opioid was administered. At incision heart rate increased further and at this point the vaporiser was checked and found to be empty. Midazolam and propofol were immediately given to deepen anaesthesia and the vaporiser filled. The patient reported hearing voices, being unable to move and feeling someone "…cleaning their tummy and then a tube going in…" The patient received an offer of counselling.

The movement of a patient from anaesthetic room to theatre is a period of risk for AAGA

Human factors: distractions and organisational issues on transfer

8.32 The Panel noted several cases where AAGA had arisen at induction, apparently because of distraction, fatigue and organisational issues; i.e., a desire to increase rapid turnover of cases, or last minute changes in list order or operating theatre, etc. This topic is discussed further in the Human Factors chapter (Chapter 23).

Failure to turn on a vaporiser was an important cause of AAGA at induction (and early in maintenance)

A middle aged patient experienced AAGA in the early part of the operation. The patient could not move, felt their buttocks being positioned, placement of sheets under their sacrum and heard a detailed conversation The patient knew something was wrong and panicked because they could not move . The patient tried to scream out but could not. The patient "…felt violated, and then everything went blank…" The patient told the recovery nurse immediately on waking and post-operative discussion with the on-call anaesthetist suggested the patient was very distressed and psychologically affected. After intravenous induction and administration of a muscle relaxant the machine record of volatile concentrations showed no agent detected for a period of 15 minutes after arrival in theatre. On transferring the patient into theatre the anaesthetist was distracted by failure of the pulse oximeter and accidentally omitted to turn on the volatile anaesthetic agent. During this period both heart rate and blood pressure were elevated.

Problems with intravenous induction of anaesthesia, including neuromuscular blockade

8.33 Five cases (7%) occurred when the induction agent went back up the intravenous line or when the cannula 'tissued'.

An anaesthetist attempted an RSI but experienced unexpected difficulty. The patient subsequently reported attempts at intubation and a feeling of suffocation when bag/mask ventilation was performed. Although the incident was very brief the patient was distressed, feared death and developed a new anxiety state related to a 'near death experience'. The report suggests that the thiopental had backtracked up the intravenous giving set because a one-way valve failed. No more thiopental was prepared or available and no-one was available to help prepare any more.

8.34 In two cases (where the recorded dose of thiopental is very adequate on a dose per kilogram basis) it was suggested by the reporter that underdosing may have occurred because the thiopental was not fully dissolved. This is similar to cases reported in Chapter 16 (Obstetrics) and Chapter 13 (Drug Errors).

8.35 In two cases the report suggested that the neuromuscular blocking drug had been given too early in the induction process. In neither case was the drug suxemethonium.

NMBs should not be administered until loss of consciousness has been confirmed

Patient experience and assessment of care

8.36 Superficially it might seem that in terms of duration or sensation, patient reports during induction and transfer were mild and generally self-limiting: Nine (13%) of reports were of auditory sensation only although three included distress; 24 (34%) were confined to tactile sensation without pain of which a third caused distress. Paralysis was specifically mentioned in 36 (51%) of reports (and was more

commonly associated with distress), and pain was reported in 7 (10%). The feeling of movement or positioning was uncommon, (5, 7%, patients) as were visual experiences or bright lights (2, 3%, patients). Distress was present in 30 (43%) reports using the Michigan score. The longer-term impact as judged by modified NPSA score was no different in range from that occurring at other phases (see Patient Experiences, Chapter 7).

8.37 The common experience of auditory sensation in several reports, suggests that professional conduct and communication with the patient might mitigate adverse impact when AAGA occurs.

A young patient due to undergo urgent surgery was assessed by a very junior trainee. The trainee predicted a normal airway, but during RSI with thiopental and suxamethonium, laryngoscopy was Grade 3 and intubation failed. Help was called and a senior trainee attended and secured the airway.

No additional induction agents were given, and the patient awoke at end of surgery reporting AAGA. However, the patient's experience was a positive and reassuring one as they appreciated the efforts the doctors were making to keep things safe. The patient thanked the doctors for their care.

8.38 Quality of care was assessable in 65 cases: it was deemed 'good' in 19 (26%) of cases, mixed in 22 (31%), and poor in 24 (33%).

8.39 Poor care referred to poor pre-operative assessment, poor standards of charting, poor decision making, and poor management. Distraction was described as contributory in some cases, and this reflects poorly on theatre systems which require anaesthetists to leave the patient to assist in other matters. Poor charts were often referred to by the Local Co-ordinator as making identification of causes and timings very difficult, and the Panel was sensitive to the risk of negative hindsight bias in such cases in classing the report as poor vs. good. Examples of good care include prompt cessation of surgery, reassuring patients during the event if AAGA is suspected, the rigorous checking of potential causes, an early apology and offers of counselling.

8.40 In 69 cases there was sufficient information to assess preventability: AAGA was judged preventable in 42 (58%) of reports, possibly preventable in 13 (18%) and not preventable in 14 (19%). Preventable factors included: underdosing of induction agent by weight (often by apparently limiting drug dose to one vial rather than using a weight-based dose); underdosing of neuromuscular blockade, making intubation more difficult; RSI used when apparently not strictly necessary, which made intubation predictably more difficult; failing to prepare additional intravenous induction drugs; and actions which increased the risk of error (such as turning vaporisers off during intubation, and/or failure to turn it on immediately after intubation). The most striking example was a patient with a previous airway problem and a past history of AAGA, where lack of adequate history-taking and airway assessment led to problems at induction which contributed to another episode of AAGA.

DISCUSSION

Dosing

8.41 For AAGA to occur at induction of anaesthesia means that some stimulus such as airway manipulation occurs before the patient has attained a sufficient degree of unconsciousness. The anaesthetist's dilemma is that on one hand the airway needs to be secured promptly (an example being RSI, where there is concern about aspiration; or a difficult airway where there is concern about hypoxia); but on the other hand, that the duration of unconsciousness may not endure for protracted airway management.

8.42 At the very least, avoidance of AAGA at induction requires some reference to minimum published doses of induction agent, and these are given below (Table 8.1). Where there is a concern about co-morbidities such as cardiovascular instability then anaesthetists may reasonably plan to administer lower than published doses, and this can be readily justified. It is, however, notable that in the cases of AAGA due to induction agent underdosing this was rarely, if ever, due to concerns over co-morbidities, nor was there clear explanation as to why such low doses had been used.

Table 8.1 Standard dose ranges for (non-obstetric) induction agents. Doses are quoted as milligram per kilogram bodyweight. The reference is in a condensed form and full references are at the end of the chapter

Agent	Adult dose range	Reference
Propofol	1.5-3mg/kg	Caro (2013)
Thiopental	4-6mg/kg	AnaesthesiaUK
Etomidate	0.2-0.35mg/kg	Holdcroft A et al., 1976
Ketamine	1-2mg/kg (i.v.)	Caro (2013)

8.43 There were a small number of instances where intentional underdosing of induction agent was used to reduce cardiovascular side effects. Provision of anaesthesia in a critically ill or unstable patient is challenging, but in principle the Panel felt that greater attention could have been paid to cardiovascular optimisation (e.g. by better use of inotropes or fluid resuscitation) rather than simple reduction in anaesthetic dosing (see also ICU Chapter 17). Where reduced dosing is deemed unavoidable, then (if possible) the higher risk of AAGA should be communicated as part of the consent process. Furthermore, the use of reduced volatile anaesthetic concentrations in the face of cardiovascular instability is one that warrants consideration of specific DOA monitoring

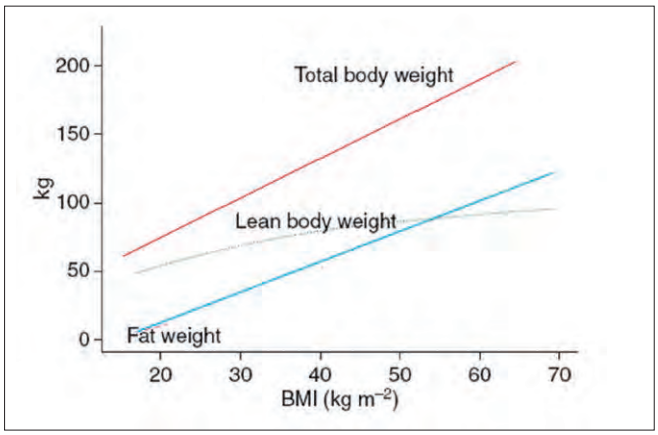
8.44 The use of low induction doses (<2mg/kg of propofol or <4mg/kg of thiopental), and the increased volume of distribution in obese patients were commented on by the Panel, who were unanimous in their view that a thiopental dose of barely 2mg/kg is inadequate in healthy patients. The duration of anaesthesia would have been prolonged by thiopental doses closer to 5 or 6mg/kg or propofol doses larger than 2mg/kg. There were numerous examples of apparent 'dosing by ampoule'; i.e. thiopental 500 mg, propofol 200mg and suxamethonium 100mg appeared commonly stated induction doses.

Obesity

8.45 As compared with the Activity Survey, there was an excess of obese and morbidly obese patients in Certain/probable or Possible AAGA cases at induction. Whereas obesity or morbid obesity represents ~22% of the general anaesthetic population overall, it represents 35% of AAGA cases at induction.

8.46 The relationship between total and lean body weight in obese patients is well known (Figure 8.3). In obese patients fat weight and lean weight do not increase in proportion as body weight increases; the former increases disproportionately.

Figure 8.3. Increase in total, lean and fat body weight with increasing body mass index; fat weight increases out of proportion to lean weight, and constitutes an ever increasing proportion of total body weight in the obese (re-drawn from Ingrande & Lemmens, 2010)



8.47 It is recognised that anaesthetic drugs, which are very fat soluble, distribute in the fat and therefore have reduced availability for action on target organs (i.e. the effective volumes of distribution are greater in the obese): consequently, larger doses are needed. For example, thiopental shows a ~60% lower peak plasma concentration after a single dose in obese vs. normal weight subjects (Wada et al., 1997).

8.48 Cardiac output is also relevant as it determines the speed of redistribution of an administered drug, and cardiac output is proportionately higher in the obese. Thus for both propofol and thiopental, volumes of distribution and clearances increase with total body weight (Ingrande & Lemmens., 2011).

8.49 Current recommendations are that induction drug doses should be based on lean body weight (Ingrande et al., 2011). This would result in induction doses indeed being limited to about one ampoule of propofol or thiopental even in the very obese (Figure 8.3). However, this advice also recommends that propofol infusions (in contrast to induction dosing) should better be titrated to total body weight. The recommendation of limited induction dosing appears to be based on the observation that obese subjects administered propofol based on *lean* body weight required similar doses as lean subjects given propofol based on *total* body weight using the endpoint of unresponsiveness at induction (Ingrade et al., 2011). However, it is apparent from NAP5 and other data that even when this endpoint is attained, AAGA can result with stronger stimuli (e.g. airway manipulation or instrumentation).

8.50 One concern about using dosing to total body weight is that it results in very high doses of induction agents that might result in extreme cardiovascular instability. In other words, the drug effects on the cardiovascular system do not parallel the effects on relevant brain systems involved in consciousness. The administered dose required to achieve suitable unconsciousness comes at the price of exaggerated haemodynamic response. However, data on whether this is actually the case are sparse and Lam et al. (2013) have found no haemodynamic instability when obese patients are administered induction doses titrated to total body weight.

8.51 The results of NAP5, indicate that induction is a high risk phase of anaesthesia for AAGA, and that AAGA may be more common in the obese. This raises the possibility that dosing of induction drugs based on total body weight might be a better strategy to reduce the risk of AAGA. Further research is required.

RSI and thiopental

8.52 The observed association of AAGA with RSI is of concern. Conventional RSI involves pre-oxygenation, application of cricoid force and a rapid induction with a pre-judged dose of induction agent and immediate administration of a rapid acting neuromuscular blocking drug. Traditionally, the neuromuscular blockade was with suxamethonium, but with rapid reversal of rocuronium now possible this may be a suitable alternative. The goal of RSI is to achieve prompt unconsciousness and paralysis, to enable immediate tracheal intubation during the limited period of safe apnoea time.

8.53 It is clear that elements of RSI can predispose to AAGA. In the 'classic' RSI there is no co-administration of opioid and no scope for assessing that the prejudged dose of induction agent has been adequate. The high numbers of unmodified RSI cases reported to NAP5 suggest that this technique has significant hazards.

8.54 The Panel therefore judged that a re-evaluation of what is regarded as a suitable RSI is warranted, and whether all of its conventional elements are necessary to achieve the goal of reducing aspiration risk. Several questions are pertinent

(a) Would administration of opioids (or other adjuncts) lower the risk of AAGA while still achieving the goals of RSI?

(b) Is there time to assess the effect of induction agent, and provide more if needed?

(c) Can the administration of the rapidly acting neuromuscular blocking drug be delayed slightly to check conscious level (and/or even check the ease of bag-mask ventilation, itself a test of depth of anaesthesia)?

(d) Does thiopental have a place in modern anaesthetic practice, and what is that place?

8.55 RSI with thiopental was notably over-represented in cases reported to NAP5. A dose of thiopental of ~4mg/kg as commonly used for RSI produces a wide spread of bispectral index values (BIS) including a significant number with BIS values >70 (Sie et al., 2004). Thiopental also has a relatively *short* duration of action (due to rapid redistribution) and the period of unconsciousness it induces is frequently *shorter* than the duration of paralysis caused by suxamethonium (Heier et al., 2001). These facts, combined with the infrequent use of thiopental outside RSI (as demonstrated in the Activity Survey) raise questions over the utility of thiopental (especially without opioids) for RSI. Propofol, despite a possibly slower onset time, has a slightly *longer* duration of action and additional dosing is easier to judge, so may be a more rational choice to ensure unconsciousness during intubation (Sie et al., 2004).

Rapid sequence induction with thiopental was a risk factor for AAGA

Difficult airway management

8.56 Avoiding AAGA due to unanticipated airway problems starts with identification of patients with difficult airways at pre-operative assessment and the formulation of an appropriate strategy. While it is relatively common that a patient who is predicted to have a difficult airway turns out to be easy (i.e., the positive predictive value of current predictive tests is low) it is rare for a patient predicted to be easy in fact to be difficult (i.e. the negative predictive value

of existing tests is high; Shiga et al., 2005). There were several examples where an airway assessment had not been recorded. Failure to perform or act on airway assessment was an important feature of NAP4 (Cook et al., 2011), and it appears there is an unfortunate overlap in the consequences of this for both airway management and AAGA. It is also surprising that the clear messages of NAP4 do not yet appear to have been learnt.

8.57 To avoid AAGA, anaesthesia should continue during prolonged attempts at securing the airway. The alternative, in cases of difficult airway management is to wake the patient (Henderson et al., 2004). Anaesthetists should therefore adhere to prevailing airway management guidelines and make clear the path they are following in their management algorithms. Where the decision is made to wake the patient, it is logical to omit further induction or opioid drugs. On the other hand, if the airway plan involves continuing efforts, consideration should be given to how AAGA will be avoided.

8.58 Relying solely on volatile agents to maintain anaesthesia during prolonged intubation is irrational, as repeated attempts at intubation do not permit time for effective bag mask ventilation. Furthermore, when intubation fails, bag mask ventilation is also much more likely to be difficult (Kheterpal et al., 2013).

8.59 Thus either:

(a) anaesthetists should manage the airway in an anaesthetised patient using a series of different management options and equipment – in which case they need to ensure the patient remains fully anaesthetised. In this scenario, continued administration of intravenous agent would seem more logical than use of volatiles since the uptake of the latter is likely impaired or absent during difficult airway management.

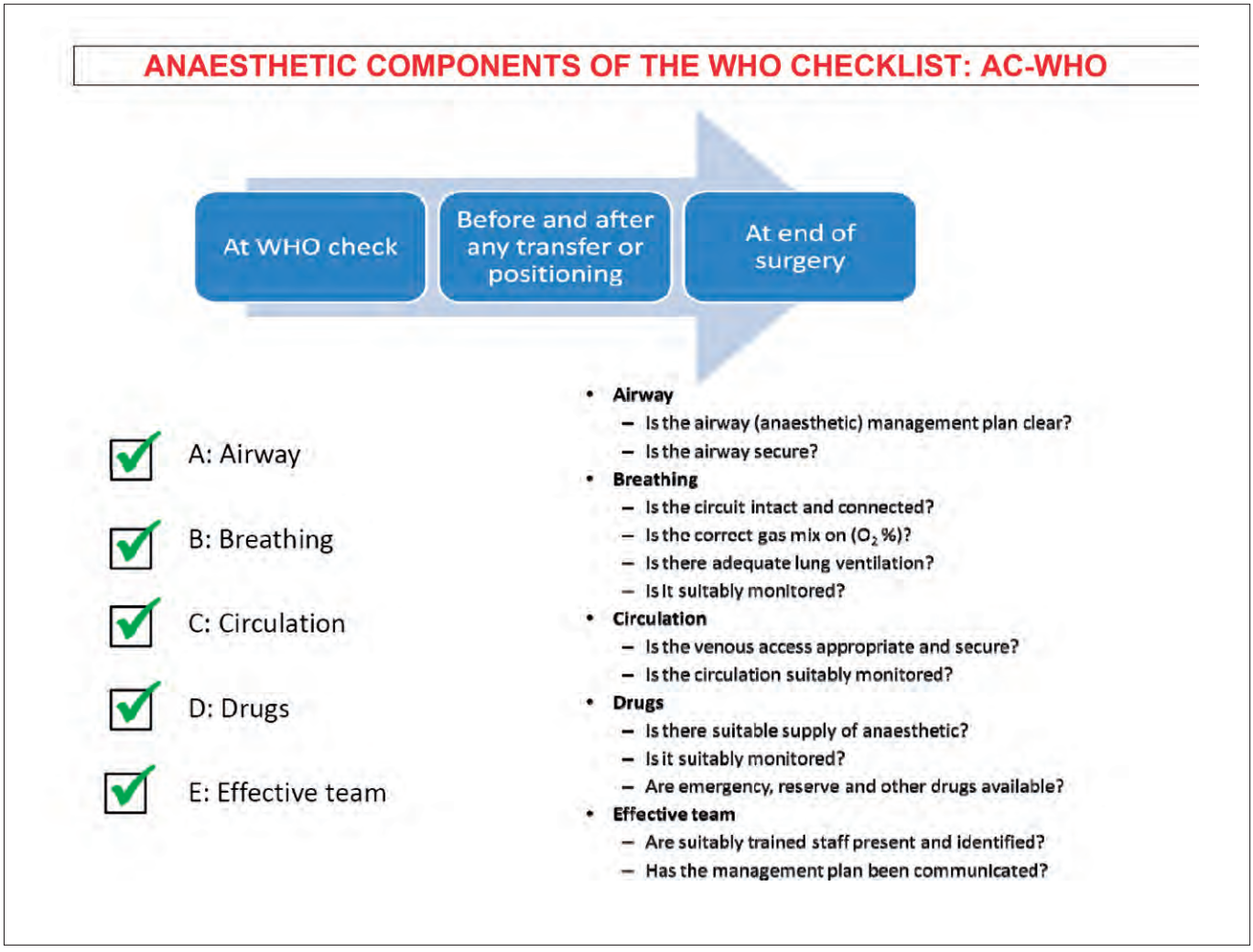


Figure 8.4. A proposed NAP5 Anaesthesia (sub)checklist of the WHO checks. This should be conducted on every movement of the patient

Or:

(b) anaesthetists should plan a wake up strategy – in which case they need to cease airway manipulation, cease anaesthetic administration, reverse neuromuscular blockade (if possible) and awaken the patient.

8.60 Where the decision was to continue with airway management and therefore with anaesthesia, the review Panel expressed reservations about the use of thiopental. The need for dissolution creates delays in administration unless several doses are drawn up in advance, mixing may not always be perfect, and it is unclear if thiopental has any advantage over other induction drugs in this setting. These limitations should raise questions as to what extent this drug should retain a role in modern anaesthetic practice.

8.61 The Panel noticed reference to turning off vaporisers during laryngoscopy and reduction of anaesthetic room 'pollution', but considered that turning off the fresh gas would achieve the same result without the risk of AAGA because the absence of fresh gas is immediately obvious and when turned on again, the delivery of volatile would automatically be restored. Some newer anaesthetic machines incorporate a time-limited facility to pause anaesthetic agent delivery during circuit disconnections, which might reduce AAGA due to such events.

Transfer into theatre and 'mind the gap'

8.62 Transfer of the patient from anaesthetic room to theatre, where there are further distractions such as positioning is a time of increased risk for AAGA. Volatile anaesthesia needs to be discontinued in the anaesthetic room, and then restarted in theatre. We received several reports of AAGA when this process failed. Even during total intravenous anaesthesia (TIVA) some pumps become disconnected or can fail unexpectedly. Several measures might help prevent these mishaps and include:

(a) adoption of a suitable 'checklist' to be applied after every transfer of the patient. Such a checklist might include confirmation that there is appropriate fresh gas flow, monitoring, and delivery of anaesthetic (See Figure 8.4).

(b) using appropriately high fresh gas flows and drug concentrations (or priming the anaesthetic circuit) on re-connection to an 'empty circuit' to avoid volatile 'washout';

(c) diligent use of low volatile or low MAC alarms

(d) appropriate use of specific DOA monitors as monitors of anaesthetic delivery. However, over-reliance on such monitors can cause its own problems (see Chapter 20 DOA).

Movement of patients requires discontinuation of anaesthesia and monitoring. This 'gap' in delivery may lead to AAGA. A checklist may be helpful

8.63 A suitable time to conduct the proposed checklist is at the same time as the WHO safer surgery checklist. Figure 8.4 presents a very simple version that could be adopted.

8.64 Eliminating the use of anaesthetic rooms would reduce one step in the transfer of anaesthetised patients and so prevent the cases of AAGA associated with this. Their role in modern anaesthesia could usefully be re-evaluated.

8.65 The use of a 'low end-tidal' alarm for volatile agents (and perhaps also TIVA devices) should alert the anaesthetist to the fact that insufficient agent is being administered. Some newer anaesthetic machines incorporate targeted end-tidal volatile concentrations which have the potential to reduce AAGA. However, such alarms must be carefully designed not to be misleading or intrusive during planned emergence or if TIVA is planned as well as between cases.

Human factors

8.66 Distraction and fatigue were mentioned in several cases. Operating theatres are considered high-pressure environments, but this 'pressure' should be only in the sense that careful attention is needed to the management of each patient. There is no reason for the theatre environment as a whole to be an inevitable risk to patient safety. Now that there are sophisticated planning tools for surgical operating lists based on known times to perform the operations listed (Pandit & Tavare, 2011), over-booking surgical lists and consequent time pressure between cases must be regarded as an avoidable and serious safety risk (Phillips, 2010).

Patient experience

8.67 The sensation of paralysis is not usual for patients and hence is a very distressing experience. Even well-prepared volunteers find it unpleasant (Topulos et al., 1993). NAP5 confirms that it leads to considerable long-term problems (see Chapter 7, Patient Experience). It is therefore incumbent upon anaesthetists to avoid paralysing patients who are not unconscious, yet the Panel found several reports of elective cases where non-depolarising neuromuscular blocking drugs were administered, either concurrently with the induction agent, or before establishing sufficient levels of unconsciousness. Past reasons for this technique were to rapidly create optimal conditions for tracheal intubation when available agents (pancuronium, tubocurarine) were very slow in onset (Katz, 1971; Minsaas & Stovner, 1980). However, the more rapidly acting agents available today make this a rationale with minimal benefit and considerable risks for AAGA at induction.

8.68 Auditory experiences were common. Remarks of an unprofessional nature do not reassure a patient who is experiencing awareness, fear, and possibly pain. On the other hand, patients were reassured to hear that their carers had recognised the problem and were addressing it; anaesthetists may wish to consider how to communicate with patients both routinely and especially when they think may be aware.

IMPLICATIONS FOR RESEARCH

Research Implication 8.1

There is scope for investigating the utility and practicality of using DOA monitors during induction of anaesthesia, especially to assess if their use reduces the incidence of AAGA.

Research Implication 8.2

The notion of a 'rapid sequence induction' and what it means in modern anaesthetic practice could usefully be re-evaluated. Particular areas of interest include: Which induction drug should be used? Should opioids be used? In which groups of patients is RSI indicated (e.g. whether it should normally be used in, say, the obese, diabetic patients, those with reflux, etc)? Is there time to assess adequate depth of anaesthesia (or even assess mask ventilation) before administering neuromuscular blockade?

Research implication 8.3

Further *in vivo* research is needed to establish the optimum dosing regimen for obese patients, which avoids overdose while reducing the increased risk of AAGA seen in this group in NAP5.

Research Implication 8.4

'Smart' end-tidal anaesthetic concentration alarms, could usefully be further developed that alert the anaesthetist when agent levels fall too low. The technical challenge is that they should be sensibly adaptable for changing levels of agent during a case.

Research Implication 8.5

Airway management research should, amongst other things, focus on whether 'wake up' or 'keep asleep' is the optimum method of managing a failed tracheal intubation, and the implications this has for risk of AAGA.

Research Implication 8.6

Research or debate should establish whether there are benefits to using thiopental that counter the disadvantages identified in this Report.

Research Implication 8.7

Research is needed into developing an appropriate checklist for anaesthesia (perhaps incorporated into, or an extension of, the WHO checklist) to be applied after any patient transfer, to act as an *aide-memoire* to check that the key components of anaesthesia and monitoring are in place. Specifically, the utility of the checklist proposed in this NAP5 report should be assessed.

Research Implication 8.8

Research is needed into anaesthesia-specific timings (including preparation and recovery timings) that can be incorporated into surgical list planning in rational ways, to reduce all risks (including AAGA) associated with the otherwise avoidably high-pressure environment of operating theatres.

Research Implication 8.8

Research or debate should establish the benefits and risks of separate anaesthetic rooms.

RECOMMENDATIONS

RECOMMENDATION 8.1
Standard induction doses for intravenous agents should be used as a reference in dosing. Deviating greatly from these requires justification.

RECOMMENDATION 8.2
During routine induction, loss of consciousness after induction should be verified by loss of response to verbal command and simple airway manipulation (e.g. jaw thrust) before undertaking further anaesthetic interventions, including the administration of neuromuscular blocking drugs.

RECOMMENDATION 8.3
Formal airway assessment is a mandatory component of anaesthesia. If a difficult airway is anticipated, a clear management strategy must be communicated to anaesthesia assistants and to the surgical team. A patient with a difficult airway must also be considered to be at higher risk of AAGA at time of induction, and (unless it is planned to secure the airway awake or sedated) this risk should be communicated to the patient as part of the process of consent.

RECOMMENDATION 8.4
When airway management becomes prolonged, the anaesthetist should decide whether to awaken the patient or to continue to try to secure the airway; if the latter, general anaesthesia must be continued. This is more logically done by continued administration of an intravenous agent.

RECOMMENDATION 8.5
Anaesthetists should exercise caution when using thiopental for RSI. This caution should include appreciation of the need to have additional doses of an appropriate induction agent for possible use during prolonged airway management.

RECOMMENDATION 8.6
Obesity should be considered a risk factor for AAGA at induction, especially if RSI is planned. Careful dosing is required to ensure adequate but not excessive dosing.

RECOMMENDATION 8.7
Intentional underdosing of anaesthetic drugs at induction to avoid cardiovascular instability is appropriate in some circumstances, but the risk of AAGA should be considered and where it is unavoidable:

(a) The higher risk of AAGA should be communicated to the patient.
(b) Invasive monitoring should be considered to enable accurate early use of vasopressor drugs and adequate doses of anaesthetic agents to be administered safely.
(c) Specific depth of anaesthesia monitoring should be considered.

RECOMMENDATION 8.8
Anaesthetists should regard transferring an anaesthetised patient from anaesthetic room to theatre (and by logical extension all patient transfers) as a period of risk for AAGA. There are several interventions that can mitigate this risk; among these is by the use of a suitable checklist as proposed by NAP5.

RECOMMENDATION 8.9
Anaesthetists and organisations should ensure that operating lists are planned in a rational manner that explicitly includes adequate time to ensure safe conduct of anaesthesia, and that will reduce pressures and scope for distractions.

RECOMMENDATION 8.10
At all times, conversation and behaviour in theatres should remain professional, including where there is a situation or concern that AAGA is a risk (e.g. RSI, prolonged intubation, transfer).

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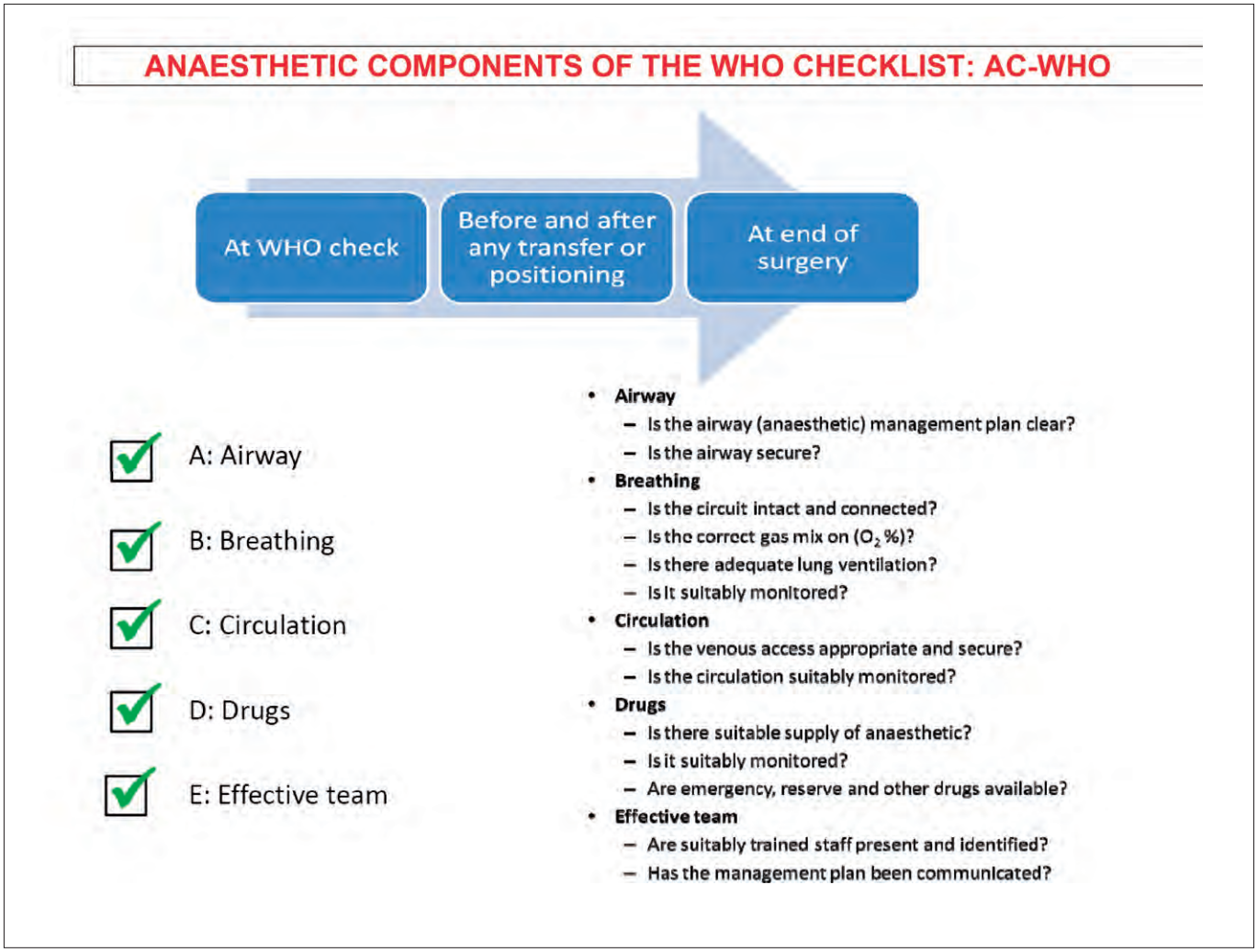
ABCDE checklist



A proposed NAP5 Anaesthesia (sub)checklist of the WHO checks. This should be conducted on every movement of the patient

CHAPTER
9

AAGA during the maintenance phase of anaesthesia


Jeremy J Radcliffe


James H MacG Palmer


Kate O'Connor

HEADLINE

9.1 Although previous studies of AAGA have focussed on events during the maintenance phase ('during surgery') of anaesthesia, only a third of NAP5 cases fell into this category. Many of the AAGA reports during surgery were in fact due to contributory factors at or soon after induction or transfer (e.g. failure to turn on vaporiser after transfer). Other contributory factors identified were deficiencies in monitoring or responding to levels of end-tidal volatile agent, stopping volatile delivery too soon and intentionally low doses of agent. Superficially, 'TIVA' was over-represented in this group of reports, but non-TCI TIVA techniques predominated. Shorter perceived experiences did not reduce the psychological harm that was reported.

BACKGROUND

9.2 In NAP5 we defined maintenance as the period between the start of the surgical intervention up to when it was complete. Ghoneim et al. (2009) suggested that three-quarters of episodes of AAGA may have occurred during the maintenance phase, but timing an event, which may be brief, is not necessarily easy even in a prospective study (Errando et al., 2008).

9.3 Accidental awareness during surgery was, in a sense, first demonstrated in public by Horace Wells. The *Connecticut Hartford Courant* (9 Dec 1846) prints Wells's description of his (in)famous public demonstration of dental extraction during nitrous oxide administration in January 1845: "*A large number of students, with several physicians, met to see the operation performed – one of their number to be the patient. Unfortunately for the experiment, the gas bag was by mistake withdrawn much too soon, and he was but partially under its influence when the tooth was extracted. He testified that he experienced some pain, but not as much as usually attends the operation.*" This seems to be a case of stopping administration of anaesthesia too soon before the start of surgery.

9.4 Existing literature discussing AAGA during maintenance can be grouped into: (a) case collections in cohort studies or sometimes detailed individual reports (Aaen & Moller, 2010; Rampersad, 2005), (b) assessments of implicit (Schacter, 1987) or explicit memory (Deeprose et al., 2004), (c) studies of depth of anaesthesia monitor use including isolated forearm technique studies (Russell, 2013a and b), or review or guidance articles (e.g. Apfelbaum, 2006). All the above studies attribute AAGA to three broadly separate causes:

(a) Overly light anaesthesia in patients at risk; especially in those undergoing emergency or obstetric procedures or in those with cardiovascular impairment, including in sepsis or trauma.

(b) Equipment malfunction (or human error in the use of equipment).

(c) Patients with a 'physiological resistance' to anaesthetic agents (e.g. tobacco smoking, heavy alcohol consumption, possible interaction with other centrally acting medication). Innate (e.g. genetic) resistance is also a possibility.

Maintenance is the phase when inherent resistance to anaesthetic agents may be most likely to present

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

9.5 Of the 141 Certain/probable and Possible (Class A and B) reports of AAGA, 51 (36%) involved AAGA during the maintenance phase (four of these involved AAGA at induction and maintenance, and one at maintenance and emergence).

9.6 The patient characteristics in this group of patients were similar to those in the overall group of AAGA reports (see Chapter 5, Methods). Thirty-two (64%) of reports classified were from female patients. Of the 51 patients, 23 (46%) were of normal body habitus, 19 (38%) were overweight or obese, one patient was underweight and in 8 (16%) the body habitus was not recorded. 18 reports (36%) related to patients undergoing NCEPOD urgent or emergency procedures, compared with 23.6% in the Activity Survey. ASA classes were: 1 and 2, 76%; 3, 20% and 4 and 5, 4%: i.e. there did not seem to be an excess of patients with significant comorbidity.

9.7 In 39 cases (78%), maintenance was with a volatile agent, using nitrous oxide in 14 (27%); an identical proportion of use found as in the Activity Survey. Possibly because some reports were historical, volatile agents were the principal drug in different proportions in the reports vs the Activity survey (sevoflurane 46%, desflurane 12%, isoflurane 12%, halothane 2%, enflurane 4% vs 57%, 13%, 21%, 0%, 0% respectively).

9.8 In 11 (22%), maintenance involved a TIVA technique, including nitrous oxide in one case. Of these, seven cases (14% of maintenance cases) used a TCI regime (two following or with volatile agents), three by calculated IV infusion, and one by repeated manual IV boluses. This exceeded the proportion of TIVA use in the Activity Survey (~8%). Intravenous anaesthesia is discussed elsewhere (Chapter 18).

9.9 The grade of the most senior anaesthetist was known in 49 cases. In 36 reports (71%), care was delivered by a consultant, in ten (20%) by SAS grades, and in three by senior trainees. The distribution is similar to the Activity Survey, with 71% of anaesthetics delivered by consultants and 85% by non-trainees. In seven (14%) cases the anaesthetist was in a locum post: compared with 7% of anaesthetics delivered by a locum anaesthetist in the Activity Survey.

9.10 EEG-based depth of anaesthesia (DOA) monitoring was used in 3 of the 51 cases (6%); all used bispectral analysis (BIS); i.e. double the use reported in the Activity Survey). In some cases, there appeared to be conflicting information about depth of anaesthesia as based on interpretation of information provided by the BIS monitor and end-tidal monitoring.

9.11 End-tidal volatile monitoring was recorded or implied in the majority of reports (33 of 40; 83%) of volatile anaesthetic cases.

An elderly patient with cardiovascular co-morbidities underwent general surgery, and two months after surgery reported AAGA. The patient recalled the presence of the tracheal tube, the abdomen being sutured closed, pain, hearing people talking, a sensation of paralysis and being unable to move. The patient was not distressed and gave a neutral report of the experience. The anaesthetic (intravenous induction with volatile maintenance) included BIS monitoring and remifentanil TCI. End-tidal concentrations of sevoflurane (in 50% oxygen) ranged between MAC 0.6-0.9. BIS values were recorded in the 40s and briefly in the low 50s.' (MAC 0.6 at this point).

9.12 Patients reported a wide range of durations of experience of awareness, from a few seconds to 60 minutes (median five minutes); AAGA lasted an estimated <1 min in 34%. The eight patients who subsequently reported a PTSD-like condition had broadly similar durations of experience (median five minutes).

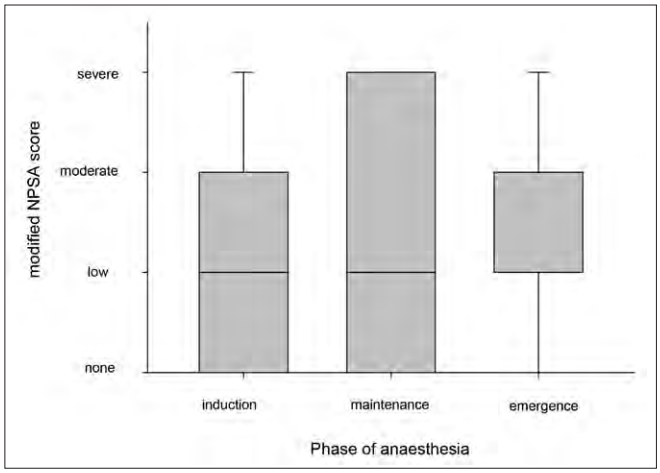
9.13 Of the patients who described the phase of surgery during which they experienced AAGA, 20 (40%) described it as the start of surgery (knife-to-skin) and 27 (54%) at a later period of surgery. In six patients the AAGA experience was reported to last for most of the procedure.

9.14 The commonest experience during maintenance was pain and paralysis (19; 37%) which was almost always distressing (in 84% of these). Paralysis alone was experienced by ten (20%) and pain alone by six (12%). Isolated tactile or auditory sensations were reported by six and ten patients (12% and 20%) respectively.

9.15 Distress was reported more commonly if pain or paralysis were present: 50% of those reporting pain and 75% of those reporting paralysis. Nearly half the patients experiencing tactile sensation also reported distress. None of those who reported only auditory experiences were distressed by them.

9.16 Despite the higher incidence of pain and paralysis in this phase of anaesthesia compared to the induction or emergence phases (Chapters 8 and 10, respectively), the overall proportion of patients distressed during maintenance was lower than at emergence (54% during maintenance vs 46% at induction and 73% during emergence). There was a broadly similar longer-term impact as judged by modified NPSA scores (Figure 9.1).

Figure 9.1. Boxplots for modified NPSA scores by phase of anaesthesia



9.17 About half the patients (28; 55%) had been offered follow up contact or more formal psychological support following their report of AAGA. In terms of impact, eight reports (16%) made reference to a PTSD-like state, and 14 (28%) described lesser anxiety symptoms. Eleven patients (22%) had initiated a process of formal complaint at the time of the report to NAP5.

9.18 In 37 patients (74%) there were elements of inadequate care identified:

(a) Errors with a vaporiser in 13 patients (26%).

(b) An intentionally (but inappropriately) low dose of anaesthesia in 17 (34%).

(c) Inappropriately early cessation of anaesthesia in 4 (8%).

9.19 Vaporiser errors included being left switched off after transfer (ten instances (20%), an empty vaporiser unnoticed (two cases) or incorrectly mounted (one case). Distraction was specifically cited as contributing to vaporiser errors in four (8%) reports.

A middle-aged patient underwent a short procedure under intended general anaesthesia. Immediately post-operatively, the patient reported recall of being positioned but could not move, and that there was a feeling of violation. The patient was panicked and very scared. The patient estimated that an interval of 15 minutes elapsed before everything went blank. The patient developed symptoms of PTSD. The anaesthetic had been an intravenous induction, with neuromuscular blockade for insertion of a supraglottic airway. On transfer to theatre the volatile agent was inadvertently not restarted and the expired concentrations were <0.5 MAC for ~ 15 minutes. The patient was tachycardic and hypertensive during this period. Distraction by a malfunctioning pulse oximeter was cited.

A patient underwent an emergency operation and immediately reported having heard the stapling of the skin whilst paralysed. The patient also recalled a discussion about 'sweating'. The experience lasted ~30 minutes. There was distress, sleep disturbance and unpleasant dreams. The anaesthetist had mistakenly turned off the vaporiser prematurely at the end of surgery.

9.20 However, in 13 (26%) of reports no cause of the episode of AAGA could be ascertained. In nine (18%) patients, AAGA was reported while documented care appears to have been of good quality.

An obese patient underwent general surgery. Later, the patient reported having seen lights, people overhead and experienced pain (like 'animals biting'). The patient tried to (but couldn't) speak; all this lasted about one minute. The patient developed new sleep disturbance, a new anxiety state, nightmares, flashbacks, PTSD-type symptoms and has was referred for psychology assessment and therapy. The anaesthetic maintenance included apparently appropriate opioids, local anaesthetic infiltration and appropriate levels of volatile agent.

9.21 The cases involving TIVA are discussed in detail in Chapter 18, but contributory factors included low dosing, non-standard or erroneous use of TIVA machines, omission of opioids when apparently required and disconnections.

A healthy patient undergoing elective ENT surgery reported that they had been awake during surgery but unable to move. They reported a strange feeling of being asleep but being able to see and know what was going on. In addition to recall of events in the anaesthetic room, they remembered that they tried to cry so that they could show people that they were awake. Then they recall being transferred on to the operating table, people talking and the pressure and pain of a needle being inserted, then an intense burning sensation and thinking that they couldn't survive this. Then they lost consciousness. The anaesthetist had used propofol TCI target (between 3 and 7 mcg/ml plasma target) and tramadol and ketamine boluses combined with lignocaine and magnesium infusions. The patient received psychology review for a newly established post-traumatic stress disorder.

DISCUSSION

9.22 It is perhaps surprising that AAGA during the maintenance phase, during surgery, is not more common as a proportion of all the AAGA reports. Whereas the level of stimuli during induction is likely to be relatively modest and brief, during surgery the levels of nociceptive stimulus rises dramatically and therefore might be expected to predispose to AAGA. The fact that ~40% of reports in the maintenance phase relate to the brief period of 'knife to skin' is consistent with a notion that the induction dose may have been (in retrospect) inadequate or may have worn off by time of surgery (see Chapter 8, Induction) or indicate an unpredicted stimulus.

9.23 Although the incidence of pain and paralysis as a combination of symptoms was more common during maintenance than in other phases of anaesthesia, this arose largely at the start of surgery, or less commonly towards the end of surgery, as brief experiences. There was therefore considerable overlap in the symptomatology of this group of patients as compared with induction and emergence cohorts (see Chapters 8 and 10).

9.24 In Chapter 8 (Induction) we propose use of a checklist to ensure anaesthesia is being delivered before surgery starts. Based on our findings it seems logical that this (or a similar) checklist might reduce the incidence of AGAA at the start of surgery. This could be tested by research. Any such checklist should be undertaken before the start of surgery, and the surgical team should formally confirm with the anaesthetist that it is appropriate to start surgery, before doing so.

9.25 However, over half the reports relate to a later phase of surgery. Speculatively (but logically), the intensity of surgical stimulus can vary during an operation, and there may be times when it is sufficient to overcome the unconsciousness induced by anaesthesia, unless this is always carefully titrated to stimulus.

9.26 It might be anticipated that, since lower doses of anaesthetic might be employed in patients who are more unwell or unstable, a worse ASA grade is associated with AAGA. There were some instances in which the Panel felt dosing had been intentionally (and inappropriately) reduced for this reason, but generally this was not the case. Reasons for this lack of apparent association might be that, generally anaesthetists are dosing appropriately in these cases, or that sensitivity to anaesthetic parallels physiological instability (i.e. the more unwell the patient, the more sensitive to anaesthetic). As referred to elsewhere, early use of vasoactive agents will in many cases obviate the need to inappropriately reduce anaesthetic doses, even in high risk patients (see Chapter 8 Induction, Chapter 17 ICU).

9.27 Strikingly, in about a quarter of reports in the maintenance phase, the Panel could find no cause or contributory factor. This finding differs from the analysis of induction and emergence phases, where causative/contributory factors were readily ascertained (e.g. related to difficulties in airway management or residual neuromuscular blockade). This raises the possibilities that (a) an inherent (possibly genetic) resistance to the effects of anaesthesia might exist, and (b) if it does, then it is revealed during the maintenance phase of anaesthesia.

9.28 The inherent difficulties of monitoring TIVA are discussed elsewhere, but it was surprising that several reports of AAGA during maintenance were associated with vaporiser problems that went undetected despite end-tidal monitoring. End-tidal monitoring is of value only if appropriate alarm limits are established, audible alarms are on, and these are acted on. In-depth analysis is required of the 'human factors' elements that promote likely distraction, or process disorders that lead to these oversights. However it is notable that studies that have concluded that end-tidal gas monitoring is as effective as DOA monitoring in preventing AAGA have used rigorous protocols that include

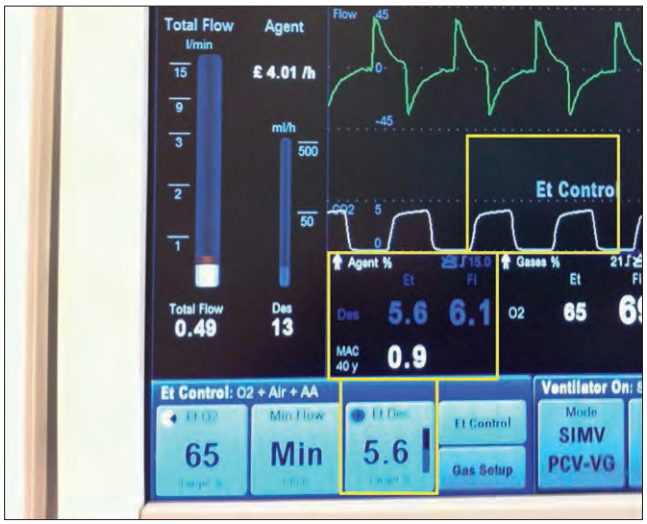
(a) enabled end-tidal gas alarms (b) audio alarms (c) in some cases text alert to the anaesthetist to inform them of alarm activation (d) protocolised responses to the alarm (Avidan et al., 2011; Mashour et al., 2012) .This rigour may not be reflected in 'standard care' (Myles et al., 2004).

9.29 End-tidal agent monitor alarms will provide an alert to indicate an unexpectedly low (or high) delivery of anaesthetic only if activated, at an appropriate level, for the whole duration of the anaesthetic procedure. The use of default alarm conditions should be considered. More sophisticated alarm process design may enable their use to be more keenly adopted.

9.30 For situations where an agent monitoring alarm is not employed there would be benefit from a vaporiser design which indicates an alarm when its contents are almost exhausted. Given that some vaporisers (desflurane) already have a power supply this should not prove impossible and is indeed available on some more modern machines. Reliance on a visual method for assessing the level of filling can lead easily to mistakes or omissions.

9.31 Newer anaesthetic machines are able to deliver 'targeted end-anaesthetic concentrations' even at low flows and this may also prove beneficial and is an avenue for future research.

Modern anaesthetic machines can maintain end-tidal gas concentrations at set levels (here 0.9 MAC of desflurane) which may help in reducing risk of AAGA



9.32 It is notable that over half of the reports were associated with pain. This suggests that, regardless of the dilemmas in monitoring the conscious state, when AAGA occurs during surgery pain is a prominent feature. This statistic would suggest that where AAGA is suspected during surgery, prompt deepening of anaesthesia should be coupled with administration of analgesia.

9.33 Consistent with data elsewhere in this Report, even short episodes of AAGA can be very distressing, and can be associated with longer term psychological morbidity and suffering.

9.34 The relatively stable maintenance phase of anaesthesia (in contrast to the more dynamic events at induction and emergence) should offer the most reliable conditions to test the possible impact of the use of DOA monitors. It is intriguing, and perhaps concerning, that 3 of 51 cases of AAGA during maintenance occurred during use of DOA monitors and further that there were episodes of AAGA when DOA monitoring data were reported to be in the recommended range throughout surgery. In one case, the depth of anaesthesia was judged more by the output of the DOA monitor than by the end-tidal volatile concentration (a dichotomy that can clearly create a genuine dilemma). However these three cases are too few on which to draw robust conclusions regarding the benefit (or harm) associated with DOA use. This is also discussed elsewhere (see Chapter 20, DOA). The risk of AAGA when end-tidal agent concentration is >0.7 MAC is extremely low (Aranake et al., 2013).

IMPLICATIONS FOR RESEARCH

Research Implication 9.1

The maintenance phase of anaesthesia most reliably offers a pseudo-steady state of anaesthesia, in which assessing the efficacy of DOA monitoring is less likely to be influenced by dynamic changes in conscious level. Research testing the utility of such monitoring should specify the phase of anaesthesia being examined, as outcomes may not be the same for induction, maintenance or emergence.

Research Implication 9.2

Research should seek to resolve the dilemma posed by the issue of how best to interpret a low DOA monitor output reading coupled with unexpectedly low anaesthetic concentration, since this can either indicate that the patient is sensitive to the anaesthetic agent, or that the DOA monitor output is incorrect.

Research Implications 9.3

Research should establish if there exists any inherent relative resistance to the effects of anaesthesia (e.g. genetic) and if so, which polymorphisms may be involved.

Research Implication 9.4
Perhaps in addition to monitors dedicated to measuring consciousness level (depth of anaesthesia), further research should be aimed at developing specific monitors for detecting the level of pain/nociception (analgesia or (anti)nociceptive monitoring).

Research Implication 9.5
Research should establish the optimum form of alarms to alert the anaesthetist to inadequate anaesthetic vapour delivery.

Research Implications 9.6
Further research should establish whether (and at what level) targeted (e.g. servo- or closed-loop) end-tidal volatile delivery can reduce AAGA.

RECOMMENDATIONS

RECOMMENDATION 9.1
An anaesthetic checklist should be conducted before the start of surgery to confirm (amongst other things) delivery of adequate anaesthesia. This might usefully be incorporated into the WHO checklist.

RECOMMENDATION 9.2
The surgical team should formally confirm with the anaesthetist that it is appropriate to start surgery, before doing so.

RECOMMENDATION 9.3
If AAGA is suspected during maintenance, then prompt attention should be paid to increasing analgesia, as well as deepening the level of unconsciousness. As recommended elsewhere, verbal reassurance should be given to the patient during this time.

RECOMMENDATION 9.4
Anaesthetists should exercise great caution in interpreting the outputs of processed EEG- based DOA monitoring as indicating adequate anaesthesia, in the face of unexpectedly low administered anaesthetic concentrations.

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CHAPTER
10

AAGA during extubation and emergence


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Ellen P O'Sullivan

HEADLINE

10.1 Almost a fifth of the reports received by NAP5 occurred during emergence, and 85% of these patients experienced the distress of paralysis while awake. The Panel judged 88% of cases as being potentially preventable with appropriate use of a nerve stimulator, better communication, and maintenance of anaesthesia until full reversal of neuromuscular blockade. In a third of cases communication failure within the team highlighted poorly-judged selection, dose, or timing of neuromuscular drugs. In all except one case airway management was with a tracheal tube. Lack of education about the rapid offset of newer volatile agents was cited as contributory in some cases. As elsewhere, these cases highlight the fact that adverse outcomes were more often associated with the use of neuromuscular blocking drugs.

BACKGROUND

10.2 Induction of anaesthesia underwent a sea-change after the introduction of thiopentone so that inhalational induction became almost restricted to children or those with fear of needles. The conduct of extubation and emergence has changed gradually so that awake extubation (including removal of supraglottic airways) is now common; a practice that has recently been actively advocated in authoritative guidelines (Popat et al., 2012). The introduction of propofol in the 1980s, the introduction of volatile agents with lower blood gas solubility accelerating emergence, and the use of the laryngeal mask instead of the tracheal tube have all facilitated this change.

10.3 The much faster emergence seen with propofol, sevoflurane or desflurane means that some vague recall of recovery has perhaps become normal, and the experience of expelling a laryngeal mask or receiving oxygen in part remembered. In the authors' experience older patients recall induction with 'gas', but now some patients report that "*something must have gone wrong; I woke up with oxygen on*". Publications on patient experiences in recovery are scarce, but have sought to develop objective scores relating to patient support, comfort, emotions, physical independence, and pain (Myles et al., 2000; Faleiro & Sinclair, 2006; Gornall et al., 2013).

10.4 More rapid emergence and re-acquisition of airway reflexes has reduced the risk of laryngospasm (historically a barrier to attempting awake extubation). Although awake extubation was described by Bourne (1947), the majority of elective surgical procedures at that time were followed by extubation under deep anaesthesia and spontaneous breathing. Only patients with 'full

stomachs' had their trachea extubated awake, and these while in the recovery position and head down (Wylie & Churchill-Davidson, 1972; Atkinson et al., 1982).

10.5 Developments in anaesthetic drugs and anaesthetic practice have been followed by pressures to increase numbers of day-case surgeries, improve theatre turnover and champion enhanced recovery. All these have driven processes that emphasise theatre efficiency, rapid transit through recovery and early resumption of normal patient activities. These have been in turn supported by an increased tendency to manage the airway with the less invasive supraglottic airway, or to extubate the patient already 'awake' before handing their care over to the recovery nurse for a briefer period.

10.6 Most recently, the Difficult Airway Society published comprehensive guidance which included the need to plan for extubation and to reverse or antagonise neuromuscular blockade before allowing the patient to awaken (Popat et al., 2012). In these guidelines, awake extubation is emphasised as the default method, with 'asleep extubation' generally reserved for low-risk cases with specific indications.

10.7 The availability of shorter-acting neuromuscular blockers with rapid offset times (e.g. mivacurium) and temptingly simple pharmacological elimination (e.g. atracurium, cis-atracurium) also played a part in the change to awake extubation (something probably more difficult with drugs such as pancuronium). Improved efficiency of reversal of neuromuscular paralysis with sugammadex has provided another tool in the armamentarium of rapid emergence from anaesthesia and paralysis.

10.8 With patients more frequently awake at extubation as a result of these changes in practice, it might reasonably be predicted that recall of this phase of anaesthesia would also become more common.

10.9 Anaesthetists have been reported as reluctant to communicate detailed information to patients about anaesthesia, perhaps through concern about heightening patient anxiety (Gillies & Baldwin, 2001). Explanation of emergence and recovery room experience was minimal and tracheal extubation was almost never mentioned (Oldman et al., 2004). More recently this haphazard approach has been improved and patient information booklets have come into widespread use (e.g. RCoA, 2008). Provision of such information prior to anaesthesia is now as a result an expected standard of care. The extent to which these documents describe emergence, extubation and recovery is, however, sparse. Predictably therefore, experience of extubation and recovery may be interpreted by patients as part of surgery.

10.10 As noted in Chapter 6, Results, emergence is a dynamic process and 'full emergence' is difficult to pinpoint which, not only means that this is a period when unintended (or unrecognised) wakefulness may occur, but also means that it is difficult to define. For the purposes of NAP5, emergence was defined as any time after the end of surgery, when the patient reported they were awake when they felt they should still have been unconscious. This definition – emphasising the patient's perspective for purposes of reporting and analysis – focuses on aspects of emergence which cause potential distress or dissatisfaction. It also enabled us to include cases where drug errors or failure to reverse neuromuscular blockade caused paralysis (and hence perceptions of AAGA) in the recovery period.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

10.11 Of the 141 reports assessed by the Panel as Certain or probable, 26 cases (18%) involved the emergence phase (one involved both maintenance and emergence; two involved both induction and emergence). In a further three cases (not included here) there was doubt as to the exact phase of AAGA, but emergence may have been involved. In several cases (several included here but also some excluded) it was difficult to judge whether recalled events related to emergence or events in recovery after emergence.

10.12 In line with the proportions reported in the Activity Survey, 17 (65%) were reports from women and nine (35%) described immediate or urgent care. Body habitus was known in 22 patients: of these eight (36%) were obese, five (23%) overweight, eight (36%) normal weight, and one (4%) was underweight. All but one (96%) received neuromuscular blockade.

10.13 Airway management was with a tracheal tube in 21 patients (81%) and awake extubation was planned in 16 of these (asleep extubation was planned in one and in five the decision was unclear). In three reports extubation was not planned and the report related to transfers after the end of surgery. In one, a supraglottic airway was used.

10.14 An anticholinesterase (reversal) drug was administered to 11 patients of the 19 (57%) who had received non-depolarising agents other

than mivacurium. A nerve stimulator was used in only six (24%) patients who had received neuromuscular blockade. Inappropriate reversal was not used in those patients who had mivacurium or suxamethonium alone. No patient received sugammadex.

10.15 The predominant symptom was paralysis, which was distressing. Of the 26 patients, 22 (84%) reported paralysis. Only four patients did not find paralysis distressing. Two patients reporting distress only felt touch (the tracheal tube or laryngeal mask), rather than the sensation of inability to move that was felt by the majority. Two patients specifically reported a sense of suffocation and terror. However, the longer term impact in terms of the modified NPSA score (median 1.5 (interquartile range 0.75–2.25), range (0–3) was modest.

A young patient woke rapidly after elective surgery, was extubated in theatre but had residual weakness in recovery. Three days later the patient described "waking up with the tube in" and being unable to speak. There was paralysis, difficulty moving the jaw or swallowing and the experience lasted about five minutes. After a technique employing diazepam premedication, propofol, fentanyl, and vecuronium for tracheal intubation, maintenance was with a volatile agent. Awake extubation was planned, so neostigmine administered but no nerve stimulator was used to check its effect. Further neostigmine was administered in recovery after the problem of inadequate reversal was recognised on the anaesthetic chart.

10.16 Of the 26 cases, 23 (88%) were judged preventable. One was deemed not preventable, and in two cases, poor charting prevented a judgement. In 11 cases (42%) the absence of, or failure to use, a nerve stimulator was identified by the Panel as contributory or causal. In six (23%) patients the Panel judged that the neuromuscular blocker had been administered too close to the anticipated end of surgery, had been ill-chosen for the duration of the procedure, or had been given in too great a dose for the procedure. In another six, reversal appeared to have been given only after the patient exhibited signs of residual paralysis.

Almost a quarter of episodes of AAGA were reported to occur during emergence or in recovery

A young patient underwent oral surgery. They reported being awake but paralysed at the end of surgery and hearing voices calling their name. They tried to be logical and work out what was happening, but heard staff mention something to 'bring them round'; the patient assumed this was a defibrillator and panicked. Staff noticed the patient crying and administered reversal. The anaesthetic was induction and maintenance with TCI propofol and remifentanil and atracurium used before intubation. Neostigmine was administered at the end of the procedure but timing in relation to stopping the propofol was unclear. The LC's report states that a nerve stimulator and further neostigmine were used after the potential for AAGA was recognised; this was on the anaesthetic chart.

10.17 In eight patients (30%) communication between anaesthetist and patient, between anaesthetist and surgeon or between two or more anaesthetists, was assessed as causal/contributory to the episode of AAGA. In one case, the surgeon informed theatre staff that the operation was 'finished' when in fact the operation continued; in another, an anaesthetic trainee felt that the consultant had given instruction to reduce the anaesthetic delivery early towards the end of the case. Apparent unfamiliarity with the speed of offset of short acting agents (e.g. desflurane) was cited in four cases and distraction (from handovers or from involvement of other anaesthetists present) in another four.

Mistimed, poorly monitored or unreversed neuromuscular blockade was the predominant cause of AAGA at emergence

10.18 The most common neuromuscular blocker used (19 (73%) reports) was a non-depolarising agent alone; in a further five cases its use followed suxamethonium. Atracurium was used in 15 (58%) patients, mivacurium in five (19%), rocuronium in three (12%) and vecuronium and suxamethonium in a single case each. The distribution of NMBs in general use was not collected by the Activity Survey. There was reference to genetic testing in three patients who received mivacurium and experienced prolonged blockade. In one patient there was possibility of dual block.

A frail elderly patient with multiple co-morbidities underwent a brief expedited procedure. Induction was with remifentanil, propofol and mivacurium. Maintenance was with sevoflurane then desflurane in oxygen/air with ventilation through a SAD. After surgery the patient appeared 'slow to wake up'. Mivacurium apnoea and awareness were suspected and a nerve stimulator was then used only after the suspicion to confirm this. Anaesthesia was re-commenced and the patient was extubated some hours later. The patient remembered feeling unable to move or communicate, but thought "I'll come round soon". The experience lasted about a minute and the patient did not feel overly distressed. A full explanation was given, but some slight psychological distress persisted.

10.19 Only one patient who received no neuromuscular blocker made a report of AAGA at emergence.

A young elective day-case patient for a minor procedure reported an experience of awareness to an anaesthetist. The patient remembered having something in their mouth and not being able to breathe, then recalled waking up. The experience was brief (seconds to minutes) but the patient had nightmares for three nights afterwards and was scared the same thing would happen again. The technique used was propofol, cyclizine, and alfentanil with airway management by SAD. The volatile agent used was not named, but MAC values of ~1.2 were recorded. The inability to breathe might represent obstruction rather than paralysis, but could represent a catatonic-like reaction to cyclizine.

10.20 In summary, the Panel assessed 23 reports (88%) as being potentially preventable with appropriate use of a nerve stimulator, better communication, and maintenance of anaesthesia until full reversal of neuromuscular blockade. Education was cited as contributory in several reports, mainly related to knowledge about the variability of duration of neuromuscular blockade, the rapidity of offset of newer volatile agents, and the need to fully explain the experience of planned awake extubation. The apparent failure to investigate the possible genetic cause of prolonged neuromuscular blockade in some of the patients who received mivacurium or suxamethonium was disappointing.

A young fit patient after emergency abdominal surgery reported hearing stapling of the skin and was paralysed and unable to move or communicate. The patient recalled a conversation about his sweating and this all lasted from skin closure to extubation; about 30 min. The patient was distressed, unable to sleep on the first post-operative day and had unpleasant dreams. The desflurane vaporiser was turned off prematurely at the end of surgery.

10.21 In several instances, verbal reassurance provided to, or heard by, the patient during emergence appeared to probably mitigate adverse longer-term impact.

The patient's episode of awareness started in recovery after surgery. The patient was unable to cough, talk, move their limbs and open their eyes (as they were taped shut). The patient experienced experienced ear/neck pain and the sensation of leg swelling. When a relative came to visit, the patient could hear the anaesthetist providing an explanation and reassurance about the problem. At this time the patient felt reassured.

DISCUSSION

10.22 There are considerable similarities between this group of reports of AAGA at emergence/extubation and those caused by syringe swap/drug error (i.e. Class G) discussed in Chapter 13 (Drug Error). In the latter group, patients were invariably aware but paralysed without anaesthesia as a result of inadvertent administration of a neuromuscular blocking drug. In the emergence reports, patients are invariably aware and paralysed as a result of inadvertent mismatch between the time course of return of consciousness *versus* the return of motor capacity. In both groups the prevalence of distress is very high, because the sensation of paralysis is highly unusual and leads to ideations of loss of control, or fear that something terrible is about to happen (see Chapter 7, Patient Experience).

10.23 Yet, of note, and in contrast to the 'pre-induction' drug swap cases (which had the highest modified NPSA scores of any group in NAP5), the cases occurring during emergence had low modified NPSA scores, indicating that marked psychological morbidity was uncommon (Figure 10.1). One explanation might be that relatively prompt recovery from residual anaesthesia in this group mitigated patient experiences and sequelae, but this is speculative.

Early cessation of short acting drugs was associated with AAGA during emergence

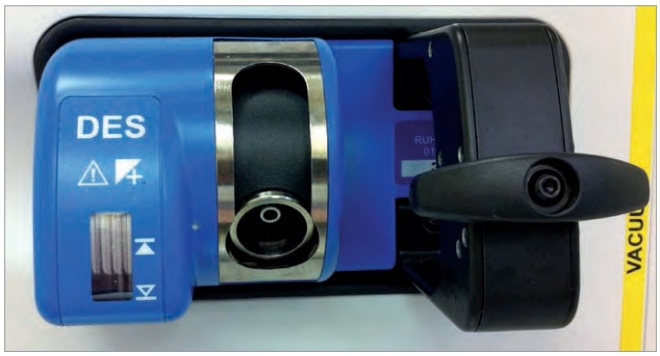
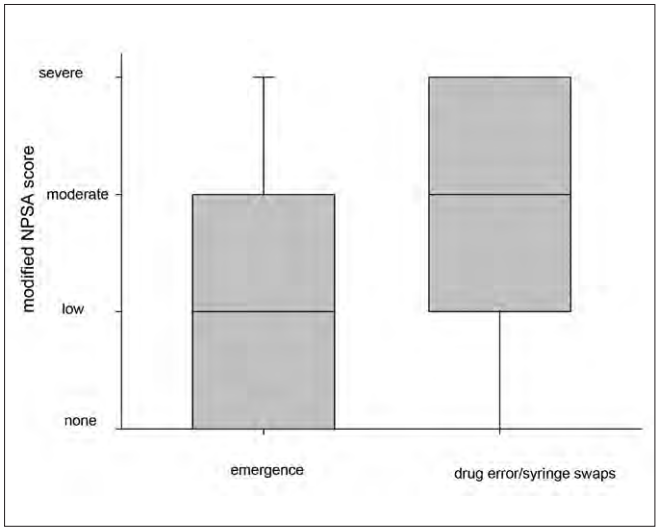


Figure 10.1. Boxplot of modified NPSA score for cases at emergence and for syringe swaps/drug errors (see Chapter 13). Note that the whereas the median impact for emergence cases is 'low' with 'severe' being rare, the median for drug errors is 'moderate' with 'none' being uncommon



10.24 The Panel considered that the current management of neuromuscular blockade by the anaesthetic community (as reflected by the Activity Survey and in these reports) was surprising and indeed fell short of best practice. Neuromuscular blockade is required to facilitate certain types of surgery (e.g. abdominal, cardiac, thoracic, etc) and perhaps a case can be made for its use in certain patient groups (e.g. to facilitate controlled ventilation in the obese or those with impaired lung function or difficult airways). The effect of all drugs should ideally be monitored: thus, end-tidal monitoring is used for volatile agents, blood pressure for vasoactive agents, etc. For neuromuscular block, the only appropriate monitor is the nerve stimulator. So it is surprising that in the Activity Survey, a nerve stimulator was employed in a minority (38%) of cases where nondepolarising block was used.

10.25 Current AAGBI guidelines (AAGBI, 2007) specify that a nerve stimulator should be available for use. However, they they do not specify that it should *always* be used whenever nondepolarising blockade is employed. This is in striking contrast to recommendations concerning the end-tidal monitoring of volatile agent.

10.26 It is possible that anaesthetists generally feel that during surgery, the measure of drug effect that matters is the response of the surgical team to the degree of muscle relaxation (i.e. objective measures provided by a nerve stimulator are relatively unimportant). A common experience is that despite apparently adequate blockade as measured by the nerve stimulator, the surgical team finds the patient 'tight' or breathing, or *vice versa*. This lack of apparent correlation between subjective (team) feedback and objective measurement can undermine faith in the use of a nerve stimulator. Some anaesthetists might reasonably argue that they provide good conditions for surgery without ever using such monitoring.

10.27 However, based on our results, it seems at least as relevant that a nerve stimulator should be regarded as a monitor of 'motor capacity'. When reduced, the 'train of four' (or another suitable index) signifies obtunded *motor capacity*, which leads to distress in an awake patient. A full return of neuromuscular function as assessed by nerve stimulation is a *necessary* (i.e. minimum), but not *sufficient* condition for motor capacity. A patient in whom it has only just returned may still feel partially paralysed, or weak and lack full muscle strength, and therefore be distressed. Understanding the term *motor capacity*, is helpful in understanding the proper role of the nerve stimulator in anaesthetic practice.

10.28 Even a single dose of a neuromuscular blocking drug can lead to residual paralysis (Debaene et al., 2003). Failure to reverse neuromuscular blockade adequately will predictably result in residual paralysis. Baillard et al. (2000), Murphy et al. (2008) and Di Marco et al. (2010) have all shown residual paralysis is commonplace and often goes undetected. Residual paralysis is an under-appreciated problem after anaesthesia, and best practice revolves around coupling information from a nerve stimulator (e.g. train of four ratio >0.9) with use of reversal agent (neostigmine or sugammadex). Baillard et al. (2005) showed that a programme of education could reduce residual curarisation from 62% to 3.5%.

10.29 The possibility that residual paralysis and AAGA were present does not seem to have been foremost in the minds of those managing patients in these reports. The details of some reports suggested that every other avenue was explored before the presence of persistent neuromuscular blockade was considered.

Failure to monitor return of neuromuscular function (as a measure of motor capacity) was a contributory factor in half of cases of AAGA at emergence and all were judged preventable

10.30 Anaesthetic agents in common use, especially sevoflurane, desflurane and propofol, have rapid offset times. Reversing neuromuscular blockade only after cessation of anaesthetic delivery runs a risk of unintentional awake paralysis. It would seem prudent that anaesthetic delivery is stopped only after recovery from neuromuscular blockade is confirmed (i.e. a train of four ratio of >0.9) and when it is certain consciousness will not return before surgery finishes.

10.31 Muscle groups recover from neuromuscular blockade at different rates, and spontaneous ventilation should not be relied on alone as an indicator of full recovery from neuromuscular blockade and hence *motor capacity*.

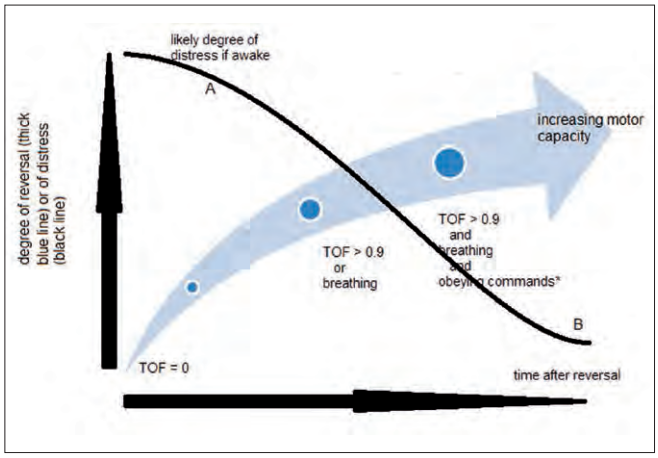
10.32 Neuromuscular blockade impairs *motor capacity* directly and general anaesthesia by contrast impairs *mental capacity*, with voluntary motor function (a desire to move) reduced only as a consequence. To avoid adverse symptoms, the first should be restored before the second. What is unknown is the degree of neuromuscular block that reliably allows voluntary movement. Ali et al. (1975) suggested that respiratory function in awake but partially paralysed volunteers was possible, albeit obtunded, even at TOF ratios ~0.6.

10.33 There were several reports which suggested that it had been recognised that residual paralysis and awareness were likely. However, no reports described actions to alleviate the distress caused during this phase of anaesthesia. Equally surprising was that

sugammadex was not recorded as being used in those situations where it might have been indicated.

10.34 Figure 10.2 illustrates the points made above, reinforcing the need to restore motor capacity and mental capacity in an appropriate order and the adverse effects of not doing so.

Figure 10.2 Illustratration of the relationship between the degree of reversal of neuromuscular blockade (y-axis) versus the signs of reversal (thick blue line), as a function of time after reversal. Also shown is the likely degree of distress (black line), if anaesthesia has been ceased. TOF = train of four ratio. At point A, soon after administering reversal, there is little motor capacity and therefore, a high degree of likely distress if the patient is awake. At point B, there is considerably higher motor capacity and low degree of distress if the patient is awake



10.35 The Panel noted a need for better communication between anaesthetist and surgeon at critical points in surgical procedures. The recommended 'ABCDE' anaesthetic checklist (see Chapter 8, Induction) before the start of surgery is a potentially useful signal to the surgical team that the patient is ready for surgery. It is also useful for surgeons to communicate when they are coming to the end of surgery, to enable the anaesthetists to prepare for emergence. A clear statement from the surgeon that the 'operation is over' (when all interventional contact with the patient has ceased, and not before) could be used as a formal cue to permit emergence from anaesthesia.

10.36 The notion of 'awake tracheal extubation' warrants some discussion. The majority of cases of AAGA at emergence occurred during 'awake extubation'. The rationale for awake extubation being a safe method relies on the idea that awake, co-operative patients are able to maintain their own upper airway and breathe well, such that when extubated there is unlikely to be respiratory difficulty. However, this rationale relies upon there being adequate recovery from/reversal of neuromuscular blockade, and in the cases reported here this was not the case.

10.37 Patients who reported AAGA during emergence rarely mentioned feeling the tracheal tube per se, but rather they experienced distressing paralysis. This cohort of patients therefore mainly consists of patients in whom awake extubation was attempted before they had fully recovered from neuromuscular blockade. The DAS Extubation Guidelines are completely clear that full neuromuscular recovery is an absolute prerequisite for attempted awake extubation; being actually 'awake' is only a secondary requirement. Furthermore, these Guidelines stress the need for the patient to obey motor commands (which are normally commands to squeeze fingers and open the mouth, etc). It is difficult to imagine how, in these reports where patients felt paralysed after 'awake extubation', these steps had been carefully followed. Perhaps these NAP5 results indicate that some anaesthetists may have placed erroneous emphasis on the patient simply being 'awake', rather than being fully recovered from neuromuscular blockade.

10.38 In the Activity Survey, ~1.8 million patients were estimated to undergo airway removal awake after general anaesthesia (~820,000 after neuromuscular blockade). Yet, only 26 patients in NAP5 reported the experience as AAGA (1:69,200 or 1:35,000 respectively). This underlines the fact that airway removal *per se* is not an unpleasant experience and that the main reason for distress is continued paralysis.

10.39 Regardless of the details of anaesthetic practice involved, the relatively high proportion of NAP5 cases associated with emergence implies that patient expectations had not been optimally managed. Hence, the process of consent should acknowledge that this phase of anaesthesia (like the dynamic phase of induction) is a time of relatively high risk of AAGA.

IMPLICATIONS FOR RESEARCH

Research Implication 10.1
There is a need for research into optimal methods of communication between anaesthetic and surgical teams, to signal critical time points during surgery.

Research Implication 10.2
Further research is needed on how the depth of neuromuscular blockade assessed objectively correlates with the ability to respond voluntarily (e.g. do patients feel they can move, if they need to, at a train-of-four ratio ~0.5, etc). Similarly, it may be important to examine why some patients feel distressed when paralysed but others appear not to.

Research Implication 10.3
Research or consensus should establish a recommendation for the optimum role for sugammadex in the treatment of residual paralysis, compared with conventional reversal agents.

RECOMMENDATIONS

RECOMMENDATION 10.1
Anaesthetists should recognise that residual paralysis at emergence is interpreted by patients as AAGA. When recognised, it should be managed using the same Recommendations in this Report as apply to AAGA arising in other phases of anaesthesia, with the same level of psychological support.

RECOMMENDATION 10.2
When planning an awake extubation, this should be explained to the patient as part of the consent process, including the possibility of recall of the tube in the airway or difficulty in moving or breathing at this time.

RECOMMENDATION 10.3
In addition to communication throughout surgery, there should be formal confirmation from the surgeon to the anaesthetist and other theatre staff that surgery has finished. This point should be at the actual completion of all interventional procedures (including dressings, post-surgical examinations, etc) and could be usefully linked to the sign-out section of the WHO checklist.

RECOMMENDATION 10.4
The nerve stimulator should be used to establish motor capacity. An adequate response to nerve stimulation (e.g. return of a 'train of four' ratio of >0.9, or other suitable measure) is a minimum criterion of motor capacity. Following this assessment, anaesthetists should use additional signs such as spontaneous breathing and motor response to command before full motor capacity is judged restored.

RECOMMENDATION 10.5
The relevant anaesthetic organisations should consider including nerve stimulators as 'essential' in monitoring guidelines, whenever neuromuscular blocking drugs are used.

RECOMMENDATION 10.6
All patients who have less than full motor capacity as a result of pharmacological neuromuscular blockade should remain anaesthetised.

RECOMMENDATION 10.7
Anaesthetists should regard an 'awake extubation' (as stressed in DAS Extubation Guidelines) as an undertaking in a patient who primarily has full motor capacity, and secondarily is co-operative to command. Being 'awake' alone does not fulfil any safe conditions for tracheal extubation.

RECOMMENDATION 10.8
The possibility of pseudocholinesterase deficiency should be considered whenever using mivacurium or suxamethonium. Where suspected, anaesthesia should be maintained until full recovery from neuromuscular blockade is confirmed. Genetic testing should be arranged.

RECOMMENDATION 10.9
During emergence, speaking to patients to explain what is happening provides important reassurance about potentially unusual sensations such as tracheal intubation or partial paralysis.

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CHAPTER
11

Risk factors: patient and organisational


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HEADLINE

11.1. This chapter presents a numerical analysis of 110 Certain/probable AAGA (Class A) reports to NAP5. This cohort, which provides the best quality data for analysis was compared with data from the NAP5 UK anaesthetic Activity Survey. This cohort is considerably larger than many previous analyses attempting to identify risk factors. Factors increasing risk of AAGA appear to be: female gender; age (younger adults, but not children); obesity; seniority of anaesthetist (junior trainees); previous AAGA; out of hours operating; emergencies; type of surgery (obstetric, cardiac, thoracic, neurosurgery), and use of neuromuscular blockade. The data is also supportive of the following as risk factors: difficult airway; obesity with difficult airway. The following factors were not risk factors for AAGA: ASA; race; use or omission of nitrous oxide.

BACKGROUND

11.2 A wide variety of patient (and organisational) factors have been identified as being associated with an increased incidence of AAGA (Table 11.1), but the results are markedly inconsistent. In Table 11.1, factors in blue in the first column are associated with directly conflicting results in the literature as to whether they increase, have no effect or even decrease risk of AAGA.

11.3 In addition to risk factors in Table 11.1, reduced drug doses or interruption of drug administration are cited by most sources as causes of AAGA. In historical series, anaesthetic techniques associated with no volatile agent are, unsurprisingly, associated with an increase in AAGA (Errando et al., 2008). However, as this is of historical interest only, it is not considered further here.

11.4 In this chapter we consider patient and organisational factors associated with AAGA. The chapter is largely a numerical analysis. We have used the Class A (Certain/probable) cases reported to NAP5, and have compared the incidence of potential risk factors to that reported in patients undergoing general anaesthesia in the Activity Survey.

Gender

11.5 Most studies report an increased incidence of AAGA in women. The evidence supporting this is conflicting (see Table 11.1). As Caesarean delivery with general anaesthesia has traditionally been accepted as having an increased risk of awareness, any study that includes obstetrics will be likely to demonstrate an increased incidence in women. Women appear to recover more quickly from general anaesthesia than men (Buchanan et al., 2006; Gan et al., 1999) which may put them at increased risk of AAGA at emergence and might indicate reduced sensitivity to anaesthetic agents.

Table 11.1. Risk factors associated with AAGA in large adult cohorts (yes = risk factor; no = not risk factor). Factors in column 1 shown in blue have conflicting results between studies regarding their role as a risk factor for AAGA. (BZ = benzodiazepines; NMB = neuromuscular blockade)

	Ranta et al., 1998	Domino et al., 1999	Sandin et al., 2000	Sebel et al., 2004	Wennervirta et al., 2002	Errando et al., 2008	Ghoneim et al., 2009	Aranake et al., 2013
Number of cases in cohort	2,612	-*	11,785	19,575	3,843	3,991	-*	
Certain/probable case of AAGA	10	61	14	25	4	39	271	
Possible cases of AAGA	9	0	4	46	7	5	0	
Female gender	No	Yes	Yes	Yes			?	Yes
Age	No	Younger		??			Younger	Younger
ASA class	No	Low		High				Low
Obesity	No						No	Yes
Difficult airway		?					No	
Previous AAGA			?				Yes	Yes
BZs protective			No			Yes	Yes	
Urgency of surgery		Elective			No	No		
NMB		Yes	Yes			No	No	
Concomitant drugs					No			Yes**
Alcohol								Protective
Human factors		Yes	Yes			Yes		
TIVA						Yes	Yes	
Type of surgery	No	Obstetric, Gynaecology		Abdominal, Cardiac, Thoracic, Eye.		Obstetric	Obstetric, Cardiac	
Time of day						Night		

* case series of reports exclusively of AAGA; ** opiate and anticonvulsant users.

11.6 Medicolegal series of cases of awareness in the UK and the USA have demonstrated that a higher number of claims come from women. Domino et al. (1999) reported that 77% of US claims were from women. Mihai et al. (2009) reported that 74% of UK claims were from women and that 29% of claims arose in obstetric general anaesthesia. This may indicate that gender influences reporting rates as well as susceptibility to AAGA.

Age

11.7 Age affects anaesthetic sensitivity and MAC (Nickalls & Mapleson, 2003). There are conflicting reports on the effect of age on the risk of AAGA (see Table 11.1). Paediatric patients have been considered at increased risk of AAGA, and this is discussed in more detail in Chapter 15 (Paediatrics).

ASA score

11.8 Some studies have reported that patients with a higher ASA score, are at increased risk of AAGA and others have reported the converse (see Table 11.1). Intentionally reduced doses of anaesthetic drugs, both at induction and during the maintenance phase, because of concerns over cardiovascular and other effects, may contribute to this. Bogetz & Katz (1984) reported this when identifying a high incidence of AAGA in patients after surgery for major trauma with minimal anaesthesia. In modern practice, improved monitoring, early use of vasopressors and the facility to manage patients for extended periods in recovery and critical care areas might be expected to reduce this incidence. This is discussed further in Chapter 8 (Induction) and Chapter 17 (ICU).

11.9 In conflict with this, Domino et al. (1999) reported that claims associated with AAGA were more common in patients with a low ASA (possibly because they are more robust, they need higher concentrations of anaesthetic).

Obesity

11.10 Obesity has been identified as a risk factor for AAGA (see Table 11.1). There are many potential reasons – (see Chapter 6 (Main Results) and Chapter 8 (Induction) for further discussion. Inadequate drug dosing is one potential cause. Obesity significantly affects the pharmacokinetics and pharmacodynamics of many anaesthetic agents. Obesity is associated with increased body fat content, increased lean body mass, increased blood volume and cardiac output, reduced total body water and alterations in plasma protein binding: overall volume of distribution is increased (Ingrande & Lemmens, 2010). Peak drug plasma concentrations may be reduced by increased total blood volume and changes in regional blood flow. Oxidative and reductive hepatic metabolism is increased, and increased renal blood flow and glomerular filtration rate leads to increased renal clearance of many anaesthetic drugs (Marik & Varon, 1998). Due to the cardiovascular and respiratory effects of obesity, pharmacodynamic effects of anaesthetic drugs may be altered leading to an increase in risk of complications (e.g. hypoxia with opioids; Adams & Murphy, 2000). Current recommendations (Nightingale et al., 2013) stipulate a reduction in dose (on a weight basis) of induction agents, muscle relaxants (except suxamethonium), opioids and TCI propofol.

Difficult airway management

11.11 Patients in whom airway management is difficult may be vulnerable to AAGA due to offset of the effect of induction agents, failure to administer anaesthesia during difficult airway management or failure of volatile agents to reach the patient when mask ventilation is ineffective or there is airway obstruction (see Chapter 8, Induction, for further discussion).

11.12 Obesity is a risk factor for difficult airway management (Langeron et al., 2014) including difficult mask ventilation (Langeron et al., 2000), difficult supraglottic airway insertion (Ramachandran et al., 2012), failed mask ventilation with failed intubation (Kheterpal et al., 2013) and major complications of airway management (Cook et al., 2011). This may further increase the risk of AAGA in the obese population.

Resistance to anaesthesia and genetics

11.13 AAGA may arise from an intrinsic resistance to anaesthesia. Ghoneim et al. (2009) reviewed 271 published reports of AAGA, and reported that 1.6% described a previous history of awareness. In the BAG-RECALL study, 11% of patients with definite or possible AAGA had a previous history of AAGA (Avidan et al., 2011). In most epidemiological studies of AAGA, cases are reported with no apparent cause (e.g. Sandin et al., 2000, Errando et al., 2008).

11.14 Most recently Aranake et al. (2013) reported a secondary analysis of 26,490 patients enrolled in three major trials investigating AAGA (B-Unaware, BAG-RECALL and MACS), including 241 patients

with a previous history of AAGA. Patients with a history of AAGA had a 5-fold greater incidence of AAGA (1.7%) during the trials than a group of paired controls who did not (0.3%): anaesthetic management did not differ between the groups. In an accompanying editorial Pryor & Hemmings (2013) raised the possibility that increased risk of awareness with recall might be due as much to variations in memory formation and retention as to issues relating to anaesthetic sensitivity. See also Chapter 9 (Maintenance).

11.15 In Aranake et al.'s study the relationship between volatile anaesthetic concentration and BIS differed between the two groups. Patients with a history of AAGA had a lower BIS score (~5 units) at low anaesthetic concentrations and BIS changed less for given changes in anaesthetic concentration compared to controls.

11.16 The reasons why some patients may be insensitive to anaesthetic drugs and require higher doses are not completely understood but pharmacogenetics are likely to be important. Ezri et al. (2007) investigated MAC requirements in three ethnic groups and demonstrated variation with ethnicity. A limitation of this study was that confounding characteristics such as lifestyle were not accounted for.

Concomitant drug and alcohol use

11.17 While it is held that concomitant use of drugs (opioids, benzodiazepines, anticonvulsants and alcohol) may alter the risk of AAGA, there is very little robust evidence to support this and what there is, is conflicting (see Table 11.1). In particular, early papers considered at length whether (omission of) benzodiazepine premedication pre-disposed to AAGA – with conflicting results. Sedative drugs might alter anaesthetic requirements by pharmacokinetic effects (such as altered metabolism e.g. inducing hepatic cytochrome P450) leading to altered drug metabolism. Drug and alcohol use may also alter pharmacodynamic sensitivity to anaesthetic agents leading to resistance.

Other factors

11.18 Organisational factors such as urgency of surgery, day and time of anaesthesia, seniority of the anaesthetist, whether the anaesthetist is a locum and other factors are of interest in determining risk for AAGA. These are also considered here.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

11.19 There were a total of 110 class A (Certain/probable) reports of AAGA. These reports were the most complete and contained the most reliable information on patient and organisational factors. Our analysis is therefore restricted to these 110 patients. Statistical comparisons were made using the chi-squared test (*Analyse It*, Leeds University, UK).

11.20 Throughout, we use the data from 15,460 patients undergoing general anaesthesia in the Activity Survey as a comparator, to examine whether certain characteristics were more commonly present in patients reporting AAGA than in the UK surgical population. Where data was not available ('not recorded') this was not analysed but is included for AAGA reports for clarity. While any association identified strictly implies increased risk of *reporting* AAGA, for most factors it is reasonable to assume this is due to an increased risk for AAGA itself. TIVA is not considered here as it has a whole chapter dedicated to it (Chapter 18 TIVA).

Gender

11.21 Females were significantly over-represented in Class A reports compared with the Activity Survey ($p<0.026$; Table 11.2). If the 13 obstetric reports are excluded the proportion of female cases falls to 58% but still remains significantly higher than males ($p<0.05$).

Table 11.2. Patient gender in Class A reports and Activity Survey general anaesthetics ($p = 0.026$ for male vs female)

	Class A cases (%)	Activity Survey (%)
Female	70 (63.6)	8,109 (53.0)
Male	40 (36.4)	7,183 (47.0)
Total	110	15,292

Race

11.22 Table 11.3 indicates that the distribution of patients of different racial origin rates was the same in Class A reports of AAGA and in the Activity Survey.

Table 11.3. Ethnic origin in Class A reports and Activity Survey general anaesthetics (p = 0.42 for difference in distribution of race AAGA reports vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Asian/Asian-British/ Indian	4 (4.1)	837 (5.5)
Black/Afro-Caribbean	1 (1.0)	430 (2.8)
Chinese/Japanese/ SE Asian	0 (0.0)	86 (0.6)
White Caucasian	92 (94.8)	13,694 (89.5)
Mixed/Other	0 (0.0)	256 (1.7)
Total	97	15,303
Not recorded	13	157

Age

11.23 The distribution of ages in Class A reports to NAP5 differed significantly from that in the Activity Survey, p<0.0001 (Table 11.4). The distributions suggest increased risk of reports of AAGA in younger and middle aged adults, but not in children. This is discussed further in Chapter 15 (Paediatrics).

Table 11.4. Age distribution (years) in Class A reports and Activity Survey general anaesthetics (P<0.0001 for difference in age distribution AAGA reports vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
<1	0 (0.0)	197 (1.3)
1-5	1 (0.9)	1,004 (6.6)
6-15	4 (3.7)	1,447 (9.5)
16-25	15 (13.8)	1,424 (9.3)
26-35	26 (23.9)	1,701 (11.1)
36-45	19 (17.4)	1,926 (12.6)
46-55	20 (18.2)	2,128 (13.9)
56-65	12 (11.0)	2,128 (13.9)
66-75	8 (7.3)	1,928 (12.6)
76-85	3 (2.8)	1,162 (7.6)
≥86	1 (0.9)	267 (1.7)
Total	109	15,312
Not recorded	1	148

ASA physical status

11.24 Table 11.5 indicates that the distribution of patients' ASA grades was the same in Class A reports of AAGA and in the Activity Survey.

Table 11.5. ASA physical status in Class A reports and Activity Survey general anaesthetics (p = 0.23 for comparison of distribution AAGA vs Activity Survey)

ASA Grade	Class A cases (%)	Activity Survey (%)
1	34 (31.2)	6,274 (41.2)
2	54 (49.5)	6,041 (39.6)
3	18 (16.5)	2,491 (16.3)
4	3 (2.8)	395 (2.6)
5	0 (0.0)	44 (0.3)
Total	109	15,245
Not recorded	1	215

Obesity

11.25 There was a disproportionately high proportion of obese patients in Class A reports of AAGA compared with the Activity Survey general anaesthetics (see Table 11.6) (p=0.01).

Table 11.6. Patient body habitus in Class A reports and Activity Survey general anaesthetics (p=0.01 for comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Underweight	4 (4.0)	463 (3.1)
Normal	36 (36.4)	8,004 (54.3)
Overweight	27 (27.3)	3,514 (23.8)
Obese or morbidly obese	32 (32.3)	2,753 (18.7)
Total	99	14,734
Not recorded	11	726

Difficult airway management

11.26 In the AAGA Class A cohort, 92 airways (84%) were managed with a tracheal tube (2 double lumen), 13 with a supraglottic airway device, three with facemask, one with a Hudson mask and one with direct 'tracheal ventilation'. In the Activity Survey a tracheal tube was used in 44.6% of cases and a supraglottic airway (SAD) in 51.3%. Difficulty with airway management was a factor in 27 Class A cases (26.5% of those for which data was available (Table 11.7). Twenty three reports described difficult intubation, five reported difficult mask

ventilation, three reported difficult SAD insertion and one reported bronchospasm; in five cases there were combined difficulties. Six inductions were combined gaseous and intravenous (and 104 intravenous) but none of these gaseous inductions involved difficult airway management. Eight (38%) of the cases of primary difficult intubation and Class A AAGA occurred during rapid sequence induction, which was used in <8% of general anaesthetics in the Activity Survey. This topic is discussed in more detail in Chapter 6 (Main Results) and Chapter 8 (Induction).

Table 11.7. Difficult airway management in Class A reports and in Activity Survey general anaesthetics

	Class A cases (%)
No	75 (73.5)
Yes*	27 (26.5)
Not recorded	8
Total	110

*21 difficult intubation; 3 difficult mask ventilation and difficult insertion of supraglottic airway device; 2 difficult mask ventilation followed by difficult or failed intubation, 1 bronchospasm during intubation.

Obesity and difficult airway management

11.27 Of the 32 obese or morbidly obese Class A patients, ten were difficult to intubate, 21 were not, and in one case this was not recorded. Of reports of AAGA in obese patients, 31% involved difficult airway management and 37% of the cases of difficult airway management associated with AAGA were in obese patients.

Anxiety

11.28 Six (6.1%) of 99 Class A patients were identified as anxious. A total of four sedative premedications were administered (three benzodiazepine and one opioid/atropine) to three anxious and one non-anxious patient.

Anaesthetic resistance and history of AAGA

11.29 In 13 (22%) of 104 Class A reports in which preventability could be assessed, it was deemed that AAGA was unpreventable and anaesthetic conduct was good (i.e. no clear cause for AAGA). In ten (77%) of these cases the Panel considered one possibility was intrinsic anaesthetic insensitivity.

11.30 Forty eight Class A reports provided information about previous general anaesthetics and two (4.2%) patients reported previous AAGA. Twenty-eight class A patients underwent a subsequent anaesthetic, and in 24 cases where information was available, there was no report of subsequent AAGA (Table 11.8). These data support the suggestion that a past history of AAGA should be considered a risk factor for AAGA.

Table 11.8. Occurrence of AAGA during prior and subsequent general anaesthetics in Class A reports

	Class A cases (%)
Previous general anaesthetic	67
No AAGA	46 (95.8)
AAGA	2 (4.2)
Not recorded	19
Subsequent general anaesthetic	28
No AAGA	24 (100.0)
AAGA	0 (0.0)
Not recorded	4

Drugs

11.31 The frequency of drugs use that might influence risk for AAGA, in Class A reports is shown in Table 11.9. In many cases, patients were taking multiple relevant agents. Comparative data from the Activity Survey is not available.

Table 11.9. Relevant drug use in Class A reports

	Class A cases (%)
Opioids (including tramadol)	19 (17.3)
Antidepressants	10 (9.1)
Anticonvulsants*	8 (7.3)
Benzodiazepines	4 (3.6)
Excessive alcohol	6 (6.5)
Illicit drugs	1 (0.9)
Beta blockers	11 (10.0)
Thyroxine	5 (4.5)
Steroids	5 (4.5)
Beta2 agonists	20 (18.2)
None of the above	60 (54.5)
Total	110

* all gabapentin or pregabalin

Time of day

11.32 There was a disproportionately high proportion of evening and nightime operating in Class A reports of AAGA compared with the Activity Survey general anaesthetics (see Table 11.10), $p<0.0001$.

Table 11.10. Time of day anaesthesia started in Class A cases and Activity Survey general anaesthetics. Day (08:00 –17:59), Evening (18:00–23.59), Night (00.00–07:59). (p<0.0001 for comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Day	87 (87.0)	14,311 (93.7)
Evening	17 (17.0)	723 (4.7)
Night	6 (6.0)	240 (1.6)
Total	110	15,274
Not recorded	0	186

Day of Week

11.33 The distribution of weekday and weekend operating in Class A reports is shown in Table 11.11. Comparative data from the Activity Survey is not available.

Table 11.11. Day anaesthesia started in Class A cases

	Class A cases (%)
Weekday	90 (83.3)
Weekend	18 (16.7)
Not recorded	2
Total	110

Urgency of surgery

11.34 There was a disproportionately high proportion of urgent and emergency anaesthesia cases in Class A reports of AAGA compared to the Activity Survey general anaesthetics (see Table 11.12), p<0.0001.

Table 11.12. Urgency of surgery in Class A cases and Activity Survey general anaesthetics (P<0.0001 for the comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Elective	59 (53.6)	10,416 (71.3)
Expedited	6 (5.5)	957 (6.6)
Urgent	32 (29.1)	2,892 (19.8)
Immediate	13 (11.8)	337 (2.3)
Total	110	14,602
Not recorded	0	858

Seniority of staff

11.35 There was a disproportionately high proportion of junior anaesthetists in Class A reports of AAGA compared with the Activity Survey general anaesthetics (see Table 11.13) (p = 0.003). Career grade staff were also over-represented numerically but to a lesser extent.

Table 11.13. Seniority of staff in Class A cases and Activity Survey general anaesthetics (p = 0.003 for the comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Consultant	65 (64.4)	11,547 (75.0)
Career grade	20 (19.8)	2,197 (14.3)
SpR 4-7	8 (7.9)	1,080 (7.0)
SpR3 / CT3	3 (3.0)	200 (1.3)
CT1-2	5 (5.0)	176 (1.1)
Total	101	15,200
Not recorded	9	260

Locums

11.36 Table 11.14 indicates that the presence of a locum anaesthetist was associated with an increase in the prevalence of Class A reports of AAGA, but this did not reach statistical significance.

Table 11.14. Substantive and locum staff in Class A cases and Activity Survey general anaesthetics (P = 0.077 for comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Substantive	88 (88.0)	14,040 (92.6)
Locum	12 (12.0)	1,115 (7.4)
Total	100	15,155
Not recorded	10	305

Type of surgery

11.37 The distribution of types of surgery in Class A reports of AAGA differed significantly from that in Activity Survey general anaesthetics (see Table 11.15), p<0.0001. Surgical specialties over-represented by more than two-fold in the reports of AAGA were:

- Obstetrics; 14.8-fold
- Thoracic; 4.1-fold
- Cardiac; 3.3-fold
- Neurosurgery; 2.5-fold

11.38 Of note: there is uncertainty over the accuracy of the obstetric data reported in the Activity Survey (See Chapter 16 (Obstetric) for further discussion) however even a 2-fold error in data would still leave a 7-fold excess of obstetric cases in Class A AAGA reports.

Table 11.15. Surgical specialty in Class A cases and Activity Survey general anaesthetics (p = 0.001 for comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Orthopaedics and trauma	12 (11.0)	3,389 (22.1)
General	31 (28.4)	3,183 (20.8)
Gynaecology	11 (10.1)	1,789 (11.7)
ENT	16 (14.7)	1,478 (9.6)
Urology	1 (0.9)	1,384 (9.0)
Dental	0 (0.0)	611 (4.0)
Plastics	2 (1.8)	556 (3.6)
Maxillofacial	0 (0.0)	411 (2.7)
Ophthalmology	3 (2.8)	271 (1.8)
Neurosurgery	6 (5.5)	325 (2.1)
Gastroenterology	1 (0.9)	260 (1.7)
Vascular	2 (1.8)	246 (1.6)
Radiology	1 (0.9)	238 (1.6)
Cardiac	5 (4.6)	216 (1.4)
Cardiology	1 (0.9)	165 (1.1)
Thoracic	4 (3.7)	140 (0.9)
Obstetrics	13 (11.9)	128 (0.8)*
Psychiatry	0 (0.0)	125 (0.8)
Pain	0 (0.0)	22 (0.1)
Other minor procedure	0 (0.0)	262 (1.7)
Other major procedure	0 (0.0)	126 (0.8)
Total	109	15,325
Not recorded	1	135

Nitrous oxide

11.39 Table 11.16 indicates that nitrous oxide was used equally frequently in Class A reports of AAGA and in the Activity Survey general anaesthetics.

Table 11.16. Nitrous oxide use in Class A cases and Activity survey general anaesthetics (p = 0.26 for comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Yes	26 (27.7)	4,216 (28.6)
No	68 (72.3)	10,504 (71.4)
Total	94	14,720
Not recorded	16	740

NMBA

11.40 There was disproportionately high use of NMBs in Class A reports of AAGA compared to the Activity Survey general anaesthetics (see Table 11.17), p<0.0001.

Table 11.17. Use of neuromuscular blocking drugs in Class A cases and Activity survey general anaesthetics (p < 0.0001 for comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Yes	4 (3.7)	6,911 (45.8)
No	104 (96.3)	8,163 (54.1)
Total	108	15,074
Not recorded	2	386

Difficult airway management and neuromuscular blockade were both associated with an increase in risk of AAGA

DISCUSSION

11.41 The 110 Class A cases prospectively reported to NAP5 and the >15,000 cases in the Activity Survey represent a considerably larger cohort than most studies in Table 11.1, with the exception of the studies of Domino et al. (1999) and Ghoneim et al. (2009), which were selected case series and without robust comparators.

11.42 The above univariate analysis provides statistical evidence that the following patient and logistical factors are disproportionately over-represented in the Class A cases reports to NAP5 and can therefore be considered risk factors for AAGA:

- Female gender.
- Age (younger adults, but not children).
- Body habitus (obesity).
- Seniority of anaesthetist (junior trainees).
- Previous (but not subsequent) AAGA.
- Time of day.
- Urgency of surgery (emergencies).
- Type of surgery (obstetric, neurosurgery, cardiac, thoracic).
- Use of neuromuscular blockade.

The presence of a locum anaesthetist increased the frequency of AAGA compared with a substantive doctor, though the difference was not statistically significant.

11.43 The data is also supportive of the following as risk factors based on the prevalence of these factors in the NAP5 Class A reports, compared to known incidences in general surgical populations:

- Difficult airway.
- Obesity with difficult airway.

11.44 This analysis provides statistical evidence that the following factors are not risk factors for AAGA:

- ASA.
- Race.
- Use or omission of nitrous oxide.

11.45 This analysis has not provided evidence one way or the other for the following factors, due to lack of robust comparators or incomplete data. The presented data may be useful for others' research:

- Concomitant drugs.
- Excess alcohol.
- Pre-operative anxiety.
- Day of week of anaesthesia.

11.46 This chapter is simply to provide a numerical analysis of the most robust dataset in NAP5. Further aspects of risk factors are discussed in relevant chapters.

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CHAPTER
12

Reports of AAGA after sedation


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HEADLINE

12.1. Approximately one in five of all reports of AAGA that NAP5 received followed intended sedation rather than general anaesthesia. The rate of reports of 'AAGA' following sedation appears to be as high as after general anaesthesia. The experiences of those reporting AAGA after sedation and the psychological sequelae were similar in nature, though perhaps less in severity than reports of AAGA after anaesthesia. Reports of AAGA after sedation represent a failure of communication between anaesthetist and patient and should be readily reduced, or even eliminated by improved communication, management of expectations and consent processes.

BACKGROUND

12.2 NAP5 focuses on patient reports of AAGA. These reports may arise when a patient has not actually received general anaesthesia. It is well recognised that reports of AAGA may occur after sedation (Samuelsson et al., 2007; Mashour, 2009; Kent, 2013). In the study by Samuelsson et al., 5% of patients reporting AAGA had received intended sedation. In Kent's study of self-reports to the ASA awareness registry, 27 of 83 (33%) patients who reported AAGA had received intended sedation: 50% by an anaesthetist and 50% by a non-anaesthetist.

12.3 Indeed one study of >60,000 patients, where patients were asked rather generically 'if they experienced any problems related to anaesthesia', reported no statistically significant difference in the rate of reports of AAGA after general anaesthesia or sedation (0.023% vs 0.03%, p=0.54, relative risk of AAGA in general anaesthesia (GA) vs non-GA 0.74 0.28-2.0 (Mashour, 2009).

12.4 Reports of AAGA after sedation imply two things: first that the patient does not have a full understanding of the intended level of consciousness, and second that the level of consciousness experienced was likely undesirable.

12.5 Esaki et al. (2009) studied 117 patients undergoing regional anaesthesia or 'managed anaesthesia care', and performed a structured interview assessing expected and experienced levels of consciousness. 'Complete unconsciousness' was the state most often expected and also the state most often reported as subjectively experienced. A notable finding in this study was that only 58% of patients reported that their expectations of conscious level for the procedure were set by the anaesthesia provider.

12.6 Reports of AAGA after sedation are not trivial. Kent et al. (2013) compared the experiences and sequelae of patients in the ASA awareness registry whose anaesthesia care was intended to be general anaesthesia with those who had

undergone regional anaesthesia and sedation. The sensations experienced during the event included auditory, tactile and painful sensations and feelings of paralysis. Three quarters of these patients reported distress. Between 25-40% of these patients reported flashbacks, nightmares, anxiety and depression and chronic fear. Although these symptoms were less frequent than in the cohort of patients in the registry who reported AAGA after general anaesthesia, the frequency of long term sequelae did not differ significantly.

Definitions

12.7 There is no colloquial or agreed definition of 'sedation' accessible to patients. The online Oxford English Dictionary (2014) defines sedation (self-fulfillingly) as a verb of action; 'The action of allaying, assuaging, making calm or quiet.', Wikipedia (http://en.wikipedia.org/wiki/Sedation) defines sedation as '*…reduction of irritability or agitation…to facilitate a medical procedure…*' whereas older dictionaries refer to alleviation of pain (Baker, 1956; Onions, 1991).

12.8 The report of the Academy of Medical Royal Colleges defines levels of sedation (consistent with the terms used by the ASA; Table 12.1) as '…drug-induced depression of consciousness, a continuum culminating in general anaesthesia'.

(a) *Minimal sedation* is where the patient responds normally to verbal commands. Cognitive function and physical co-ordination may be impaired, but airway reflexes, and ventilatory and cardiovascular functions are unaffected.

(b) *Moderate sedation* is a state where purposeful responses to verbal commands or light tactile stimulation are maintained. Conscious sedation is a term also applied here, which is a degree of depression of the mental state allowing surgery to proceed where verbal contact is maintained with the patient throughout the period of surgery;

(c) In *deep sedation* the patient responds purposefully only to repeated or painful stimulation; the patient may have depressed respiration and may need a degree of airway support.

12.9 One important limitation of all these definitions in these reports is that sedation is defined by its outcome from the sedationist's perspective, rather than as the actual state of mind the patients might find themselves in as a result of drug administration. Thus from the patient's perspective, responding to verbal stimulation could encompass a wide range of mental states, some of which are acceptable (to the patient) but some unacceptable. Also, these definitions are difficult to use when the conscious level changes rapidly in response to a stimulus or use of a short-acting drug such as propofol (i.e. the definitions lend themselves better to description of a steady state than a dynamic one).

12.10 Indeed the literature highlights different perspectives on sedation. Because analgesia is an important goal, patients frequently misunderstand what sedation is (Chatman et al., 2013) and many want to be completely unaware and have no pain or recall (Subramanian et al., 2005). It is not clearly defined what the purpose or endpoint of sedation is for a caregiver, but first principles suggest that the prevention of awareness of unpleasant aspects of the procedure as well as blunting recall of pain are amongst the important aims (Chatman et al., 2013; Kent et al., 2013). From the patient's perspective, the boundary between sedation and general anaesthesia is obscured (Esaki et al., 2009).

Table 12.1. Continuum of depth of sedation: definition of levels of sedation/analgesia with respect to patient response and intervention required

	Minimal sedation/ anxiolysis	Moderate sedation/analgesia ('conscious sedation')	Deep sedation/ analgesia
Responsiveness	Normal response to verbal stimulus	Purposeful response to verbal or tactile stimulus	Purposeful response after repeated or painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required
Ventilation	Unaffected	Adequate	May be inadequate

12.11 Individual response to sedation may be unpredictable (Gross et al., 2002); a dose of benzodiazepine producing a drowsy state in one person may have little effect in another, render a third unresponsive and a fourth disinhibited. As compared with the relatively predictable relationship between dose and effect for anaesthesia, where the endpoint is unconsciousness, the relationship is far less certain for sedation. Furthermore, this effect in any individual patient may vary over time such that conscious level may very easily vary during a procedure.

Practice

12.12 The Gloucester scoring system has been used by gastroenterologists and is a potentially useful scale to help monitor the quality of sedation as judged by the clinician. (Table 12.2; Valori & Barton, 2007)

Table 12.2. Gloucester comfort score with definitions

1. Comfortable: Talking/comfortable throughout
2. Minimal: One or two episodes of mild discomfort without distress
3. Mild: More than two episodes of mild discomfort without distress
4. Moderate: Significant discomfort experienced several times with some distress
5. Severe: Frequent discomfort with significant distress

12.13 Detailed information about UK sedation practice is limited. We know that there is considerable heterogeneity of the patients and techniques but we know little of what patients experience except perhaps, in intensive care (Sheen & Oates, 2005). Phenomena such as depersonalisation (where the mind finds it difficult to relate to the body) or 'awake dreaming' may be common experiences which may be distressing if they are not anticipated. Even an awake patient undergoing regional anaesthesia may have experiences which are unpredictable (Karlsson et al., 2012).

12.14 Obtaining consent for sedation requires clear communication by the person taking consent so there is a mutual understanding of the process, aims and limitations of sedation (see Chapter 21, Consent).

12.15 Sedation administered by anaesthetists and non-anaesthetists likely differs in both the drugs used and the levels of sedation intended. However the number of episodes of anaesthetist and non-anaesthetist delivered sedation is unknown.

12.16 As compared with non-anaesthetists, sedation administered by anaesthetists tends to involve more potent drugs with lower therapeutic indices, such as propofol combined with opioids or ketamine, because they are effective for a wide range of procedures and have the capacity for rapid control of conscious level. In many countries the role of the anaesthetist-sedationist has expanded with both procedural sedation and 'managed anaesthesia care' (standby care) developing into additional roles for anaesthetists in gastroenterology, cardiac and emergency department settings. The extent to which this trend will be followed in the UK is unknown.

12.17 Current intercollegiate guidelines recommend that non-anaesthetists have special training to administer sedation. Training is the main recommendation from the Academy of Royal Colleges (2013) and NICE (2010).

12.18 Other guidance on sedation, as from Scottish Intercollegiate Guidelines Network (2002); British Society of Gastroenterologists (2003); Royal College of Radiologists, (2003); Royal College of Anaesthetists and Royal College of Surgeons (2007); NICE, (2010); Royal College of Anaesthetists and College of Emergency Medicine (2012), concentrate on the safety and technical aspects of the process. There is an inherent assumption in all these documents that both practitioner and patients know what sedation is; these reports do not at all address the issues of consent and explanation. Only the NICE guideline emphasises the need for clear explanation and what the alternatives might be.

Numbers

12.19 There are few estimates of the numbers of UK patients having different procedures under sedation. The largest groups of adult patients having sedation delivered by non-anaesthetists are probably those undergoing gastrointestinal endoscopy, cardiac angiography and dentistry, but there are no good estimates of practice or number of cases, except perhaps, in the field of endoscopy.

12.20 The older literature contains some data, but it is not known how relevant this is for current practice. A postal survey of endoscopists revealed that upper gastrointestinal endoscopy was commonly performed using benzodiazepine sedation with or without an opioid such as pethidine (Daneshmend et al., 1991). In 1995 a survey of two UK regions by the Audit Unit of the British Society of Gastroenterology gathered data on 14,149 gastroscopies; of these <5% were carried out with

general anaesthesia and ~85% were performed with sedation (Quine et al., 1995). A recent national audit of colonoscopies found that >20,000 colonoscopies were carried out over a two week period (Gavin et al., 2013) giving an annual estimate of ~500,000. This audit found that ~89% of patients underwent conscious sedation using midazolam (with pethidine in 56% and fentanyl in 35%); nitrous oxide was used as the sole agent in ~4%. Less than 1% of patients underwent either deep sedation with propofol or general anaesthesia. The majority of patients were said to be comfortable but ~10% of patients experienced moderate or severe discomfort. In children, the most common procedures are considered to be painless imaging, minor painful procedures, endoscopy and dentistry (NICE, 2010), but the number of children sedated per year for these is unknown.

12.21 Even though the focus of NAP5 is reports of accidental awareness during 'general anaesthesia', for all the reasons described above we judged it important to include patient reports of AAGA that occurred when patients had undergone procedures under sedation but believed they had (or should have) been anaesthetised.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

12.22 There were 32 reports (from 31 patients) of AAGA in which sedation was actually the level of consciousness intended by the caregiver. This compares with 141 Certain/probable or Possible (i.e. Class A and B) reports of AAGA. Although the absolute numbers appear small, this means that approximately one of every four or five patients who makes a report of AAGA has not undergone general anaesthesia, but has been sedated.

12.23 Of the 32 reports, ten (31%) were by men and 22 (69%) by women; 12 (38%) reports involved procedures where sedation was provided by clinicians other than anaesthetists. Figure 12.1 shows the histogram of ASA status. The number of cases by specialty is shown in Figure 12.2. Almost all cases were undertaken during the day on weekdays.

Figure 12.1. ASA status of sedation cases

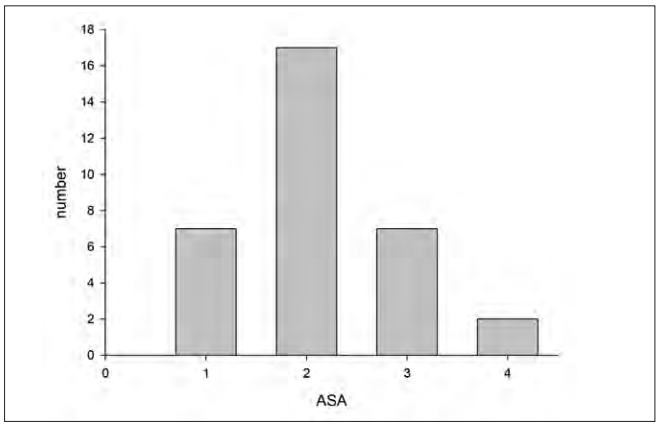
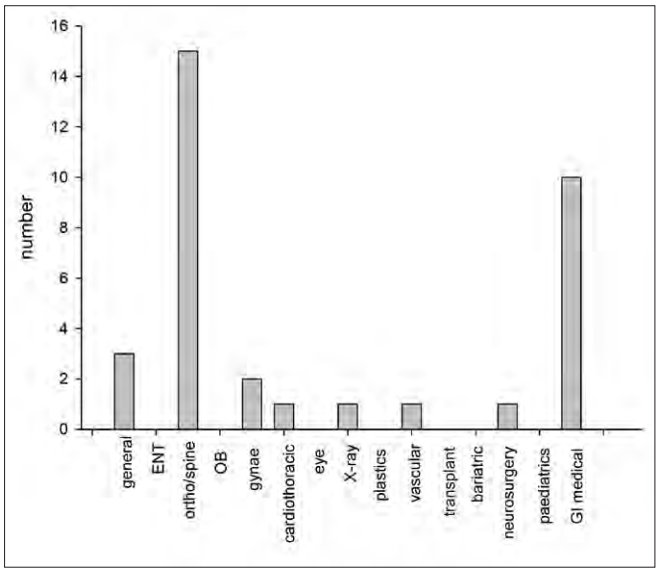


Figure 12.2. Number of sedation cases by specialty. ENT = ear, nose, throat; OB = obstetrics; X-ray = cases in radiology; GI medical = medical gastroenterology



12.24 In terms of the degree of supporting evidence, 26 (81%) of the reports were classified as having 'high' or 'circumstantial' and five (16%) 'plausible'. Evidence no sedation reports were assessed as implausible but one was classed unconfirmed.

12.25 Midazolam was the sole sedative agent in 17 reports (53%), propofol was the sole sedative in 8 cases (25%) and was combined with temazepam or midazolam in a further four cases (12%). In one case there was no record of the drugs used. Opioids were used in 44% of cases as co-agents. Information on the doses used was not available to the Panel.

12.26 The Panel judged that miscommunication, or lack of managed expectations was the main contributory or causal factor in all but six reports (i.e. 81%). In many cases, patients reported that caregivers had specifically used the words they would 'be asleep' or 'light anaesthesia' which they interpreted as being unconscious.

A patient reported hearing hammering during an orthopaedic operation performed with regional anaesthesia and sedation, and was aware that their hands were pulling at the drapes and of people talking and asking the patient to keep still. The patient was not upset or disturbed in any way by this and experienced no pain. However the patient categorically said that the doctor had not explained the possibility of being partially awake or sedated for the procedure.

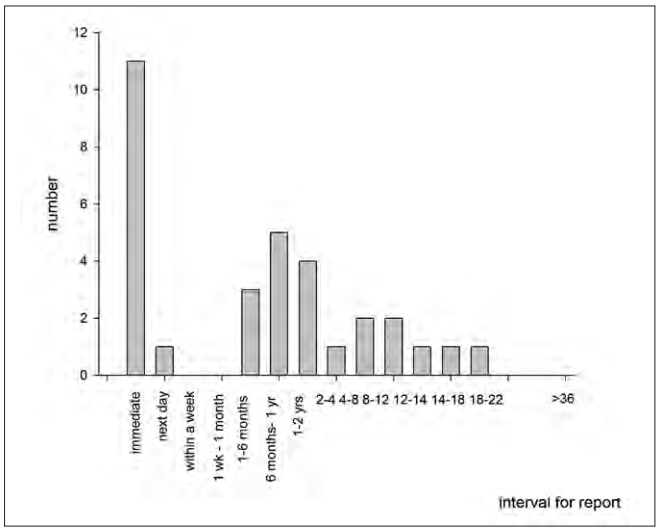
A patient reported: "I woke up and could hear discussion going on around me and the anaesthetist waved his hand in front of me. I was told it would be a light anaesthetic but expected to be asleep. I woke during surgery, heard some hammering and someone saying 'That's a good fit'. I wasn't afraid, and wasn't in pain." The patient expressed surprise, thinking: "This shouldn't be happening should it?" The patient reported the same experience following a second joint replacement a year later. The anaesthetic plan had been regional anaesthesia with sedation for an orthopaedic operation.

12.27 It was surprising that in four cases the patient was explicitly informed that they would not be unconscious and even signed a form of consent to that effect, yet made a report of perceived AAGA.

A young patient underwent endoscopy performed by a non-anaesthetist and found the procedure very distressing being tearful in recovery, saying that they had been informed they would 'be asleep'. The patient had signed a consent form and been provided information that stated: 'Sedation: You will be given a sedative to help you relax, together with some painkillers. This is given via a needle in your hand or arm and will make you drowsy and relaxed but is not a general anaesthetic. You will be able to hear and follow simple instructions during the procedure. You may not remember much about the procedure as the sedation may cause some short term memory loss. However, people often respond differently to the sedation. Some are very drowsy and have little memory of the whole event, whilst others remain more alert'.

12.28 Almost half of the patients made their report immediately after the procedure or the day after. The other patients delayed their report for months or years – the longest delay being 22 years (Figure 12.3).

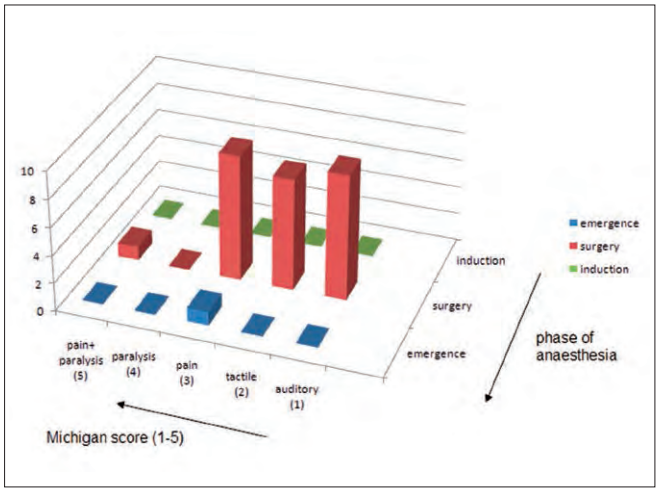
Figure 12.3. Histogram of time interval before sedation cases made a first report of perceived AAGA



12.29 In terms of the experience of the reported AAGA, almost all events arose during the phase of the intervention (or 'surgery') and none at 'induction' (which is perhaps understandable as there is no clear phase of induction during sedation). One report described experiences during the 'recovery' phase. See Figure 12.4.

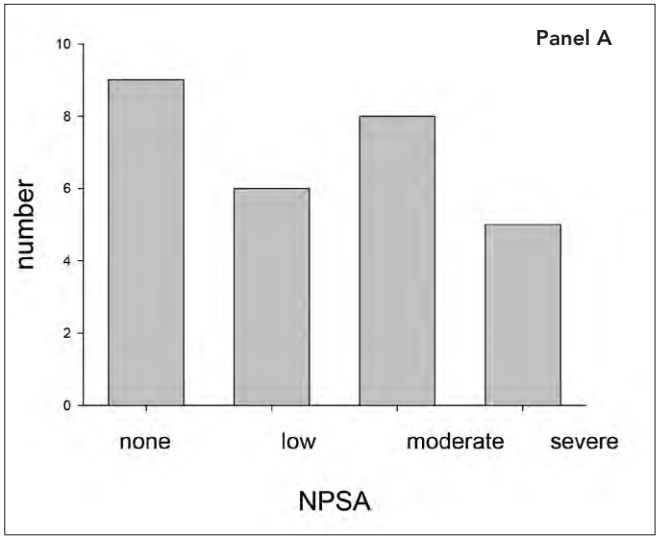
About two-thirds of experiences involved auditory and tactile sensations (i.e. Michigan scores 1 and 2). About a third of patients reported pain, and there was one instance of paralysis plus pain. This last was associated with distress at the time. In total about half the patients (15) reported distress, more so if pain was experienced (8 of the 15).

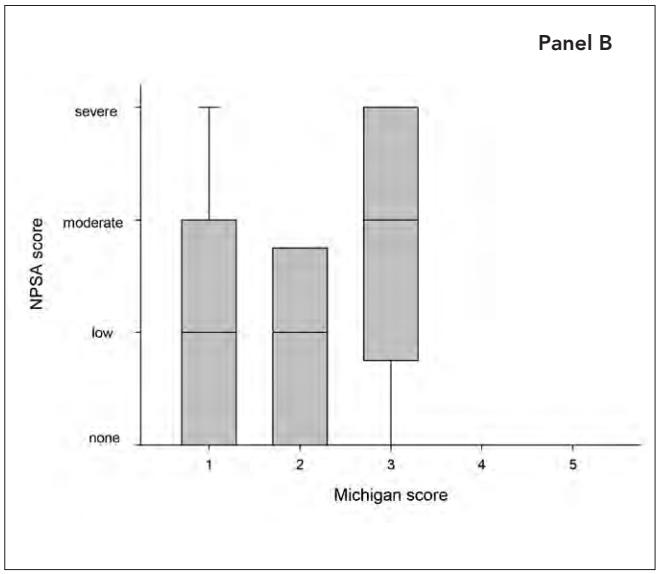
Figure 12.4. Distribution of Michigan scores across the 'phases' of sedation. Michigan 1 = auditory sensations; 2 = tactile sensations; 3 = pain; 4 = paralysis; 5 = paralysis and pain



12.30 The degree of longer term harm as assessed by the modified NPSA score was moderate or severe in about half the cases (Figure 12.5A); i.e. a perception of AAGA had considerable impact on the patients, even when in fact they had received intended sedation. However there was little correlation between symptoms and longer-term sequelae (Figure 12.5B).

Figure 12.5. Panel A: Distribution of impact (modified NPSA score); Panel B: Boxplot of the modified NPSA score by patient experience (Michigan scale)





The patient did not like the drape being over their face, nor the sounds of the saw and drilling which they found unbearable. They bit on their fist to stop themselves screaming 'Stop!' during the procedure. They said there was no one to talk to during the operation or to inform that they were not coping and expected to be 'naturally asleep'.

A patient reported that they woke up in the operating theatre three times while under the anaesthetist's care. They reported being able to see the surgeon cutting into their limb. The anaesthetist asked if the patient wanted to go back to sleep and they said 'Yes'. They woke up a further two times during surgery and during a further anaesthetic procedure. The notes recorded a well-documented plan of 'sedation, spinal and nerve block at end' but the patient stated they were promised they would be completely unaware of the procedure. The patient experienced pain during the nerve block and reported that they were 'mentally scarred' and 'phobic of having any more surgery'. The patient was referred to a psychologist.

DISCUSSION

12.31 Patients may report AAGA despite not having a general anaesthetic. The reasons for this are explored in Chapter 21 (Consent). For those patients who do report AAGA after sedation or regional anaesthesia the experiences are not dissimilar to those reported after AAGA and there may be significant psychological sequelae.

12.32 The data from NAP5 reinforces that from Kent et al. (2013). Using a patient registry that recruits self-referred patients, they found that 27 of 80 AAGA cases in fact underwent sedation (31%). The spectrum of symptoms experienced by these patients was broadly similar to our finding in Figure 12.5B. Kent et al. found the incidence of tactile/ auditory experiences was ~20%; of pain ~10%; and of distress ~80%. However, they reported a higher incidence of paralysis (~25%) and pain with paralysis (~45%). It is unclear why none of our reports also complained of any 'paralysis' from regional anaesthesia.

12.33 Kent et al. (2013) were able to examine in detail the longer term psychological sequelae, with overall 40-50% of patients experiencing a mix of symptoms including anxiety, flashbacks, nightmares, depression and chronic fear. NAP5 methodology did not have the resolution to explore this level of detail, but our finding that about half of patients experienced moderate or severe impact (Figure 12.5B) is consistent with their results.

12.34 These findings emphasise three points:

(a) The importance of investigation of all reports of AAGA to confirm, amongst other things, that general anaesthesia was in fact intended (and/ or expected) by the patient.

(b) The importance of ensuring that both patient and practitioner agree and understand the intended level of sedation when that is intended.

(c) That reports of AAGA after sedation are not trivial and should be managed as other reports.

12.35 From the Activity Survey we estimate that there are ~310,000 anaesthesia-administered cases of sedation (i.e. minimal, moderate or deep sedation) per year. There were 20 reports of AAGA where sedation was administered by anaesthetists. This yields an estimate for perceived AAGA during anaesthetist-administered sedation of ~1:15,500. This seems at least as common as Certain/probable or Possible AAGA reports after anaesthesia (~1:20,000; Chapter 6, Main Results).

12.36 The number of sedation cases by non-anaesthetists is unknown. Gavin et al. (2013) estimated ~500,000 colonoscopies and Quine et al. (1995) ~400,000 sedated gastroscopies. It therefore seems likely that well over 1 million sedation episodes take place in the UK each year, with the vast majority of sedated patients managed by non-anaesthetists. We cannot guarantee that NAP5 detected all reports of perceived AAGA that were made to non-anaesthetists and therefore make no effort to estimate an incidence.

12.37 Such data would be important to explore the speculation that where an anaesthetist is involved, patients automatically have a greater expectation of 'anaesthesia' (i.e. complete unconsciousness) simply because of the job title of the person involved.

12.38 However, Gavin et al. (2013) reported discomfort and pain rates to be ~10% and even if a tenth of these patients expected full unconsciousness and thus report AAGA, this would result in ~500 patients a year perceiving AAGA after sedation for colonoscopy alone. In line with suggestions by Gavin et al. more research is needed on patient experiences after interventions where sedation is undertaken by non-anaesthetists.

12.39 Communication with patients undergoing procedures under sedation could be improved. Terms such as 'we'll give something to make you sleep', or 'you won't be aware of anything' should be avoided as they describe a state of anaesthesia or total amnesia and thus misinform the patient. While the only record a patient has of events is their (fragmented) memory, a written signature provides some reassurance (to all involved) that clear information was originally provided. Most sedation cases are elective so there is ample opportunity for written information to be provided beforehand. This information should, amongst other things, make clear that the patient may retain memory of the procedure. See also Chapter 21, Consent.

Failures of communication were the cause of almost 90% of reports of 'AAGA' after sedation

12.40 The Activity Survey estimates about 500,000 patients underwent procedures awake supervised by anaesthetists, but none of these reported AAGA (i.e. patients who were awake, unlike some sedated patients, did not expect to be fully unconscious).

12.41 Table 12.3 indicates some useful forms of words that help define sedation from the patient's perspective.

Table 12.3. Continuum of depth of sedation: definition of levels of sedation/analgesia with respect to patient response and intervention required

	What will this feel like?	What will I remember?	What's the risk related to the sedation drugs?
Not sedated; awake	I am awake, possibly anxious. There may be some mild discomfort (depending on the what I am having done)	Everything	Nearly zero
Minimal sedation	I am awake and calm. There may be some mild or brief discomfort	Probably everything	Very low risk
Moderate sedation	I am sleepy and calm but remain in control. I may feel some mild discomfort	I might remember some things	Low risk
Deep sedation	I am asleep. I will not be in control	Probably very little	Higher risk. My breathing may slow when I am asleep – and I may need help to breathe – a tube might be inserted into my nose, mouth or (rarely) windpipe. I will need oxygen and special monitoring
Anaesthesia	I am deeply 'asleep' and unable to respond	Very unlikely to remember anything	Higher risk (but the presence of an anaesthetist increases safety). My breathing may slow or stop and my blood pressure and heart rate may fall. I will need a specialist doctor to look after my breathing and support my blood pressure and heart rate I will need oxygen and special monitoring and equipment

RESEARCH IMPLICATIONS

Research Implication 12.1
More collaborative research between anaesthetists and other specialists involved in sedation is needed on patient experience and outcomes after sedation for interventional procedures, especially where sedation is conducted by non-anaesthetists.

Research Implication 12.2
It would be interesting to compare if patient expectations or recollections differ (regardless of information provided) between sedation conducted by an anaesthetist versus a non-anaesthetist.

Research Implication 12.3
Sedation offers a rich research base for the study of retention of information and memory. This is highly relevant for how best to take consent from patients undergoing procedures under sedation.

Research Implication 12.4
NAP5 received no reports relating to instances of patient-controlled sedation. The efficacy and practicality of patient controlled sedation might be a useful avenue for further research.

Research Implication 12.5
The question whether different drugs used in sedation have differential influences on aspects of the experience of recall is amenable to further research? (i.e., do some drugs tend to impair memory while others impair the perception of noise vs touch, etc?).

RECOMMENDATIONS

RECOMMENDATION 12.1

Patients undergoing elective procedures under sedation should be provided with written information well in advance of the procedure. This should emphasise that during sedation the patient is likely to be aware, and may have recall, but that the intention is to improve comfort and reduce anxiety. It should be stressed that sedation is not general anaesthesia.

RECOMMENDATION 12.2

On the day of procedure, sedation should be described again from the patient's perspective, using terminology such as that suggested in Table 12.3 as a guide.

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CHAPTER
13

Drug errors and awake paralysis


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HEADLINE

13.1. This chapter describes cases of brief awake paralysis reported to NAP5, as a result of drug errors that led to a neuromuscular drug being administered without prior anaesthesia. Although it can be argued that these cases are not technically 'accidental awareness during general anaesthesia' the experiences and consequences for the patient are similar to AAGA. NAP5 received reports of 17 such cases. It is notable that the distress during the patient experiences and the subsequent psychological distress was of a greater severity than all other cases of AAGA.

BACKGROUND

13.2 An early landmark study of human error as a cause of untoward anaesthetic outcomes was published by Cooper et al. (1978). At that time, a syringe swap or the unintended administration of an incorrect drug was the third most common cause of anaesthetic critical incident (human error involving disconnection of circuit or inadvertent changes in gas flow being the two commonest). Syringe swaps now account for an even higher proportion of critical incidents in anaesthetic practice because, over time, the latter two have been virtually eliminated. Osborne et al. (2005) reported that of 4,000 reports received by the Australian Incident Monitoring Study (AIMS), there were almost as many cases of awake paralysis due to syringe swaps as awareness during anaesthesia.

13.3 More recent incident reporting studies suggest a rate of drug error of 1 every 140 anaesthetics (Webster et al., 2001; Zhang et al., 2013). This is almost certainly an underestimate as many unrecognized errors are not reported. Given these odds, it is almost inevitable that an anaesthetist will make drug errors during their career; yet many practitioners remain in a state of denial that they could make such an error, preferring to believe that they are less fallible than their colleagues (Evley et al., 2010).

13.4 Many errors are due to slips or lapses in concentration that occur in the multi-tasked setting in which anaesthetists work. It is important that the broader environment in which anaesthetists work, is not forgotten as a source of contributory factors to drug error: the likelihood of a final slip or lapse may be increased by many 'latent factors' (see Chapter 23, Human Factors). At an individual level, haste, inattention and distraction are likely to increase the risk of drug errors. The practice of anaesthesia involves continuous vigilance, and that may be impaired by the effects of fatigue.

13.5 Reason's classic 'Swiss cheese model' of human error in medical care explains that the coincidental lining up of 'holes' or faults in the protective

barriers in the environment is what allows errors to manifest as patient harm (Reason, 2000).

13.6 During syringe swaps patients are likely to have the distressing experience of total paralysis (perhaps including painful fasciculations with suxamethonium) in the absence of any anaesthetic agent that reduces consciousness. Patient experiences include awake-paralysis, distress, fear of dying and that paralysis may be permanent. PTSD may follow. As both a feeling of paralysis and distress at the time of awareness are associated with worse psychological sequelae after AAGA (Samuelsson et al., 2007, Ghonheim, 2009) it is not surprising that these cases are associated with a high rate of severe psychological sequelae (Mihai et al., 2009).

13.7 There have been several solutions suggested to reduce the incidence of drug errors in anaesthesia and other branches of medicine. These include checking drugs with another person before administration ('two person checking' or 'double checking') and also the use of technology (bar code scanning). Both systems have been trialled in anaesthesia (Evley et al., 2010).

13.8 While double checking of drugs has an appeal, there are recognised problems with it as a solution. To be effective, the double-checking must include all phases of drug administration (drawing up, drug selection and drug administration). A recent UK study found it was impractical due to the inability to ensure two individuals were present whenever drug administration was required (Evley et al., 2010). The evidence from other areas of medicine that double checking reduces drug error is limited. A systematic review identified a single RCT which reported that it reduced ward-based drug error from 2.98 to 2.12 per 1000 drug administrations (one error prevented in every 1,162 drug administrations, Alsulami et al., 2012), which the authors described as of 'unclear clinical advantage'. Toft has described 'involuntary automaticity' as an explanation of why double (or even multiple) checking may still enable errors to occur (Toft & Mascie-Taylor, 2005). There is a tendency to 'see what you expect to see' and while there may be mechanisms to reduce its effect it may not be entirely avoidable.

13.9 Bar-code scanning also appears to be a reliable solution but previous studies have identified many shortcomings with currently available systems and there are important cost implications (Evley et al., 2010). In order to prevent scanning of a syringe that in fact contains the wrong drug, bar-code scanning systems for drugs ideally need to be combined with systematic use of pre-filled syringes. Such systems have been trialled with evidence of modest benefit in reducing drug error but no clear evidence of patient benefit (Merry et al., 2011).

13.10 At the time of writing neither two-person checking nor scanning-based systems are in routine use, nor widely recommended in anaesthetic practice.

13.11 While litigation as a result of drug errors causing permanent harm in anaesthesia appears rare, drug errors from syringe swaps leading to awake paralysis is prominent in these claims (Mihai, et al. 2009). Such claims are almost invariably judged to represent sub-standard care and litigation is almost invariably successful (see Chapter 22, Medicolegal).

13.12 There are several separate problems:

(a) *a syringe swap* occurs when a drug error occurs because drug from the wrong syringe is administered;

(b) *a drug labelling error* occurs when the contents of the syringe are different to that indicated on the label, either because drug was drawn up from the wrong ampoule or the wrong label was applied;

(c) *a drug omission* occurs when the intended drug is omitted due to failure to draw up a drug in a dilutant.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

13.13 We used Class G of the AAGA reporting system as a miscellaneous category. This rapidly filled predominantly with syringe swaps and drug error; of which there were 17. These cases equal 1 in 8 of all definite and probable cases reported to NAP5. The 17 UK cases comprised 11 syringe swaps, five drug labelling errors and one omission error. There was suspicion of omission errors (either no drug given, or partial mixing) in several other cases not included here. Fifteen of 17 drug errors occurred at induction of general anaesthesia; two occurred due to accidental injection of neuromuscular blocking drug or local anaesthetic during intended regional anaesthesia.

13.14 Thus, three difficult-to-classify cases originally in this class are not considered further in this chapter. One was an awareness of inhalational induction in a child; one was awareness of cricoid pressure and one was likely partial paralysis in recovery.

13.15 The demographic characteristics of the patients in this group were similar to the patients in the Activity Survey: median age 36-40, median weight 70kg, median BMI 26kg/m^2, and this suggested that all types of patient were susceptibleto syringe swaps.

13.16 Most cases were ASA 1 or 2, and most events occurred during daytime hours. Thus it did not appear to be the case that these events were related to out-of-hours or emergency surgery.

13.17 Most events were reported immediately, except one case which was reported after several years.

13.18 The median perceived duration of the paralysis was very short, 60 (10-180 [5-900]) sec. One case where the experience was very long did not appear to have been administered any anaesthetic during the episode, perhaps because the syringe swap was not recognised and the diagnosis was initially unclear.

A young, anxious patient was undergoing elective orthopaedic surgery. To alleviate anxiety, the anaesthetist planned to give midazolam 2mg but the patient became unresponsive and was hand ventilated via a face mask. Two consultant colleagues arrived to help and it was later observed that the patient was behaving similarly to an inadequately reversed patient. Reversal was given and the patient started responding again. The patient was later able to give a detailed description of being paralysed and unable to respond to the anaesthetist's commands (to take deep breaths and opening eyes). There was fear of death. The episode lasted 15 min. The patient developed unpleasant dreams, nightmares and flashbacks, and symptoms of PTSD. The patient received counselling for this. A formal complaint was received by the trust.

13.19 All cases except one occurred on induction, before surgery started.

13.20 Most patients (15, 88%) experienced paralysis but two patients did not experience this sensation despite the drug error and experienced only tactile or auditory sensations. Pain was uncommon, (1 of 17, 6%) arising only once and that was in conjunction with paralysis. The majority (11 of 17; 65%) experienced distress at the time of the event. Distress was more common during brief awake paralysis than in definite and probable cases of AAGA (Table 13.1).

Table 13.1. Comparison of the immediate impact (Michigan D denoting distress) and longer term impact (Wang scale and modified NPSA score >2; i.e. moderate or severe) for Class A and B (Certain/probable) versus G (awake paralysis). In all categories, the impact of the last appears more adverse

NAP5 Class	Michigan D	Wang 5	NPSA >2
Definite/probable Class A	54%	35%	24%
Possible Class B	36%	36%	16%
Awake paralysis Class G	65%	47%	41%

13.21 Three (18%) of the drug error cases led to a formal complaint or initiation of legal action at the time the case was reported to NAP5, a little higher than was the case with Certain/probable cases (16% in Class G vs 11% of all Class A/B cases).

13.22 The Panel judged that all cases of awake paralysis caused by drug error were preventable, and therefore, the quality of clinical care was generally deemed to be poor in the period leading up to AAGA. In contrast, quality of care after the event was frequently good (77% cases), largely because the event was promptly recognised and well managed (Table 13.2).

13.23 The majority of syringe swaps that led to AAGA in NAP5 were due to events that led to administration of a neuromuscular blockade without being preceded by a hypnotic agent (Table 13.3). In one case lidocaine was given instead of an antibiotic which led to cardiovascular and respiratory collapse and need for resuscitation. The patient recalled events during the resuscitation.

Table 13.2. Panel judgements on quality of care and preventability for each of the Class A and B (certain/probable) versus Class G (awake paralysis). Notwithstanding the inherent difficulties of the judgement (discussed in Chapter 5, Methods), quality of care before AAGA was always judged poor in Class G and always judged preventable

	Quality of care before AAGA			Quality of care after AAGA			Preventable
AAGA Class	Good	Mixed	Poor	Good	Mixed	Poor	Yes
Certain/probable, Class A	26%	31%	39%	70%	7%	14%	73%
Possible, Class B	29%	32%	29%	55%	10%	17%	29%
Awake paralysis, Class G	0%	23%	77%	77%	6%	12%	100%

Table 13.3. Drugs involved and psychological impact of ten syringe swaps. (NMBD: unidentified neuromuscular blocking drug)

Drug Given	Drug intended	Michigan	NPSA score
Suxamethonium	Anti-emetic	4D	Severe
Atracurium	Saline flush	4D	Severe
NMBD	Midazolam	4D	Severe
Suxamethonium	Fentanyl	4	None
Suxamethonium	Fentanyl	2	None
Lidocaine	Antibiotic	1	Moderate
Atracurium	Saline flush	4D	Severe
Rocuronium	Midazolam	4D	Severe
Rocuronium	Midazolam	4	Moderate
Cefuroxime	Thiopental	4D	Low

13.24 The psychological sequelae of AAGA for the patient in this setting can be particularly severe. Of note: the severity does not appear to be related to duration of experience and even a few seconds of unintended paralysis can lead to prolonged psychological sequelae (also see Chapter 7, Patient Experience).

General anaesthesia was planned for a middle-aged obese patient for drainage of an abscess. The anaesthetist intended to give an anti-emetic before the induction dose of propofol, but mistakenly gave suxamethonium. The error was recognised immediately. The patient was aware for 30 seconds. The patient was extremely distressed in recovery and reported to staff that they had been paralysed, unable to breathe and felt they were going to die. In the post-operative period the patient was very angry and litigation was started.

13.25 The risk of a drug error is logically reduced by avoiding giving unnecessary drugs at the time of induction.

A young patient undergoing emergency surgery was anaesthetised out-of-hours by two trainees planning to undertake a rapid sequence induction. Suxamethonium was given instead of fentanyl while the patient was awake. The mistake was recognised quickly and the patient was anaesthetised with propofol. The patient had recall for a few seconds but no pain or discomfort and was generally unconcerned by the whole event.

Swaps involving larger syringes, such as in induction agent and antibiotic, also led to paralysis and AAGA, as the antibiotic was mistaken for induction agent. Perhaps understandably, this did occur with thiopental and antibiotic (but just one case). Equally understandably, no drug error arose with propofol.

In some of these cases poor communication within the team involving more than one anaesthetist led to these errors. Identifying and agreeing the roles of each anaesthetist in such teams is likely to reduce error.

A patient undergoing an urgent laparotomy for bowel obstruction was under the care of three anaesthetists on an emergency list; the plan was to administer fentanyl followed by thiopental and suxamethonium. Unfortunately, cefuroxime was mistaken for thiopental and administered instead. The patient's trachea was intubated but the patient became markedly tachycardic and hypertensive. The error was then realized and thiopental was administered. Post-operatively the patient recalled the sensation of being unable to breath, the discomfort of cricoid pressure and an unpleasant sensation of a tube being passed into the back of their throat. This experience lasted for a maximum of two minutes. The patient was not overly concerned about this event and overall hospital experience was very positive.

The similarity of appearance of thiopental and cefuroxime in close proximity

13.26 Seven drug preparation errors were reported (six of labelling error and one drug omission): and all led to awake paralysis and severe psychological sequelae. (Table 13.4).

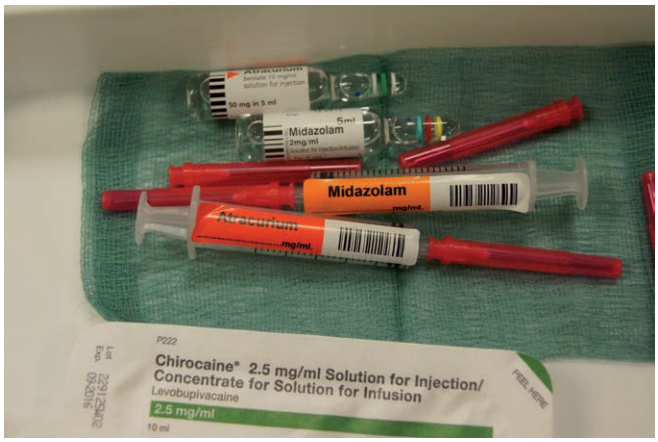
Table 13.4. Drugs involved and psychological impact of six ampoule-labelling and one drug-omission error. (*there was a suggestion that parexocib was also intended)

Drug Given	Drug intended	Michigan	NPSA score
Atracurium	Midazolam	4D	Moderate
Suxamethonium	Fentanyl	4	Low
Suxamethonium	Ondansetron	4D	Low
Atracurium	Midazolam*	4D	Low
Cefuroxime	Thiopental	2	None
Water	Thiopental	4D	Severe
Suxamethonium	Fentanyl	4D	Severe

13.27 The fundamental cause of most cases of wrong labelling or incorrect preparation appeared task-related. Distractions and perceived time pressures during the drawing up of drugs may lead to errors.

A middle aged patient was due to undergo elective shoulder surgery. The anaesthetist intended to sedate the patient before performing an interscalene block and then induce general anaesthesia. Atracurium 10mg was injected instead of the intended midazolam. The patient recalled feelings of panic, acute distress and the awareness of a very rapid heart rate. The anaesthetist quickly recognised that a muscle relaxant had been administered, and anaesthesia was induced within a few minutes. Whilst drawing up drugs in preparation for the case, the anaesthetist had been distracted by the ODP's request to leave the anaesthetic room to fetch equipment from a nearby store room. On return to the original task, atracurium was inadvertently drawn up into the syringe labelled as midazolam. Both ampoules were of similar size and nearly similar colour. The anaesthetist's explanation to the patient in recovery post-operatively was graciously accepted, and no formal psychological support or treatment was required.

Illustration of the similarity of labelled syringes for midazolam and atracurium left in close proximity



An anxious young patient was due to undergo general anaesthesia for minor surgery. Spontaneous respiration was planned. The patient remembered the anaesthetist's reassuring words that they would soon be asleep, then remembered their arm 'dropping' and being unable to hear their breathing. The consultant anaesthetist immediately realised that suxamethonium had been given instead of fentanyl, and administered a dose of propofol whilst continuing to reassure the patient. A single loose ampoule of suxamethonium had been placed lying close to the fentanyl and other induction drugs in the tray. This arose because the hospital had instituted a policy preventing the entire box of suxamethonium being removed from the fridge (to avoid room temperature degradation). Instead, the ODP had placed a single ampoule of suxamethonium on the tray. The patient was supported, a full explanation offered, and they suffered no long term impact.

An example of a single loose ampoule of suxamethonium and how easily it might be drawn instead of (in this example) ondansetron

13.28 Preparation error accounted for a minority of the drug error cases reported to NAP5. A common thread between them was pre-existing organisational elements that were likely to have increased the chance for error to be introduced (i.e. latent errors).

13.29 The practice of having a delay between drawing up a dilutant into a pre-labelled syringes and then later mixing/adding the active drug led to AAGA through drug omission.

A middle-aged patient required a general anaesthetic for expedited surgery. After induction the anaesthetist noticed greater than expected fasciculations in the patient. Following intubation, a volatile agent was immediately commenced. At this point the anaesthetist realised that no induction agent had been administered, only suxamethonium. In that hospital, thiopental was kept in a central store, so was not immediately available for mixing. After finishing the previous case, the anaesthetist forgot that the thiopental had not been mixed and proceeded with a rapid sequence induction. The patient was induced with a syringe containing only water (but presumably labelled as thiopental). In recovery, the patient reported experiencing paralysis and was clearly afraid: ''I thought I might not make it through the operation''. The patient was aware of being intubated and was unsure how long it would last but soon after lost consciousness. The patient developed a new anxiety state, flashbacks and possible PTSD. The patient subsequently had meetings with the clinical director and counselling was arranged.

DISCUSSION

13.30 The cases in this chapter are perhaps more accurately termed 'unintended awake paralysis', but are perceived by the patient as 'accidental awareness'. The adverse impact is commonly severe. This underlines the reality that paralysis whilst conscious is a potentially harmful experience. Of note: the impact of paralysis in generating distress and longer-term harm, which is also emphasised elsewhere – Chapters 6, Results; 8, Induction; 9, Maintenance; 10, Emergence; and 19 NMB.

13.31 The majority of drug errors causing awareness in this category are due to simple syringe-swaps of similar sized syringes, or similar coloured fluids, such as suxamethonium vs. fentanyl or ondansetron (all normally drawn in 2ml syringes); non-depolarising drugs vs midazolam (both normally in 5 ml syringes); or antibiotics vs thiopental (both usually in 20 ml syringes). Indeed, not a single error was reported for dissimilar sized syringes (Tables 13.3 and 13.4).

13.32 However, the overall incidence of drug error related to neuromuscular blockade must be regarded as low. The Activity Survey indicates ~2.8 million general anaesthetics per year, with 44.8% (~1.25 million) involving neuromuscular blockade. This represents one report of accidental paralysis for every 70,000 general anaesthetics involving neuromuscular blockade.

13.33 Recurring themes in the details of the cases were mention of staff shortages, a pressured environment with 'busy' lists. Some hospital policies for the storage and preparation of drugs appeared misguided and themselves were contributory to error (see Chapter 23, Human Factors).

13.34 Distractions during critical moments can have very serious consequences. Jothiraj el al. (2013) reported that other anaesthetists and circulating nurses are the most common causes of distractions. In terms of individual conduct, it seemed that a lack of vigilance and having several similar sized syringes on the same drug tray may be contributory.

13.35 Although checking ampoules and labels with a second person is theoretically attractive, the evidence base for checking with a second person before drawing up or giving a drug is weak. Although double-checking is accepted as necessary in other familiar settings (e.g. the administration of blood products), the value of checking routinely administered drugs in the anaesthetic context is more controversial.

13.36 When two people are responsible for the same task, neither person is truly responsible. There are several examples of this phenomenon in this report, where two anaesthetists have been present during a case, yet perhaps nobody was truly leading the team. Paradoxically, the introduction of double-checking for routine drug administration could worsen 'involuntary automaticity' and reduce, rather than increase, patient safety.

13.37 A technical solution to the problem would involve use of pre-prepared drug syringes and use of scanning technology to 'check' drugs before administration. Any method would need to accommodate the need for rapid response to a changing situation during surgery, and hence the need to have a range of drugs immediately available whose use was not anticipated.

13.38 Short of such technology, anaesthetists need to accept that they are all prone to making errors and should therefore, develop robust individual mechanisms to protect themselves. The anaesthetist needs to recognise their vulnerability to these potentially very serious incidents, and develop layers of defence to prevent drug errors; particularly those involving the unintended administration of neuromuscular blocking drugs. In this context the NAP5 data suggests several strategies that could reduce error.

13.39 Anaesthetic departments should work with pharmacy departments to take ampoule

appearance into proper consideration when choosing suppliers and should avoid frequent, changes of drug suppliers. If this is unavoidable, then it must appear on the hospital risk register.

13.40 Individual strategies that may be helpful include reserving 5ml syringes for neuromuscular blockade only, double-labelling of these syringes or, if available, using coloured syringes or different syringe types.

13.41 Although often relegated to being a routine, perhaps subconscious task, anaesthetists should appreciate that preparing drugs is a potentially high risk activity and so be careful to avoid all distractions during this period. The need to read all ampoules and use labels is self-evident, but any doubt or concern or distraction should lead to consideration that the wrong drug may have been prepared.

13.42 Perhaps greater attention is also needed to organising the anaesthetic workspace, with attention to detail on where and how the most potentially 'dangerous' drugs (i.e. the neuromuscular blocking drugs) are kept and handled (e.g. in separate trays). Part of this is the need to avoid unnecessarily complicated anaesthetic techniques and avoid the administration at induction of drugs not directly necessary (e.g. anti-emetics, which can often safely be administered later).

13.43 After an error had happened, the patient experience appeared greatly influenced by anaesthetic conduct. In some cases hurried efforts were made to reverse paralysis without attending to the patient's level of consciousness, while in others reassurance of the patient and ensuring comfort was prioritised. In the latter group, it seemed that patients, on understanding events, appeared to have considerably more benign experiences and fewer or no sequelae.

13.44 Where a drug error leading to accidental paralysis has occurred there are three priorities, in order: first, immediately reassuring the patient that they are safe, whilst second, inducing anaesthesia promptly to mitigate continued adverse impact (including airway management) and last, to consider reversing the paralysis at an appropriate time (e.g. guided by nerve stimulator monitoring).

IMPLICATIONS FOR RESEARCH

Research Implication 13.1

Further research is needed into issues relating to the cause and prevention of drug error in anaesthesia. Relevant questions include: Whether errors are more frequent when drugs are prepared by anaesthetists vs assistants vs double checking? Which strategies for double checking might reduce error? What sort of psychology is involved when teams double-check drugs?

Research Implication 13.2

The design of technical solutions to minimise drug error offers large scope for further research, to establish how the right drug is given at the right time to the right patient. This might include further analysis of interventions involving barcoding, or pre-prepared drugs, or drugs released from fridges or cupboards only on specific request.

RECOMMENDATIONS

RECOMMENDATION 13.1

Hospitals should take ampoule appearance into account to avoid multiple drugs of similar appearance. Hospital policies should direct how this risk is managed. This may require sourcing from different suppliers.

RECOMMENDATION 13.2

The relevant anaesthetic organisations should engage with industry to seek solutions to the problem of similar drug packaging and presentation.

RECOMMENDATION 13.3

Anaesthetists should develop clear personal strategies in the preparation of drugs that minimise or avoid scope for drug error. This includes the recognition that preparation of drugs for use is a potentially high risk activity, in which distractions should be avoided. This applies particularly to neuromuscular blocking drugs.

RECOMMENDATION 13.4

Where a drug error leading to accidental paralysis has occurred there are three priorities, in order: first, immediately reassuring the patient that they are safe, whilst second, inducing anaesthesia promptly to mitigate continued adverse impact (including airway management) and last, to consider reversing the paralysis at an appropriate time (e.g. guided by nerve stimulator monitoring).

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CHAPTER
14

AAGA in cardiothoracic anaesthesia

Jonathan H Mackay

HEADLINE

14.1. NAP5 received four reports of AAGA during cardiac surgical procedures and four during thoracic surgery. Based on the Activity Survey data this gives an incidence of reports of AAGA in cardiac and thoracic surgery of 1 in 10,000 and 1 in 7,000 respectively: both higher than the overall incidence of reports. Most reports in this field involved either brief interruption of drug delivery (caused by human error or technical problems) or use of intentionally low doses of anaesthetic drugs in high-risk patients.

BACKGROUND

14.2 Cardiac surgical patients have traditionally been considered at increased risk of AAGA due to a combination of surgical, anaesthetic and patient factors.

14.3 Surgical myocardial protection strategies in the early years were frequently associated with severely depressed post-bypass myocardial function and so to avoid this, anaesthetic techniques in the pre-propofol era were consequently traditionally largely opioid based and relatively devoid of cardio-depressant inhalational anaesthetic agents or benzodiazepines (Lowenstein et al.,1969). However, this may have increased the risk of AAGA.

14.4 Patients with minimal cardiac reserve and those undergoing emergency cardiac surgery were regarded as particularly vulnerable to AAGA.

14.5 Improvements in myocardial protection and the introduction of more modern anaesthetic techniques over the next two decades, appeared to reduce the incidence of recall of intra-operative events after cardiac surgery from >10% with high dose opiate techniques described above, to 1.1% with a more 'balanced' anaesthetic technique consisting of benzodiazepines, low dose fentanyl and a volatile agent (Phillips et al., 1993).

14.6 Institution of the cardiopulmonary bypass (CPB) phase is an especially vulnerable time. The acute effects of haemodilution and possible sequestration of some drugs into the bypass circuit are potential contributory factors. Although it is possible to administer volatile anaesthetic agents during CPB, there may be delays in achieving therapeutic partial pressures when volatile agents are first administered (Mets, 2000). Many revascularisation operations are now undertaken off-pump. The impact of avoiding bypass on incidence of AAGA is unclear.

14.7 Because cerebral metabolism and anaesthetic requirements decrease by 6–7% for every 1°C fall in temperature below 37°C, the risks of AAGA are reduced during hypothermic CPB (Hogue et al., 2012). Importantly, however, the risk of AAGA is increased during rewarming (Liu et al., 2005).

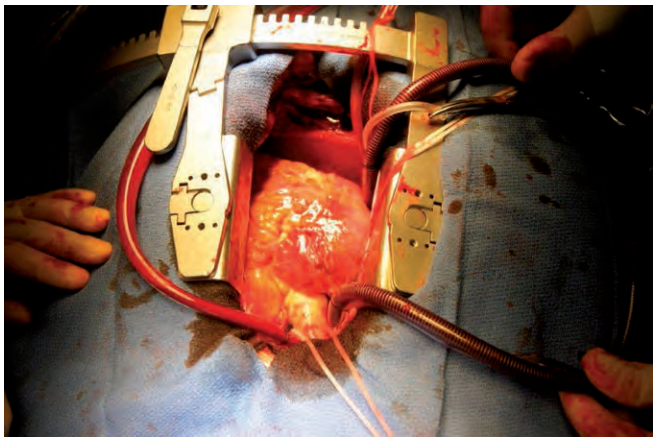
14.8 Dowd et al. (1998) reported a 0.3% incidence of awareness in 617 consecutive low-risk cardiac patients undergoing fast track cardiac surgery. Patients underwent a structured Brice (1970)

interview by a research nurse 18 hours after tracheal extubation. The low incidence of awareness was attributed to the use of a balanced anaesthetic technique involving the continuous administration of volatile (isoflurane) or intravenous (propofol) anaesthetic agents throughout the peri-operative period. However, Dowd et al. had selected a 'low risk' population, and also did not use repeated questioning, which may have contributed to the low reported incidence. Dowd et al.'s paper highlights a change in cardiac anaesthetic practice of relevance to all anaesthetists. In response to hypotension, anaesthesia was traditionally 'lightened'. In contrast, more recent education of cardiac anaesthetists emphasises the need to maintain anaesthesia throughout periods of hypotension and to initiate early treatment of low blood pressure with fluid, vasopressor or inotropic support.

14.9 Ranta et al. (2002) reported on the conscious recollections of >900 patients after cardiac anaesthesia. The incidence of definite awareness with recall was 0.5% and the incidence of possible recall was 2.3%. They found that lower doses of midazolam had been used in those patients with awareness and recall.

14.10 Most studies indicate that factors making for high-risk in cardiac surgical patients (e.g. ejection fraction <30%, cardiac index <2.1 $l.min^{-1}$ $.m^{-2}$, severe aortic stenosis or pulmonary hypertension) also increase risk of AAGA, and are associated with up to a 1% incidence of awareness. Almost half of over 2400 patients in the B-Aware study underwent either high-risk cardiac surgery or cardiothoracic transplantation (Myles et al., 2004). Cardiothoracic surgical patients accounted for a similar proportion (6 of 13) of cases of definite AAGA, with incidences of AAGA of ~ 1:120 and ~1:600 in the routine care and BIS groups respectively. Similarly patients undergoing planned open-heart surgery made up 36% of the 6000 patients recruited to the BAG-RECALL (2011) study, but 52% (14 of 27) definite or possible cases of intra-operative awareness in that study, yielding an overall incidence of ~1:150 (~0.6%) for cardiac anaesthesia.

Cardiac surgical patients may be at increased risk of AAGA because anaesthetic dosing is reduced to maintain cardiovascular stability in high-risk patients – here a patient undergoing heart transplant



14.11 Thoracic surgical patients are also at increased risk of awareness compared with the general surgical population. Most operations require administration of neuromuscular blockade to facilitate one-lung ventilation and many of the patients are elderly or frail with multiple co-morbidities. Because many patients undergo bronchoscopy before surgery via a single lumen tube and then need re-intubation with a double lumen tube, there is inevitably a brief period of discontinuity of lung ventilation and volatile anaesthetic delivery, and a potentially increased risk of failure to turn the vaporiser back on if the anaesthetist is distracted.

14.12 Rigid bronchoscopy is associated with a particularly high incidence of haemodynamic disturbance and awareness risk during anaesthesia (Bould et al,. 2007). Anaesthesia for this procedure is challenging due to a 'shared airway' with the surgeon, the need for deep anaesthesia, yet full neuromuscular blockade and rapid recovery. Recent North American and UK guidelines advocate using depth of anaesthesia monitoring for patients receiving TIVA and a muscle relaxant (Mashour et al., 2013; NICE, 2012).

14.13 In summary, patients undergoing both cardiac and thoracic surgery are generally considered to be at an increased risk of AAGA.

Operations such as rigid bronchoscopy require brief anaesthesia, full neuromuscular blockade and TIVA. All are risk factors for AAGA

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

Cardiac data

14.14 There were four reports of AAGA during cardiac anaesthesia classed as Certain/probable or Possible (Class A and B). One arose in the catheter laboratory and one case was during return to theatre for re-operation for bleeding. Thus there were only two reported AAGA cases during the primary surgical procedure.

14.15 Two cases involved experiences of touch (one of which was distressing to the patient; Michigan 2 and 2D), one of pain (during a line insertion as part of cardiac catheterisation in a child; Michigan 3D) and one of paralysis after induction (Michigan 4D).

14.16 Cardiac cases constituted ~1% of the UK reported caseload during the Activity Survey denominator study (~40,600 cases annually). This yields an overall NAP5 incidence of reports of AAGA of ~1:10,000 (~0.01%). This is perhaps twice as high as the general incidence in NAP5 of such reports of ~1:20,000, but much lower than in previous literature of cases of AAGA of 1:150.

14.17 According to the Society for Cardiothoracic Surgery (SCTS) website (www.scts.org/), 34,174 major cardiac surgical cases (excluding catheter laboratory cases and cases of post-operative bleeding) were undertaken in 2012. Given that estimated 40,600 NAP5 cases also includes GA catheter lab cases and returns to theatres for bleeding, there is good agreement of the NAP5 Activity Survey with confirmed SCTS data.

14.18 Specific EEG-based depth of anaesthesia monitoring was used in 31% of cardiac cases in the Activity Survey and, broadly in proportion with this, BIS was used in one of the four cardiac cases of AAGA in our cohort. The numbers are however too small to draw any meaningful conclusions regarding any preventative effect of DOA monitoring on AAGA in this setting.

A middle aged patient was urgently taken back to surgery for bleeding following a valve repair. During positioning an increased blood pressure and heart rate were noted by the anaesthetist and additional anaesthetic agents administered. The anaesthetist planned to employ intentionally light maintenance levels in view of the clinical situation, so used a BIS monitor whose values were recorded as <60 during induction and throughout surgery. The patient later recalled waking up hearing a specific discussion whilst being positioned on the operating table, and being unable to communicate this. The patient's estimate of the duration was ~30 seconds. The patient was moderately psychologically distressed and concerned about possible awareness during any further general anaesthetics.

An anxious young patient required emergency CABG following a coronary catheter procedure. Anaesthesia in pre-bypass period was a hybrid technique using TCI propofol, medium-dose fentanyl, rocuronium, and 0.6% end-tidal isoflurane. The patient later reported neither pain nor the experience of being paralysed, but was aware of somebody lifting and drawing on the leg and specific conversations. The patient described a sensation of "being alive only in their head with only their brain and ears still working". This was extremely distressing and the patient was frightened and feared death. The patient suffered a psychotic episode afterwards and developed post-traumatic stress disorder.

A patient reported, after a delay of some years, AAGA during elective CABG surgery. Induction was with 5 mg alfentanil, 5mg etomidate and pancuronium. The end-tidal concentrations of (an unspecified) volatile agent were in the range 0.1 – 0.23%. There was no haemodynamic recording until 40 minutes after induction of anaesthesia. The patient remembered being unable to move, breathe or speak and feared death. The patient developed flashbacks brought on by the prospect of further cardiac surgery. The patient was distressed and described this as 'a very effective form of torture', but there was no pain nor recall of the procedure. However, the delay in reporting was to avoid "the anaesthetist getting into trouble".

Thoracic data

14.19 There were four reports of AAGA during thoracic anaesthesia. One report occurred at induction due to failure to turn on the vaporiser after inserting a double lumen tracheal tube. One was a case of inadequate reversal of neuromuscular blockade, with recall of extubation that arose in recovery. There were only two reported cases of awareness during the primary surgical procedure: one of these arose due to a failure to recommence vapour on moving to the operating room; the other arose because of a tissued intravenous cannula.

14.20 Thoracic cases made up ~0.7% of UK reported caseload during the Activity Survey (~28,000 cases). This yields a NAP5 incidence of reports of AAGA of ~1:7,000, similar to the estimated incidence for cardiac cases, and notably higher than the incidence of ~1:20,000 overall.

14.21 Specific depth of anaesthesia monitoring was used in ~24% of thoracic cases in the Activity Survey, but none was used in any of the four thoracic AAGA reports.

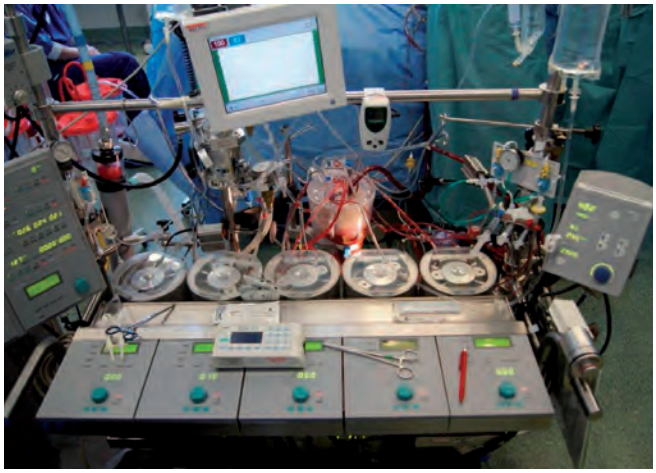
A young patient with airway obstruction underwent elective surgical rigid bronchoscopy. The intended anaesthesia was a target controlled infusion of propofol, with midazolam and fentanyl, suxamethonium and mivacurium. Surgery involved jet insufflations, rigid bronchoscopy and tube exchange. However the patient was aware and reported being curious and surprised hearing the surgeon talking to the nurse after induction. The patient signalled this by blinking the eyes, all lasting several minutes. The anaesthetist recognised a failure of the cannula.

DISCUSSION

14.22 There are too few cardiothoracic cases of AAGA reported to NAP5 to make robust recommendations. Combining the cardiac and thoracic data results in a total of eight Certain/probable or Possible reports, with a combined denominator estimated by the Activity Survey of 68,600. This yields an estimated incidence of reports of AAGA of ~1:8,600 (~0.01%).

14.23 This is very much lower than previous estimates of cases of AAGA of up to ~1:150, but those have employed repeated Brice questioning. The differences in methodology of NAP5 versus other studies using Brice have been discussed elsewhere (Chapter 5, Methods), and additional factors may be relevant for cardiothoracic anaesthesia that explain the disparity.

Cardiothoracic anaesthesia is traditionally considered a high risk specialty for AAGA and NAP5 confirmed this



14.24 Perhaps elderly cardiothoracic patients are more tolerant and less liable to mention an AAGA episode. Age-related attitudes to AAGA could be a contributory factor to the difference in incidence. Indeed, it is notable that there were no reported cases of AAGA in patients aged >50 during their primary surgical procedure.

14.25 Cardiothoracic patients are invariably warned pre-operatively that they will likely be awake in intensive care or high dependency units, with tracheal tube and invasive monitoring in place; therefore, the experience of awakening whilst the lungs are ventilated with limited ability to move, etc, is not entirely unexpected.

14.26 Another interpretation is that the NAP5 estimate of incidence reflects factors including changed anaesthetic practice with more attention to maintaining anaesthesia during periods of haemodynamic instability or bypass, etc.

14.27 Cardiothoracic anaesthesia would seem to lend itself well to research questions relating to whether EEG-based monitoring helps achieve the optimum balance between too light and too deep levels of anaesthesia.

IMPLICATIONS FOR RESEARCH

Research Implication 14.1

There is scope to combine aspects of the NAP5 methodology with previously published methods using the Brice questionnaire in cardiothoracic surgery. The incidence of AAGA needs to be ascertained, with an emphasis on the phase of anaesthesia/surgery in which the AAGA arises, and the degree to which the 'awareness' was anticipated by patients in this surgical group.

Research Implication 14.2

If in cardiothoracic surgery the incidence of AAGA found using the Brice questionnaire is as high as 1:150, and if mortality/morbidity are high, then this surgery type presents an important focus to test the hypothesis that specific depth of anaesthesia monitoring helps achieve the optimum balance between too little and too much anaesthesia.

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CHAPTER
15

AAGA in children

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HEADLINE

15.1. Patients aged up to 16 years old were classed as children. There were eight cases of Certain/probable or Possible awareness in children reported to NAP5, and 13 cases that were judged unassessable. The incidence of reports of AAGA in children in NAP5 is significantly lower than the previously reported incidence in prospective studies which used a Brice-type questionnaire. Some cases were first reported decades after the event, and by patients who reported significant psychological distress as a consequence. A minority of cases were reported by patients aged ≤5 years old. Differences in patient experience, memory formation, childhood perceptions and parental attitudes may contribute to the apparent low rate of reporting of cases of AAGA in children.

BACKGROUND

15.2 There are five recent publications investigating the incidence of recall of events during anaesthesia in children undergoing 'modern' anaesthesia. The incidences range from 0.2 to 1.2% (see Table 15.1). All of the studies gathered reports by direct questioning of a series of children using various modifications of the Brice questionnaire (Brice et al.,1970). Combining all the data, the overall incidence of awareness was 0.74% (~1:135; Davidson et al., 2011).

15.3 The contributing researchers had used different methods to determine recall, and there were other important possible differences in their patient samples, yet these data may be the best current estimate of AAGA incidence in children. It is clear and noteworthy that 0.74% (~1:135) is appreciably higher than the 0.1–0.2% incidence (~1–2:1,000) of AAGA found in adults (Avidan et al., 2008; Avidan et al., 2011; Myles et al., 2004; Sandin et al., 2000; Sebel et al., 2004; Wennervirta et al., 2002). Existing evidence therefore suggests that AAGA may be more common in children than in adults.

15.4 In addition to the raw incidence, the type and quality of experience is also relevant. In all these studies, children reported mainly tactile and auditory phenomenon (on average in 79% and 55% of children, respectively) and even though some had been scared (24%) or in pain (24%), children did not appear distressed afterwards. When seven of the cases from a previous study (Davidson et al., 2005) were followed-up, none needed psychological treatment (Phelan el al., 2009). Nevertheless, children can develop post-traumatic stress disorder (PTSD) following AAGA. Osterman et al. (2001) reported 16 children who came forward in response to a public advertisement and nine of these were assessed as having moderate to severe PTSD related to AAGA. However, these were by definition a self-selecting group.

15.5 There are reasons to make us suspect that AAGA is fundamentally different in children compared with adults. In the studies above, the youngest child was 6 years old (there were six 6–year olds, five 7–year olds and five 8–year olds). Anaesthesia technique,

Table 15.1. Recent publications of incidence of AAGA in children

Authors	Incidence	Number	Age range (yrs)
Davidson et al., 2008 Blusse Van Oud-Albas et al., 2008 Davidson et al., 2005 Malviya et al., 2009 Lopez and Habre, 2009	0.2% 0.6% 0.8% 0.8% 1.2%	1 of 500 6 of 928 7 of 864 14 of 1784 5 of 410	5–12 3–16 5–12 3–15 6–16
Aggregate: from Davidson et al., 2011 (95% CI)	0.74% (0.29-1.19%)	33 out of 4486	3-16

dose requirement, use of neuromuscular blocking drugs, level of consciousness monitoring, types of surgery, patient appreciation of events (real or imagined), memory formation and communication ability are all different from adults, and these factors may explain the differences between adult and child incidences and experiences of AAGA.

15.6 In the 1970s, thiopental, halothane and suxamethonium were in everyday use, whereas today, propofol, isoflurane, sevoflurane and a variety of neuromuscular blocking agents are standard drugs. McKie & Thorpe (1973) found that ten of 202 (~5%) children experienced AAGA with these older regimens. Before, the 1990s, the popular 'Liverpool technique' involved profound neuromuscular blockade with high dose opioid and nitrous oxide with no volatile agent and four of the ten AAGA patients in the McKie & Thorpe study received this technique. Another study of 220 children undergoing the Liverpool technique reported that none of the children had recall, but 23 (~10%) experienced peri-operative dreaming (Hobbs et al., 1988), and that this was also associated with use of suxamethonium. A subsequent study of 144 children reported that the incidence of dreaming was reduced from 17% to 3% by the use of a small dose of tubocurarine before suxamethonium (O'Sullivan et al., 1988) and it was proposed that muscle-spindle activation caused by suxamethonium muscular fasciculation may provoke dreaming. Although the high incidence of dreaming implies some degree of cerebral functioning, none of these patients had recall of intra-operative events.

15.7 Dreaming was also investigated by (Huang et al., 2005) who found that 10% of 864 children receiving isoflurane and nitrous oxide anaesthesia experienced intra-operative dreaming. It is reasonable therefore to conclude that dreaming is common and possibly not influenced by anaesthetic technique. Huang et al. (2005) reported that children distinguished clearly between what they recalled and what they dreamed, with dreams featuring fantastical themes such as birds, tortoises, and chocolate far removed from the experiences featuring in the AAGA reports.

15.8 Halothane was gradually replaced by sevoflurane during the 1990s. The potency of these two agents is debated. The MAC of halothane (~0.8%) is lower than that of sevoflurane (~2.2%), suggesting it is more potent. However, at equi-MAC doses there is less EEG suppression with halothane (Schwab et al., 2004), which would indicate it is less potent. The simplest explanation is that these two agents have different effects on the EEG. A more complex explanation relies on MAC being a measure of spinal cord, not cortical action. Halothane has a greater effect at the spinal cord (and therefore lower MAC) than sevoflurane and therefore, paradoxically, there is less suppression of cortical activity with halothane than with sevoflurane (i.e. despite a lower MAC, halothane is in fact the less potent agent (Antognini et al., 2002; Antognini & Carstens, 1999; Jinks et al., 2003). There are however no data to suggest AAGA is more common with halothane.

15.9 NAP5 offers an important opportunity to explore reports for paediatric experiences, insights, common problems and themes.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

15.10 For the purposes of NAP5 we defined a child as aged <16 years old.

15.11 There were 24 reports relating to children under the age of 16 years, and nine of these were classified as Certain/probable or Possible. There were four reports of AAGA from children in the age group 1–5 years. Due to the nature of the reports, in this chapter (unlike others) we also consider Unassessable reports.

15.12 Thirteen reports were Unassessable (Class E) or Statement Only and this formed the largest group in children. These cases lacked supporting evidence on which to judge them, meaning we were unable to make strong conclusions regarding accuracy, causes, experiences and sequelae. Although the reports were interesting and often compelling, because adequate details were not available, they could not be assessed or categorised further.

15.13 Nevertheless some Unassessable reports had common themes and are worthy of comment. Twelve of the 13 patients in this Class did not report their experience until years later, and sometimes there had been other anaesthetics in the intervening period between the AAGA event and the patient or carer making the report. It is worth emphasising that NAP5 only accepted new reports of AAGA: i.e. only cases that had never been reported to a healthcare professional before. The longest interval between AAGA and the report in this unassessable category was 62 yrs. The youngest patient at the time of AAGA was reported as having been aged ~5 yrs. Five adults expressed general anxiety or specific fears as a result of their experience, and two seem to have been traumatised (complex anxiety, and nightmares). One patient had only told her mother that she had been aware, and another had not been believed by relatives or carers. Four Unassessable reports were of AAGA during tonsillectomy.

15.14 However, the details of many unassessable reports were very sparse such that it was often difficult or impossible to speculate on the sort of operation or when the incident might have occurred.

15.15 In the Unassessable reports, six patients had long-term anxiety states which varied in severity. One patient seemed to be untroubled, yet admitted to nightmares related to her AAGA experience. Another was 'fearful' of future anaesthesia.

Gaseous induction was under-represented in reports of AAGA from children

Table 15.2. Summary of classification of NAP5 reports in children and young people. ICU, intensive care unit; swaps refers to syringe swaps (see Chapter 5, Methods for classifications)

Age range (years)	All classes	Class A or B (Certain/ probable)	Class C (Sedation)	Class D (ICU)	Class E (Unassessable) or Statement Only	Class F (Unlikely)	Class G (Swaps)
1–5	5	1			1	2	
6–10	9	3			6		
11–15	10	4			6		
All ages	300	141	32	6	89	12	20

Vignettes from reports classed Unassessable or Statement Only

A patient now in their 70s remembered "people doing things" in his mouth during a tonsillectomy at the age of ~12 yrs.

A patient now in their 70s reported a period of wakefulness during surgery as a 12-year old child: he couldn't move but could hear. The patient had many anaesthetics since, yet this was the first time they had reported this incident.

A now ~50-year-old was fearful of anaesthesia because of being "awake and screaming throughout" during a tonsillectomy aged about 5 years.

A parent, bringing their child to a pre-op clinic, told of their own experience when they were 6 years old. They remembered having instruments put into their mouth and also a bright light overhead. The patient subsequently suffered with recurring nightmares and had some anxiety about future anaesthetics based on this experience.

During an operation on their leg in the 1970s, when aged 13 years, a patient remembered having had pain in their leg and being unable to say anything or move. There were no voices heard and the patient did not recall anyone operating. The patient had only ever told their mother.

A patient now in their 30s was anxious before their operation and admitted this was because they had been awake during an anaesthetic when aged 6. The patient had told their mother but she had replied that they were imagining it or not telling the truth.

A 45-year-old reported waking up with what the Panel felt was likely to be a mouth gag in place during tonsillectomy when aged 10 years.

15.16 There were eight Certain/probable and Possible cases and, because they are few and diverse in nature, all are presented below in order of the age at which the AAGA took place. Some reports are certainly very vague as to the timing, but the Panel consensus was that on balance of probabilities and given the details provided elsewhere relating to anaesthesia and surgery, they fitted the categories to which they were assigned.

Vignettes from Certain/probable and Possible reports

A 15-year-old underwent an urgent operation. The anaesthetic involved a gaseous induction, paralysis and intubation, regional anaesthesia and then a change to TCI propofol. During surgery the patient moved in response to intra-operative blood sampling but there was no obvious response to surgery. The next day the patient remembered their leg being cut.

A child aged 11–15 years remembered being "put to sleep" but was unable to speak or move and remembered something was placed in their mouth. Before falling asleep the child described being pushed through doors into theatre. Intravenous induction including an opioid was followed by volatile anaesthesia and nitrous oxide.

At the end of surgery a child aged 11–15 years had residual weakness in recovery. Three days later the child remembered awakening with a tube in their mouth and in pain.

A patient aged 11–15 years underwent a prolonged cardiac catheterisation under general anaesthesia. A Hickman line was inserted towards the end of the anaesthetic and the patient remembered a pricking feeling. This was reported by the parents two years later.

15.17 There were two reports judged Unlikely or not AAGA (Class F). The reports illustrate that the sparseness and vagueness of the details sometimes led the NAP5 Panel to decide that, although AAGA was possible, the child's words did not necessarily mean that the experience was one that related to AAGA.

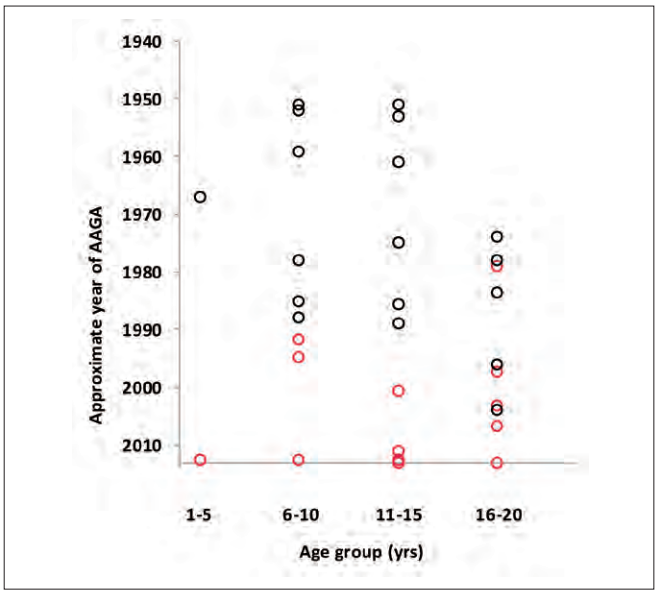
Vignettes from reports judged unlikely or not AAGA

Before anaesthesia for removal of a leg plaster cast a 15-year-old said "this is when the saw goes buzz and my plaster is cracked". There had been several previous anaesthetics and all had seemed uneventful.

A mother reported that her toddler was distressed and had nightmares after sedation for a procedure. There were no further details provided.

15.18 There were often long intervals between the AAGA and reporting. Figure 15.1 shows the interval between AAGA and reporting according to the age group of the patient at the time of AAGA. Of all the reports about children (<16–year–old), only five were made by children or parents within a year of the event. Most reports were made many years later.

Figure 15.1. Year of AAGA, demonstrating interval between AAGA and first report. All reports were made in 2013; the y-axis relates to the approximate year of event. Red circles are Certain/probable and Possible reports; black circles are /unassessable reports. Note that the reports judged most likely to be valid are made more promptly; the longer the time interval the more likely they are to be judged Unassessable



15.19 There were five Certain/probable and three Possible reports in children. Of these reports two involved pain or paralysis, and four experienced perioperative distress. Over a longer timescale, three patients reported increased anxiety about subsequent anaesthesia. None were said to have psychological problems at the time of reporting.

15.20 Of Class A&B patients one was aged 1–5 years, three 6–10 years and four 11–15 years. ASA classes were three ASA 1 , one ASA 2, three ASA 3 and one unknown. All underwent intravenous induction (one unknown) though drugs varied (thiopental, propofol and ketamine). Half of the patients received sevoflurane, two isoflurane and one halothane. Five received nitrous oxide and three did not, four received neuromuscular blockade, two did not and in two it was not recorded. The phase of AAGA was induction in five, maintenance in two and emergence in one. Comparisons with the Activity Survey should be cautious as some reports were delayed but the absence of gas inductions is perhaps notable.

15.21 Inadequate analgesia was judged a contributory factor in three out of eight cases. One cause was a delay in continuing the anaesthetic after induction. Another factor was inadequate reversal of neuromuscular blockade. In four cases, no cause could be determined. The small number of reports prevents statistical analysis or investigation of associations between AAGA and anaesthetic technique. The reports did not give sufficient detail to make observations on the doses of anaesthetic drugs and the timings of AAGA in relation to the doses given. Depth of anaesthesia monitors were not used in any of these cases.

DISCUSSION

15.22 There are two major findings of this chapter. The first is that very few children themselves reported AAGA. The second finding is that patients can delay reporting an AAGA event that occurred as a child for many years.

15.23 That only eight children reported AAGA that was classed Certain/probable or Possible suggests a surprisingly low incidence compared with the data published by Davidson et al. (2011) of an incidence 0.74% (~1:135). The NAP5 Activity Survey estimates that 488,500 general anaesthetics are administered to patients aged <16 years in the UK annually. This yields an incidence of just ~0.002% (or ~1: 60,000).

Table 15.3. Number of children (<16 yrs) having sensations and experiences during AAGA; comparison with Class E (Unassessable) cases

Class	pain	paralysis	tactile	auditory	visual	dreaming	distress
Certain/probable or Possible (Class A&B; (n=8)	2	2	2	1	0	0	4
Unassessable (Class E; n=13)	2	2	6	2	2	0	7

15.24 If 0.74% is the true rate of AAGA, there should be approximately 3,700 children per year in the UK with recall of events during general anaesthesia. The explanation for the disparity in figures is possibly that these two incidences are of different events. NAP5 is a study of spontaneous reporting and did not involve direct questioning. It appears that, if the data of Davidson et al. (2011) are correct, the vast majority of children who experience some form of AAGA simply do not report it.

15.25 If children have AAGA but do not report it, they may delay their reporting until they are adults and our set of 13 Class E (Unassessable) and Statement Only reports support the presumption that many children do not report their AAGA until they are much older. Unfortunately, because of the delay, these reports were frequently Unassessable because hospital records and other supporting evidence are no longer available. Nevertheless, these delayed reports were plausible as stories, and it is reasonable to consider them to have some relevance.

15.26 This group who delayed reporting is also interesting because approximately half of them had long term psychological effects which raises the possibility that at least part of the reason for non-reporting at the time is that the experience was too traumatic to report. However, because these cases were Unassessable, we simply cannot be sure the distress was specifically caused by AAGA and not related to other distressing experiences of undergoing surgery, or adverse experiences suffered in the course of life. Research is needed to establish if adverse memories are related to AAGA, or to the experience of hospitalisation, etc (Lerwick, 2013).

15.27 Previous studies suggest that appreciable long-term distress is uncommon in children after AAGA (i.e. that established by Brice-type questioning), and that few need psychological treatment (Phelan et al., 2009). Intuitively, parents would normally be expected to be very sensitive to behavioural changes in their children after anaesthesia, especially where this was causing adverse reactions out of proportion to what they would regard as normal stresses of needing surgery. Regardless of whether children experience AAGA more frequently than adults, the current consensus appears to be that the consequences are less likely to be severe. However, our NAP5 reports (especially the unassessable, Class E, cases) may represent a different cohort, being spontaneous reports perhaps more likely, therefore, to exhibit long term sequelae.

Reports of AAGA from children may be delayed. Reports should be listened to carefully and children believed

15.28 The reasons why children do not report their AAGA experiences are worth examining – and ripe for future research. We can speculate that reasons might include the nature of the experience not being sufficiently compelling or interpretable. Or, children may lack the language or vocabulary to explain what happened. Distress, fear and confusion may inhibit communication. Their awareness may be difficult to separate from dreaming or nightmares. Children are likely to tell their parents first, and therefore the report often depends on the parents. Their parents may have a reassuring influence and may suppress reporting. In the NAP5 cohort, one patient had only told their mother, and another said that they were disbelieved by their parents. Perhaps the parent's perception of what has happened is a dominant factor. All these possibilities may limit or prevent the communication of the child's experience. A child might find it difficult for social reasons to report AAGA but, with the passage of time, they may consolidate memories and feel able to report their childhood experiences later, particularly when anxious about a further operation. Even adults may decline to report AAGA without obvious reason (Villafrance et al., 2013).

15.29 It is plausible that children are less likely to form memories of AAGA because they lack understanding or information about what happens during surgery. Nevertheless there is good evidence to suggest that by the time children have sufficient language ability to report their experiences, they also have sufficient memory ability to recall AAGA.

AAGA was rarely reported by younger children

15.30 Recall can be demonstrated in infants of 7 to 8 months old, who are able to find hidden objects, with retention increasing with age (Bauer, 1996). By age 9 months, information can be retained for four weeks, by 10 months for up to 6 months, (Carver & Bauer, 2001) and at age 11 months up to 12 months (Bauer, 1996; McDonough & Mandler,1994). At age 2 to 3 years language and a sense of self develop, and both of these are important in the formation of explicit memory (Howe et al., 1994). Adults generally do not remember their childhood events before the age of 3 to 4 years (this is termed infantile amnesia), although very emotional events are recalled from a younger age so there are reports of young adults who can remember their hospital admission when they were aged 2 years (Usher & Neiseer, 1993). Infantile amnesia develops gradually though, so 5–7-year-olds in Bauer's recent study were able to recall 60% of events they discussed with their mothers in a recorded conversation at age 3 (Bauer and Larkina, 2013). Source memory – the ability to recall where or when a remembered event occurred – improves dramatically at this age (Drummey & Newcombe, 2002), making it more likely that children who experience AAGA from around 6 years onwards will be able to recall it as something that happened during anaesthesia.

15.31 Adult memories of childhood AAGA may be somewhat immune to the passage of time for several reasons: emotional events tend to be well encoded in memory (Cahill & Mcgaugh, 1996), memories of AAGA are perhaps unlikely to have been discussed and shared with others, which is a potential cause of memory distortion (Pryor & Root, 2013), and such memories are less likely to have been overwritten by other similar experiences than memories of more common events.

15.32 There are pharmacological factors that could affect AAGA. The concentration of inhalational anaesthesia required to maintain immobility in small children is higher than in adults (Mapleson 1996) and if dosing is titrated to adult values this could expose children to greater risk of AAGA. However, MAC is related to the dose required to cause suppression of the spinal cord rather than the cerebral cortex (Antognini & Carstens 2002), and if the inhalational dose is adjusted to MAC then it is likely that the cerebral cortex is anaesthetized more deeply in small children than in adults. This would be consistent with the NAP5 finding that AAGA in children is, if anything, rarer than in adults.

15.33 The number of Certain/probable or Possible reports was fewer in children (8) than in adults (133). Using the NAP5 Activity Survey data for denominators, we estimate the incidence of these reports to be ~0.002% (1 in 60,000) in children (denominator of 488,500), and ~0.005% (1 in 17,000) in adults (denominator of ~2,300,000).

15.34 In the NAP5 Activity Survey data sample, neuromuscular blockade was used less frequently in children than in adults (25% v 50%). The increased need for neuromuscular blockade in adults may be because the spectrum of surgical interventions is different, or perhaps because adults have degenerative or ischaemic cardiovascular diseases that prevent them receiving high doses of anaesthetic to achieve immobility. Since AAGA is so intimately linked with use of neuromuscular blockade, these factors may partially explain why reports of AAGA were more common in adults.

15.35 The historical timing of AAGA might be linked with types of drugs used at that time. There was only one report of AAGA 40–50 years ago but seven reports from 20–40 years ago. The 'Liverpool technique' was in use throughout these years but probably ceased being used around 20 years ago. Halothane is no longer used for induction of anaesthesia and probably stopped being used in most UK hospitals around ten years ago. Nevertheless, no obvious cluster can be seen in Figure 15.1.

15.36 Depth of anaesthesia (DOA) monitoring has not been used commonly in children (Myles et al., 2003), but this may be changing. A survey of paediatric anaesthetists in the UK and abroad has shown that there is a general recognition that AAGA is a problem in children, and 10% of those questioned said that they used DOA monitoring (Engelhardt et al., 2007). The NAP5 Activity Survey found that very few (~0.5%) children had processed

EEG or related monitors during anaesthesia. The EEG of awake and naturally sleeping infants is different from adults, and commercial monitors of processed EEG have not been validated in small children.(Murat & Constant, 2005; Shander & Lobel, 2005), which may explain a reluctance to use them.

15.37 The detection of awareness during muscle relaxation can be achieved with the isolated forearm technique (Russell & Wang, 1996; Tunstall, 1977), and the method has been used successfully in children over the age of 5 years. Byers & Muir (1997) found that eight of 41 children (~20%) responded to command during halothane anesthesia and more recently Andrade et al. (2008) found that two of 184 children (~1%) responded during isoflurane anaesthesia. Interestingly, no child, in either study, could recall any intra-operative event.

15.38 The paucity of AAGA cases involving children reported to NAP5 means it is unjustified to make specific recommendations about prevention and management of AAGA in this group. Nevertheless we offer some learning points:

(a) Spontaneous reporting of AAGA by children after their anaesthesia is very rare. When it is reported this may be delayed until adulthood (when inevitably confirmation of its veracity and interpretation becomes very difficult if not impossible).

(b) However, when made, children's reports of AAGA can be as reliable as those from adults.

(c) Reports of AAGA may be received by parents but not transmitted further, though the reasons for this are unclear. Children should be believed and treated sympathetically.

(d) Serious long term psychological harm and anxiety states are rare, but do occur after AAGA in children.

IMPLICATIONS FOR RESEARCH

Research Implication 15.1
The finding that many children wait for years before reporting AAGA, and that about half of these appear to suffer adverse psychological symptoms or new anxiety states warrants further research to establish if AAGA is a specific cause, or if memories are conflated with the trauma of surgery or hospitalisation.

Research Implication 15.2
Long-term follow up of children who spontaneously report AAGA vs those who admit it on direct (Brice) questioning will help establish if there is a difference between the two cohorts in the type of experience of AAGA.

Research Implication 15.3
Research into memory formation in children is highly relevant for paediatric anaesthesia and the study of AAGA in children. It would be important to ascertain how anaesthetic drugs interact with memory formation in children.

Research Implication 15.4
There is considerable scope for assessing the utility of depth of anaesthesia monitoring (including both EEG-based methods and the isolated forearm technique) in children.

Research Implication 15.5
There is a need to define more clearly the explicit psychological support needed by a child (as compared with an adult) distressed by an experience of AAGA who reports it soon after the event.

Research Implication 15.6
The psychological impact (and hence support needs) of an adult reporting AAGA experienced as a child are important to define. It is unknown if these are different from the needs of an adult who delays reporting of AAGA that occurred originally in adulthood.

Research Implication 15.7
There appears sparse basic pharmacokinetic or pharmacodynamic data for common anaesthetic agents in children. Without this important information, it will be difficult or impossible to understand anaesthetic action, and hence solve the problem of AAGA in children.

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CHAPTER
16

AAGA in obstetric anaesthesia


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Nuala Lucas


David G Bogod

HEADLINE

16.1. There were 14 cases of AAGA during obstetric general anaesthesia reported to NAP5. Obstetric cases account for 0.8% of general anaesthetics in the NAP5 Activity Survey but ~10% of reports of AAGA to NAP5, making it the most markedly over-represented of all surgical specialties. Most reports of AAGA occurred after Caesarean section, but a number of cases were reported following obstetric anaesthesia for other procedures. Obstetric general anaesthesia includes most of the risk factors for AAGA, including use of rapid sequence induction with thiopental and neuromuscular blockade during maintenance, in a population with a relatively high incidence of obesity and difficult airway management. The urgency of the situation frequently necessitates surgery beginning within moments of induction.

BACKGROUND

16.2 Scott (1991), writing about awareness during Caesarean section, stated that it '*is due to too little anaesthetic and is the fault (not the bad luck) of the anaesthetist*'. This is not particularly helpful. It is self-evident that 'more anaesthetic' will at a certain dose, make it nearly impossible for the patient to be aware: the problem is knowing how much to give, and how best to monitor it.

16.3 It has long been believed that the incidence of AAGA in obstetrics is higher than in the non-obstetric population. Concerns about deleterious effects of anaesthetic drugs on the fetus, (both directly and via the impact on maternal haemodynamics) and the potential to increase maternal blood loss though decreased uterine tone, have led anaesthetists to minimise anaesthetic dose: that is, to administer 'light' anaesthesia.

16.4 Following the introduction of neuromuscular blockade and tracheal intubation to anaesthetic practice in the UK in the late 1950s, anaesthesia for obstetric procedures was generally induced with thiopental 200–250 mg and maintained with nitrous oxide. With this technique, the incidence of AAGA was reported to be as high as ~4% (Moir 1970; Crawford, 1971). This was reduced to <2% by the practice of adding ~0.5% halothane, although it was turned off after delivery to maintain uterine tone (Moir, 1970).

16.5 Anaesthetists were also taught to use rigid drug-dosing protocols, applying the same regimen for all patients regardless of variation in individual patient characteristics. The pitfalls associated with such an approach are demonstrated by the remarkable case of a woman who experienced AAGA during two separate anaesthetics, even though the anaesthetist on the second occasion knew her history (Lyons & Macdonald, 1991).

16.6 Several epidemiological studies have provided further evidence of increased risk of AAGA in the

obstetric population (Errando et al., 2008; Ghoneim et al., 2009). An important recent study on the topic was by the Australian and New Zealand College of Anaesthetists (ANZCA) trials group in 2005–6, who reported two cases of AAGA in 768 cases (0.26%, 1:384) Paech et al., 2008).

16.7 Regional anaesthesia is now the norm for Caesarean section and in England and Wales in 2013, Hospital Episode Statistics (HES) data reported that general anaesthesia was used for only 8% of all Caesarean sections, most of which were emergency cases (www.hscic.gov.uk/catalogue/PUB12744). The marked reduction in the use of general anaesthesia in obstetric practice, combined with changes in training means individual anaesthetists' experience of general anaesthesia is much more limited than in the past.

16.8 Although thiopental remains the most widely used induction agent in UK obstetric anaesthetic practice, a recent survey of UK anaesthetists found that 55% 'hardly or never' used thiopental outside obstetric practice, with 87% using it less than once per month (Murdoch et al., 2013).

16.9 Past surveys have indicated that isoflurane and sevoflurane are used by >95% of obstetric anaesthetists for maintenance, with sevoflurane the drug of choice. Snaith et al. (2010) reported that 85% of anaesthetists used nitrous oxide in obstetric cases, although only 44% used it outside of obstetrics. Similar practices were reported in the ANZCA trials group study (Paech et al., 2008).

16.10 The optimum dose of thiopental for induction is still disputed. Recommendations range from a maximum of 4 mg/kg (British National Formulary, 2014) to 4–8 mg/kg (Harrad & Howell, 2000). The mean dose in the ANZCA study was 4.9 mg/kg (Paech et al. 2008). When the recommended dose was increased from 3–4 mg/kg to 5–7 mg/kg in one centre, the incidence of AAGA fell from 1.3% to 0.4% (Lyons 1991). Textbooks of obstetric anaesthesia contain the advice that the recommended maximum dose in adults may not be sufficient in the obstetric population (Collis, 2002; Yentis et al., 2004). Overall, current opinion suggests that the induction dose of thiopental for the healthy parturient should be no less than 5 mg/kg.

16.11 Several studies in non-obstetric patients suggest that intubation tends to be carried out at higher BIS readings, following induction with thiopental compared with propofol. Beck et al (2006) reported that thiopental induction was associated at intubation with higher BIS values and more patients with BIS >60. BIS rose a mean of 8 points at intubation. Sie et al. (2004) compared thiopental 4mg/kg or propofol 2mg/kg and reported significantly fewer patients with BIS <60 at 1, 2 or 3 minutes in the thiopental group with up to 50% having BIS>60 at 2 minutes. Heier et al. (2001) reported that when thiopental 5mg/kg and suxamethonium 1mg/kg was administered to volunteers and allowed to wear off: 58% experienced awareness while still paralysed, though none were distressed by the sensation of paralysis. Taken together, these studies highlight the variable effect and short duration of thiopental. There is no reason why this should not also be the case in the obstetric population.

16.12 In a recent study Zand et al. (2014) studied BIS and the isolated forearm technique (IFT) during caesarean section. Anaesthesia was induced with thiopental 4.5mg/kg and maintained with sevoflurane 1.8–2.2% in 50% nitrous oxide before delivery. BIS could not reliably differentiate between positive and negative isolated forearm responses during induction, intubation and skin incision and 46% of patients demonstrated a positive isolated forearm response during airway management. Interestingly no post-operative recall was reported despite use of a Brice questionnaire post-operatively.

16.13 Concerns about using propofol for obstetric anaesthesia include:

(i) slower onset;

(ii) a short distribution half-life;

(iii) the potential for more hypotension at induction with potentially deleterious effects on placental blood flow (Moore et al., 1989) and (iv) the reported complication of profound maternal bradycardia in association with suxamethonium (Baraka, 1988). Despite these concerns, propofol is probably the most commonly used induction agent for general anaesthesia in obstetrics outside the UK (Rucklidge, 2013); reassuringly, case reports of adverse effects are not accumulating.

16.14 An inspired oxygen concentration of >50% has been routinely used before delivery to maintain fetal oxygenation, but has not been demonstrated to improve neonatal outcome when compared with 33%, in the absence of fetal compromise (Lawes et al., 1988).

16.15 An end-tidal MAC of around 0.5 for the halogenated volatile anaesthetics is advocated in order to avoid a tocolytic effect on the uterus. However a higher

MAC has not been associated with increased blood loss (Lyons & Macdonald, 1991).

16.16 Other factors may play a role in the increased incidence of AAGA in the obstetric population:

(a) Obstetric patients do not receive sedative or analgesic premedication.

(b) The majority of general anaesthetics are administered for non-elective Caesarean section and consequently patients' anxiety levels are likely to be high.

(c) The physiological changes of pregnancy (e.g. tachycardia) may mask the clinical signs of inadequate anaesthesia.

(d) Increased cardiac output decreases the duration of action of intravenous anaesthetics, and at the same time prolongs the time to establish effective partial pressure of volatile agents.

(e) A category 1 Caesarean section requires induction of anaesthesia followed by tracheal intubation and then commencement of surgery as rapidly as is compatible with maternal safety. There may be insufficient time for the drugs to take full effect before airway manipulation or surgery.

(f) Rapid sequence induction is almost invariably used in the UK and is coupled with an increased risk of difficult and failed intubation in the obstetric population (Quinn et al., 2013).

(g) A single ampoule of suxamethonium represents an adequate dose for a patient weighing no more than 70 kg. Under-dosing of suxamethonium may worsen intubating conditions and exacerbate the risk of AAGA. Even a dose of 1.5 mg/kg may be inadequate due to the increased volume of distribution in pregnancy; (O'Brien & Conlon, 2013).

(h) The incidence of obesity is increasing in the obstetric population (Helsehurst et al., 2007) and, if regarded as an independent risk factor for AAGA (see Chapter 11, Risk Factors), may be contributory.

(i) The majority of anaesthetics for non-elective Caesarean sections are given by trainees often outside of the main theatre suite and out-of-hours with distant supervision (Hawthorne, 1996). Paech suggested 'trainee stress' may be a contributory factor in obstetric AAGA (Paech et al., 2008).

16.17 To summarise, obstetric patients have hitherto been considered to have a higher risk for AAGA for multiple reasons.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

16.18 Data from the Activity Survey confirmed the uniqueness of obstetric anaesthetic practice.

16.19 Almost 2/3 of all anaesthetic activity between 00.01 and 08.00 hrs was obstetric, including 23% of Category 1 lower segment Caesarean section (LSCS). Thiopental was used for <3% and RSI for <8% of anaesthetic inductions, but both were used for >90% of Caesarean sections. An opioid was used in 25%. Nitrous oxide was used for >70% of Caesarean sections but <30% non-obstetric cases.

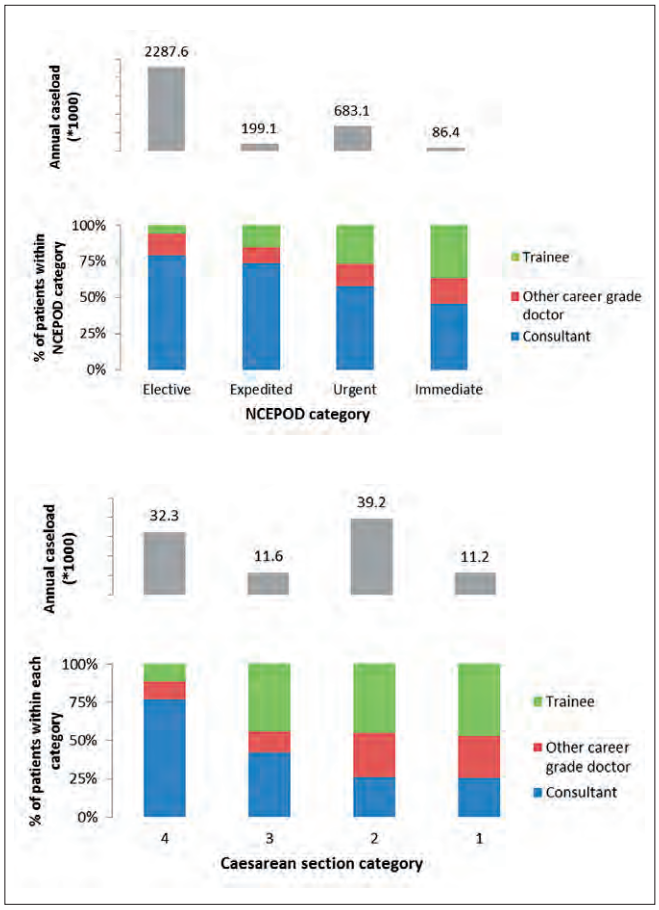
16.20 Anaesthesia for Category 1–2 Caesarean section was less often performed by consultants than other (non-obstetric) emergencies and more often by quite junior trainees (Figure 16.1 and 16.2). This is unsurprising given that, in contrast with emergencies outside obstetrics, urgent delivery may be necessary within a few minutes, such that senior staff may not be able to attend in time. Comparison of management of obstetric and non-obstetric emergencies should be approached with caution, as it should be borne in mind that the NCEPOD classification excludes obstetric cases, and an NCEPOD 'emergency' should not be regarded as synonymous with a 'category 1' Caesarean section (immediate threat to life of the mother or fetus; Lucas et al., 2000).

16.21 There were 14 cases of AAGA in obstetric patients: 13 in Class A (Certain/probable) and one in Class B (Possible). In addition to these 14 cases, there were two cases involving drug errors (Class G) and 12 'Statement Only' cases (which are discussed elsewhere (Chapter 6, Main Results).

16.22 The obstetric cases thus represent 14/141 (~10%) of the total number of Certain/probable and Possible AAGA cases. In the NAP5 Activity Survey obstetric general anaesthetics constituted 0.8% of the total general anaesthesia cases for the UK. Thus, obstetrics is over-represented in AAGA cases by a factor of >10 (see also Chapter 6, Main Results and Chapter 11, Risk Factors).

16.23 All the experiences in obstetric cases concerned awareness at induction or soon after, bearing in mind that incision normally follows very shortly after tracheal intubation. All except one case involved use of neuromuscular blockade; in none of these was the use of a specific depth of anaesthesia monitor recorded (See Table 16.1 for other characteristics).

Figure 16.1. a and b: (a) NCEPOD urgency (non-obstetric cases) and most senior anaesthetist present and (b) Caesarean section (general and regional anaesthesia) urgency and most senior anaesthetist present. Top chart shows estimated annual caseload according to NCEPOD or Caesarean section urgency category. Bottom chart shows % of patients, within each category, according to most senior anaesthetist present. Note: category 1,2 and 3 are all forms of emergency Caesarean section. Caesarean and NCEPOD categories are not directly equivalent



16.24 Four of the Caesarean sections (33%) were described as Category 1. In the Activity Survey, the proportions of Categories 1–4 general anaesthesia Caesarean sections were respectively: 39%, 37%, 10% and 14%. Thus Category 1 cases do not appear to be over-represented in patients who reported AAGA to NAP5 (see table 16.1).

16.25 Five cases involved airway or respiratory difficulty. There were two cases of failed intubation (one was managed with a laryngeal mask; one allowed to waken), two other cases of difficulty with intubation and one case of bronchospasm. Of four obese patients, two had airway problems. Difficult airway management and obesity are discussed further in Chapter 8, Induction and Chapter 7, Risk Factors. In two cases, retrograde flow of induction agent into the giving set was considered contributory.

Table 16.1. Characteristics of obstetric cases. LSCS, lower segment Caesarean section; Category 4 elective; Categories 3 – 1 increasing degrees of urgency; in hours = weekday 08–18.00; out of hours = outside these times and weekends; obesity = BMI >30. *one patient had bronchospasm; **all cases without monitoring were >10 years old, except one where propofol boluses were used in non-LSCS case

Variable	Number
LSCS Category 1 Category 2 Category 3–4	12 5 4 3
Non-LSCS operations	2
In hours: out-of-hours	5:9
Consultant: SAS: trainee: unknown	1:5 : 5:1
Body habitus normal: obese	10:4
Thiopental dose recorded as 'low' or <4 mg/kg	7
Nitrous oxide used yes: no	8:6
Airway difficulty yes: no	9:5*
End-tidal monitoring yes: no	10:4**

A solo anaesthetist was asked to anaesthetise an obese parturient for a Category 1 Caesarean section, late at night in a unit remote from the main hospital. Following a failed spinal, anaesthesia was induced with thiopental and suxamethonium. The induction agents backtracked up the giving set despite the use of an anti-reflux valve. There was no one available to prepare more induction agent. Intubation was difficult with multiple attempts made. Finally an LMA was inserted and sevoflurane in 50% oxygen and nitrous oxide was used to maintain anaesthesia. On waking the patient was very distressed and reported feeling the attempts at intubation and a feeling of both paralysis and suffocation during bag-mask ventilation. She subsequently developed a new anxiety state following what she considered to be a near-death experience.

A trainee was called to administer general anaesthesia for an urgent forceps delivery and performed a rapid sequence induction with thiopental and suxamethonium. However, the intravenous giving set became occluded during injection. Later, the patient recalled having something "rammed down my throat" but nothing after that – an experience lasting a few seconds. She did not seem perturbed by the experience, understanding the need to deliver her baby as rapidly as possible.

16.26 In four cases, spinal or epidural anaesthesia had failed, necessitating general anaesthesia, and in two cases the anaesthetists at the time considered that neuraxial blockade was contra-indicated. In 4 of 10 Category 2–4 Caesarean sections the Panel could find no reason why general rather than regional anaesthesia was chosen. Indeed in one case the patient had an epidural in situ for labour, one was an elective case, (when there would have been no pressure of time necessitating the use of general anaesthesia) and in one difficult intubation had been anticipated pre-operatively.

A patient with a previous history of neurosurgical intervention was booked for a 'patient choice' elective Caesarean section and general anaesthesia, but presented in labour prematurely during the night. The urgency was classified as category 3 (i.e., needing early delivery but no threat to mother or fetus). Surgery was delayed until the patient was fasted. The trainee anaesthetist did not record an airway assessment, but proceeded with a rapid sequence induction, during which tracheal intubation failed. Ventilation was easy, and after two intubation attempts the patient was woken up and senior help summoned. The patient subsequently underwent awake fibre-optic intubation for the operation. After surgery the patient reported that she had been awake and paralysed during the failed intubation and heard conversation relating to the events. She was terrified. She developed a new anxiety state and was referred for counselling.

16.27 In seven of the 12 Caesarean section cases there was concern expressed by the Panel that the dose of thiopental was low. In one case the thiopental dose was <3 mg/kg given to an obese woman who subsequently also developed bronchospasm. In another, thiopental 300 mg was administered to a patient in whom difficult intubation was anticipated.

16.28 Nitrous oxide was used in 57% of AAGA reports (Table 16.1) compared to >70% of Caesarean sections in the Activity Survey.

16.29 There were several cases of human error. As seen elsewhere (Chapter 8, Induction), in two cases there was a delay in turning on the volatile anaesthetic following induction.

An obese parturient underwent a Category 1 section in the early hours. General anaesthesia was chosen as there was a history of spinal injury. Induction employed what was described as 'a small hypnotic component'. There was a delay of a few minutes before the sevoflurane vaporiser was turned on and from the start a total gas flow of <1 L/min was used in a circle system, with 50% oxygen in air and opioids given only after delivery. At the routine anaesthetic follow-up the next day, the patient recalled a painless sensation of being cut and being unable to communicate or move that lasted a few minutes. There appeared to be no adverse sequelae at the time of reporting.

16.30 There were two cases involving syringe swaps, (both emergency procedures), which are also discussed elsewhere (Chapter 13, Drug Errors). In one a large dose of intravenous lidocaine was given instead of an antibiotic during surgery complicated by massive haemorrhage. In another antibiotics were given instead of thiopental.

An unwell patient with pre-eclampsia considered severe enough to preclude neuraxial blockade was anaesthetised by a consultant for a category 2 Caesarean section out of hours. The anaesthetist had spent several hours pre-operatively stabilising the blood pressure with anti-hypertensives. The unit's protocol had recently changed to recommend antibiotic therapy before skin incision, so cefuroxime was drawn up ready for administration. For induction, the anaesthetist administered magnesium, fentanyl, rocuronium and in error, cefuroxime, instead of thiopental. After the cords were sprayed with lidocaine before intubation, the lack of hypnosis was noted. Thiopental 375mg was then given. The anaesthetist questioned the patient in recovery who recalled that she had been aware of the laryngoscope being inserted and wondered 'if she should have been asleep for this bit'. She was not worried by the experience as she trusted the clinicians who had been looking after her for several hours.

16.31 The duration of AAGA was brief. In all but one case the episode lasted <5 minutes and in ten cases a few seconds only.

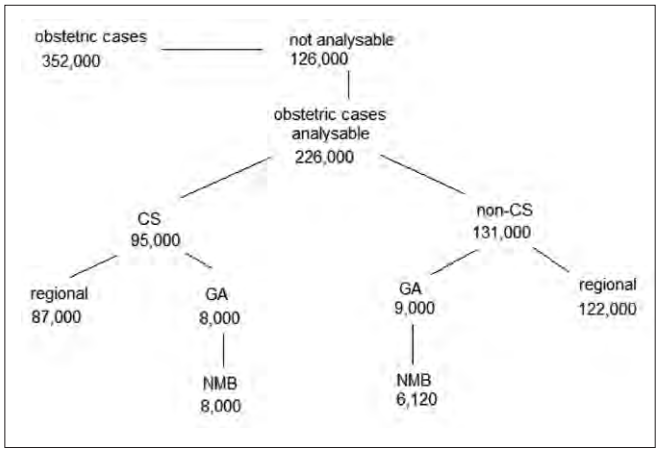
16.32 In three (21%) cases, new significant psychological morbidity was reported: in ten cases there were apparently no sequelae. In one case the patient had indicated a decision to litigate at the time of the report, which may indicate an adverse psychological impact.

Data limitations

16.33 The denominator for obstetric and Caesarean section cases is less robust than for other sections of the NAP5 project. This section explains this is some detail – for clarity. However as Figure 16.2 below indicates the possible under-estimation of the denominator has little major impact on estimates of incidence.

16.34 A problem with the Activity Survey specifically for obstetric data, was the number of uninterpretable forms (Figure 16.2). Of the estimated 352,300 obstetric cases annually, there were 17,000 general anaesthetics. However on 34% of the forms collected, further details were absent; a marked increase compared with other specialties. This leads to concerns about the accuracy of the denominator (and in turn the estimated incidences we calculate). To try to address this we compared our denominator for obstetric activity with HES data. Because the HES data covers only England, whereas the Activity Survey included the whole UK, we used a multiplier (based on populations of the various countries) of 1.2 to estimate UK-wide 'modified HES' activity.

Figure 16.2. Flowchart of cases from the Activity Survey of obstetric activity. CS = Caesarean section; GA = general anaesthesia; NMB = neuromuscular blocking drug



16.35 In the Activity Survey data non-Caesarean section regional anaesthesia cases were likely to have been mainly neuraxial blocks for labour analgesia. The type of non-Caesarean section procedures carried out under GA is uncertain but may have been for examination under anaesthesia, manual removal of placenta, control of haemorrhage or just wrongly coded.

16.36 To complicate matters further, the authors of the HES data have also raised concerns about their accuracy: specifically, regarding the data on general anaesthesia for obstetric procedures that are not Caesarean sections it is noted that the data '… should be treated with caution as these represent unlikely events' (www.hscic.gov.uk/catalogue/PUB12744).

16.37 The Activity Survey included 2,880 obstetric cases that apparently received general anaesthesia without neuromuscular blockade. These are hard to explain as intubating the trachea without muscle relaxation in the obstetric population would be considered negligent by the majority of UK anaesthetists.

Table 16.2. Incidence of AAGA based on Activity data denominators. CS = Caesarean section; GA = general anaesthesia

	Estimated annual	AAGA	
	Number of cases	Number	Incidence
All obstetric GAs	17,000	14	1:1,200 (0.08%)
CS under GA	8,000	12	1:670 (0.15%)
GA for other procedures	9,000	2	1:4,500 (0.02%)

16.38 There are concerns about both the Activity Survey obstetric data and the HES obstetric data (see above). We therefore present the obstetric data in two ways: firstly using the assessable Activity Survey data as a denominator and secondly using the 'modified HES data' (i.e. corrected for UK population) see Table 16.3. This leads to two sets of incidences with that based on NAP5 being higher than that based on HES data. We hope that in the future more precise data on national obstetric general anaesthesia activity will clarify this.

Table 16.3. Comparison of Hospital Episode Statistics (HES) data with Activity Survey data for obstetric activity. GA = general anaesthesia; LSCS = lower segment Caesarean section; regional = neuraxial block; *** = specified by HES as instrumental and spontaneous delivery

	Activity Survey estimate	HES data estimate*	Ratio HES Activity Survey:	Modified HES: Activity Survey ratio**
Total GAs	17,000	19,100	1.12	1.35
GAs for LSCS	8,000	9,194	1.15	1.38
GAs for non-LSCS***	9,000	9,538	1.06	1.27

*HES data for England only.
**Each ratio is multiplied by 1.2 (based on population of UK vs England) to provide a comparator ratio of assessable data captured by the Activity Survey compared to modified HES data (i.e. extrapolated to UK population)

16.39 Based on Activity Survey data, the estimated incidence of reports of AAGA during all obstetric general anaesthesia is 1:1,200 (0.08%) which is more than 12 times greater than the overall incidence in NAP5 of ~1:15,000. Incidence based on modified HES data is presented in Table 16.4.

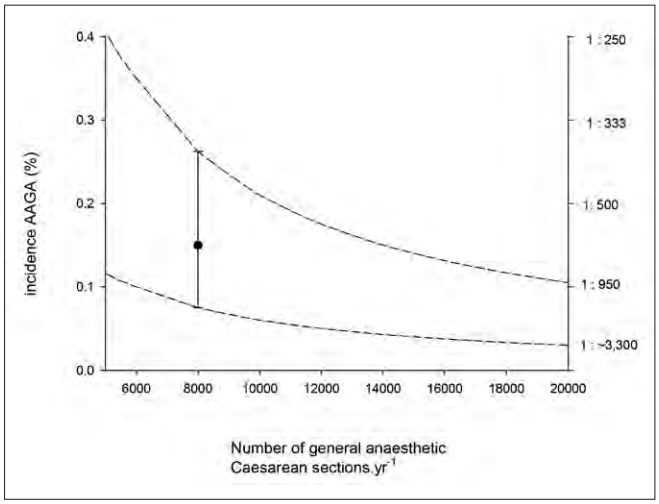
16.40 Using the Activity Survey estimate of 8,000 general anaesthetic Caesarean sections per annum yields an incidence of AAGA in Caesarean section of ~1:670 (0.13%) (Table 16.4). This estimate is about half the incidence estimated by Paech et al. (2008), of ~1:384, using the Brice survey in obstetric practice. The incidence based on modified HES data is presented in Table 16.4.

Table 16.4. Comparison of incidence of AAGA for all obstetric cases and for Caesarean section using Activity Survey data and Modified HES data (i.e. corrected for UK population)

	Activity Survey denominator	Modified HES denominator
Incidence of AAGA – all obstetric cases	1 in 1,200	1 in 1,640
Incidence of AAGA – Caesarean sections	1 in 670	1 in 920

16.41 Using Poisson distribution confidence intervals Figure 16.3 shows the effect an underestimate or overestimate of the denominator would have on estimates of incidence of AAGA during Caesarean section. As can be seen, increasing the true denominator (i.e. our estimate being an underestimate) has a rather modest impact on the estimate of incidence of AAGA.

Figure 16.3. Plot of Poisson distribution confidence intervals to indicate how varying denominator (true number of Caesarean sections per year) impacts on the estimate of incidence of AAGA during Caesarean section. The dashed lines indicate the 95% confidence limits for incidence of AAGA assuming the numerator remains stable and the denominator varies. The vertical line indicates the NAP5 estimate of number of Caesarean sections based on the Activity Survey. As can be seen increasing the true denominator (i.e. the NAP5 estimate being an underestimate) has a rather modest impact on the estimate of incidence of AAGA



DISCUSSION

16.42 The data from the Activity Survey yield a denominator for much of NAP5. In the obstetric population however, the assessable denominator data appear to be an under-estimate and incidences of AAGA based on this may be over-estimates by about one third.

16.43 As previously noted many Activity Survey forms for obstetrics were incomplete or un-analysable. This did not apply to any other subset of patients or subspecialty we examined, where attrition rates were <5% at most. Irrespective of this, using denominator data either from the Activity Survey or from HES, indicates that reports of AAGA in obstetrics are markedly more common than in other areas of practice. This is especially the case for Caesarean section.

16.44 For obstetric patients, the gap between reports of AAGA and incidence of AAGA from a Brice questionnaire appear less marked than in other areas of practice. Why this is so is uncertain but one possibility is that post-operative anaesthetic follow-up of patients after Caesarean section is very rigorous, and that perhaps the visit more readily facilitates reporting of AAGA. In this regard, although the delay in reporting had a wide range (up to 22 years), in the majority of cases the patient reported the episode either on the same or the next day. Three reports

were made to the anaesthetist involved in patient care, whilst five cases were reported during the routine postnatal anaesthetic round the following day.

16.45 In other chapters (Chapter 8, Induction and Chapter 7, Risk Factors) rapid sequence induction, especially with thiopental, neuromuscular blockade and difficult airway management is identified as a risk factor for AAGA. This is likely to contribute to the increased incidence of AAGA seen in obstetric anaesthesia. In the obstetric population RSI with thiopental followed by neuromuscular block is routine practice, and the incidence of failed intubation is reported to be ~1 in 224 (Quinn et al., 2013).

Rapid sequence induction is a risk factor for AAGA in obstetric anaesthesia, as it is in other specialties

16.46 A recurring theme in the Induction section of this Report is the need to 'mind the gap' (Chapter 8, Induction). In emergency Caesarean section during general anaesthesia, an anaesthetic room is rarely used, and the 'obstetric gap' refers to the very short period between induction of anaesthesia (by RSI) and the start of surgery. This is a period when rapid redistribution of the intravenous induction agent and slowly increasing partial pressure of the volatile anaesthetic may lead to a gap in effective anaesthetic depth. Delays in starting the volatile agent (difficult airway management, delay in turning on the agent or a slow 'wash-in' due to low flow techniques) will exacerbate this effect and increase the risk of AAGA.

16.47 Syringe swaps accounted for 14% of obstetric AAGA cases and both cases involved antibiotics. In one, a recent change of policy led the anaesthetist to change practice and draw up the antibiotic before delivery, making the possibility of syringe swap more likely. In the other case, the urgency of the case was a distracting factor.

16.48 There is good evidence that general anaesthesia for emergency obstetric procedures is associated with greater maternal mortality than central neuraxial blockade (Ginosar et al., 2005). Yet, in a proportion of cases there appeared to be no apparent indication for choosing general anaesthesia and indeed, sometimes good reason to avoid it. The relative risks and benefits of regional versus general anaesthesia always need to be considered, with the risk of AAGA amongst the latter. A failed regional anaesthesia followed by difficult general anaesthesia includes the risks of both and such circumstances were also not infrequent in reports to NAP4 (Cook et al., 2011). Such a situation might usefully be highlighted as a time of increased risk for both airway and AAGA complications and one in which senior staff should be involved rather than automatically proceeding to general anaesthesia.

16.49 The Activity Survey shows that 2–3% of Category 3 Caesarean sections are undertaken by trainees out of hours. There is rarely any indication to undertake elective high risk cases (including those at increased risk of AAGA), out of hours by single-handed trainees. The timing of such cases should be decided by discussion between consultant obstetric and consultant anaesthetic staff, and in most instances with care delivered by consultants.

16.50 In some cases, the need to care for their new-born seemed to ameliorate the adverse impact of AAGA on the patient. A trusting relationship between clinician and parturient prior to the episode of AGAA exerted an apparently highly protective effect. Some of the comments reported in Statement Only cases (see Chapter 6, Main Results) may still be relevant today. One woman did not report the event for nearly 50 years because she did not want to '*get the anaesthetist into trouble*'. Another '*did not want to make a fuss*', '*I thought being awake was inevitable*'.

16.51 In most of the more contemporaneous reports, end-tidal concentrations of anaesthetic agent were monitored, both during induction and maintenance. Nitrous oxide was used in a smaller proportion of obstetric AAGA cases than in the Activity Survey.

16.52 The use of specific DOA monitoring during obstetric general anaesthesia appears very sparse (in the Activity Survey, the only use of a DOA monitor in obstetric practice was a single use an E-entropy monitor in just one non-Caesarean section case). This may reflect lack of confidence that such monitors provide clinically useful information (Pandit & Cook, 2013), or the perceived

impracticality (because of slow response time) of using such monitors in obstetric practice. However, in the cases studied by the ANZCA group, one-third of patients received DOA monitoring, none of whom experienced AAGA (Paech et al., 2008), suggesting practices vary internationally.

16.53 In summary, obstetric anaesthetic practice differs in several ways from other areas of practice, and anaesthetists providing obstetric anaesthesia must manage a unique combination of challenges. Factors, some of which are unavoidable, contributing to an increased risk of AAGA include:

(a) Rapid sequence induction.

(b) Use of thiopental (in inappropriately low doses in some cases).

(c) Use of neuromuscular blockade.

(d) Increased risk of difficult airway management.

(e) Increased incidence of obesity.

(f) A short period between anaesthetic induction and start of surgery.

(g) A high rate of category 1 and 2 Caesarean section and surgery performed out of hours resulting in high rates of non-consultant care.

16.54 This combination of risk factors is particular if not unique, to current obstetric anaesthetic practice. Obstetric anaesthesia should continue to be regarded as a high risk sub-specialty for AAGA.

The roles of thiopental vs propofol for induction in obstetric anaesthesia could usefully be examined

IMPLICATIONS FOR RESEARCH

Research Implication 16.1
Studies are required to further establish the optimal dose of thiopental for obstetric induction.

Research Implication 16.2
Further studies are required to assess the effect of propofol as an anaesthetic induction agent in the compromised mother and fetus.

Research Implication 16.3
The safe minimum inspired oxygen fraction during general anaesthesia for Caesarean section, especially in the presence of suspected fetal compromise, needs to be established to guide the maximum recommended fraction of nitrous oxide.

Research Implication 16.4
Further research is needed on the effect of syntocinon infusions to maintain uterine tone when high concentrations of volatile agent are used.

Research Implication 16.5
Further research is needed to clarify the optimum timing and dosing of opiates during anaesthesia for Caesarean section.

Research Implication 16.6
Further research is needed more clearly to define the incidence of AAGA as identified by the Brice questionnaire in the obstetric population.

Research Implication 16.7
Further research is needed to explore whether factors make obstetric patients more likely to report episodes of AAGA than the non-obstetric population; perhaps to improve self-reporting rates in the latter.

RECOMMENDATIONS

RECOMMENDATION 16.1
Anaesthetists should regard obstetric patients, particularly those undergoing Caesarean Section, as being at increased risk for AAGA. This risk should be communicated appropriately to patients as part of the consent process.

RECOMMENDATION 16.2
Consideration should be given to reducing the risk of AAGA in healthy parturients by (a) the use of increased doses of induction agents (b) rapidly attaining adequate end-tidal volatile levels after induction without delay (c) use of nitrous oxide in adequate concentrations (d) appropriate use of opoids (e) maintaining uterine tone with uterotonic agents to allow adequate concentrations of volatile agents to be used.

RECOMMENDATION 16.3
Before induction, the anaesthetist should have decided what steps to take if airway management proves difficult, with maternal wellbeing being the paramount consideration, notwithstanding the presence of fetal compromise. An additional syringe of intravenous hypnotic agent should be immediately available to maintain anaesthesia in the event of airway difficulties, when it is in the mother's interest to continue with delivery rather than allow return of consciousness.

RECOMMENDATION 16.4
Anaesthetists should regard failed regional technique leading to the need for general anaesthesia for obstetric surgery to be an additional risk for AAGA (and for other complications).

RECOMMENDATION 16.5
Anaesthetists should regard the presence of antibiotic syringes during obstetric induction as a latent risk for drug error leading to AAGA. The risk can be mitigated by physical separation, labelling or administration of antibiotics by non-anaesthetists. Using propofol for induction mitigates the risk of this drug error.

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CHAPTER
17

AAGA during general anaesthesia in intensive care


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Tim M Cook

HEADLINE

17.1. There were seven case of AAGA reported during intended general anaesthesia in critically ill patients in the Intensive Care Unit or Emergency Department. Themes included underestimating anaesthetic requirements in sick, obtunded or hypotensive patients. Problems also arose when low-dose propofol infusions were used to maintain anaesthesia for procedures or transfers. All patients were paralysed during their AAGA and experienced distress or psychological harm. Most episodes were judged to be avoidable.

BACKGROUND

ICU and NAP5

17.2 Critically ill patients admitted to intensive care units (ICUs) are often deeply sedated for relatively prolonged periods (e.g. days or weeks) to reduce the discomfort caused by tracheal tubes or to increase patient compliance with mechanical ventilation (Samuelson et al., 2006; Rowe et al., 2008). This is in contrast to the predominantly healthy elective surgical population who undergo short episodes of general anaesthesia for definitive procedures.

17.3 Common practice is to use continuous sedation for prolonged ventilation and other invasive organ support (Payen et al., 2007; Jackson et al., 2010). This is not intended to be 'anaesthesia', since complete unconsciousness is not intended. During periods of critical illness and recovery the level of sedation is often intentionally varied. It would be expected for patients to have clear awareness of their surroundings and events during much of their recovery.

17.4 It is widely recognised that patients may have distressing recall of their time on ICU (Schelling et al., 1998; Jones et al.,1979; Jones et al., 2001). Notwithstanding the importance of this topic, NAP5 restricted itself to the examination of awareness *during general anaesthesia* and therefore this aspect is outwith its remit.

17.5 Many invasive procedures (e.g. tracheal intubation, tracheostomy, transfer of patients for procedures outside ICU, surgical procedures) are performed on ICU patients using general anaesthesia. NAP5 therefore did include reports of AAGA arising from ICU patients during procedures performed with intended general anaesthesia. We also included reports that arose during the initiation of intensive care management (which might have been in the emergency department (ED) or elsewhere outside ICU), and reports that related to the transfer of patients to and from the ICU. We classed all these as 'ICU reports' (Class D).

17.6 Critical illness is associated with rates of delirium as high as 83% (Ely et al., 2001). Delirium can lead

to the formation of delusional memories (Jones et al., 2000), which can persist beyond the duration of critical illness (Jones et al., 2001). This makes separating false or distorted memories from fact difficult, and means that investigating reports of AAGA in ICU is a significant challenge.

Therefore, the purpose of this chapter is to:

(a) Present the reported cases of AAGA in the intensive care population.

(b) Discuss any inferences that can be made from the data and highlight any areas in which improvements in management might be made.

AAGA and critical illness

17.7 Because of their critical illness and actual or potential organ failure, there are likely to be physiological and pharmacological factors that influence safe conduct of general anaesthesia and may predispose these patients to AAGA. Organisational and cultural aspects of ICU care might influence this risk too.

17.8 Induction of anaesthesia in critically ill patients poses several problems. First, during the early phase of their illness, patients can often present with a combination of hypovolaemia, vasodilatation, hypotension and organ failure. Use of standard doses of anaesthetic induction agents risks cardiovascular complications including further hypotension, myocardial depression, cardiovascular collapse, deterioration of organ function or cardiac arrest. Most induction and sedative agents have a dose-dependent effect on blood pressure in the healthy population (Sebel & Lowden, 1989; Grounds et al., 1985; Battershill et al., 2006; Win et al., 2005) and this is exaggerated in the critically ill (Aitkenhead et al., 1989).

17.9 Jaber et al. (2006) examined 253 ICU tracheal intubations with a variety of intravenous induction agents, and reported a 25% rate of cardiovascular collapse (systolic BP <65mmHg, or <90mmHg for >30 minutes despite fluid loading) and 2% rate of cardiac arrest. An observational study of 410 ED emergency tracheal intubations reported a cardiac arrest rate of 4.5% (Heffner, 2013). In contrast, the cardiac arrest rate in the elective anaesthetic population is reported to be 0.014% (1.4:10,000) (Newland et al., 2002).

17.10 Secondly, critically ill patients may be obtunded as a result of their illness, further complicating an assessment of required drug dosages. In several studies, tracheal intubation on the ICU occurred in between 7% and 9% without the use of an induction agent (Jaber et al., 2006, Koenig et al., 2014).

17.11 Airway difficulty or failure in critically ill patients is increased compared with the operating theatre setting (Cook et al 2011a and b; Nolan & Kelly, 2011). Contributory factors likely include the almost universal need for rapid sequence induction (RSI), lack of respiratory reserve, inexperienced personnel and environmental factors (Cook et al 2011a and b).

17.12 As a consequence of the above factors, it is a common and rational practice to reduce the dose of induction agent used for induction of anaesthesia in the critically ill (Reschreiter et al., 2008). In a recent study of 472 urgent tracheal intubations on a medical ICU (Koenig et al., 2014), propofol was used as a sole agent in 87% of cases with a mean dose of 99 mg (1.4 mg/ for a 70 kg adult). Rates of AAGA were not reported. In recent years ketamine has increased in prominence as an induction agent for the critically ill as it better maintains cardiovascular stability, but judging point of loss of consciousness can be difficult (Smischney et al., 2012).

17.13 The trend in management of critically ill patients is to minimise the depth and duration of sedation and, even in the most heavily sedated, to periodically interrupt sedation to assess cognitive function and minimise drug loads (Reschreiter et al., 2008; Jackson et al., 2010; Barr et al., 2013; Strøm et al., 2010; Kress et al., 2000). However, many critically ill patients require general anaesthesia for painful procedures, surgical interventions and for transfer outside the ICU for investigations or treatment. It is likely that practice varies between ICUs and the number of general anaesthetics administered on ICUs or for transfer is unknown.

17.14 AAGA may occur when general anaesthesia is administered to ICU patients for specific procedures. Many of the reasons described above regarding AAGA at tracheal intubation also apply here. Further factors potentially predisposing to AAGA might include: the necessity to use intravenous anaesthesia, the absence of anaesthetic machines, the absence of nitrous oxide, lack of an endpoint when inducing anaesthesia in an already obtunded or already sedated patient, the complexity of providing anaesthesia while 'in motion' for transfers, and on-going physiological instability and organ dysfunction which alter safe dosing, pharmacokinetics and pharmacodynamics.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

17.15 The NAP5 Activity Survey provides an estimate of 29,000 general anaesthetics per year administered (by anaesthetists) in either the ICU or the ED (equivalent to ~1% of all UK anaesthetist-delivered general anaesthetics), and 54% involved RSI.

17.16 Of the 308 cases reviewed by the NAP5 panel, 7 (2.3%) cases involved intensive care patients either in ICU (three cases), ED (two cases) or during a transfer from ICU (two cases). Five reports involved female patients and five involved a morbidly obese patient (BMI 45–60 kg/ m^^2) All of these reports were considered to be based on high quality (grade A) evidence.

17.17 In four cases anaesthesia care was provided by a consultant intensivist or anaesthetist and in the remainder by anaesthetic/ICU trainees ranging from CT1 to ST6.

Reports at intubation

17.18 There were three cases where AAGA occurred around the time of induction and intubation; RSI was used in all cases.

17.19 AAGA was reported by two peri-arrest patients (one during CPR) and by several patients during documented profound hypotension.

17.20 In several cases the dose of induction agent (or even its complete omission) made the possibility of AAGA likely, and in several reports both the LC and the Panel judged the dose of induction agent was too low.

17.21 In only one of the seven reports of AAGA in ICU were vasopressors or inotropes used to support the cardiovascular system during induction of anaesthesia. Three reports described recall of induction of anaesthesia and tracheal intubation. All three patients received non-depolarising neuromuscular blockade after initial suxamethonium administration. In one case, in a peri-cardiac arrest situation, a neuromuscular blocking drug was administered as a sole agent to facilitate tracheal intubation. In the other two cases, propofol (+/- ketamine) was used for induction with doses of approximately 0.4 mg/kg and 1.2 mg/kg respectively.

An otherwise healthy middle-aged patient, was tracheally intubated in the ED for management of acute severe asthma. An RSI was conducted by an anaesthetic trainee with ketamine 20mg, propofol 30mg and suxamethonium followed by rocuronium. Significant hypertension was present immediately after intubation requiring further boluses of propofol before a propofol infusion was started. The following day after exubation the patient reported being aware throughout the entire intubating process lasting several minutes.

A middle-aged, obese patient collapsed due to arrhythmia after a procedure performed under local anaesthesia. Intubation was attempted, initially unsuccessfully without medication and then successfully after administering suxamethonium. Isoflurane anaesthesia was then commenced and a central line inserted. The patient was then transferred to radiology and anaesthesia was maintained with low dose boluses of propofol and continued neuromuscular blockade. Sedative infusions using a pump were started only after arrival in ICU. When extubated, the patient immediately reported the episode of awareness describing a period of AAGA throughout resuscitation, intubation, and transfer to and from radiology.

17.22 One of the three cases involved difficulty in intubation by a very junior anaesthetist, requiring a second more senior operator to take over. No recorded additional hypnotic agent was administered during intubation until patient 'distress' was noted.

Maintenance of anaesthesia and transfer in the critically ill

17.23 Two reports described events likely to have occurred soon after intubation (insertion of invasive monitoring lines, nasogastric tube insertion, patient transfer) and two during interventions performed later on during their stay.

17.24 In all these cases a neuromuscular blocking drug was administered before the episode of AAGA.

A middle-aged patient on chronic multiple opiate and benzodiazepine medications was anaesthetised in the ED for management of severe pneumonia. Modified RSI and tracheal intubation was followed by initiation of neuromuscular blockade and an infusion of propofol at 100mg/hr. The patient was transferred to radiology. After extubation the following day the patient reported awareness of events after intubation, including arterial line insertion, transfer and positioning in radiology (but not tracheal intubation).

A middle-aged, morbidly obese, patient required urgent endoscopy for bleeding. After tracheal intubation with a modified RSI and neuromuscular blockade, anaesthesia was continued by administration of a bolus dose and a propofol infusion at 100mg/hr. The patient subsequently reported AAGA throughout the procedure lasting at least 30 minutes. The patient reported inability to move and that they were "trying to move to tell them to stop". Movements eventually alerted staff to the patients wakefulness. The patient suffered psychological distress as a result of the experience.

17.25 In all four cases, hypnotics were administered by infusion: propofol in three cases and midazolam/fentanyl in one. Depth of anaesthesia (DOA) monitoring was not used in any of the cases.

17.26 Perhaps notably, all patients reporting AAGA on ICU received only a short duration of sedation and mechanical ventilation, lasting approximately 24 hours. Most reports were made soon after extubation and all within four days of the event.

17.27 In addition to the seven reports from ICU and ED there were three further Certain/probable cases (Class A) that involved transfer of a post-operative patient to ICU. AAGA occurred during transfer in two of these cases and either during emergence or transfer in the third. All involved transfer with anaesthesia maintained with a low dose non-TCI propofol infusion. All were judged definite AAGA and were judged preventable. All involved neuromuscular blockade, all involved patient experience of paralysis, two involved patient distress and two led to prolonged psychological sequelae. The cases have very similar themes to the ICU cases.

Transfer of ventilated patients often requires paralysis. If adequate anaesthesia is not also provided the patient may experience AAGA. A low dose fixed rate propofol infusion may not guarantee anaesthesia

Patient experiences and psychological effects

17.28 Patient experiences of AAGA were assessed using the Michigan scoring system. All patients experienced distress during the episode of awareness, characterised by fear, anxiety and/or a feeling of suffocation. Two patients reported paralysis and distress without pain (Michigan score 4D) and five reported pain, paralysis and distress (Michigan score 5D) (Mashour et al., 2010).

A patient experienced AAGA during transfer and a procedure performed in radiology. The patient reported awareness throughout the procedure, including the painful insertion of a drain, which was described as "something exploding in my tummy".

The patient recalled something being pushed down his throat and the sensation of being strangled, lasting several minutes.

After reporting an episode of AAGA the patient self-discharged from ICU. The patient described the episode which occurred during intubation as "one of the worst things I have ever been through" and as "really hurting". The patient stated "I have never been so scared in my life and I was scared during my whole stay."

17.29 The degree of longer-term harm as assessed by the modified NPSA scale was moderate or severe in five of seven cases.

17.30 The NAP5 panel judged four of these seven cases of AAGA to be preventable.

17.31 No reports of AAGA from ICU were judged to be a result of delirium, delusion or false memory.

DISCUSSION

17.32 Because of the structure and focus of NAP5 it is likely that reports of AAGA occurring in ICU were less likely to be captured than those in an anaesthetic environment. The complexity of ICU interventions inevitably means that the line between what is judged an 'intervention' and 'maintenance treatment' is a fine one.

17.33 NAP5 received seven reports of AAGA arising from general anaesthetics administered in the ICU or ED and, as the Activity Survey estimates 29,000 general anaesthetics are delivered in these departments per year in the UK, the apparent

incidence of reports of AAGA in this population is ~1 : 4,100. However there are major caveats to this estimate. First, the Activity Survey did not include tracheal intubation for initiation of critical care management as an anaesthetic procedure, and it is also likely that the activity survey may not have captured all general anaesthesia used for patient transfers. Second, on receiving a report of possible AAGA in an ICU patient, clinicians had to judge if the report related to a period of maintenance (not reportable to NAP5) or to an intervention (reportable to NAP5): this may have been difficult. Third, as with all incidences reported in NAP5, it should be noted that all estimates relate to reports reaching clinicians, rather than absolute incidences of AAGA. The fact that no reports were made after prolonged delays after the experience raises the possibility that delayed memories (discussed in Chapter 7, Patient Experience) may be responsible for under-reporting.

17.34 The small number of reports of AAGA from ICU makes inferences difficult. All cases were considered to be supported by high quality evidence, and all involved a clinical setting where general anaesthesia rather than sedation would have been expected/intended. We therefore simply comment on some apparent themes and identify learning points, but do not make recommendations for clinical practice.

Procedures such as percutaneous tracheostomy require general anaesthesia in a critically ill patient, usually performed on the ICU. Both patient and location present challenges for delivery of safe and effective general anaesthesia

Learning points

17.35 All cases where AAGA was reported from the ICU/ED involved critically ill patients. Concerns about the adverse effects of induction of anaesthesia would have been justified. The performed procedures were appropriate and RSI was used appropriately.

17.36 In common with the vast majority of anaesthetic reports, all cases of AAGA from ICU involved patients who had received a neuromuscular blocking drug, so when used, the risk of AAGA should reasonably be considered higher.

17.37 All ICU reports were associated with distress and the majority with subsequent psychological harm. This should guide a supportive approach to an ICU patient who reports AAGA (see Psychological Support Pathway, Chapter 7, Patient Experience).

17.38 AAGA in the critically ill may occur despite cardiovascular instability. Early support of the cardiovascular system that then enables increased doses of anaesthetic agents is likely to reduce distressing AAGA.

Early use of fluids and vasopressors may enable effective doses of anaesthetic to be administered. However, in critically ill patients this may be a particular challenge

17.39 Critical illness, leading to an obtunded mental state also does not guarantee absence of consciousness that retention of a memory for events. This implies the pathological brain state preventing spontaneous or reflex movement does not inevitably prevent perception. Even patients with lowered conscious levels should receive adequate anaesthesia for intubation and surgical procedures where this is safe.

17.40 Where critical illness demands a significant reduction in the doses of anaesthetic agents that can be safely administered, the possibility of wakefulness should be considered. Patient explanation and reassurance are likely to be of benefit to patients experiencing AAGA.

17.41 Notwithstanding these comments, the Panel noted that AAGA during anaesthesia in the critically ill may not be completely avoidable without putting patients at risk of major harm from the cardiovascular complications of anaesthetic agents.

17.42 In several cases AAGA arose soon after intubation and involved infusions of propofol (without opioids) in patients who had received neuromuscular blocking drugs. Delay in starting infusions and use of very low dose infusions contributed. Patients receiving low dose non-TCI infusions of propofol while paralysed are likely to be at increased risk of AAGA (see Chapter 18, TIVA). Use of TCI infusions might lead to more appropriate doses of anaesthetic agent being administered. Using a checklist prior to intubation (such as that described in NAP4, (Cook et al., 2011c), or a checklist as suggested in Chapter 8 (Induction), should reduce the risk of delays in initiating appropriate anaesthetic/sedative (and vasopressor/inotrope) infusions.

17.43 There is scope for research in validating the use of DOA monitoring in the critically ill (Nasraway et al., 2002; Vivien et al., 2003). In the Activity Survey, only three patients out of 29,000 undergoing general anaesthesia in ICU or ED received DOA monitoring (one BIS, one entropy and one other; ~1:10,000). It is not known how many UK or Irish ICUs have immediate access to DOA monitoring.

17.44 Delays in starting infusions of anaesthetic agents were on more than one occasion, attributed to distraction. In one case, difficult airway management and a failure to administer extra induction agent, likely contributed to AAGA. Management of critical illness is inevitably complex and is a rich potential source of human factors impacting on delivery of reliable safe care.

17.45 It is notable that all ICU AAGA reports were made by patients who had short ICU stays with a short period of intubation, and that the interval to reporting the episodes was also consistently short. This raises several questions, including the possibility that episodes of AAGA may occur but be forgotten when critical illness or sedation is prolonged.

17.46 Overall the data reported here raise concerns about a higher incidence of AAGA during anaesthesia in patients from ICU than in other settings. However our methodology, which focussed primarily on theatre practice, means we cannot confirm this. Relevant national organisations could usefully consider whether further research should be commissioned to study this important area and whether our learning points could drive recommendations for practice.

IMPLICATIONS FOR RESEARCH

Research Implication 17.1

There is scope for further research on the utility of specific depth of anaesthesia monitoring in the ICU setting. The current access of ICUs to specific depth of anaesthesia monitoring is unknown.

Research Implication 17.2

Research might better establish if anaesthesia induction of the critically ill using drugs such as ketamine (with or without opioid), with intrinsic sympathomimetic properties, can better maintain cardiovascular stability.

Research Implication 17.3

Further research might establish if there is a role for targeted controlled infusions of propofol in both anaesthesia for and transfer of ICU patients.

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CHAPTER
18

Total intravenous anaesthesia

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HEADLINE

18.1. There were 28 Certain/probable or Possible reports of AAGA involving intravenous anaesthesia. In 21 of them total intravenous anaesthesia (TIVA) was used for induction and maintenance of anaesthesia, and in seven the patient received both a volatile anaesthetic and an IV infusion of propofol. Twenty four cases occurred in theatre and an important cause was failure to deliver the intended dose of propofol. One quarter of cases occurred when anaesthesia was initiated or continued outside the operating theatre (where volatile anaesthesia would have been impossible). In these cases the commonest cause of AAGA was the administration to a paralysed patient of an inappropriately low dose infusion, usually as a fixed-rate infusion. More than three-quarters of the 28 cases of AAGA were considered to have been 'preventable'. All anaesthetists need to be skilled in the administration of intravenous anaesthesia, and these results suggest that is not currently the case.

BACKGROUND

18.2 In the UK and Ireland general anaesthesia for procedures in the operating theatre is most commonly induced by administering a bolus of an intravenous anaesthetic drug, and then maintained with an inhaled anaesthetic agent. An alternative technique is to use an intravenous drug for both induction and maintenance of anaesthesia (total intravenous anaesthesia). Propofol is preferred because there is usually a relatively rapid and clear-headed recovery even after prolonged infusion, and for the purposes of this chapter the term TIVA indicates anaesthesia maintained by propofol infusion unless stated otherwise. During some surgical procedures (e.g. on the airway) administration of an inhaled anaesthetic is not practical and TIVA is required.

18.3 In addition when general anaesthesia is administered during patient transfer or in an area which does not have the equipment required to deliver inhaled anaesthesia, TIVA must be used as there is no practical alternative.

18.4 The blood (and therefore brain) propofol concentration required for anaesthesia varies between individuals and cannot be predicted in advance. However, some patterns are evident. Older patients on average require a lower propofol concentration than younger patients, while other anaesthetic, sedative and opioid analgesic drugs reduce drug requirement during surgery (Reves et al., 2007). A co-infusion of remifentanil may be administered and at higher doses markedly reduces the propofol concentration needed for anaesthesia (Milne et al., 2003). More major or stimulating surgery increases the propofol concentration required while effective regional anaesthesia reduces it. The propofol (blood or brain) concentration required for maintenance of anaesthesia

will usually be between 1.5 and 6.0 µg/ml (Reves et al., 2007).

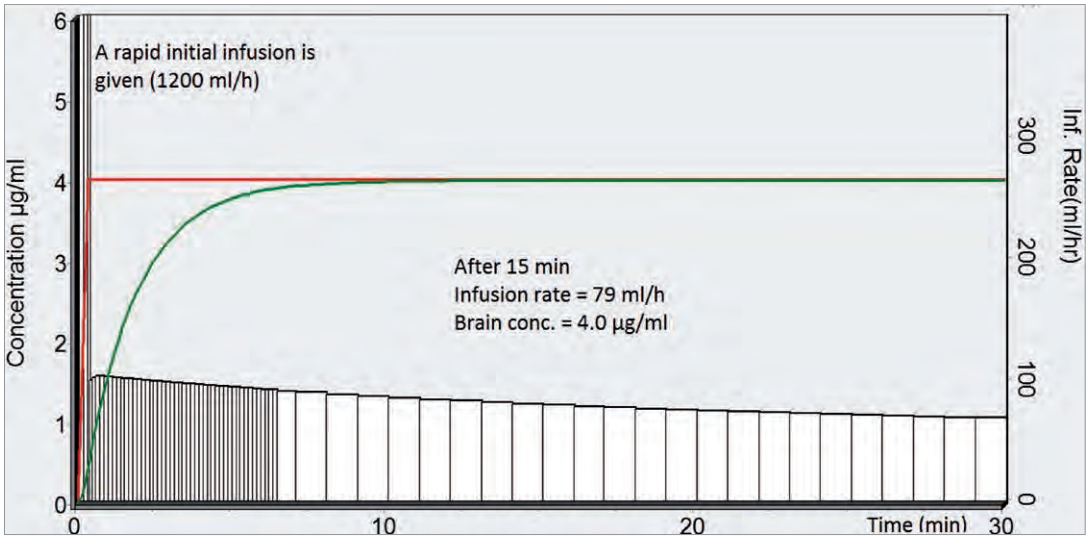
18.5 TIVA may be administered by giving an initial bolus followed by a continuous infusion at a set rate in ml/h or mg/kg/h. Regimens have been designed to maintain a constant blood propofol concentration. For example, Roberts et al. (1988) described a manual infusion scheme for a target blood propofol concentration of 3 µg/ml, consisting of a loading dose of 1 mg/kg followed immediately by an infusion of 10 mg/kg/hour for 10 minutes, 8 mg/kg/hour for the next 10 minutes and 6 mg/kg/hour thereafter. An overall mean blood propofol concentration of 3.67 µg /ml was achieved within two minutes and maintained stable for the subsequent 80–90 minutes of surgery.

18.6 However in practice, adjustments to vary the blood propofol concentration are often necessary in response to clinical signs and/or the output of a depth of anaesthesia (DOA) monitor. Making such adjustments is awkward when a manual infusion regimen such as that of Roberts et al. (1988) is used. To increase the blood propofol concentration an additional bolus is required followed by a higher infusion rate. However, it can be difficult to calculate the necessary size of bolus and new infusion rate. To decrease the blood propofol concentration the infusion is paused for a period and then resumed at a lower infusion rate. Again, calculating how long to stop the infusion for and how much to reduce the rate by can be difficult.

18.7 The first commercially available target controlled infusion (TCI) system, the 'Diprifusor' (Glen, 1998), was introduced in 1996 for the induction and maintenance of anaesthesia in adults. TCI pumps incorporate a pharmacokinetic model of the distribution of propofol in the body and its elimination from the body. The anaesthetist enters patient variables such as the body weight and the required blood concentration 'target'. The software in the pump then calculates the size of the bolus (delivered as a rapid infusion) and the infusion rates required to achieve and maintain this. The actual blood propofol concentration typically differs somewhat from the calculated concentration displayed by the pump, but raising or lowering the blood concentration is easier than with a manual infusion regimen. The anaesthetist simply increases or decreases the target blood concentration. Administration of propofol by TCI pump has become a commonly used technique for TIVA in the operating theatre in the UK and Ireland.

18.8 TCI pumps also display the brain or effect site concentration of propofol, and in some pumps a target effect site may be chosen rather than a target blood concentration. Different pharmacokinetic models may be incorporated in the pumps, and there is debate about which achieves the closest match between the calculated and actual propofol concentrations. Figure 18.1 shows a simulation of the blood and effect site concentrations over the first 30 minutes of an anaesthetic.

Figure 18.1. Pharmokinetic simulation of an anaesthetic in which the target blood propofol concentration in a 70 kg patient is set to 4 µg/ml and then left unchanged. Time in minutes is on the x-axis and propofol concentration on the y-axis. The red line is the calculated blood concentration and the green line the calculated brain or effect-site concentration. The white blocks show the infusion rate of 1% propofol in ml/h as indicated on the y-axis on the right (TIVAtrainer Marsh pharmacokinetic model with a blood-brain equilibration rate constant of 0.6/min)



18.9 There are several methods by which TIVA anaesthesia may be administered (intermittent bolus, fixed rate infusion, infusion based on a manual algorithm, TCI and mixtures of these). This means that TIVA-anaesthesia may encompass several heterogeneous techniques, which might not be equivalent in efficacy or safety, and may hamper understanding of the technique. We are not aware of any robust recommendations that make one of these techniques the 'standard'.

18.10 There has been debate about whether or not the use of TIVA is associated with a higher incidence of AAGA than an intravenous induction/volatile maintenance technique. Sandin and co-workers reported similar incidences of AAGA with both techniques in their studies (Sandin et al., 2000; Nordström et al., 1997). However, other studies have suggested that the incidence of AAGA may be higher with TIVA (Errando et al., 2008, Morimoto et al., 2011)

18.11 Whereas with inhaled anaesthetic drugs the end tidal anaesthetic gas (ETAG) concentration may be continuously measured and displayed, similar monitoring is not available for TIVA. If the delivery of propofol to the patient is interrupted for example by disconnection between the infusion tubing and intravenous cannula, then this may go undetected as the infusion pump will continue to display adequate delivery, and alarm systems do not recognise this problem (Safe Anaesthesia Liaison Group, 2009). Table 18.1 lists some of the possible problems that can arise with delivery of the IV anaesthetic.

18.12 One potential advantage of TIVA is that it ensures a continuous delivery of anaesthetic from the moment of induction. In contrast, a technique of intravenous induction followed by volatile anaesthetic maintenance necessarily involves a period when the former is switched to the latter. The concentration of intravenous agent declines while the concentration of volatile anaesthetic rises but there is potential for a 'gap' during which inadequate anaesthetic is administered. This is more likely if there is a delay in starting the volatile agent (e.g. a delay in turning on the vaporiser) or a delay in the agent reaching the patient (e.g. prolonged airway management). A similar gap may occur on changing from a volatile to an intravenous anaesthetic for instance for transfer at the end of surgery.

18.13 Because of the problems inherent in monitoring TIVA delivery, discussed above, the use of specific DOA monitoring is often recommended when TIVA is used. The National Institute for Health and Care Excellence (NICE) expressed the view that patients receiving TIVA were not at higher risk of AAGA, but recommended that the use of DOA monitors should be an option in these patients (NICE, 2012).

Table 18.1. Potential problems with drug delivery from intravenous anaesthesia pumps

Problem	Prevention / Detection / Solution
IV cannula disconnection or 'tissuing' (i.e. subcutaneous rather than IV infusion)	Cannula or central venous catheter visible and accessible during procedure
Disconnection of infusion tubing from pump or at an intermediate connection point	Pump and tubing connections visible; use of Luer lock syringes
Low battery / pump paused	Modern pumps usually have an audible alarm
Occlusion of IV cannula; tap or clamp closed	Pump high infusion pressure alarm
'False' occlusion alarm because of small cannula or long infusion tubing	Adjustable high infusion pressure alarm and users trained in their adjustment
'Backtracking' of propofol into intravenous fluid infusion tubing when the infusions are given through the same cannula/catheter lumen	One-way valves to prevent back-tracking
Use of 1% propofol in a pump which has been programmed for the use of 2% protocol or vice versa	Stocking of only one concentration of propofol
When using infusions of both propofol and remifentanil, insertion of the propofol syringe into the pump programmed for remifentanil and vice versa.	Prominent pump displays with the drug name and perhaps colour-coding of the pump LCD displays to match the colour of the syringe labels

Pump programming errors may lead to failure to deliver intended anaesthesia during TIVA and risk AAGA

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

18.14 The distribution of reports of AAGA by anaesthetic technique (volatile vs TIVA +/- neuromuscular blockade +/- processed EEG monitoring) is discussed in detail in Chapter 20, DOA and is not repeated here.

18.15 In the Activity Survey (Sury et al., 2014), 5.8% of general anaesthetics were by propofol infusion. In theatres 90% of these were TCI techniques, while in radiology, intensive care units (ICU) and emergency departments (ED) only 18% were.

18.16 In Class A and B there were 28 reports of AAGA associated with TIVA or mixed volatile/intravenous techniques. Twenty-four were in the operating theatre setting: 19 Certain/probable AAGA and 5 Possible AAGA (all the possible AAGA cases were TCI infusions).

18.17 One report of AAGA described intermittent thiopental and suxamethonium, but as this is a technique of only historical interest it is not included in the analysis in this chapter

18.18 Table 18.2 presents the distributions of TIVA techniques in the Activity Survey and in Certain/probable and Possible reports of AGAA. Here we compare only cases and Activity Survey data to the theatre setting, as denominator data may be less reliable outside theatres. Comparing these

Table 18.2. Techniques used to maintain anaesthesia in those UK Activity Survey cases (actual results) where general anaesthesia was induced in theatres, and Certain/probable and Possible cases of AAGA. *counted as TIVA (952; 6.6%)

	AAS		AAGA		Ratio AAGA: Activity Survey
	n	%	n	%	
Volatile agent	13,479	93.1 %	112	82.4%	0.89
Propofol infusion TCI*	764	5.3%	14	10.3 %	1.94
Propofol infusion not TCI*	82	0.6 %	2	1.5 %	2.50
Intermittent boluses*	106	0.7 %	1	0.7%	1.00
Both volatile agent and propofol infusion	48	0.3 %	7	5.1%	17.00
Total	14,479	100%	136	100%	–

distributions enables a ratio to be calculated as a crude indicator of whether a particular technique is 'over-represented' (i.e. a higher risk technique).

18.19 Excluding cases where intermittent bolus propofol was used, of the 27 cases who received TIVA, or volatile anaesthesia followed by TIVA 25 (93%) received a neuromuscular blocking drug. In the single case involving intermittent boluses of propofol no NMB was given.

18.20 Notwithstanding the small number of AAGA cases in some categories, Table 18.2 indicates an approximate two-fold over-representation of cases where a propofol infusion was used for maintenance, as compared with the Activity Survey. However the most striking over-representation is for cases where there was a mix of volatile and TIVA technique.

18.21 Anaesthetics comprising a mixture of volatile and intravenous technique were most commonly cases where patients were transferred using a propofol infusion after maintenance with volatile. In one case (not shown in Table 18.2) no agent at all was used for transfer, leading to an experience of awake paralysis on arrival in ICU.

18.22 In eight cases, maintenance of anaesthesia with a volatile agent would not have been possible for all or part of the case. These were one case of bronchoscopy in theatre, three cases of maintaining anaesthesia after surgery and four cases of anaesthesia outside theatre.

Anaesthesia in theatre

18.23 There were 11 Certain/probable cases involving propofol infusions alone. Certain/probable reports are those with the greatest case detail and for which causation is clearest. These cases are important in the discussion of increased risk of AAGA and TIVA and therefore are all briefly described here.

18.24 In these cases the causes of AAGA were: (i) failure to deliver the intended dose of propofol (four cases), (ii) mistiming of propofol administration in a paralysed patient (four cases), and (iii) under-dosing of propofol when mixing remifentanil with propofol in the TCI infusion (i.e. a 'non-standard' regime (three cases).

(i) Two cases were as a result of the 'tissuing' or 'failure' of the IV cannula and in at least one of these the cannula was not visible during surgery; in a third case the anaesthetist was using TCI propofol and remifentanil, and mistakenly reversed the syringes; in the fourth case the anaesthetist completely forgot to connect the propofol infusion to the IV cannula before 'induction' and administration of an NMB.

(ii) There were two cases in which an NMB had been administered and paralysis produced before loss of consciousness at induction, and two in which the patient experienced awake paralysis because the NMB was still acting when they woke up after surgery.

(iii) In one case propofol and remifentanil were mixed in the same syringe and in another both were given as boluses followed by a manual infusion; in the final case a spinal-epidural was combined with a fixed rate propofol infusion (in ml/h with no bolus recorded) where the patient breathed spontaneously via a 'Hudson' type mask.

18.25 The modified NPSA score for patient harm was none in six of the cases, moderate in two and severe in three. Eight of the eleven cases were judged preventable.

18.26 The other eight Certain/probable reports in theatre comprised: one case of intermittent boluses of propofol and seven cases with a combination of intravenous and volatile agents (two administered concurrently and five sequentially). This latter group included three patients who had received a volatile anaesthetic in theatre which was turned off towards or at the end of surgery and replaced with a continuous fixed rate infusion of propofol for transfer elsewhere. In one case the cause of AAGA was thought to be a 'tissued' IV cannula while in the others it was thought that inadequate doses of propofol were given to maintain anaesthesia in patients who were still paralysed by NMBs (see below – anaesthesia outside theatre).

18.27 All five possible cases used TCI TIVA.

Anaesthesia outside theatre

18.28 Four Certain/probable reports were of patients who received a propofol infusion for intended general anaesthesia in the ICU, radiology departement or the ED. The cause of the awareness in most of these cases appeared to be propofol doses that were too low. A further three similar cases, classified as ICU cases, are discussed in Chapter 17, (ICU), and there is considerable overlap of the results and messages.

18.29 The Activity Survey indicates that 4% of all general anaesthetics and 12% of all TIVA general anaesthetics were induced outside theatres. As seven (23%) of the AAGA cases involving TIVA were induced outside theatre (four Certain/probable cases and three ICU cases) this suggests that TIVA general anaesthesia outside theatre is of higher risk for AAGA than TIVA in theatres.

18.30 In contrast to the cases where TIVA was used during operations in theatre, when it was used for anaesthesia outside theatre (and for transfer after theatre) non-TCI fixed rate infusions were used in all cases and in some of these cases no bolus 'loading dose' was given.

TIVA may need to be administered in areas outside the normal operating theatre environment. In NAP5 this setting was a risk factor for AAGA during TIVA

After an emergency procedure in theatre, a patient was transferred to ICU for post-operative ventilation. The following day the patient reported recollection of voices ('needs to go to ICU') and being unable to move but no pain. Anaesthesia had been maintained in theatre with desflurane in oxygen/air, and then a propofol infusion (with no initial bolus documented) had been started for transfer to ICU. An NMB had been given and not reversed. It was thought that the awareness probably resulted from rapid elimination of desflurane and an insufficient dose of propofol to maintain anaesthesia.

18.31 In two of the reports, patients experienced awareness during general anaesthesia for an MRI scan. Not only were low doses of propofol infused but the propofol infusion pumps alarmed and stopped infusing, probably because of the extra resistance of additional infusion tubing required to reach from the pumps to the patient in the scanner. In each case some additional boluses of propofol were given but were not sufficient to prevent AAGA. Management would likely have been affected by the anaesthetist not being beside the patient during the scans.

DISCUSSION

18.32 Failure to ensure delivery of the intended anaesthetic dose was an important cause of AAGA during TIVA in theatre, in one case in the recovery room and two outside theatre. This has been reported previously (Sandin & Norström, 1993). Several of the potential causes of interruption of delivery of TIVA to patients described by SALG and shown in Table 18.1 – were seen in reports to NAP5. Specific training and attention to detail in the practical aspects of ensuring drug delivery during intravenous anaesthesia is required.

18.33 Other cases occurred when TIVA was initiated too late or stopped too early in patients affected by NMB drugs. Similar cases were also seen when intravenous induction agents were used prior to volatile maintenance (see Chapter 19, NMB and Chapter 8, Induction) so this problem is not exclusive to TIVA.

18.34 There were relatively few reports of AAGA in theatre associated with inadequate dosing while using a TIVA TCI technique – except as a result of cannula problems and errors in the use of infusion pumps. The Activity Survey confirms that a TCI is the commonest TIVA technique in theatre. Taken together, this suggests there is not a frequent problem with the TCI pharmacokinetic models leading to underdosing. In contrast, a number of cases of AAGA were reported with non-TCI infusions, despite these being used as intended by the operator.

18.35 Reports of AAGA in association with TIVA infusions often involved 'mixed' intravenous and volatile techniques, either sequentially or concurrently. Overall there appeared to be a 17-fold over-representation. However, we cannot be certain how reliably the Activity Survey captured conversion of a volatile anaesthetic to an intravenous one, so this finding might be interpreted cautiously.

18.36 One quarter of Certain/probable and possible reports described intravenous anaesthesia initiated outside the theatre or initiation of intravenous anaesthesia after surgery for transfer and treatment elsewhere. In these cases administration of volatile anaesthesia would have been difficult or impossible. Three similar cases were included in the ICU section (see Chapter 17, ICU). Taken together this highlights 'out of theatre' use of TIVA as a higher risk setting for AAGA.

18.37 In these cases the commonest cause of AAGA was inadequate dosing: both due to failure to administer a loading dose of propofol and/or

administration of a notably low dose fixed rate infusion. Propofol was routinely administered using a non-TCI method and often as fixed-rate infusion: infusions of 10ml/hr were seen in several cases. The Activity Survey confirms that TCI infusions are rarely used during TIVA outside theatres (see para 18.15). None of these patients received DOA monitoring.

18.38 Figures 18.3 and 18.4 show pharmacokinetic simulations of the predicted blood and brain propofol concentrations following doses such as those seen in AAGA cases during transfer or anaesthesia outside theatre. The predicted brain concentrations achieved are well below the range usually required for adequate anaesthesia in theatre (i.e. 1.5–6 µg/ml). The use of manual rather than TCI infusions in these cases may have made administration of an appropriate dose more difficult.

18.39 Because it is necessary to use intravenous anaesthesia during (sometimes unplanned) transfers and in locations where the facilities for volatile-based anaesthesia are not available, it is important for all anaesthetists to be trained in the administration of TIVA. However, surveys of anaesthetic trainees in the UK suggest that most consider their training in the technique to be inadequate and that they lack confidence in using TIVA (Madhivathanan et al., 2010).

18.40 Preventability was assessed by the Panel in 25 of the 28 Certain/probable, and possible reports involving TIVA: 19 (75%) were considered to have been preventable. The commonest contributory factor identified was education and training.

18.41 The use of processed EEG DOA monitors, in the context of intravenous techniques, is discussed further in Chapter 20, DOA.

18.42 In summary: observed crudely the data from NAP5 might be interpreted as indicating an excess of reports of AAGA when anaesthesia is maintained with TIVA. However deeper analysis indicates that such cases often occur in situations when there is no alternative to maintenance of anaesthesia with TIVA; when mixed volatile/TIVA techniques or non-TCI techniques are used; when the result of poor technique in the use of TIVA, or when there are frank errors. Intravenous anaesthesia initiated outside theatre was over-represented. There is less evidence to suggest an excess of reports of AAGA when TIVA is used correctly and with a target controlled infusion.

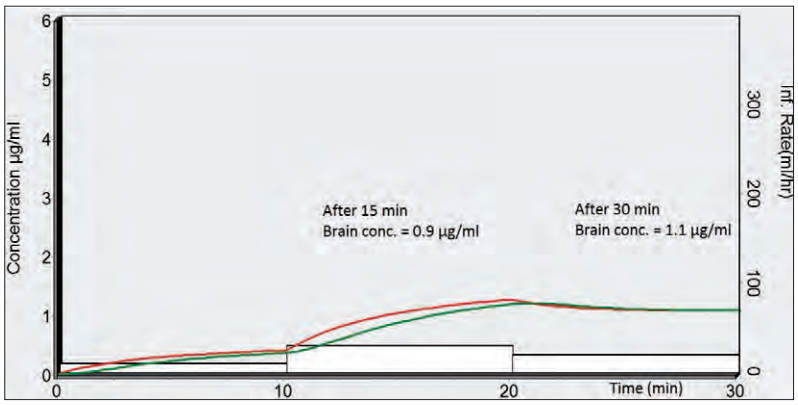


Figure 18.3. Pharmokinetic simulation of an anaesthetic in a 70 kg patient in which there is no propofol bolus dose, an infusion of 1% propofol at 10 ml/h for 10 min then 30 ml/h for 10 min then 20 ml/h for 10 min. Time in minutes is on the x-axis and propofol concentration on the y-axis. The red line is the calculated blood concentration and the green line the calculated brain or effect-site concentration. The white blocks show the infusion rate of 1% propofol in ml/h as indicated on the Y-axis on the right. (TIVAtrainer Marsh pharmacokinetic model with a blood-brain equilibration rate constant of 0.6/min)

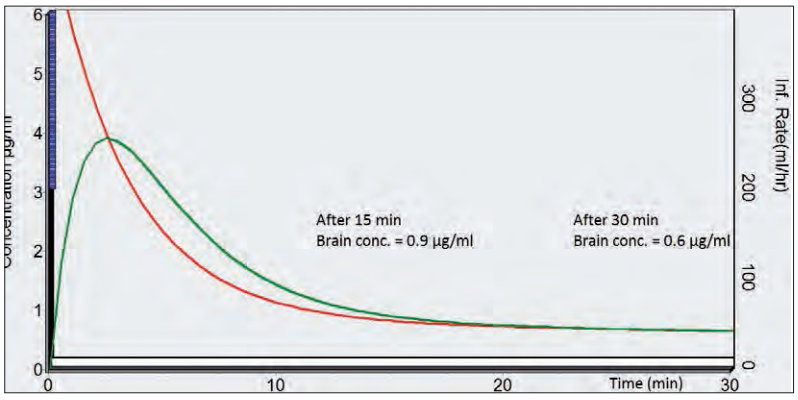


Figure 18.4. Pharmokinetic simulation of an anaesthetic in a 120 kg patient in which a bolus of 200 mg of propofol is followed immediately by a continuous infusion of 10 ml/h of 1% propofol. Time in minutes is on the x-axis and propofol concentration on the y-axis. The red line is the calculated blood concentration and the green line the calculated brain or effect-site concentration. The white blocks show the infusion rate of 1% propofol in ml/h as indicated on the y-axis on the right. (TIVAtrainer Software Version 9-B; Marsh pharmacokinetic model with a blood-brain equilibration rate constant of 0.6)

IMPLICATIONS FOR RESEARCH

Research Implication 18.1
Research should compare the performance and outcomes from target-controlled infusions vs manual infusion regimens when TIVA is used during patient transfers and for anaesthesia outside the operating theatre.

Research Implication 18.2
Research should identify suitable protocols for maintaining adequate anaesthesia when changing from volatile to TIVA during an anaesthetic.

RECOMMENDATIONS

RECOMMENDATION 18.1
All anaesthetists should be trained in the maintenance of anaesthesia with intravenous infusions.

RECOMMENDATION 18.2
When using total intravenous anaesthesia, wherever practical, anaesthetists should ensure that the cannula used for drug delivery is visible and patient at all times.

RECOMMENDATION 18.3
Depth of anaesthesia monitoring should be considered in circumstances where patients undergoing TIVA may be at higher risk of AAGA. These include use of neuromuscular blockade, at conversion of volatile anaesthesia to TIVA and during use of TIVA for transfer of patients.

RECOMMENDATION 18.4
The relevant anaesthetic organisations should establish a set of standards and recommendations for best practice in the use of TIVA.

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CHAPTER
19

Neuromuscular blocking drugs


Alastair F Nimmo


Wouter R Jonker


Jaideep J Pandit

HEADLINE

19.1. Slightly fewer than half (46%) of the general anaesthetics administered in the United Kingdom include the use of a neuromuscular blocking drug (NMB). However, almost all (97%) reports to NAP5 of certain or probable unintended awareness during planned general anaesthesia concerned patients who had received an NMB. The cases of 'accidental awareness during general anaesthesia' reported to NAP5 were therefore overwhelmingly cases of 'unintended awareness during paralysis'.

BACKGROUND

19.2 Neuromuscular blocking drugs (also commonly referred to as neuromuscular blockers, NMBs or 'muscle relaxants') are administered during general anaesthesia to block the transmission of signals between motor nerve endings and skeletal muscles, preventing the affected muscles from contracting and also reducing their resting tone. Thus NMBs paralyse/relax the jaw and the vocal cords facilitating laryngoscopy and tracheal intubation, and various other muscles (especially of the trunk) whose paralysis may facilitate artificial ventilation and surgery.

19.3 An unparalysed patient who is awake will have the capacity to move in response to unpleasant stimuli. Such movement can be used to indicate an inadequate depth of anaesthesia. However, patients may not be able to move if they are physically restrained (as is a common component of positioning and padding for safety during surgery). It has also been suggested that even without NMBs a patient may feel paralysed by a putative effect of anaesthetics on the basal ganglia (Devor & Salkind, 2001; Sukhotinsky et al., 2005).

19.4 However, when a neuromuscular blocking drug is given, the capacity to respond by movement (i.e. *motor capacity*) is impaired or abolished, and it becomes difficult to assess if the patient is adequately anaesthetised. Unfortunately indirect autonomic or involuntary responses (such as an increase in heart rate, blood pressure or lacrimation) have all proved unreliable signs of consciousness, because they can also be influenced directly by the surgical process, or by other non-anaesthetic drugs (i.e. these reflexes can be activated by processes independent of consciousness; Schneider & Sebel, 1997).

19.5 There is good evidence that AAGA can, and does, occur in the absence of autonomic signs. Ghoneim et al. (2009) reviewed 271 cases of AAGA and reported that tachycardia was present in only 20% and hypertension in 18% of these cases. Patient movement was reported in 14%. Domino et al. (1999) reporting on a cohort of 61 medicolegal claims for AAGA (80% of which occurred during surgery) reported hypertension in 15%, tachycardia in 7% and patient movement in 1.5%.

19.6 The 'anaesthetist's dilemma' of how to detect consciousness in a paralysed patient is to some extent shared with neurologists (dealing with persistent vegetative state or 'locked-in' syndromes; Pandit, 2013). In anaesthesia, where the paralysis is temporary and induced by the practitioner, the traditional solution in this dilemma is to give a dose of hypnotic agent which experience suggests is sufficient to prevent recall in the large majority of patients. An alternative approach is to attempt to assess whether the individual patient is receiving adequate hypnotic drug by using an electronic depth of anaesthesia monitor or the isolated forearm technique, and this is discussed in Chapter 20, DOA.

19.7 Separately from the monitoring of the conscious level, it is also possible to monitor the degree of paralysis induced by neuromuscular blockade.

19.8 Because of the effect of NMBs on patients' ability to communicate and move when aware, there is concern that NMBs predispose to AAGA and to the adverse effects of AAGA when it occurs (Sandin et al., 2000). Large randomised trials such as B-Aware (Myles et al., 2004) have predominantly studied patients in whom NMBs were administered. Other large trials have not explicitly recorded NMB as a risk factor (B-Unaware/ BAG-RECALL; Avidan 2008 & 2011). In a prospective study of 11,785 patients (Sandin et al., 2000), the overall incidence of AAGA with NMB was 0.18%, compared with 0.1% when no NMB was administered. Furthermore, the adverse impact seemed greater when NMB was used: '*Four non-paralysed patients recalled intra-operative events, but none had anxiety during wakefulness or had delayed neurotic symptoms. This finding contrasts with anaesthesia with muscle relaxants, during which 11 of 14 patients had pain, anxiety, or delayed neurotic symptoms.*'

Use of a muscle relaxant increases the risk of AAGA and of sensations of paralysis

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

19.9 The NAP5 Anaesthesia Activity Survey reported that NMB was used during 46% of general anaesthetics.

19.10 Neuromuscular blockade is dramatically over-represented in the cohort of AAGA reports (see also Chapter 6, Main Results). Table 19.1 shows in more detail the breakdown of data by Class of AAGA. Of 130 cases of Certain or probable awareness, ICU cases and Drug Errors, NMBs had been administered in 130 cases (97%).

Table 19.1. Proportion of NMB use in the different categories of AAGA

	NMB	No NMB	% NMB use in AAGA
Certain or probable awareness (Class A)	107	3	97%
Possible awareness (Class B)	24	7	77%
ICU cases (Class D)	6	0	100%
Syringe swaps/drug error/ other (Class G)	17	1	95%
Total	154	11	93%

19.11 The sparseness of results makes formal statistical comparison impossible between the cohort that received no NMB vs those that did. However, even the three cases of Certain/probable awareness in which an NMB had not been administered, generally resulted in a rather vague symptomatology. In these three cases and the one case of drug error where no NMB had been administered (Classes A and G), none of the patients reported pain or paralysis and the modified NPSA scores were judged to be None, Low, Moderate and Severe in one patient each.

19.12 The seven cases of possible AAGA without NMB were even vaguer reports (which in part led to their classification as 'Possible' rather than 'Probable').

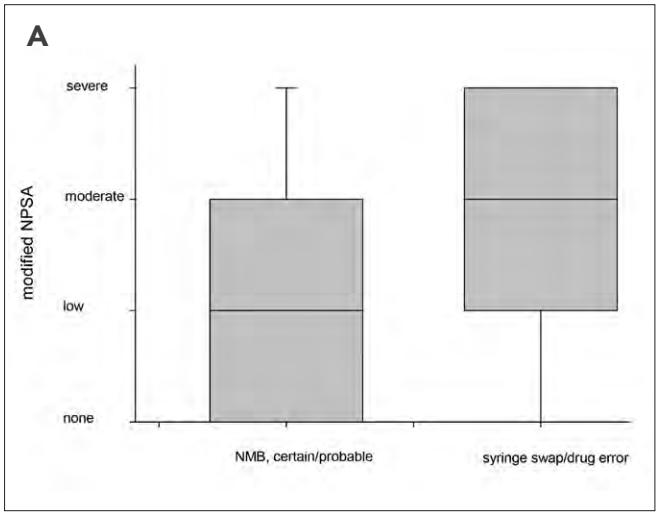
Anaesthesia was induced in a child with poor venous access in order to insert a central venous catheter. Intravenous induction was intended but the peripheral venous cannula tissued as propofol was being injected through it and induction was completed by inhalation of sevoflurane from a face mask. The child reported afterwards that he remembered the facemask application for a few seconds and did not like it.

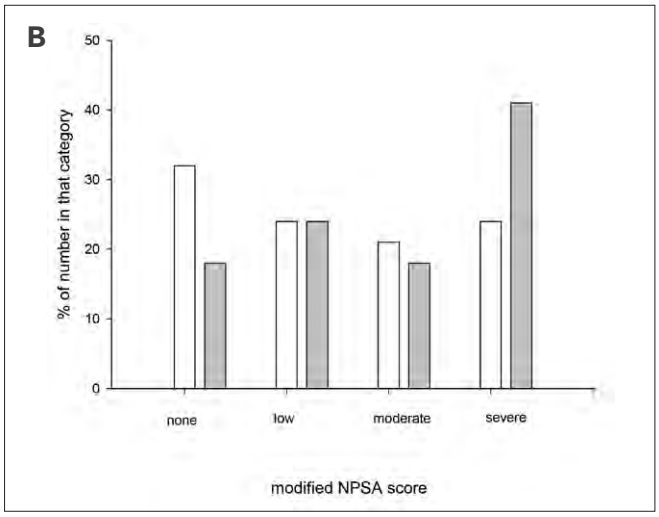
An overweight elderly patient underwent orthopaedic joint surgery under a combined spinal and epidural anaesthetic. The patient breathed oxygen spontaneously through a simple Hudson-type face mask and 1% propofol was administered by infusion at 30-40 ml/h with no record of a bolus being administered. The patient reported expecting to be asleep but was aware of their leg being positioned before surgery and was distressed by this. The plan for anaesthesia had been documented as being 'CSE+GA' (i.e. combined spina-epidural plus general anaesthesia).

A young patient underwent minor surgery. Intravenous anaesthesia was induced and a laryngeal mask airway was inserted. The patient was transferred to the operating room where anaesthesia was maintained with isoflurane in oxygen and air. Before surgery, the patient sat up on the operating table and tried to grab the surgeon. Additional anaesthetic was rapidly given. The anaesthetist questioned the patient in the recovery room after surgery, who reported a dream in which he sat up in the operating theatre.

19.13 A comparison is possible of longer term psychological sequelae (using the modified NPSA scores) between those patients in the Certain/probable category who received NMBs (Table 19.1) and those patients in whom there were syringe swaps or drug errors. This latter group generally experienced paralysis without any hypnotic agent. Figure 19.1A shows that whereas the median score for the former was 'low' with 'severe' being a relatively infrequent consequence, for the latter, the median score was 'moderate', with 'no impact' being less common. Although this statistical analysis highlights the greater psychological morbidity in the patients with unmodified 'awake paralysis' (see Chapter 13, Drug Errors) modified NPSA scores were still 'severe' for 25% of Class A cases (Figure 19.1B).

Figure 19.1. (A) Boxplots of modified NPSA scores for Certain/probable patients who received NMB vs patients in whom drug error or syringe swaps led to accidental paralysis. (B) The same data plotted as bar charts of the % in the respective group exhibiting the degree of impact: white bars, Certain/probable cases; grey bars, syringe swaps/drug errors.





19.14 While most Certain/probable and ICU cases reported their experiences promptly, if all 11 reports of AAGA without NMB are considered there appears to have been considerable delay in reporting: a median of over three years with one patient reporting after almost 40 years (median 1,203 days (7 – 3,650 [0 – 14,158] days.

19.15 In contrast, in cases, where NMBs were administered, AAGA resulted in considerable distress. Distress at the time of the episode was reported in 51% of all reports where NMBs were used, in 61% when paralysis was also experienced and in 77% when both paralysis and pain were experienced.

An elderly patient underwent orthopaedic surgery with anaesthesia including NMB. On transfer to theatre volatile anaesthesia was unintentionally omitted. On surgical incision, hypertension was noticed and volatile re-commenced. On waking in recovery the patient reported having heard voices and experiencing severe pain: the knee 'opened up like a flower; there was a very strong pushing against the leg'. The patient tried to shout and move, but could not and then felt an extreme, sharp, agonising pain of a knife slicing into skin with flesh pulled apart, the patient felt paralysed and was terrified. The patient subsequently developed flashbacks and re-living experiences, and felt traumatised.

A young patient underwent an urgent abdominal surgery. On the anaesthetic chart the first drug documented as being given was an NMB followed by propofol. The patient clearly remembered the anaesthetist saying "oh dear that was muscle relaxant". The experience seemed to last for a long time before induction. The patient felt paralysed, unable to speak or move and feared death. The patient became terrified about future anaesthetics, with sleep disturbance and worry about death on a daily basis.

A young patient underwent anaesthesia for ENT surgery during which NMB was administered. When the patient awoke in the recovery room it appeared that the effect of the NMB had only been partly reversed and their muscles were still very weak. A further dose of reversal was given. "It was really horrible, I could hardly see them moving and talking around me, I was unable to talk or to move, I felt that my chest was too tight. I was very scared, I thought I will be paralysed and unable to move, it was really bad experience." The patient developed anxiety and fear about anaesthesia and flashbacks. The patient required psychological support.

19.16 Yet, not all patients experiencing 'awake paralysis' were distressed by the experience and if the patient understood the cause of the inability to move this may have reduced distress.

A young patient underwent an urgent general surgical procedure. A year later they reported that they had been aware during surgery, feeling paralysis and pain in the abdomen, and wanting to ask for pain relief. The patient also heard voices talking about drugs and saw bright lights through closed eyes. The paralysis was not a great worry as the patient knew 'you were supposed to be paralysed during the operation'.

19.17 An experience of paralysis associated with NMB during AAGA was not restricted to the maintenance (surgical) phase of anaesthesia: 24% of all Certain/probable and Possible reports described it at induction and 16% at emergence.

19.18 When unintended awareness during NMB was suspected by the anaesthetist, immediate verbal reassurance appeared to reduce the patient's distress.

A patient inadvertently was given suxamethonium before induction. The anaesthetist immediately recognised the error and induced anaesthesia. The patient experienced paralysis, was afraid they were dying from a stroke and had flashbacks for 2-3 days afterwards. However the patient was very reassured by the anaesthetist's immediate explanation, "I know what's happening and I can fix it", during the critical event, and had minimal long-term sequelae.

19.19 At emergence, AAGA was generally caused by mistimed or mismanaged NMB, failure to monitor the effects of NMB and failure to consider idiosyncratic responses to single doses of NMBs. These reports are discussed in Chapter 10, Emergence.

DISCUSSION

19.20 The vast majority of NAP5 reports were of unintended awareness during neuromuscular blockade. Indeed, 'unintended awareness during neuromuscular blockade' may be a better term than unintended awareness during general anaesthesia to describe the principal problem reported to NAP5. There were over twice as many patient reports of paralysis alone (59) than pain alone (26).

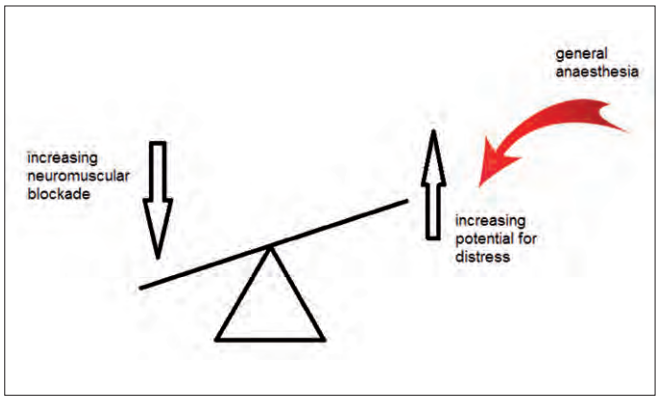
19.21 Furthermore, the majority (61%) of patients who experienced paralysis were distressed. Descriptions suggest that this was probably because they could not rationalise an entirely novel experience. Distress at the time of the episode appears to be an important factor in determining longer term adverse effects (Chapter 6, Main Results and discussion in Chapter 7 Patient Experiences).

19.22 The anaesthetist who administers a neuromuscular blocking drug assumes a great responsibility for ensuring the patient's welfare. Physiologically, the patient will die within minutes unless the airway and ventilation are adequately maintained. Psychologically, it is essential to ensure unconsciousness during paralysis.

19.23 Two-thirds of the cases of unintended awareness during NMB reported to NAP5 occurred before or after rather than during surgery. Even a very brief (seconds) episode of paralysis sometimes led to severe distress and long-lasting psychological sequelae. Any case in which neuromuscular blockade is used must be regarded as carrying increased risk of AAGA.

19.24 Conceptually, unopposed global neuromuscular blockade might be imagined as an intervention with capacity to cause great psychological harm, unless it is counteracted by general anaesthesia (Figure 19.2).

Figure 19.2. Diagrammatic representation of the balance between neuromuscular blockade and distress,the latter ameliorated by general anaesthesia. When the 'seesaw' is balanced (in neutral position) there is no neuromuscular blockade and no distress)



19.25 In support of the above model, it is notable that the group of patients who experienced the worst psychological sequelae after AAGA were those who experienced awake paralysis without any co-administration of anaesthetic drugs. This was the group of patients who were administered NMB before intended anaesthesia due to syringe swap/drug error (see Chapter 13, Drug Errors).

19.26 Disruption of the balance of Figure 19.1 by unopposed neuromuscular blockade can occur at any time during anaesthesia. Thus NAP5 contains reports of paralysis at induction, on transfer into theatre, during surgery, during transfer from theatre, and during recovery.

19.27 Reflecting on these reports of AAGA, it can be argued that the main 'purpose' of general anaesthesia is not really to manage the pain of surgery. Pain can clearly be very effectively and separately controlled by analgesics or regional anaesthesia, and many operations are conducted with the patient awake. Rather, general anaesthesia is an essential condition to allow patients to tolerate the global paralysis that is required for some surgical procedures. Whereas it is eminently possible for pain to be well managed in an awake patient, it would seem rare for awake patients to tolerate even modest periods of complete paralysis. Adopting this view of the purpose of general anaesthesia would help underline the importance of global paralysis in an awake patient.

IMPLICATIONS FOR RESEARCH

Research Implication 19.1

Further research into development of reliable sensitive and specific means of detecting AAGA during paralysis would be of benefit to patients.

Research Implication 19.2

It would be important for research to develop a model to explain the psychological response to different degrees of global paralysis during anaesthesia (and in comparison to other circumstances).

Research Implication 19.3

It is worth investigating the hypothesis that patient responses differ to different degrees of paralysis in different limbs or parts of the body (e.g. those induced either by neuromuscular blockade, or regional anaesthesia, or disease).

RECOMMENDATIONS

RECOMMENDATION 19.1
Given the potentially serious consequences of paralysis unopposed by general anaesthesia even for brief periods, anaesthetists should plan the use of neuromuscular blockade very carefully; assessing whether it is needed at all, if so then whether needed throughout surgery, and to what depth of blockade.

RECOMMENDATION 19.2
Care should be exercised in the handling of syringes of neuromuscular blocking drugs prepared 'in case' of need: inadvertent administration may have catastrophic results.

RECOMMENDATION 19.3
If neuromuscular blockade is planned, then anaesthetists should ensure consent, and that explanation outlines the possibility of feeling weak or unable to move, for example at the start or end of the anaesthetic.

RECOMMENDATION 19.4
If AAGA is suspected, immediate verbal reassurance should be given during the episode to minimise adverse consequences, as well as additional anaesthetic to limit the duration of the experience.

RECOMMENDATION 19.5
Anaesthetists should minimise the risk of any period of neuromuscular blockade without anaesthesia by the appropriate use of a nerve stimulator coupled with end-tidal volatile agent monitoring. Where the latter is absent or irrelevant (such as in TIVA), then specific depth of anaesthesia monitoring may be necessary.

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CHAPTER
20

Depth of anaesthesia monitoring

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HEADLINE

20.1 Specific depth of anaesthesia (DOA) monitors are rarely used in UK anaesthetic practice: in only 2.8% of general anaesthetics for processed EEG (pEEG) and 0.03% for the isolated forearm technique (IFT). Of the 141 reports to NAP5 judged to be Certain/probable/possible AAGA, six (4.3%) occurred despite use of a pEEG monitor. However lack of detail means appropriate and continuous use cannot be confirmed. These monitors appeared to be used in a 'targeted fashion': for instance, in the Activity Survey, whereas pEEGs were used in only 3.5% of cases where volatile and neuromuscular blockade (NMB) was used, they were used in 23.4% of cases with total intravenous anaesthesia (TIVA) and NMB. A crude analysis of the cases of AAGA in which pEEG was used or omitted was not able to detect whether there was a marked protective effect of its use. Only one report of AAGA in association with DOA monitoring was followed by adverse psychological sequelae. The possibility of a more subtle benefit of DOA monitors in protecting against 'AAGA with sequelae' merits investigation. Although end-tidal anaesthetic gas monitoring is an alternative to DOA monitoring, in ~75% of reports to NAP5 it would probably have been impractical or ineffective at preventing AAGA. The overall findings are supportive of the use of DOA monitoring in selected circumstances, but provide no support in others.

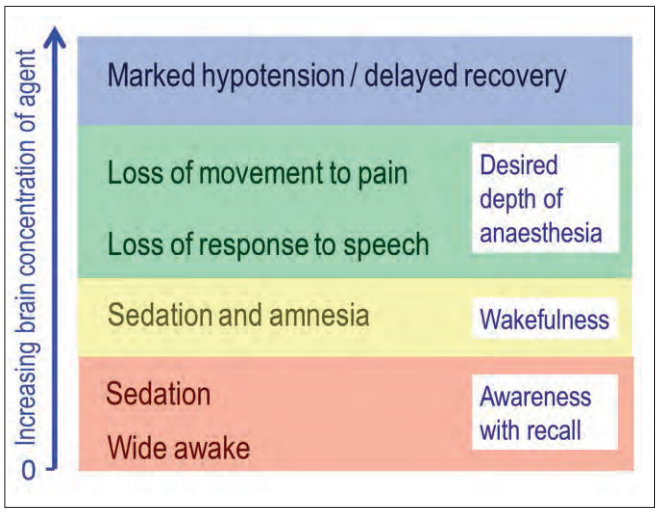
BACKGROUND

20.2 The level of consciousness in another person (a patient) is in large part assessed by the degree to which they respond or not to increasing stimuli. A patient is regarded as fully conscious when they are responsive even to mild verbal interrogation. A lack of response to speech, or immobility as the result of administration of a hypnotic/narcotic drug is taken to represent increasing depths of unconsciousness, and when there is no response even to sustained painful stimulus, the patient is judged to be in a sufficiently 'deep' plane of anaesthesia. At least, this is the case when no neuromuscular blocking drug is given, as then the patient retains the capacity to respond.

20.3 However, when a neuromuscular blocking drug is used, the capacity to respond is lost, regardless of the level of consciousness. As noted elsewhere (Chapter 19, Neuromuscular blockade) the degree of motor capacity can be objectively assessed using a nerve stimulator. In the presence of neuromuscular blockade, it becomes impossible using clinical signs (including autonomic signs) of responsiveness alone to distinguish an awake, paralysed patient from one who is suitably anaesthetised (Schneider & Sebel, 1997).

20.4 A typical pattern of effects resulting from an increasing brain concentration of an anaesthetic drug such as propofol or a volatile anaesthetic agent is broadly illustrated in Figure 20.1.

Figure 20.1. Crude representation of the effects of increasing brain concentrations on anaesthetic responsiveness in an unparalysed patient. Within the white boxes are shown the likely results in a paralysed patient, were surgery to proceed at the given level of consciousness. The brain concentration at which these effects occur varies between individuals



20.5 Certain aspects of drug dosing are well established and involve both pharmocodynamics and pharmacokinetics. Older patients typically require a lower brain concentration of an anaesthetic to produce loss of awareness than do younger patients; body weight or male-female differences can influence volumes of distribution of anaesthetic agents (Buchanan et al., 2011). The co-administration of other drugs with anaesthetic or sedative effects such as nitrous oxide, benzodiazepine or opioids reduces the brain-concentration of anaesthetic required (Aranake et al., 2013). However, there is considerable variation between individuals so that the brain concentration required to produce loss of awareness in an individual cannot be accurately predicted in advance (Aranake et al., 2013).

20.6 While it is possible to ensure unconsciousness and prevent AAGA by administering very large doses of drug, this may increase the incidence of adverse effects including delayed recovery, nausea and vomiting and post-operative confusion, but hypotension (and its sequalae) is arguably the most important.

20.7 Hypotension may add to risks of surgery, especially in those patients with pre-existing co-morbidities. In certain circumstances the incidence of hypotension during anaesthesia is markedly increased e.g. hypovolaemia, cardiac disease and cardiovascular drugs. The anaesthetist may decrease the anaesthetic dose in response to a low blood pressure (or to prevent its occurrence) and there is a risk of inappropriate or excessive reduction leading to awareness. Hence there is a genuine problem of titrating the anaesthetic to the correct dose (Yu & Liu, 2013).

20.8 In other words, the sensitivity of the brain (in terms of the hypnotic/narcotic effects of the drug) is not necessarily identical to the sensitivity of the other body systems, especially cardiovascular (e.g. in terms of the hypotensive effects of the drug).

20.9 There is a further problem, that when a neuromuscular blocking drug is given, the *capacity* to respond by movement is abolished and it becomes impossible to assess if the patient is adequately anaesthetised. Unfortunately indirect autonomic or involuntary responses (such as an increase in heart rate, blood pressure or lacrimation) have all proved unreliable signs of consciousness. They can also be influenced directly by the surgical process, or by other non-anaesthetic drugs i.e. these reflexes can be activated by processes independent of consciousness (Schneider & Sebel, 1997), and there is good evidence from large series that autonomic responses are uncommon in cases of reported AAGA (Domino et al., 1999; Ghoneim et al., 2009).

20.10 The 'anaesthetist's dilemma' of how to detect consciousness in a paralysed patient is addressed in practice by using a dose of hypnotic agent which experience suggests is sufficient to prevent recall in the large majority of patients. An alternative approach is to attempt to assess whether the individual patient is receiving adequate hypnotic drug by using a monitor of depth of anaesthesia (DOA) such as the isolated forearm technique (IFT) or a processed EEG (pEEG) monitor.

20.11 However, unless the monitor is entirely empirical (i.e. based purely on coincidental correlations of monitor output to brain state), the monitor output needs to be both generated and interpreted in the light of some macroscopic model of consciousness. In this way, three fields of enquiry are inter-related: (a) the nature of consciousness (in terms of a philosophical, conceptual understanding and a neuro-anatomico-physiological model), (b) the nature of anaesthesia (in terms of relevant neuroscientific mechanism) and (c) the principles of monitoring (in terms of how to detect a given state). As there is considerable scientific uncertainly regarding the nature of consciousness, this creates a logical problem with development of such monitoring.

20.12 Two approaches to monitoring are IFT and pEEG monitoring.

Isolated forearm technique

20.13 In the IFT, a tourniquet applied to one upper limb is inflated to above the arterial blood pressure before a neuromuscular blocking drug (NMB) is given into a vein elsewhere in the body (Tunstall, 1977; Russell, 2013a and b). Therefore, the NMB does not reach the neuromuscular junctions beyond the tourniquet and movement of the hand on that side remains possible. The anaesthetist can then observe the hand for either reflex movements or responses to command. In effect, the same assessment is now possible as in a patient who has not received an NMB (Table 20.1 and Figure 20.2).

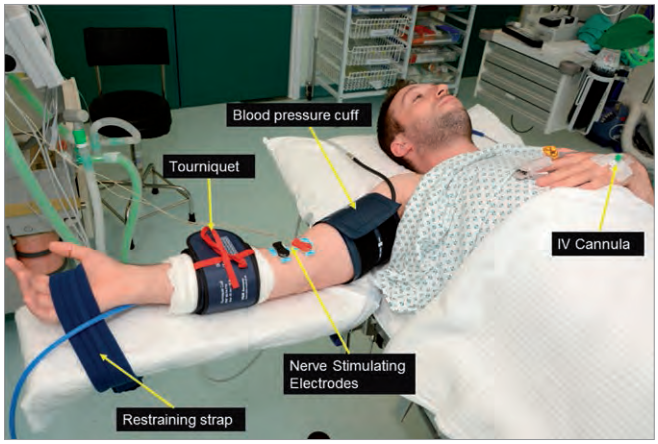
20.14 The IFT construct has, in a very elegant way, conferred or retained motor capacity in an otherwise paralysed patient. A positive motor response to command during IFT is termed 'wakefulness' (Wang, 2012): i.e. the patient is potentially awake and exhibiting signs of this, but may not have any recall of this after surgery.

Table 20.1. Russell's modification of the isolated forearm technique for prolonged use (Russell, 2013)

1.	Insert IV cannula in left forearm
2.	Apply BP cuff to right upper arm
3.	Apply padded tourniquet to right forearm
4.	Apply nerve stimulating electrodes to ulnar and/or median nerves at right elbow
5.	Induce anaesthesia, inflate tourniquet, check neuromuscular integrity, give judicious dose of relaxant and intubate
6.	Provide maintenance anaesthesia
7.	After 20 minutes deflate tourniquet
8.	If more relaxant is required inflate tourniquet give top-up dose of relaxant
9.	After 20 minutes deflate tourniquet
10.	Repeat steps 8 – 9 as required

If there is a hand response then verify this by giving the patient a different command. Neuromuscular integrity should be checked at regular intervals.

Figure 20.2. Russell's modification of the isolated forearm technique



20.15 In a study using the IFT, during most episodes of wakefulness there was no increase in heart rate or blood pressure, and no sweating or tear production suggestive of inadequate anaesthesia (Russell, 1993).

20.16 Remarkably, the reported incidences of a positive response during IFT are very high, with over a third of patients responding (Sanders et al., 2012). This may, at least in part, be because some studies employ very low doses of anaesthetic drugs, considerably lower than is perhaps usual in clinical practice (e.g. Russell, 2013a and b). A study using more conventional doses of anaesthetic drugs found a much lower incidence of responsiveness during IFT (Andrade, 2008) though not all the patients in that study received a neuromuscular blocking drug.

20.17 However, few anaesthetists have adopted the technique. The NAP5 Baseline Survey suggested only 14 of over 8,500 senior staff in the UK ever use IFT (Pandit 2013a and b). This may be because of lack of familiarity, because they perceive it to be a relatively difficult and time consuming technique to use which may distract from other aspects of patient monitoring and care or even because they do not consider it a technique of any value (Sleigh, 2013).

20.18 The state of *wakefulness or awareness without recall* identified by IFT may be the same or a very similar state as that of sedation and amnesia, commonly seen in patients who have not received a NMB and are undergoing a procedure under sedation with or without additional analgesia or regional anaesthesia. On the other hand, Pandit (2013 & 2014) has argued that when IFT patients respond to command but do not move the arm spontaneously during surgery, this represents a unique brain state (dysanaesthesia) in which the patient's perception is partially uncoupled from

sensation: that is, fully uncoupled in respect of surgery but remains coupled to verbal stimulus (Pandit, 2014). This, Pandit predicts, will (if anything is recalled) give rise to a largely neutral memory of surgery. This theory does not question the IFT as a suitable technique, but offers different interpretations of this 'monitor output'.

20.19 Recall of wakefulness after use of an IFT technique – i.e. explicit awareness – is rare. Of note there are no large studies that indicate a reduction in reports of AAGA by use of IFT. During the IFT some patients have indicated discomfort but it is not known through large cohorts whether there are long term psychological effects of this, or of being aware but comfortable.

20.20 The correlation (or lack of it) of IFT results and pEEG monitoring is discussed below.

Processed EEG monitoring

20.21 Electronic DOA monitors use forehead surface electrodes to measure the EEG, which is then processed. The most commonly used general anaesthetic drugs – propofol, thiopental and the volatile anaesthetic agents all – produce a similar pattern of EEG changes with increasing brain concentrations, and the corresponding increasing 'depth' of sedation and anaesthesia.

20.22 With increasing depth of anaesthesia, the relevant EEG changes include – in order – an initial increase in high frequency components, then an increased proportion of low frequency EEG components, an increase in amplitude of the EEG waveform, increased regularity of EEG signal (i.e. decreased entropy), burst suppression (i.e. periods of an isoelectric EEG) with deep anaesthesia and a completely isoelectric 'flat line' EEG with very deep anaesthesia.

20.23 In addition to displaying the EEG waveform, DOA monitors derive a number or index which is intended to indicate the degree to which the electrical activity of the brain is affected by an anaesthetic drug. For example, the BIS monitor displays an index between 0 and 100. This is generated by use of an algorithm based on specific measures in the pEEG but the details of this algorithm are a commercial secret. At BIS values of 60–80, the subject may respond to mild prodding or shaking, whereas values of 45–60 are associated with a 'low probability' (unquantified) of explicit recall. A BIS level of <45 is a 'deep hypnotic state' (see: www.covidien.com).

20.24 Ketamine, nitrous oxide and xenon do not produce the same pattern of EEG changes as described above. The use of the indices from pEEG monitors to guide anaesthetic administration is therefore less useful if these are amongst the anaesthetic drugs being used (Lobo & Schraag, 2011). It is not fully established how pEEG monitors perform when these drugs are used to supplement anaesthesia maintained with a volatile agent or propofol.

20.25 Even those anaesthetic drugs that lead to EEG changes reflected in changes in BIS index do not affect it identically. Therefore the probability of awareness with a given BIS score varies between agents – though the differences are modest (Glass et al., 1997; Ibrahim et al., 2001; Schwab et al., 2004).

20.26 Other than the BIS, pEEG-based depth of anaesthesia monitors used in the UK include the Narcotrend monitor and the E-Entropy monitor. DOA monitors which analyse the EEG response to auditory stimuli, i.e. auditory evoked potentials are also available but are less commonly used in the UK (Pandit et al., 2013a and b).

20.27 Several large, randomised studies have either compared anaesthesia guided by a pEEG monitor with 'standard care', or with a protocol designed to maintain a specified minimum end tidal anaesthetic gas (ETAG) concentration.

20.28 The B-Aware trial (Myles et al., 2004) compared BIS-guided anaesthesia with standard care in 2,463 adult patients (with neuromuscular blockade) at increased risk of awareness. The result was in favour of BIS, with two reports of AAGA in the BIS-guided group and 11 reports in the routine care group ($p=0.022$).

20.29 In contrast, the B-Unaware (Avidan et al., 2008) and BAG-RECALL (Avidan et al., 2011) studies compared BIS-guided anaesthesia with a protocol in which alarms were used to prompt the anaesthetist to keep the ETAG >0.7 MAC (age-adjusted). These found BIS to make no difference to the incidence of AAGA.

20.30 A Cochrane review (Punjasawadwong et al., 2007; updated in 2010) concluded that BIS-guided anaesthesia could reduce the risk of intra-operative recall in surgical patients who had a 'high risk' of awareness, when otherwise clinical signs were relied upon, but not if a protocol using ETAG alarms was used.

20.31 Based in part on this and its own analysis, NICE produced a Diagnostics Guidance report (2012) which recommended that pEEG monitoring is an 'option' in patients considered at 'higher risk' of AAGA and patients at higher risk from excessively deep anaesthesia. Furthermore, NICE stated that pEEG monitors are recommended as an option in

all patients receiving total intravenous anaesthesia (TIVA).

20.32 However, the NICE recommendations were questioned by Pandit & Cook (2013), who amongst other criticisms, noted that the terminology surrounding this advice remained unhelpfully vague. Thus the Cochrane review, perhaps unusually imprecisely, suggested pEEG monitors 'could' (rather than 'did') achieve the intended aim, and NICE only recommended it as an 'option', in a *higher risk* (undefined) category of patients. As a relatively new technology, no algorithms as to how to respond to, or interpret the monitor outputs were referred to. Perhaps the vague terminology is an accurate reflection of the pressing need for further research. The NICE report applied these recommendations to BIS, Narcotrend and Entropy equally, despite acknowledging the markedly less robust data supporting this view for the last two devices.

20.33 Furthermore, the relationships between a given pEEG monitor output (e.g. BIS reading of, say, 45 vs 55 vs 65) and the probability of consciousness is not fully ascertained.

20.34 A BIS value of <60 is said to be associated with a low probability of explicit recall but Russell (2013a and b) and Zand et al. (2014) have demonstrated that this does not necessarily mean a low probability of wakefulness without recall when using the IFT.

20.35 In addition to their use in guiding the appropriate depth of anaesthesia to prevent AAGA, DOA monitors have also been advocated as a means of avoiding excessively deep anaesthesia. This is associated with hypotension, delayed recovery and possibly increased mortality and mortality. The combination of a low BIS, low BP and low MAC values (defined as >1 standard deviation below the mean) appears to be associated with an increased 30 day mortality and increased length of hospital stay (Sessler et al., 2012). A randomised trial, the Balanced Anaesthesia Study, is being undertaken in which one year mortality rates will be compared in patients randomised to BIS targets of either 50 or 35 (see: http://balancedstudy.org.nz/).

End-tidal monitoring

20.36 ETAG monitoring with audible alarms appropriately set and turned on is a reliable way of ensuring a given amount of volatile anaesthetic is in equilibrium with body (brain) tissues.

20.37 End-tidal anaesthetic gas monitoring is not, of course, suitable or relevant when an intravenous infusion is used to maintain anaesthesia (TIVA). TIVA can be administered using target-controlled infusion (TCI) pumps which display the estimated plasma and effect-site anaesthetic drug concentrations. However, when TIVA is employed with an NMB, not only is there a limitation on measurement of the conscious level (as with all anaesthetics) but additionally there is no direct measure of the amount of drug within or equilibrated with the body (brain) tissues.

Summary

20.38 In summary whereas in the unparalysed patient, a lack of motor response to stimulus can reasonably be assumed to indicate adequate anaesthesia, this is not the case when neuromuscular blockade is used. However, all measures have their limitations. The IFT cannot be used in all cases the output of pEEG monitors does not relate to specific brain functions, and ETAG monitoring measures drug concentration rather than brain responses. TIVA poses special challenges to ensuring the correct dose is delivered. It might therefore be predicted that AAGA might be higher when neuromuscular blockade is used, or when TIVA is employed. If pEEG monitors are effective, then we might expect to see fewer patients in whom they had been used reporting AAGA than in the general surgical population. However such a reduction might not be apparent if pEEG monitors are more frequently used in patients at high risk of AAGA than in patients at low risk.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

20.39 Of the 141 Certain/probable and possible cases of AAGA, a DOA monitor (always the BIS) was used in six 4.3%, five in Class A and one in Class B. It was not used in any cases arising from ICU or syringe swap/drug errors.

20.40 In the Activity Survey, IFT was used in just five patients during the survey (~0.03% of all general anaesthetics), once when no NMB was used. No reports of AAGA described use of IFT monitoring, but 11 patients moved despite neuromuscular blockade (thus exhibiting a degree of motor capacity which they exercised). This could be regarded as 'IFT by default'.

20.41 Overall, pEEG monitoring was used in 2.8% of all general anaesthetics in the Activity Survey. This superficially implies an over-representation of the use of pEEG monitoring in the AAGA cases (by a factor of ~1.5; Table 20.2).

20.42 However, more detailed consideration is warranted, especially concerning the use of TIVA and neuromuscular blockade.

20.43 Table 20.2 shows how the combinations of volatile, TIVA and neuromuscular blockade were used in the Activity Survey. The data show a preponderance of volatile over TIVA for maintenance anaesthesia. In slightly over half of the volatile anaesthetics no NMB was given; however, when TIVA was used, it was slightly more common for NMBs to be given.

20.44 The data in Table 20.2 represent a crude 'AAGA risk profile' of the given technique. The most common technique was a volatile without paralysis and this was under-represented (ten-fold) in the cases of AAGA. However, any technique employing paralysis was over-represented, especially TIVA with neuromuscular blockade, which was more than three times as frequently seen in AAGA cases as it was used generally.

20.45 These data are not amenable to any meaningful statistical comparisons as the numbers in some categories are very small; hence this is classed as a crude risk profile that might help focus further research.

20.46 An important caveat to this crude data is that several of the TIVA cases in which AAGA was reported used a non-TCI TIVA technique and/or took place outside the operating theatre in situations where the administration of a volatile anaesthetic was not possible. Thus a more nuanced analysis is appropriate – see Chapter 18 TIVA.

20.47 It could be argued that the ten failed intubations (none of which included TIVA) were all part of an intended volatile technique. While this changes the detail of the ratios in Table 20.2 somewhat (volatile without NMB 0.11, volatile with NMB 2.1, TIVA without NMB 0.63 and TIVA with NMB 3.2) the message remains the same.

20.48 Table 20.3 shows the use of pEEG monitoring across the types of anaesthetic techniques employed. It indicates that anaesthetists use pEEGs apparently highly selectively: uncommonly when volatiles are used (and hardly at all when volatiles are used without NMB), but more commonly during TIVA (and especially when TIVA is used with NMB).

20.49 The ratios of pEEG use offer the opportunity to attempt to calculate a very crude 'protection profile' of pEEG monitoring use.

20.50 By comparison with Table 20.2, and notwithstanding the small numbers involved for some types of anaesthesia, pEEG monitoring appears to confer no advantage when no NMBs are used.

20.51 Again, this data is not amenable to any meaningful statistical analysis due to the low numbers in some cells (and in the case of volatile with no NMB technique, a zero numerator). Thus the data do not persuasively indicate whether pEEGs are protective or not. However, TIVA used with NMB yields the lowest ratio, suggesting that the greatest potential benefit of pEEG monitoring (if one exists) is most likely to be demonstrated with this technique.

Table 20.2. 'Risk profile' of different anaesthetic techniques for AAGA. Proportions of anaesthetic technique as used in the Activity Survey (n rounded up to nearest 100), compared with their representation in cohort of AAGA cases. Of the 141 Certain/probable and Possible cases, 23 were excluded as: failed intubations (judged neither volatile or TIVA, but appeared intended volatile), mixed methods (using both volatile and IV anaesthesia, either concurrently or sequentially and indeterminate techniques. This left 118 as the denominator for this second column). In the last column, a ratio of >1 indicates over-representation in the AAGA cohort; <1 indicates under-representation. The greatest over-representation in AAGA cases if for those techniques using NMB, especially with TIVA

	Activity Survey GAs with NMB specified n = 2,667,000 (%)	Proportion of AAGA cases with NMB specified n = 118 (%)	Ratio of AAGA % to Activity Survey %
Volatile, no NMB	50.9% (n= 1,357,600)	5.9% (n=7)	0.12
Volatile, NMB	41.1% (n=1,095,100)	76.3% (n=90)	1.86
TIVA, no NMB	3.7% (n=95,200	2.5% (n=3)	0.68
TIVA, NMB	4.1% (n=108,400)	15.3% (n=18)	3.73

20.52 A limitation of the analysis above is that it assumes first, that there is no systematic selection of anaesthetic technique according to other putative risk factors for AAGA, and secondly, that use of pEEG is not selective beyond type of anaesthetic. If, for instance, in patients who are suspected to be more likely to have AAGA (e.g. patients who are younger, female, obese, having higher risk surgery or with other risk factors for AAGA), there is unequal distribution of anaesthetic techniques used or of use of pEEG, then this could impact the conclusions that can be drawn from both Tables 20.2 and 20.3. Thus our conclusions should be judged with this caveat.

20.53 Of the five Certain/probable AAGA cases that employed a BIS monitor, only one experienced distress (as a result of paralysis). One patient experienced each of paralysis without distress, auditory sensations, touch, and paralysis with pain (but no distress). There was no longer-term impact as judged by modified NPSA scores, except in the patient experiencing touch, whose case the score was judged Moderate. The patient in the Possible category whom a BIS monitor was used had complained primarily about poor post-operative pain relief. They had also said that they were 'unhappy at waking up during the operation' but gave no details of the possible awareness experience. Thus, the cohort of patients who experienced AAGA when a BIS was employed, in the main experienced very modest impact and in general without distress related to the experience.

Nine months after abdominal surgery, an elderly patient mentioned overhearing a few seconds of conversation between surgeons during his operation regarding the position of the incision and other operative details, and quoted exactly what had been discussed. After intravenous induction including neuromuscular blockade, maintenance used a volatile agent (MAC charted as 0.9 at time of AAGA) and BIS was used and was charted as being in the 40s throughout. The patient was not concerned by the experience; but rather interested by it.

A middle-aged patient underwent a general surgical procedure and immediately after reported "I knew I was in trouble and I wanted to tell you but I couldn't move". The patient had no recollection of the event the next day when questioned specifically about it by the anaesthetist, and was dismissive of it all saying "It must have been just me". Anaesthesia was induced and maintained with propofol and remifentanil infusions and an NMB. BIS monitoring was used. An NMB was given not long before the end of surgery, resulting in a period of about 15 minutes after the completion of surgery before the muscle relaxation could be safely reversed. The impression was that the episode of awareness probably occurred after the end of surgery and before full recovery from the NMB. BIS was <35 during the procedure and <45 at the end of the procedure.

Table 20.3. Estimating 'protective effect' of pEEG monitoring. Proportions of pEEG monitoring use in general anaesthesia types in the Activity Survey and in the Certain/probable and Possible AAGA cases where pEEG monitoring used. In the last column, a ratio of <1 indicates use of the monitor may have a 'protective' effect against AAGA, such that there is under-representation in the AAGA cohort; >1 indicates the reverse. Monitoring appears to exhibit the greatest reduction of risk for TIVA with NMB

n in Activity Survey	pEEG monitoring (n) as % of totals in Activity Survey	pEEG monitoring (n) as % of AAGA cases	Ratio of pEEG use in AAGA %: Activity Survey % (expected n from Activity Survey)
All GAs with use or omission of NMB specified (n= 2,667,600)	2.8% (n=73,600)	5.1% (n=6)	1.82
Volatile, no NMB (n=1,357,600)	1.1% (n=15,000)	0.0% (n=0)	zero numerator
Volatile, NMB (n=1,095,100)	3.5% (n=38,300)	3.3% (n=3)	0.94
TIVA, no NMB (n=95,200)	7.8% (n=7,400)	33.3% (n=1)	4.27
TIVA, NMB (n=108,400)	23.4% (n=25,400)	11.1% (n=2)	0.47

20.54 Particular caution needs to be exercised if the index value from a pEEG monitor suggests that the patient is adequately anaesthetised, but either the dose of anaesthetic being administered is unexpectedly low for that patient, or there are clinical signs that might suggest inadequate anaesthesia.

An elderly patient underwent urgent surgery for bleeding after cardiac surgery. During positioning for surgery increased blood pressure and heart rate were noted by the anaesthetist and additional anaesthetic agents administered. When the anaesthetist reviewed the patient the next day, the patient recalled waking up whilst being positioned and accurately hearing discussion but being unable to communicate. There was some distress and the patient was concerned about possible awareness during any further general anaesthetics. A volatile anaesthetic followed an intravenous induction with neuromuscular blockade with ETAG levels held intentionally between ~0.4- 0.6 MAC and a BIS used to titrate this, with all charted values <60.

An elderly patient reported AAGA after an abdominal operation. The patient reported that they could hear people talking, that they were aware that their abdomen was being closed and that they had a tube in their mouth; then they went back to sleep. The patient experienced some pain but seemed unconcerned by the episode. An intravenous induction was followed by volatile anaesthesia maintenance with neuromuscular blockade. The end-tidal sevoflurane was charted as low as 0.4 MAC, a remifentanil infusion was used and the BIS was charted during surgery as <55.

20.55 Caution also needs to be exercised if, in fact, the BIS readings exceed the recommended upper limit of 60. If a patient later makes a report of AAGA (even one that is vague in detail), then it would be consistent with the published guidance to interpret this as supportive of the patient's report. However the current understanding of BIS monitoring is such that it is not clear how much higher than 60 and for how long a BIS score is needed to make explicit recall likely.

A middle aged patient with a chronic neurological disease and chronic pain underwent orthopaedic surgery and made a very vague report of having been 'aware', that was coupled with other unrelated complaints. A TIVA anaesthetic technique was used, with no neuromuscular blockade and a BIS was used which gave a reading of 65 briefly after the incision but was otherwise <45 (with stable cardiovascular readings).

20.56 Avidan et al. 2008 & 2011 have suggested that a protocol in which ETAG alarms are turned on and set to 0.7 age-adjusted MAC is associated with a low incidence of AAGA. It is not known whether ETAG alarms were turned on in the cases reported to NAP5. However in 80 (72%) of 110 certain/probable reports of AAGA and 106 (78%) of 136 reports that included these and also ICU and drug error cases, the ETAG alarm protocol would have been unlikely to have prevented AAGA. In 22 of these cases anaesthesia was being maintained with intravenous anaesthesia; in 43 cases awareness occurred during or immediately after induction with a bolus of intravenous anaesthetic; in 21 cases awareness occurred at the end of or after surgery after the anaesthetist had turned off the volatile anaesthetic; in two cases it was considered that awareness occurred despite an ETAG concentration of >0.7 MAC; in two cases the anaesthetist deliberately chose to aim for an ETAG concentration of <0.7 MAC (albeit in one case BIS-guided); and in 16 cases awareness occurred as a result of a drug administration error in which an NMB was given before induction of anaesthesia. While ETAG would not have been appropriate in many of these cases, the majority of cases of AAGA reports arise when ETAG would be inappropriate or ineffective.

20.57 In the other 30 cases (22%), an ETAG alarm protocol might have prevented AAGA. However in seven of these cases AAGA occurred in the anaesthetic room or during transfer to theatre, so it would have been necessary for the ETAG alarm protocol to have been used in the anaesthetic room. In a further seven cases the anaesthetist forgot to turn on the vaporiser immediately after transferring the patient into theatre or after inducing anaesthesia in theatre. In this situation an ETAG alarm protocol would only be likely to prevent awareness if the alarm was enabled by default. Otherwise there is a risk that an anaesthetist who forgets to turn on the vaporiser also will forget to turn on the ETAG alarm.

20.58 It is not possible to estimate the extent to which a pEEG monitor might have prevented AAGA in the reported cases. A pEEG monitor could not be expected to have prevented awareness in the 16 cases resulting from drug administration errors (Chapter 13, Drug Errors). In order to have potentially prevented AAGA occurring during or shortly after induction, it would have been necessary (and logical) to have started using the monitor before induction. Similarly, in order to have potentially prevented AAGA cases at emergence,

it would have been necessary to continue using the monitor until recovery from neuromuscular blockade was assured.

DISCUSSION

20.59 One difficulty in interpreting the reports to NAP5 of AAGA in which BIS monitoring was used is that we do not have a continuous record of the output of the BIS monitor, but rather a report of the BIS output at intervals on the anaesthetic record. Thus, we cannot be certain what the BIS values were at the times when the patients had recall of events. It is also not clear whether the monitors were continuously observed, appropriately alarmed or the alarms acted on. Nevertheless, these are cases during which the anaesthetist is likely to have used the DOA monitor as an aid to adjusting the dose of anaesthetic and to have aimed to achieve a BIS value below 60.

20.60 In one of the five Certain/probable AAGA cases, the events recalled by the patient occurred on induction, and it was thought that the BIS monitor may not have been used at that stage of the anaesthetic. In another of the cases the recollection was probably of events after surgery but before full reversal of the NMB, and we cannot be certain whether or not the anaesthetist continued to use the BIS monitor and if so whether they aimed to achieve a BIS value <60 throughout that period.

20.61 In the other three cases, the patients recalled events during maintenance of anaesthesia – one during positioning for surgery, the second during surgical incision and the third during wound closure. These are all periods increased in stimulation and this may have contributed to AAGA at these times. Moving a patient who has a tracheal tube, making or starting to close an abdominal incision are all events that are likely to lead to an increase in 'arousal' and may result in an increase in heart rate, blood pressure and BIS value. The BIS value, like the heart rate and BP, will rise only after the stimulating event.

The displayed BIS value is calculated from data gathered over the last 15 to 30 seconds of EEG recording and updated every second. In a study during which the signal given to a BIS monitor was switched between EEG recordings from awake patients and EEG recordings from anaesthetised patients (Zanner, 2009) it took a mean of 25 s for the value displayed by the monitor to fully reach a value corresponding to the new state.

20.62 In clinical practice if a BIS monitor is used 'reactively' (i.e. the anaesthetist only increases anaesthetic depth when BIS rises above the target range in response to a stimulating event) during light anaesthesia there will be a delay in achieving deeper anaesthesia first for the time for anaesthetist to react and then for the increased anaesthetic drug to have effect. Good anaesthetic practice involves anticipating that an event such as the start of surgery is about to occur and that an increase in anaesthetic drug dose is likely to be required. The DOA monitor may then be used to guide further adjustments after the stimulating event has occurred. Therefore, one criticism of pEEG monitors is that they only provide information about the conscious state after it has arisen. Thus it may be argued, that pEEG monitors sometimes only mitigate the extent of AAGA rather than actually prevent it. What is really needed is a monitor that alerts to a 'pre-conscious' state. However the same argument applies to other modes of monitoring, including the IFT.

20.63 BIS may rise at times of increased surgical stimulus or perhaps simply as a result of fluctuations in brain activity when the surgical stimulus is stable. Maintaining the patient to a target value BIS of 55–60 which (albeit below the upper limits of current guidance) will nevertheless logically expose the patient to greater risk (or probability) of inadequate anaesthesia than if maintained at a BIS 40–50. This underlines the inherent problem of simply using 'threshold values' for pEEG outputs, when in fact the true situation is a highly dynamic one. Anaesthetists should be attentive to all such limitations of DOA (mis)use.

20.64 When DOA monitors are used in patients who have not received an NMB, or in whom the effect of the NMB is wearing off, then forehead and facial muscle electrical activity (electromyography, EMG) may be analysed by the monitor as well as EEG activity. EMG activity is predominantly of higher frequency than EEG activity but there is an overlap in the frequency ranges and the amplitude of the EMG is much larger than that of the EEG. EMG 'contamination' of the EEG signal may result in an increase in the value displayed by the DOA monitor making interpretation of the output more difficult. The Entropy monitor displays two numbers, State Entropy and Response Entropy, with higher frequency EMG activity being deliberately included when the Response Entropy value is derived.

20.65 In a patient whose muscles are not fully paralysed by an NMB, reflex movements in response to painful stimuli may occur despite a DOA monitor

displaying an index value associated with a low likelihood of recall. This situation resembles an IFT-by-default, but it is not known if in this scenario more weight should be given to the patient movement or to the DOA monitor output.

20.66 The reports of AAGA received by NAP5 indicate that the problem of unintended awareness is overwhelmingly that of awareness during neuromuscular blockade (see Chapter 19 Neuromuscular Blockade). In patients who have not received an NMB, clinical assessment of the response to speech and pain is possible and the risk of unintended awareness is low. NAP5 has shown no compelling evidence that DOA monitoring would reduce this further but is not designed so to do (Tables 20.2 and 20.3).

20.67 The clinical trials by Avidan et al (2008 & 2011) suggest that ETAG alarm protocols are as effective as a BIS-guided protocol in reducing the risk of awareness. However, in the B-Unaware study all four cases of definite awareness occurred during surgery and in the BAG-RECALL study all nine of the cases of definite awareness occurred during surgery. In contrast, in the majority of the reports received by NAP5, awareness occurred around the time of induction with an intravenous anaesthetic bolus or at /after the end of surgery when anaesthetic administration had been deliberately reduced or stopped. Therefore, the NAP5 results were generally sparse in relation to the phase of anaesthesia where ETAG monitoring might have the most impact.

20.68 In certain circumstances, DOA values may not be an accurate reflection of the hypnotic state – for example values may be altered by electrical interference, EMG activity or abnormal EEG activity. Some anaesthetic drugs such as nitrous oxide and ketamine do not have the same effects on the EEG as the commonly used intravenous and volatile anaesthetics. NAP5 data do not have the resolution to provide further comment on these aspects.

20.69 Most DOA monitors provide much more information to the anaesthetist than just the derived index value. For example, the BIS monitor (Figure 20.3) provides the EEG waveform, a measure of EEG signal quality, a measure of EMG activity and the Suppression Ratio (i.e. the percentage of the time during which the EEG is isoelectric if burst suppression is present). Optimal use of a DOA monitor involves using all the information it provides together with the information from the other patient monitors, clinical judgement and experience. The DOA value may be a useful extra piece of information but it should be taken along with all the other available information before making a judgement about whether anaesthetic dose should be adjusted.

20.70 However, at present the method of integration of this information remains highly subjective, almost in the manner of an intangible art form. It is desirable to define more precisely exactly how all this information should be optimally or quantitatively combined, and such practical guidance as to *how to* use pEEG monitors (as a question apart from whether to use them) is lacking. Recently, Schneider et al. (2014) proposed a scheme for achieving this, integrating information from BIS and cardiovascular variables to produce a quantitative multimodal index (Sleigh, 2014).

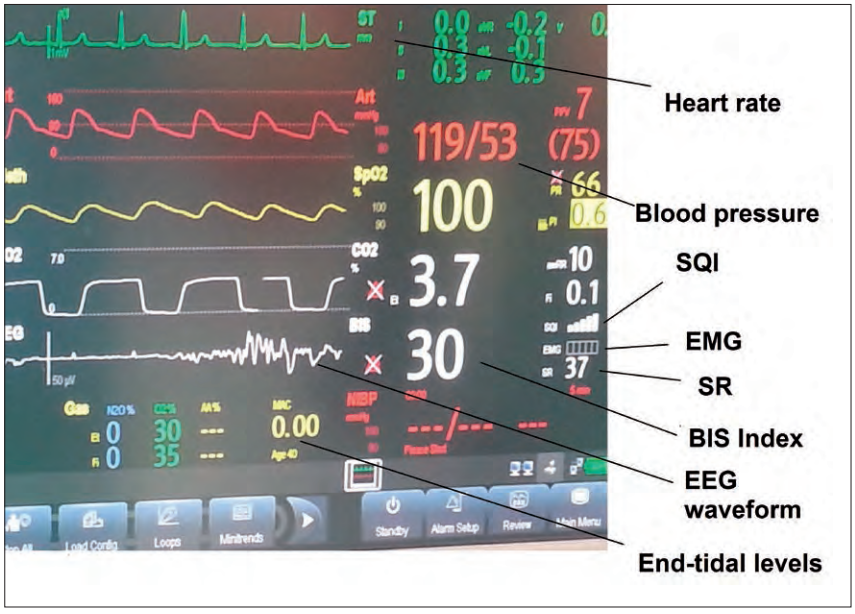


Figure 20.3. An example of the useful additional information available apart from the single numerical output from an EEG-based DOA monitor. The EEG waveform from (in this example) a BIS monitor provides additional information to the BIS index value of 30. Here the EEG shows 'burst suppression' with isoelectric periods indicating deep anaesthesia. The suppression ratio (SR) is the percentage of the time that the EEG is isolectric (37% in this case). There is a high EEG signal quality index (SQI) and no EMG activity has been detected (EMG). The heart rate, blood pressure and end-tidal levels (in this case no volatile or nitrous oxide used), or the estimated plasma or effect site concentration from the TIVA/TCI pump (not shown) also provide additional information. It is desirable to integrate these sources of information to guide the next steps in anaesthetic dosing as suggested by Schneider et al. (2014) and Sleigh (2014).

20.71 These putative objective algorithms would need to address problems such as dichotomy of the information provided by DOA monitor outputs and other variables such as blood pressure or ETAG. For example, when ETAG is very low, it is expected that the pEEG output is high: but what is the best reaction to a situation when it is also low? Problems are also raised by AAGA in the dynamic phases of anaesthesia, induction and emergence, and NAP5 has shown the importance of these phases as times for AAGA.

20.72 It makes theoretical sense to apply DOA monitoring at or before induction if it is planned to use it. However, an ideal monitor would not be contaminated by things like fasciculations or movement of the head and neck that can accompany airway management at induction. How best to react to a situation where the DOA monitor output rises sharply in the middle of airway manipulation or laryngoscopy would need to be defined, especially in the context of a rapid sequence induction or urgent need to secure the airway.

20.73 Zand et al. (2014) reported that during anaesthetic induction for Caesearan section in which IFT was employed, up to 46% of patients moved their hand, but BIS could not discriminate between those who responded and those who did not (no patient had explicit recall). While it may be logical, if using DOA monitors, to apply them from before the start of surgery, further research is needed to interpret their outputs in this dynamic phase of anaesthesia.

20.74 Similarly at emergence, it is the intention to awaken the patient and DOA monitor outputs are expected to rise; again an ideal monitor would not be contaminated by interference from muscle activity that accompanies this. Perhaps the real utility of DOA monitoring in this phase is to ensure that full muscle power (i.e. motor capacity, as measured by a nerve stimulator) has returned before awakening (as measured by the DOA monitor).

20.75 Although independent evidence for focussing the use of DOA monitoring in patients receiving TIVA is sparse, it is entirely logical when NMB is also used. There are few, if any, ways of monitoring the effect of TIVA in a paralysed patient and point of care blood propofol measurement is not widely available.

20.76 Although very few AAGA cases in whom DOA monitoring had been used were reported to NAP5, distress and severe long term impact in these cases was sparse, suggesting that perhaps, the control of anaesthesia in these cases was, despite being associated with AAGA, not one that led to adverse outcome. This finding should inform future trials of the efficacy of DOA monitoring in reducing AAGA. Rather than study the effect of monitoring in an unselected cohort, it may be more appropriate to focus on specific groups (e.g. patients with neuromuscular blockade and receiving intravenous anaesthesia). Furthermore, a 'binary' view of AAGA may be erroneous and greater attention may need to be paid to the specific impact on patients who experience AAGA. Thus even if in a trial the overall incidence of AAGA is unaffected by pEEG monitoring, it would be important if it were found that this monitoring mitigates adverse impact.

20.77 In summary, the NAP5 data appears to offer no support to a recommendation of universal specific DOA monitoring. However, it identifies the use of neuromuscular blockade in any context as an important risk factor for AAGA, and DOA monitoring may have a role in this situation. Specifically, the combination of TIVA with neuromuscular blockade may confer the highest risk for AAGA, and it is in this cohort that the use of DOA monitoring appears to confer the greatest protection (a hypothesis that warrants formal investigation). If, however, technologies for specific DOA monitoring are to be more widely adopted and optimally used, there needs to be a more coherent approach to research, training and development of pragmatic guidelines than there has hitherto been.

The importance of, or correct response to, a brief rise in BIS values above 60 is not currently known

IMPLICATIONS FOR RESEARCH

Research Implication 20.1
There is considerable scope for research using the isolated forearm technique, with implications for both fundamental science and anaesthetic practice. One question is the degree to which a positive response is associated with later adverse impact; another is how the incidence of positive IFT response is influenced by specific anaesthetic drugs or techniques. Further research into IFT responses when standard (rather than lower than usual) anaesthetic drug doses are administered is also needed.

Research Implication 20.2
Research on DOA monitors should extend to study their use in the dynamic phases of general anaesthesia (induction and emergence).

Research Implication 20.3
Research should focus on developing pragmatic algorithms aiding the integration and interpretation of all information available relating to depth of anaesthesia. There should be particular focus on resolving dichotomies, e.g. where blood pressure or end-tidal levels indicate the depth should be 'light' but DOA monitoring indicates the reverse.

Research Implication 20.4
Clinical trials seeking to establish the efficacy of DOA monitoring could usefully focus on patients undergoing anaesthesia with neuromuscular blockade and with intravenous anaesthesia.

RECOMMENDATIONS

RECOMMENDATION 20.1
Anaesthetists should be familiar with the principles, use and interpretation of specific depth of anaesthesia monitoring techniques (i.e. the available EEG-based monitors and the isolated forearm technique). Relevant anaesthetic organisations should include this monitoring in their core training programs.

RECOMMENDATION 20.2
The relevant anaesthetic organisations should develop pragmatic protocols or algorithms for the use of all available information about depth of anaesthesia (including information from DOA to guide anaesthetic dosing.

RECOMMENDATION 20.3
Anaesthetists should recognise that neuromuscular blockade constitutes a particular risk for AAGA. Use of a specific form of depth of anaesthesia monitor (e.g. pEEG or IFT) is logical to reduce risk of AAGA in patients who are judged to have high risk of AAGA for other reasons, and in whom neuromuscular blockade is then used.

RECOMMENDATION 20.4
If specific depth of anaesthesia monitoring is to be used (e.g. pEEG or IFT) then it should logically commence, if feasible, before/at induction of anaesthesia and continue until it is known that the effect of the neuromuscular blocking drug has been reversed sufficiently.

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CHAPTER
21

Consent in the context of AAGA


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HEADLINE

21.1 This chapter discusses the specific issue of AAGA as a potential complication or risk of general anaesthesia, in the context of obtaining informed consent for anaesthesia. A minority of Certain/probable and Possible reports of AAGA to NAP5 (44%) appeared to have a clear record of consent for anaesthesia. There was evidence of a specific pre-operative discussion of accidental awareness in only three cases. However, a specific warning of AAGA alone did not appear to mitigate adverse psychological impact when AAGA occurred. The incidence of perceived AAGA after sedation was at least as high as after general anaesthesia: these problems arose in large part due to issues of communication and consent. This chapter discusses the difficulties involved in obtaining informed consent for general anaesthesia. It is not intended to be a comprehensive document relating to consent and anaesthesia. The data from NAP5 do, however, provide information about the nature of the complication, with an emphasis on brief periods of awareness that are not always painful or distressing but that can involve a sensation of paralysis. The data also inform the communication of the magnitude of risk pertaining to different types of anaesthesia (e.g. the use of neuromuscular blockade or the risk in certain subspecialties such as obstetrics). Anaesthetists can use this data to inform their approach to consent. Patient information and consent for sedation should clearly distinguish the effects of sedation from general anaesthesia and where appropriate, indicate that the incidence of amnesia is variable.

BACKGROUND

21.2 The concept of 'consent' reflects the ethical/philosophical autonomy of an individual, as determined by society through its laws, to determine their own fate in life. Any contact (including a medical intervention) upon a person that takes place without their informed consent is regarded in law as an assault.

21.3 Consent for surgery normally involves the surgeon explaining the details of a proposed intervention and the associated benefits and risks. The patient is then in a position to agree or refuse surgical treatment, or choose instead some alternative course of action (General Medical Council, 2008).

21.4 For almost all proposed surgical interventions, some sort of anaesthesia is normally required which can range from local anaesthesia with the patient fully conscious, through sedation, to general anaesthesia. The person normally responsible for designing and delivering the proposed anaesthetic plan is the anaesthetist. Although all doctors work in teams, anaesthetists are professionally, organisationally and legally independent of the surgeon (i.e. autonomous) and therefore, it follows that some form of separate consent for the anaesthetic is necessary (Royal College of Anaesthetists, 2003 & 2013).

21.5 In order to provide consent the patient must have appropriate mental capacity. We will not discuss the potential problems posed by providing anaesthesia in patients deemed to lack mental capacity, since no relevant cases were involved in NAP5 that raised specific issues of consent. Guidance on this aspect is provided elsewhere (British Medical Association, 2007).

21.6 This chapter focuses on those aspects specifically relating to AAGA, namely:

(a) Issues around consent in NAP5.

(b) Highlighting areas where NAP5 results indicate that consent practices can be improved with respect to AAGA.

(c) Offer suggestions as to how this can be achieved.

21.7 Discussing consent for anaesthesia with a patient, involves:

(a) A need to provide information about what procedures the patient will undergo.

(b) A need for consent concerning specific components of the anaesthetic plan, e.g. central venous epidurals etc.

(c) Information on what the patient might experience.

21.8 Much of the existing advice concerning consent is provided by the AAGBI document *Consent for Anaesthesia* (Association of Anaesthetists of Great Britain and Ireland, 2006) and by the Royal College of Anaesthetists (2013). These documents stress the need to obtain consent and the general legal framework surrounding consent. However, they do not specify whether AAGA needs to be discussed as a risk of anaesthesia, nor do they explain in what terms that risk should be optimally communicated.

21.9 Considerable debate in the anaesthetic literature has revolved around the issue of whether a patient signature for anaesthesia is necessary, separate from the signature normally required for surgery, or whether pre-prepared forms should document an appropriate list of possible risks associated with anaesthesia (Dobson, 1999; Watkins et al., 2001; White, 2004). This chapter is not concerned with the issue of separate signatures, but notes that proper consent is a state of mind (Medical Protection Society; www.medicalprotection.org/uk/anaesthetics-case-reports/too-late-for-consent).

21.10 Patients' attitudes to 'consent for anaesthesia' (as distinct from 'consent for surgery'), including the issue of signatures, are potential topics for further research (Burkle et al., 2013). Relevant questions might include: what do patients understand or expect by the term 'anaesthesia'? What aspects of the process do they generally wish to know about, and which details would they rather not know? Which specific risks of anaesthesia would they particularly wish to be informed of? Indeed, is it possible to regard 'consent' separately for anaesthesia and for surgery, or rather, as for the entire procedure as an indivisible entity?

21.11 A comment on patient expectations and consent for sedation is also relevant. Patients' reports of AAGA do not always follow general anaesthesia and previous studies indicate that between 5% and 30% of cases may occur after sedation (Samuelsson et al., 2007; Kent et al., 2013) (see also Chapter 12, Sedation). Indeed Mashour has shown that the incidence of reports of awareness after anaesthetist-delivered sedation (0.03%) does not differ significantly from that after general anaesthesia (0.023%); (Mashour et al., 2009). These findings emphasise the importance of anaesthetists ensuring that patients understand (and agree) on the specifics of the planned level of consciousness as part of the consent process.

21.12 This may be hard to achieve. Esaki & Mashour (2009) interviewed 117 patients after regional anaesthesia or 'monitored anaesthesia care'. The commonest level of consciousness expected by patients (and subjectively experienced) was 'complete unconsciousness'. Only 58% of patients had specific expectations set by the anaesthesia provider. While anaesthetists may feel they understand what 'sedation' entails, it seems that patients do not.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

Consent and documentation

21.13 NAP5 found that of the 136 cases of Certain/probable AAGA (Class A and B) for which data were available, there was a suitably clear record of consent in a minority; 60 (44%). There was evidence of a specific pre-operative discussion of accidental awareness in only three cases.

21.14 It is not known, however, if this represents an insufficient record and that appropriate information had been provided to the patient, or if it means that consent was never taken. It is also not known if patients had the chance to read information leaflets.

21.15 In those cases where specific warnings of AAGA were provided, this information alone did not appear to mitigate adverse psychological impact when AAGA did actually occur.

A middle aged patient was scheduled for elective minor lower limb surgery. A pre-operative visit was comprehensively charted by a physician assistant in anaesthetics (PAA) who specifically warned of the possibility of AAGA. Just before induction the consultant anaesthetist changed the anaesthetic plan to include tracheal intubation and inadvertently 'induced' with atracurium. This was promptly recognised and unconciousness was induced with propofol. Post-operatively the patient reported an experience of respiratory difficulty, paralysis and a feeling of dread. The patient thought they had had a reaction to the anaesthetic and that they were dying. In the following weeks, severe psychological distress developed, with heightened anxiety, tearfulness and poor sleep. The symptoms are judged to be consistent with PTSD.

A young healthy patient (with a past history of anxiety/panic attacks) required general anaesthesia for a Caesarean section. The patient had been seen by two anaesthetists during labour, one of whom specifically warned about the possibility of a difficult intubation and AAGA. General anaesthesia was induced using RSI with thiopental and suxamethonium, and apart from two attempts at intubation the procedure was uneventful. The following day routine follow-up revealed the patient had been aware for a brief period following induction, when she could not move or breathe and could feel something being done in her mouth. She was distressed and felt 'terrified', tried to blink and move her arm to alert people but was unable to do so. There was no pain and the experience passed quickly.

21.16 It is striking that there were 32 cases in NAP5 where the patient made a report of AAGA but in fact had only received sedation (in 12 of these cases, the main provider was a non-anaesthetist). This was always as planned by the care provider (i.e. not an omission or error). General anaesthesia was never intended and therefore, in large part this appeared to be a failure of communication.

21.17 Sedation is generally accepted to be a state of drug-induced altered consciousness less than general anaesthesia. In 'light sedation' a response to verbal stimulation is retained. In 'deep sedation' verbal contact may be lost, but there may still be a response to pain (Academy of Medical Royal Colleges, 2013). Sedation does not imply amnesia, although this may sometimes occur.

21.18 Sedation is often undertaken by non-anaesthetists but the issues of consent apply equally. Therefore, in this section we will adopt the word 'sedationist' as a general term, and specify the subspecialty. Issues of consent in relation to sedation can evolve into legal action.

A patient underwent an elective endoscopic gastrointestinal procedure. The procedure was longer and more complicated than anticipated. The patient expected to be unconscious but 'awoke' during the procedure and experienced severe pain. Eighteen months later, the patient filed a complaint via solicitors and this described continued extreme anxiety and new psychological symptoms including a fear of anaesthesia. The sedationist had been a consultant gastroenterologist and there was no record of a pre-operative visit, no prior written information and no documentation of consent.

21.19 Even when the quality of recording of information was otherwise extremely good, the process of consent appeared to have shortcomings. Sometimes problems arose even when the patient had received prior written explanation of sedation, or when the patient had signed a consent form specifying that sedation and not general anaesthesia was what was intended. 'Disconnection' between sedationist and patient in understanding planned sedation may occur because of inadequate explanation to the patient or inadequate listening or understanding by the patient. Patient understanding of the level of sedation should be confirmed and documented as part of the consent process.

A patient underwent uncomplicated total knee replacement. The consultant anaesthetist administered a spinal anaesthetic, a femoral nerve block and provided sedation with midazolam. Nine months later, the patient reported in clinic having been unexpectedly awake, hearing banging noises which caused fright, lasting ~10 minutes. Although the quality of peri-operative management and documentation on the anaesthetic record was judged very good, there was no documentation of verbal or written consent for sedation.

A young, fit patient underwent an elective endoscopy. The patient found the whole procedure 'very distressing', was very tearful in recovery and reported to the recovery nurse that they were told they would be asleep. The unit's practice was that patients were pre-assessed by a nurse specialist, a history taken and the management plan discussed and consent taken. The patient signed a consent form and confirmed that they had understood the sedation guidelines. The leaflet the patient was given explained: 'Sedation: You will be given a sedative to help you relax, together with some painkillers. These are given via a needle in your hand or arm and will make you drowsy and relaxed but is not a general anaesthetic. You will be able to hear and follow simple instructions during the procedure. You may not remember much about the procedure as the sedation may cause some short-term memory loss. However, people often respond differently to the sedation. Some are very drowsy and have little memory of the whole event, whilst others remain more alert'. The sedationist was a non-anaesthetist consultant who administered local anaesthetic spray to the throat and midazolam 4mg. The sedation record reported the following: Sedation Scale: 1 (Awake) and Discomfort Scale: 1 (No or Minimal Discomfort).

DISCUSSION

21.20 We recognise that the situations in which anaesthetists take consent are highly varied, ranging from the setting of a pre-operative clinic where there are fewer time constraints, to the seconds or minutes before immediate lifesaving surgery. It is perverse to assume or expect that the process of consent can be identical in all these scenarios.

21.21 One of the major problems for the consent process in anaesthesia is that for the majority of cases the anaesthetist and patient will meet only on the day of surgery and often in practice for only a few minutes, very soon before the intended surgical intervention. This is in stark contrast to the process of surgical consent for elective surgery where the patient has often formed a mental picture or gained some understanding of what is intended, perhaps from the moment of visiting the general practitioner, through the surgical outpatient clinic and so on.

21.22 AAGA is just one of very many potential risks of anaesthesia, many others being several orders of magnitude more common and more life-threatening than is AAGA. Given the practical time constraints to the process, both patients and anaesthetists must accept that it is difficult if not impossible to cover all possible risks of anaesthesia and a degree of selectivity and proportionality is inevitable.

21.23 It should now be routine practice for hospitals to provide patient information leaflets in advance of anaesthesia, explaining processes, risks and complications. This is a very important way in which complex risks like AAGA can be communicated to patients.

Issues around consent and patient information were prominent in many aspects of NAP5

21.24 Nevertheless, the pre-operative visit by the anaesthetist provides the main opportunity to confirm that this information has been received, read and understood, and to answer any questions that arise from it. This is an opportunity to personalise information given to the patient. The question to consider is what the particular patient needs to know in order to make a decision about the proposed procedure.

21.25 When patients present for emergency anaesthesia the challenges of providing a level of information equivalent to the input for elective surgery, especially about AAGA, are magnified, both for surgeon and anaesthetist.

21.26 Ideally, specific anxieties of the patient should be identified and addressed, and the anaesthetist

should confirm, to the best of their belief, that the patient has understood the information provided. The detail of documentation is likely to be proportionate to the circumstances, and may range from a shorthand note to indicate a description of routine anaesthesia to a more detailed description of the conversation.

21.27 A key concern on the part of the patient (and the anaesthetist) might be whether they will be accidentally awake during surgery. Addressing a concern about any potential complication involves several different themes:

(a) What is the nature of the complication. For example what will the patient feel? How will it affect the patient later? What further treatments might be needed to manage the complication?

(b) How common or rare is the complication?

(c) A seeking of reassurance as to the steps to be taken to minimise any risks.

21.28 For a proposed surgical intervention the patient uses this information about risk to inform their decision as to whether to proceed or not (i.e. weighs up the benefits vs the risks).

21.29 In relation to anaesthesia, this may be possible where a choice is proposed between, say, local or regional anaesthesia vs general anaesthesia. However, in many circumstances, patients often do not have any real choice about the type of anaesthesia that is possible. In these cases, the information about risks of AAGA solely inform the decision as to whether to proceed or not with surgery; rather than inform any choices about the anaesthetic.

21.30 It is not known to what extent the risk of AAGA alone influences patient choice to proceed or not with surgery.

21.31 Hence, the use of patient information leaflets is very important in conveying complex information which the patient will have time to consider. Thus a suitable form of words that satisfies the requirements might be something like: 'Have you read and understood the information about general anaesthesia or do you have any questions?' The remainder of the consultation can then be more focused on any specific areas of concern.

21.32 There is consensus that accurate information should be provided when a specific request is made and the NAP5 results help frame suitable responses to some more detailed questions about AAGA.

21.33 First, NAP5 has shed light on what is commonly the nature of AAGA. AAGA can be explained to patients as commonly being a very short-lived experience lasting a couple of minutes, often involving touch or sounds, and confined mainly to the periods in which the patient is going to sleep and in the process of waking up. Sensations of weakness or inability to move may be experienced but these will be temporary. The patient can be reassured that these are not always distressing especially when forewarned (Topulos et al., 1993). Detailed wording will need to be tailored to the context and to the patient's understanding.

21.34 The table of incidences in Chapter 6, might be used to guide explanations about the incidence of risk of AAGA. Anaesthetists might use the aggregate statistics (e.g. ~1:20,000), or data relevant to the type of operation or technique the patient is facing (e.g., ~1:8,000 if neuromuscular blockade is to be used). Clearly, great reassurance can be offered where the technique does not involve neuromuscular blockade (~1:136,000). However, perhaps at the other extreme, for Caesarean section quoting a higher incidence of risk seems justified.

21.35 In quantifying the magnitude of risk there is however, a dilemma as to whether to rely on the data from NAP5 (which are based on patient reports of AAGA) or quote the data from Brice studies (based on results of direct post-operative questioning). The incidences arising from the latter are several orders of magnitude higher. The anaesthetist's degree of belief in the respective sources of data is important. If an anaesthetist believes, on reading the NAP5 Report and its methods and analysis, that NAP5 has greatly under-reported the 'true' incidence of AAGA, then they are likely to quote the 'Brice incidence' of 1–2:1,000. If, on the other hand, an anaesthetist believes that the 'Brice incidence' over-estimates AAGA, or takes the view that the incidence that matters is what the patient spontaneously reports, then quoting the data from NAP5 as a guide would be entirely consistent.

21.36 A situation in which an anaesthetist should logically quote the 'Brice incidence' is when they intend to use the Brice questionnaire, or something like it, post-operatively.

21.37 Whichever incidence is to be quoted, anaesthetists need to be specific about the nature of the data. Thus in quoting NAP5 it would be appropriate to use wording like 'the largest study on accidental awareness has found the incidence of *spontaneous reports* to be 1 in X' or if quoting data based on Brice, 'If questioned post-operatively using structured questionnaires, 1 in 600 of patients are judged to have experienced AAGA'.

21.38 Finally, the provision of information about risk needs to be coupled with reassurance about ways in which that risk will be mitigated or managed. Anaesthetists could make reference to the monitoring of end-tidal agent levels, use of nerve stimulators, or use of specific depth of anaesthesia monitors.

21.39 Some anaesthetists might adopt a policy of using DOA monitoring in all cases where a patient specifically asks about risks of AAGA. This may provide reassurance. However, as discussed in Chapter 22 (Medicolegal), if a patient makes a later report of AAGA then a DOA reading higher than the recommended range potentially becomes evidence that the patient was, in fact, aware.

Informed consent for sedation, in context of AAGA

21.40 Recognising the important issues specific to sedation and how it is perceived by patients (and also anaesthetists/sedationists), we have devoted a separate section to this topic (see Chapter 12).

21.41 Many of the reports of AAGA submitted to NAP5 following procedures performed under sedation might have been avoided if the consent process had culminated in the patient and sedationist (a) agreeing an intended level of consciousness during the procedure, and (b) agreeing that amnesia was not expected.

21.42 Sedation should not be conflated with anxiolysis. Anxiety is a heightened emotional state which may include rational (or irrational) concern or apprehension that something bad may imminently happen (Barlow, 2000). In a state of anxiety the actual sensory input (i.e. the information obtained from the senses about one's surroundings) may also be notably different from their perception (i.e. the meaning ascribed by the patient to that sensory information). Regional anaesthesia will reduce sensory input and sedation reduces perceptual powers but neither will necessarily alter the anxious patient's tendency to interpret events in a negative way. Sedative drugs alter perceptual processing making it more difficult to make sense of the world, resulting in more effort required to focus or concentrate on events.

21.43 Sedatives often have amnesic effects through effects on the hippocampus-limbic system (Tokuda et al., 2010; Johnson et al., 1995). As a consequence of their effects on attention and memory, events that would otherwise be compelling (e.g. surgery) may no longer hold attention, or be recalled. When events are recalled these may lack structure or context (source memory). Regarding consent and sedation, it follows that drugs cannot guarantee to transform an unco-operative anxious patient into a co-operative calm one.

21.44 In taking consent for sedation the following points are usefully emphasised:

(a) Sedation is not general anaesthesia and there is no intention to eliminate sensation.

(b) Sedation may calm the patient but not eliminate all anxieties.

(c) Sedation may induce a light sleep from which the patient may rouse intermittently.

(d) The patient may be aware of surrounding events but may not particularly care or be interested in them.

(e) There may be variable amnesia for the events, such that the patient may later believe they have received general anaesthesia.

21.45 Perhaps many of the cases where patients have been dissatisfied with accidental awareness could have been mitigated by having provided more accurate information as part of the process of consent, with specific indications that brief experiences with recall are possible especially for the dynamic phases of anaesthesia (induction and emergence).

21.46 Use of pre-operative information leaflets about anaesthesia will help prepare the patient. Given the evidence from NAP5 of the psychological impact of the unexpected experience of paralysis during AAGA, information about such effects should be included where NMB is to be used.

21.47 There is a possibility that a patient undergoing sedation will believe this is general anaesthesia (and complain accordingly if they have memory for the procedure).

21.48 Therefore, due care should be taken with the process of consent for sedation, emphasising the type of patient experiences that are possible and stressing that during sedation the patient is awake, albeit with drugs that alter perceptions.

IMPLICATIONS FOR RESEARCH

Research Implication 21.1
There is scope for considerable research into patients' ideas, attitudes and expectations regarding consent for anaesthesia (as distinct from consent for surgery). What a patient understands or expects of 'anaesthesia' needs sharper definition.

Research Implication 21.2
Further research is needed to improve the measurement of pre- and peri-operative anxiety by an objective scoring system and to determine if such scores help guide the degree of sedation necessary to achieve patient satisfaction.

Research Implication 21.3
Further research could assess whether, in taking consent, some identifiable patient groups (e.g. age, gender, attitudes, culture) require more explanation than others?

Research Implication 21.4
The optimum role of non-anaesthetists in the process of consent for general anaesthesia and/or sedation is a suitable focus for research. Does this relate to patients' understanding or expectations of what 'anaesthesia' is (i.e. that they invariably expect 'anaesthesia' from an 'anaesthetist')?

Research Implication 21.5
It would be important to investigate whether patients welcome explicit discussion of AAGA before anaesthesia? If so, what information do they want and does this impact on levels of anxiety, subsequent experiences or satisfaction?

RECOMMENDATIONS

RECOMMENDATION 21.1
Patients should be provided with information about risks of anaesthesia and this should include risks of AAGA (which can be written information provided before anaesthesia).

RECOMMENDATION 21.2
Patients should be informed of the possibility of brief experience of paralysis, especially where neuromuscular blockade is used. Although desirable to avoid these symptoms, a warning would prepare the patient for the experience in the context of AAGA.

RECOMMENDATION 21.3
Anaesthetists should ascertain the degree of information that is required by a patient about the risks of AAGA, over and above that contained in information leaflets. An explanation of risks should be coupled with information about how those risks will be mitigated.

RECOMMENDATION 21.4
Anaesthetists should form an opinion on the magnitude of risks of AAGA to quote, based on the evidence available in the literature, making clear how any estimate of magnitude quoted was obtained (e.g. spontaneous report vs active questioning).

RECOMMENDATION 21.5
Anaesthetists should provide a clear indication that a pre-operative visit has taken place, and documenting that a discussion has taken place.

RECOMMENDATION 21.6
Sedationists should make efforts to ensure that the patient understands the information they are given about sedation, specifying that sedation may not guarantee unawareness for events or guarantee amnesia.

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CHAPTER
22

Medicolegal aspects of AAGA


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HEADLINE

22.1 Of the 141 Certain/probable and Possible cases, only 12 (11%) submitted a formal complaint to the hospital and a further 8 (6%) were reported to be involved in some legal action. Of the 17 Drug Error cases (where clearly error led to the AAGA and care was judged poor), just one patient submitted a formal complaint (6%) and one separate (6%) patient commenced legal proceedings. Of the 70 historical, 'Statement Only' cases, there were no complaints submitted or legal action reported. However, only 22% of reports were adjudged to have received 'wholly good' care both during and after the anaesthetic. In those cases where intra-operative care was considered to be either 'poor' or 'both good and poor', the Panel judged that the majority (78%) incidents of AAGA were 'preventable', indicating considerable potential for litigation with regard both to failure of duty of care and causation. Aftercare was considered as either 'poor' or 'both good and poor' in 22% of cases. This chapter makes recommendations to manage complaints or litigation after AAGA.

BACKGROUND

The general legal approach to a civil negligence claim

22.2 In the UK, patients seeking to bring a civil claim for negligence against their doctors must clear a number of hurdles, all of which are tested 'on the balance of probabilities', i.e. more likely than not.

22.3 First, they must show that the doctor or hospital in question had a duty of care towards them. In the context of anaesthesia, whether delivered in the National Health Service or Independent sector, this is rarely a matter of contention.

22.4 Second, the claimant needs to be able to demonstrate that there has been a failure of that duty of care. The relevant standard of care is defined by case law in each legal jurisdiction, but the principle invariably reflects the ruling stated in the widely cited Bolam case, that "*A doctor is <u>not</u> guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art ...Putting it the other way round, a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view*" (Bolam, 1957).

22.5 The Bolam principle is in reality a test of the conditions under which a doctor is *not* negligent and in other words, an anaesthetist will not be at risk of being found to be negligent if another anaesthetist, often referred to as an expert, can persuade the judge that his/her actions or decisions would have found favour with a responsible body of his peers. An expert is someone instructed by one of the opposing parties, but who acts on behalf of the Court (Civil Procedure Rules, 1998).

22.6 The judge will further apply the 'Bolitho test' to the expert testimony. The expert should have "*directed his mind to the question of comparative risks and*

benefits and has reached a defensible conclusion on the matter" (Bolitho, 1993). The Bolitho test is especially useful where there are (as is often the case) two or more experts with differing views; the judge will, in essence, decide which opinion s/he prefers, taking the Bolitho rider into account when making judgement. The judge is likely to be swayed, among other things, by the ability of the expert to provide a logical argument in support of their stance.

22.7 Third, the claimant has to have suffered harm, whether it be physical or psychological. Without harm, no matter how egregious the performance of the anaesthetist, there is no negligence in the eyes of the law.

22.8 Finally, the claimant must be able to demonstrate a direct *causative link* between the *failure of duty of care* and the *harm* that they have suffered. This is often known as the 'what if' or 'but for' test – i.e. what would have happened to the patient if the failure of duty of care had *not* occurred. It is on this element of causation that many negligence claims fail. In fact, the majority of negligence cases are unsuccessful. Even when claimant solicitors are sufficiently confident to present a case to the National Health Service Litigation Authority (NHSLA), 33% of such claims are eventually abandoned. Only 2% of cases get as far as the court, as settlement tends to be achieved in the early stages of negotiation (National Health Service Litigation Authority, 2013) or at joint settlement discussions once the evidence to be presented at trial has been compiled.

22.9 An analysis of litigation claims handled by the NHSLA relating to 'inadequate anaesthesia' between 1995 and 2007 suggested that cases of awareness during intended general anaesthesia and 'awake paralysis' accounted for 12% of all anaesthetic-related claims and >20% of all claims relating to general anaesthesia. These claims account for ~10 claims per year (Mihai et al., 2009).

22.10 This relatively small number seems somewhat at odds with the notion that the incidence of AAGA is reported to be as high as ~1:600 cases of general anaesthesia when direct post-operative questioning is used (Avidan et al., 2011). However, the figures of lower incidence (ranging from 1:1100 up to ~1:15000 cited by other authors (Pollard et al., 2007, Mashour et al., 2009, Myles et al., 2004) might more intuitively be expected to lead to fewer claims. Consistent with other medicolegal data, obstetric claims are perhaps over-represented, comprising 30% of the total for awareness and awake-paralysis.

22.11 Although small in absolute numbers, a high proportion of cases (87%) were settled in favour of the claimant, with average cost to the NHS (settlement plus legal costs) of £32,680 for awareness claims and £24,364 for awake paralysis; the latter category largely encompassed accidental administration of neuromuscular blocking drug before induction agent.

22.12 A closed claims analysis carried out in the United States (Domino et al., 1999) found a lower percentage of anaesthetic-related claims due to awareness and awake paralysis (~2%), but with a similar preponderance of female patients (77% compared with 74% in the UK study). In the awake paralysis category, care was found to be substandard in 94% of cases, and in 43% of the cases alleging recall during general anaesthesia. It is important to remember that closed claims, by virtue of the fact that they only represent those cases where legal representations have been made, are unlikely to accurately reflect the prevalence of clinical incidents (Brennan et al., 1991; Wilson et al., 1995). In the UK and USA datasets, in all claims relating to brief awake paralysis due to drug error, the claimant was successful.

22.13 Retrospective analysis of 12 negligence claims for accidental awareness handled by one of the authors (DB) over a nine-year period (where the actual outcome was unknown) suggests that all but two would have been settled in favour of the claimant, the exceptions being a case where anaesthesia was deliberately lightened to maintain cardiac output and blood pressure in a patient with a massive obstetric haemorrhage, and another where there seems to have been likely innate (possibly genetic) anaesthetic resistance to otherwise acceptable end-tidal concentrations of anaesthetic agent. Culpable cases include syringe swaps, where neuromuscular blocking drugs have been administered before induction agents, mis-mounted vaporisers, failure to allow for slow wash-in of volatile agents with low flow settings, and prolonged delays between intravenous induction and first delivery of volatile agent.

Accidental awareness during general anaesthesia and negligence

22.14 There is of course an overarching 'duty of care' on the part of the anaesthetist to the patient in the conduct of general anaesthesia for surgery, but the question of which 'duty' has been breached in respect of 'awareness' is relevant (i.e., whether there really is a 'duty' to provide complete unconsciousness), and issues of consent are important (see Chapter 21, Consent).

22.15 A patient who is led to believe that they will definitely be completely unconscious from a certain timepoint, and who finds that they have not been, will likely feel that the duty of care has been breached. In contrast, a patient fully informed that there is a chance (albeit small) of awareness, and informed of the uncertainties involved in monitoring consciousness, may not react in the same way. The use of appropriately-worded information leaflets is likely to be particularly helpful.

22.16 In cases where breach of duty of care is alleged then the Bolam test becomes relevant. Accepted standards of care are likely to be reflected in the conduct of anaesthesia, as a surrogate marker of care. These might be reasonably judged to include appropriate monitoring as is recommended in professional guidance (e.g. end-tidal concentrations of volatile agents, nerve stimulator when neuromuscular blockade is used, etc; Association of Anaesthetists of Great Britain and Ireland, 2007). Experts may also apply common sense standards that do not necessarily require specific recommendations but present unarguable logic (e.g. appropriate drug selection and dosing, and high-quality record keeping as a reflection of the attention to details).

22.17 The notion of *causality* may be important. In general, AAGA might be caused either by some failure in the supply of adequate dose of anaesthetic agent(s) (e.g. through disconnection, machine or human error/judgement, etc) or because of an intrinsic resistance to otherwise adequate doses of anaesthetic agent(s). The latter might in turn be due to factors like heightened arousal or anxiety, which antagonise effects of anaesthetic drugs at various levels (Maranets & Kain, 1999; Pandit et al., 2004), hypermetabolic conditions, concomitant medication – especially analgesics (Ghoneim et al., 2001), or possibly true genetic resistance (as yet largely unexplored in human populations; Liem et al., 2004).

22.18 Harm caused by anaesthetic awareness is generally psychological rather than physical in nature, but the severity of the reaction and its effect on the quality of life of the sufferer may be such that awards can be substantial. Unsurprisingly, it is rarely a problem for the claimant's legal representatives to demonstrate a causative link between the episode of awareness and the damage experienced by the patient.

22.19 Good record-keeping can be crucial to an anaesthetist defending a claim for AAGA, demonstrating, for example, a reasonable dose of induction agent, analgesic medication and maintenance concentrations of anaesthetic agent(s), and appropriate monitoring. Unfortunately, courts frequently find that anaesthetic records are not always as full and detailed as they should be, with the period between induction and maintenance often being particularly sketchily charted.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

22.20 In this section, it is important not to draw too many medicolegal implications from the Panel's assessment of the 'quality of care' in the cases analysed in NAP5, since the standards which they apply when judging care as 'good' or 'poor' will not necessarily match those which would be considered as appropriate by a court. The Panel did not have access to the actual case records but only to such detail as was provided by the Local Co-ordinator.

22.21 Of 110 Class A (Certain/probable) cases, only 12 (11%) submitted a formal complaint to the hospital and a further six (5%) were reported to be involved in some legal action. Of 31 Class B (Possible) cases, just two (6%) submitted a formal complaint and none started legal proceedings. Of 17 Class G Drug Error cases, just one patient submitted a formal complaint (6%) and one separate (6%) patient commenced legal proceedings. Of the Statement Only cases, there were no complaints submitted or legal action reported.

22.22 With the caveats in mind, it is of interest to note that only 31 out of 158 patients in categories Certain/probable, Possible and Drug Error (20%) were adjudged to have received 'wholly good' care both during and after the anaesthetic. Even when the 17 'drug error' cases (Class G) are removed from the denominator (i.e. where care would have been poor by definition) the figure for 'good care' is only ~22%.

22.23 In those cases where intra-operative care was considered to be either 'poor' or 'both good and poor', the Panel judged that 93/119 (78%) incidents of AAGA were 'preventable', indicating considerable potential for litigation with regard both to failure of duty of care and causation.

22.24 Aftercare was considered as either 'poor' or 'both good and poor' in 35 cases in the Certain/probable, Possible and Drug Error classes (22%). Local Co-ordinators were specifically asked to comment on what support was provided after the AAGA episode, and in a substantial minority the response was 'little' or 'none'. So, even once AAGA had been reported, anaesthetists might not always be taking

the opportunity to minimise psychological damage (and possibly the chances of the patient pursuing legal redress). Where drug error had occurred, however, aftercare was classed as 'good' in 84% of cases, suggesting that anaesthetists who have made a specific and well-defined error such as a syringe swap are generally good at following their patients up and arranging appropriate referral. Of note: the NAP5 Baseline Survey found that just 12 of 265 UK hospitals had specific guidelines for managing a case of AAGA (Pandit et al., 2013a and b).

22.25 It appears that the NAP5 Panel were more likely to regard care as poor when a patient experienced a bad outcome. Patients who were adjudged to have suffered 'severe' harm as defined by the modified NPSA classification only received both intra-operative and post-operative care classified as 'good' by the Panel on 11% of occasions, compared with 21% of patients with mild or moderate harm and 27% of those who were unharmed. This might arise from quicker detection by the anaesthetist of factors leading to AAGA and better aftercare minimising psychological damage. Alternatively, it might represent a subconscious influence of the outcome upon the judgement of care as made by the Panel (Caplan et al., 1991). Or, it may reflect the fact that adverse impact is more common when care is poor.

22.26 In many cases reported to NAP5 there was good evidence of comprehensive recording of events, good communication with patients and excellent support. These cases illustrate the advantages of keeping clear, high-quality records that can mitigate adverse impact, even when it is perhaps too late to prevent adverse patient-impact. Where duty of care has been breached, claims with good records will often settle early in the legal process without any need for the opposing anaesthetic experts to meet, and certainly without the added burden of a court appearance for the anaesthetist or the patient. Good quality record-keeping and communication with the patient should result in rapid resolution, and the learning arising from associated morbidity and mortality presentations and serious incident enquiries will help to prevent a recurrence.

22.27 In contrast, in a minority of cases staff attitudes and lack of patient support appear to have compounded the problems for the anaesthetist and trust/hospital. In some cases, evidential disparities between contemporaneous records and machine logs could even lead to trusts/hospitals or external bodies raising questions about probity.

A patient undergoing general surgery became aware in theatre, recalling specific aspects of a conversation between the anaesthetist and other staff. The patient could not move, felt panicky and wanted to scream but could not, felt violated then lost consciousness. They informed recovery staff immediately on waking. The patient was greatly distressed and after later psychological assessment, PTSD was confirmed. A clear detailed record confirmed very low/absent end-tidal and inspired volatile agent for around 15 minutes at the start of surgery. The anaesthetist confirmed that they forgot to turn on the vaporiser on transfer to theatre from the anaesthetic room, due partly to distraction from a malfunctioning pulse oximeter.

Immediately on waking from a Caesarean section, the patient recalled a burning pain at the start of surgery, feeling like a cut, then a pulling sensation. This lasted around 30 seconds then she lost consciousness. The patient was seen by the same anaesthetist afterwards who, the patient felt, did not believe her account and suggested that she was dreaming. The patient was very angry about how the incident had been handled at this encounter. The anaesthetic record indicated immediate initiation of volatile agent after induction, but the automated machine log showed a gap of several minutes before the vaporiser was turned on. The trust investigation concluded that that the patient's statement was 'entirely believable'.

An accurate contemporaneous anaesthetic record is essential if a claim of AAGA is to be defended

22.28 Where good records have been kept, it can be apparent that there is no obvious cause for the AAGA, raising the possibility of true anaesthetic (e.g. genetic) resistance or an error of patient recall. Such cases might be successfully defended. However, if the record means that there is doubt about the timing of the episode of AAGA or the levels of anaesthesia during the case, due to inadequate record keeping, then the outcome of a negligence claim might be less favourable.

During surgical outpatients many months after the event, an elderly patient accurately reported details of a conversation between surgeons regarding location of the surgical incision when converting from a laparoscopic to an open procedure; there was no recollection of pain or paralysis. The patient was unconcerned by this incident. A detailed anaesthetic record showed that, during this period, the patient was receiving a remifentanil infusion plus 0.9 MAC of sevoflurane. BIS was in place and recorded in the 40's, and cardiovascular variables were stable.

22.29 There were reports of cases where poor record keeping made it impossible to determine why the patient suffered periods of awareness which were often quite prolonged. In some cases there was probably a failure to deliver sufficient volatile agent, but it could not be determined from the anaesthetic records what concentration, if any, had been delivered. In such cases a judge is likely to conclude that poor record-keeping is highly suggestive of poor medical care: an argument that would certainly be put to the defendant anaesthetist in a very robust manner by counsel for the claimant if the case came to court. Failure to maintain anaesthesia (as evidenced by AAGA) coupled with an inadequate record means that claims of this sort will generally be indefensible, and trusts/hospitals, under instruction from the National Health Service Litigation Authority, would probably settle rapidly.

Following a general surgical procedure, a patient recalled being wheeled into theatre, feeling paralysed, a sharp sensation on their abdomen, something being 'pushed into their tummy' and accurate details of conversations. The consultant anaesthetist's chart had no record of heart rates, diastolic blood pressure, oxygen saturation, inspired oxygen, end-tidal carbon dioxide, fresh gas flows, or end-tidal volatile concentration during the nearly two-hour procedure.

22.30 Syringe-swap errors leading to the patient being awake but paralysed by a neuromuscular blocking agent will, unsurprisingly, almost invariably be recognised as a failure of duty of care, and trusts/hospitals will be advised to settle any claims arising out of such cases. Even where an indefensible error such as this has arisen, however, careful handling of the incident along with a clear and honest explanation can mitigate harm to the patient or to the reputation of the trust/hospitals.

A consultant anaesthetist gave suxamethonium instead of midazolam before induction to a patient undergoing general surgery. The consultant recognised the error and reassured the patient, saying "We know you are awake; everything is all right and you will be asleep soon" and then induced anaesthesia. The consultant anaesthetist went to talk to patient the next day to provide a fuller explanation. There was no impact on the patient who underwent a second operation uneventfully three months later.

22.31 Patients in general have a three-year window from when they realise that they may have suffered harm as a result of a negligent act in which to initiate a claim. This holds unless (a) they were a minor when the event occurred (in which case the three year clock 'starts ticking' when they achieve the age of legal majority, 18 years in the UK), or (b) they were mentally ill at the time. While some claimants successfully argue that they did not suspect that they were the victims of negligence until some years after the events in question, this might be a difficult argument to sustain in an awareness case, where it might be expected that a reasonable patient would know relatively soon or immediately that something had gone wrong. (See however, the discussion on memory in Chapter 7, Patient Experience).

Thirty-five years after undergoing thyroid surgery as a teenager, a patient reported that they recalled a few minutes of paralysis and inability to breathe. Review of the records revealed that, despite morphine 10 mg pre-medication, the patient had been noted to be excitable in the anaesthetic room, where Althesin and suxamethonium had been used for induction and halothane and nitrous oxide for maintenance. The record was typical of the era, making it difficult to reconstruct events, but this may have been either a case of difficult airway management or relative underdosing in an anxious, hyperthyroid (and hence hypermetabolic) patient.

DISCUSSION

22.32 Consistent with the literature (Mihai et al., 2009), the overall proportion of medicolegal claims after AAGA in the NAP5 cohort appears to be low, although, as litigation is often delayed, further claims may emerge as time passes. The NAP5 Baseline Survey also indicated that only about a fifth of cases resorted to complaint and only 4% to legal action (Pandit et al., 2013a and b).

22.33 However, the proportion of medicolegal claims relating to AAGA which settle in favour of the claimant is high, which suggests that anaesthetists

might have difficulty trying to mount a supportable defence when a patient recalls events occurring at a time when they should have been anaesthetised. There has evolved a public expectation that, unlike every other drug, an anaesthetic must always work. The notion that an anaesthetist, a specialist in maintaining a state of controlled unconsciousness, has failed a patient to the extent that they recall part of a surgical procedure, is an easy one for a lay person or judge to understand and criticise.

The place of res ipsa loquitur in AAGA claims

22.34 Legally speaking, it is normally a principle that the burden is upon the claimant to prove their case on the balance of probabilities, while the defendant waits for them to do so. But this important concept can be at least partly overturned by the doctrine of '*res ipsa loquitur*' ('the thing speaks for itself') which, if applicable, will allow the judge to infer breach of duty of care from the circumstances alone. The principle, which applies in England and Wales and in the form of the doctrine of 'delict' in Scotland, requires that the consequences could not normally have occurred but for a negligent act. Judges have, historically, been reluctant to apply this doctrine in clinical negligence claims, but it can be seen that the argument might at least be attempted by the claimant in cases such as AAGA that are relevant to anaesthesia (Liang & Coté, 1996; Liang, 1998; Liang & Kroll, 2000).

22.35 NAP5 provides much evidence as to why *res ipsa loquitur* should not apply to AAGA and why instead each report of AAGA should be individually assessed to establish duty of care (including consent), standards of care and degree of harm:

(a) First, it is clear that anaesthetics are like all other drugs and that genetic or other influences on anaesthetic response (Natarajan et al., 2011) will mean there must exist a natural variation of responses in the human population such that a certain, small percentage unpredictably require an unexpectedly high dose (Aranake et al., 2013).

(b) Second, the patient experience requires very careful corroboration with the facts, and NAP5 received several reports which the Panel felt were most unlikely to be genuine reports of AAGA (Chapter 6, Results). The confusion in some patients' minds between sedation and an expectation of complete unconsciousness (see Chapter 12, Sedation) underlines the complexity of anaesthetic techniques available and their impact on the state of mind (Esaki & Mashour, 2009). Samuelsson et al. (2007) reported that, of 79 patients included in a study because of previous experience of AAGA, four (5%) did not receive general anaesthesia while, in a further 29 (37%), the experience described was judged not to be AAGA. More recently, Kent et al. (2013) reported that up to one-third of patients claiming to have experienced AAGA had not actually undergone general anaesthesia.

(c) Third, there is no form of clinical assessment or monitoring available that can guarantee that a paralysed patient is anaesthetised. Were such a monitor available, then dereliction of duty would likely centre upon a failure to use, note or respond to the monitor; but this is not the case with unconsciousness in a paralysed patient. NAP5 contains several examples of Certain/probable AAGA with EEG-based monitoring employed. Although this monitoring is known to have its limitations (Pandit & Cook, 2013), it is the most sophisticated that is available.

22.36 This would all seem to make a doctrine of *res ipsa loquitur* inappropriate.

Patient complaints and litigation are uncommon after AAGA, but should be communicated to the anaesthetist involved so the department can investigate the case and arrange support for the patient

Standardising the methodology for investigation

22.37 The methodology used in NAP5 has been used to classify well over 200 reports of AAGA during the project and might provide a useful template by which reports of AAGA can be assessed. This, or a similar methodology, may help hospitals organise their Serious Incident reports and even aid courts or experts in developing a more standardised approach:

(a) The details of the patient report are very important in establishing if the AAGA was genuine. These can help classify the report as, for example. 'certain' (i.e. verified),

'probable'(i.e. a clear, potentially accurate report reflective of events that lacks verification), 'possible' (i.e. a report insufficiently precise to be reflective of specific events, but consistent with some other reports of AAGA), or 'unlikely' (i.e. a report that does not reflect any events that occurred, or is refuted by other evidence). Descriptions of interventions or conversations that actually occurred strongly support (or can refute) a report's veracity.

(b) Determining a potential cause of awareness might then be considered (i.e. separate from the determination of veracity). Detailed examination of anaesthetic conduct (including anaesthetic record and/or anaesthetist's report) is arguably the most useful way to explore any aspects that could have led to AAGA (usually through an interruption to or deficiency in administration of anaesthetic drugs).

(c) Together, these analyses can assist in assessing the likelihood that negligence was or was not a factor in the case. A Certain/probable report where there is no causality might be true resistance to anaesthetic drugs. Perhaps the reports creating the most dilemmas will be those where the report is judged 'Unlikely' and there was a deficiency in anaesthetic care.

22.38 The subgroup of AAGA cases which might be defensible will include those where a patient unexpectedly requires more than standard doses of anaesthetic agents to maintain unconsciousness. In these cases, the anaesthetist will need to be able to show that s/he reacted appropriately to any indirect signs of awareness such as hypertension and tachycardia. However, it is notable that physiological signs of awareness (tachycardia, hypertension, patient movement) do not always occur in reported cases of AAGA – none being present in >20% of cases in the literature (Ghonheim 2009).

22.39 Where difficult or failed intubation leads to a delay between intravenous induction and delivery of volatile agent, the defendant anaesthetist will have to demonstrate that, notwithstanding the obvious calls upon attention arising from the crisis, s/he has paid appropriate attention to the need to maintain unconsciousness. One exception to this may be where the anaesthetist has determined that their 'Plan B' will be to allow the patient to wake up, usually for reasons of patient safety (see Chapter 8, Induction).

22.40 Other causes of AAGA, notably accidental syringe swap, administration of the wrong drug, failure to turn on a vaporiser or to recognise that it is empty, and disconnection/'tissuing' of intravenous infusions of anaesthetic drugs, are likely to be indefensible (see Chapter 13, Drug Error and Chapter 18, TIVA).

22.41 Where questions arise relating to depth of anaesthesia during maintenance, the anaesthetist will need to be able to clearly demonstrate that appropriate doses and end-tidal concentrations of drugs were in use at the time, that (in the case of TIVA) the integrity of the intravenous line was maintained (see Chapter 18, TIVA), and that any signs of lightening (see below), such as tachycardia or hypertension, prompted a suitable response. In practice, this will mean that a very clear anaesthetic record may allow a successful defence against a claim of negligence.

The role of specific 'depth of anaesthesia' monitoring in a claim of negligence

22.42 The routine use of processed EEG (pEEG) monitoring has generated debate in the anaesthetic literature (Pandit & Cook, 2013). Some comments are relevant with respect to potential medicolegal aspects:

(a) NICE guidance only makes the recommendation that EEG monitoring should be 'considered' and offers no advice on how it should be used or interpreted to maximal patient benefit (National Institute for Health and Care Excellence, 2012). Therefore, even if it is used, there is no point of reference to assess if the monitoring was used or interpreted appropriately.

(b) The literature and the results of NAP5 suggest that little additional benefit is likely in using EEG monitoring where volatile agents are used (particularly in unparalysed patients) because, when appropriately monitored, the end-tidal concentrations during maintenance probably provide at least as useful information on likely drug effect across a wider range of drugs (Avidan et al, 2011).

(c) However, pEEG-based monitoring seems logical as an additional source of information in those patients with a previous history or family history of AAGA, or those undergoing TIVA techniques combined with neuromuscular blockade (in whom there is no other way of independently monitoring the drug dose in or its effect on the body; see Chapter 20, DOA).

22.43 There is one point of potential interest with regard to interpreting the output of any monitor for awareness (e.g. a pEEG-based monitor or the isolated forearm

technique). If the monitor suddenly 'spikes' a high reading during surgery, or if the patient moves to command during IFT, then this information (in contrast to persistently low readings or absence of response) will likely corroborate, not refute, any report from the patient of AAGA.

SUMMARY

22.44 An episode of AAGA occurring when a patient is supposed to be anaesthetised may, in some circumstances, be considered by the court as negligent until proven otherwise.

22.45 In order to have a sustainable defence against a claim for negligence resulting from an episode of AAGA, the anaesthetist will have to be able to produce a detailed, contemporaneous anaesthetic record. Particular attention should be paid to charting end-tidal volatile agent levels, bolus and infusion doses of hypnotic drugs, and indirect measurements of sympathetic stimulation including blood pressure and heart rate.

22.46 Even with a good record, AAGA arising from errors such as a syringe swap, a vaporiser which is empty or not turned on or a disconnected or 'tissued' infusion is very unlikely to be defensible.

22.47 An early sympathetic response to a complaint of AAGA may well help to mitigate the risk of complaints and medicolegal consequences. It is important that the patient understands that their account has been believed, that they have in turn been told the truth about what might or might not have gone wrong, and that appropriate action is being taken to prevent a recurrence.

IMPLICATIONS FOR RESEARCH

Research Implication 22.1
A formal analysis of cases of AAGA from the National Health Service Litigation Authority – building on the work already carried out by Mihai et al., 2009 – might help to analyse the factors involved in claims for awareness.

Research Implication 22.2
Formal legal research or discussion would be important to establish the degree to which the doctrine of *res ipsa loquitur* should apply in cases of AAGA, especially as the science underpinning the mechanisms of anaesthesia (and hence of AAGA) evolves.

Research Implication 23.3
Research is necessary into establishing the appropriate steps to take in responding to readings from depth of anaesthesia monitors. Similarly, in the isolated forearm technique, is direct questioning necessary to obtain a patient movement to command? Or is lack of spontaneous movement sign of sufficient anaesthesia?

RECOMMENDATIONS

RECOMMENDATION 22.1
There should be documentation that the risks and benefits of the anaesthetic technique have been discussed, including appropriate information about the risk of AAGA. Pre-operative written material may be an efficient way to achieve this.

RECOMMENDATION 22.2
The anaesthetist(s) who provided the anaesthesia care at the time of a report of AAGA should respond promptly and sympathetically to the patient, to help mitigate adverse impacts.

RECOMMENDATION 22.3
Anaesthetists should keep clear, accurate anaesthetic records which will help provide a defence to a claim of negligence. Equally, where a lapse has occurred, the accuracy of record-keeping in documenting the lapse should mitigate further adverse outcomes for the anaesthetist, hospital and patients, as it will serve as a focus for learning.

RECOMMENDATION 22.4
All reports of AAGA should be carefully assessed mapping details of the patient report against the conduct of anaesthetic care, using a process like that outlined in NAP5.

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CHAPTER
23

Human factors and AAGA


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HEADLINE

23.1 NAP5 identified human factors (HF) contributors in the majority of reports of AAGA, even though the NAP process is not well suited to robust analysis of such factors. The commonest contributory factor groups were: medication, patient, education/training and task. Preventing awareness by addressing human factors goes beyond simply examining the final 'action error' that leads to relative under-dosing of drugs and should consider the many latent factors that impact on this. This is particularly so for AAGA caused by drug errors.

BACKGROUND

Human factor science

23.2 There has been, an increasing acknowledgement that the safe delivery of healthcare is impacted by the manner in which humans delivering it interact with their environment. Amongst the key analyses in this regard have been the Harvard Medical Practice Study (Brennan et al., 1991) and the response by the Institute of Medicine '*To Err is Human*' (Kohn et al., 2000) which suggested that between 44,000 and 98,000 people were dying in USA hospitals each year as a result of preventable medical errors. Similar studies from other countries including the UK (Vincent et al., 2001), Australia (Wilson et al., 1995) and elsewhere, estimate that around 1 in 10 hospital in-patients suffer harm as a consequence of their treatment, 50% of which are avoidable, and that around 1 in 10 of these events lead to death. More recent studies have not shown any reduction in this rate of human error in healthcare (Sari et al., 2007).

23.3 Gawande (2007) has noted that "*progress in medicine will not be made through improved technology but rather through improved application of current knowledge and activity: in short 'doing it better'*. While an oversimplification, this sentiment is worthy of consideration.

23.4 That such matters impact on complications of anaesthesia has been recognised for many years (Cooper et al., 1978).

23.5 However 'human factors' (HF) is not the same as 'human error'. Human factors (broadly equivalent to 'ergonomics') can be defined as "*encompassing all those factors that can influence people and their behaviour. In a work context, human factors are the environmental, organisational and job factors and individual characteristics which influence behaviour at work*" (Clinical Human Factors Group http://chfg.org/what-is-human-factors).

23.6 'Clinical human factors' has been defined as "*Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities, and application of that knowledge in clinical settings.*" (Catchpole

2011, Clinical Human Factors Group, http://chfg.org/what-is-human-factors).

23.7 In the UK, an important driver for study and use of the knowledge gained to try to improve the safety, quality and efficiency of healthcare has been the Clinical Human Factors Group (http://chfg.org/), founded by Martin Bromiley.

23.8 In 2013 the National Quality Board published the *Human Factors in Healthcare Concordat* (National Quality Board, 2013). This is signed by numerous NHS and safety organisations including the Care Quality Commission, Department of Health, NHS England and the GMC.

23.9 This authoritative concordat commits to:

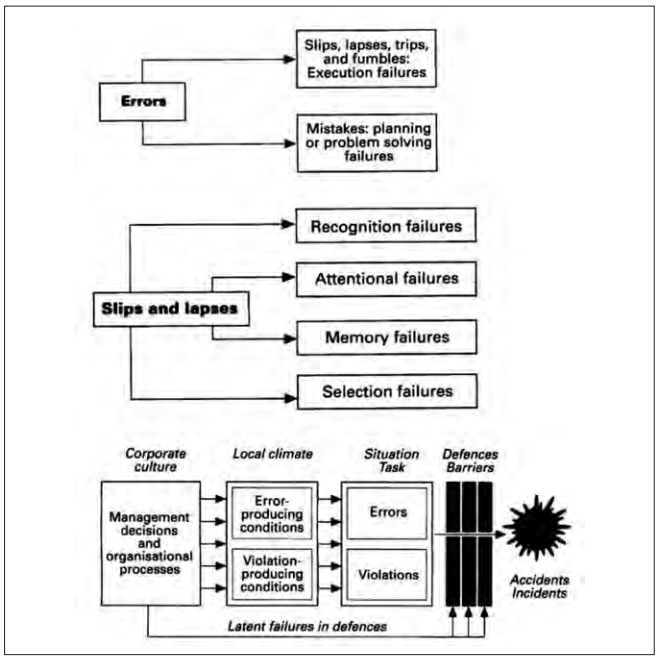
- *"raising awareness and promoting Human Factors principles and practices in healthcare;*
- *understanding, identifying and addressing current capability, barriers to adoption, future requirements and best practice in Human Factors in healthcare;*
- *creating the appropriate conditions, through commissioning, quality assurance and regulation, that support the NHS in embedding Human Factors at a local level."*

and recognises specifically that "*much of the activity to embed Human Factors in healthcare sits with frontline providers.*"

Analysing patient safety incidents using an HF approach

23.10 Reason (1995) described the final common pathway of medical errors as '*active failures*' of healthcare professionals. He divided errors into two broad divisions: '*slips/lapses*' and '*mistakes*' (Figure 23.1). In turn, slips/lapses were divided into several categories. '*Violations*' were also defined, as an intentional deviation from rules and standards-whether this be *routine violations* (cutting of corners), *optimising violations* (actions taken to further personal goals) or '*necessary/situational violations*' (made unavoidably to achieve the task) (Figure 23.1). He described contributory factors arising from the surrounding environment (in the widest sense) as '*latent failures*' (now more often termed '*factors*' or '*conditions*') – "*those circumstances that provide the conditions under which active errors are more likely to lead to patient harm, by defeating barriers in place to prevent this*" and also referred to these as "*the inevitable 'resident pathogens' within the system*". His model included the extensively quoted '*Swiss Cheese*' illustration (Reason, 2000) of how latent conditions can 'line up' and create a pathway through holes in safety barriers creating condiitions in which events and actions are more likely to cause patient harm (Figure 23.1).

Figure 23.1 Active and latent failures as described by Reason. These include 'errors' which are subdivided into 'slips' and 'mistakes' (also subclassified), and violations. The bottom panel describes how weaknesses in organisational or individual 'safety barriers' can line up to enable a series of events and actions to cause patient harm.



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23.11 Reason's work includes a flowsheet for analysis of patient safety incidents to enable '*just analysis*' of events into groups such as simple error, reckless violation, sabotage etc (Reason 1997).

23.12 The National Patient Safety Agency (NPSA), in their report Seven Steps to Safety (NPSA, 2004), recommended the formal analysis of contributory factors using a model described by Vincent, (1998) Table 23.1). Gordon et al. (2005) designed a Human Factors Investigation Tool (HFIT) to improve the investigation of the HF causes of accidents in the UK offshore oil and gas industries. It is likely to be suited also to investigation of other industries that depend on high reliability but where accidents can lead to significant harm. The tool is based on a '*threat/error model*' and emphasises the importance of situation awareness. A modified version was previously used to analyse a subset of reports to NAP4 (Flin et al., 2013). In that paper the tool was described as suitable for analysis of anaesthesia-related events because of its design "*for a dynamic, safety critical work domain where monitoring plays a key role and teams must respond to events that can escalate very rapidly.*'

Table 23.1. NPSA classifications of contributory factors in patient safety incidents. (NPSA, 2004)

Factors
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

23.13 The HFIT divides accident trajectory into four elements:

- Threats – underlying work or personal conditions that may be causal
- Situation Awareness – cognitive processes which may have preceded an action error.
- Action Errors – occurring immediately prior to the incident.
- Error Recovery mechanisms – (for near misses) actions that averted an accident.

and uses a large bank of questions to explore 28 HF elements (Figure 23.2 and 23.3). The tool requires specific training for use.

Figure 23.2. Summary of elements explored in the Human Factors Investigation Tool

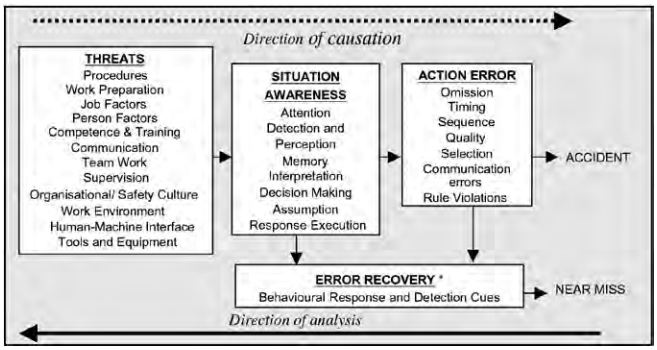

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Figure 23.3. Simplified Human Factors Investigation Tool categories for coding anaesthetic events as applied to investigation of cases reported to NAP4. (Note error recovery is omitted as no 'near misses' were considered by NAP4).

Heading	Subheading and descriptor
Action errors	Actions performed – anaesthetist, surgeon or other team member takes inappropriate action (e.g. gives a wrong drug, does not attach a required monitor)
Situation awareness	Problem detection – delays/difficulty in detecting critical change in state
	Task cognition – failures in attention, concentration, problem solving, decision making, memory
Threats	Policies, standards & procedures
	Work preparation – limitations in plans, strategies, contingency plans
	Job factors – task difficulty, inappropriate staffing levels, work pressure
	Person factors – fatigue, stress, hunger, improper motivation, physical incapability, feeling unwell
	Competence & training
	Communication – interpersonal or technical failures
	Team work – lack of shared mental model, role confusion, poor coordination
	Supervision and leadership – ineffective, no pre-task briefing, inadequate monitoring or instruction of trainee
	Work situation – conditions at work site, e.g. heat, noise, lighting, too many people crowding the workspace, night shift
	Human–machine interface – design flaws, operability, alarms
	Tools and equipment – suitability, availability, maintenance, access
	Organisational/safety culture – management, systems, norms

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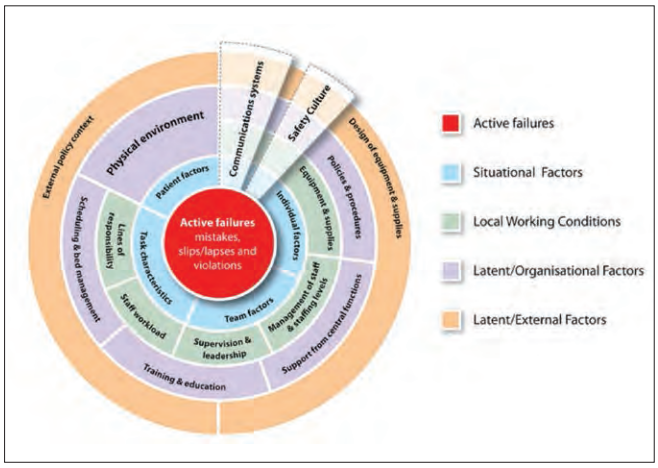
23.14 Finally, the Yorkshire contributory factors framework (Lawton et al., 2012) is derived from a systematic review of factors contributing to hospital patient safety incidents. The framework describes five domains ('active errors', 'situational factors', 'local working conditions', 'organisational latent factors' and '*external latent factors*') containing 19 types of potential contributory factors (Figure 23.4). As in Reason's model '*active failures*' are errors at the point of care delivery and 'latent factors' are conditions which make active errors more likely to happen or more likely to lead to patient harm. In the model the domains are arranged around 'active error', almost like the layers of an onion that must be peeled away one by one to find the centre. The framework uses simple terminology to describe its categories (Figure 23.5) and as such is amenable to non-expert use to improve the identification and modification of factors that cause or contribute to patient safety incidents. The framework has recently been used to analyse a fatal patient safety incident in Intensive Care (Gupta & Cook, 2013) which illustrates the ease with which it can be used and the increased learning about an incident that can result.

Figure 23.4. The Yorkshire Contributory Factors Framework



Reprinted from Lawton R, McEachan RR, Giles SJ, Sirriyeh R, Watt IS, Wright J. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. *British Medical Journal Quality and Safety* 2012;**21**:369–80 with permission.

Figure 23.5. The Yorkshire Contributory Factors Framework – Category definitions

Factor	Definition
Active failures	Any failure in performance or behaviour (eg, error, mistake, violation) of the person at the 'sharp-end' (the health professional)
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services. This includes both written (eg, documentation) and verbal (eg, handover) communication systems
Equipment and supplies	Availability and functioning of equipment and supplies
External policy context	Nationally driven policies / directives that impact on the level and quality of resources available to hospitals
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations
Individual factors	Characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work
Patient factors	Those features of the patient that make caring for them more difficult and therefore more prone to error. These might include abnormal physiology, language difficulties, personality characteristics (eg, aggressive attitude).
Physical environment	Features of the physical environment that help or hinder safe practice. This refers to the layout of the unit, the fixtures and fittings and the level of noise, lighting, temperature etc.
Policy and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality
Safety culture	Organisational values, beliefs, and practices surrounding the management of safety and learning from error
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload
Staff workload	Level of activity and pressures on time during a shift
Supervision and leadership	The availability and quality of direct and local supervision and leadership
Support from central functions	Availability and adequacy of central services in support the functioning of wards/ units. This might include support from Information Technology and Human Resources, portering services, estates or clinically related services such as radiology, phlebotomy, pharmacy.
Task characteristics	Factors related to specific patient related tasks which may make individuals vulnerable to error
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve patient safety
Training and education	Access to correct, timely and appropriate training both specific (eg, Task related) and general (eg, Organisation related)

Reprinted from Lawton R, McEachan RR, Giles SJ, Sirriyeh R, Watt IS, Wright J. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. *British Medical Journal Quality and Safety* 2012;**21**:369–80 with permission.

HF and AAGA

23.15 At its simplest, the immediate cause of AAGA (i.e. that which directly leads to the event) is failure to give enough anaesthetic. However, there are often numerous contributory factors that increase or even cause the administration of 'insufficient anaesthetic'. Reports of AAGA may also arise due to patient perceptions of AAGA based on communication issues. Excepting cases due entirely to equipment or drug malfunction or pure patient resistance to anaesthetic drugs, we might consider that HF is likely to have some role in almost all other cases of AAGA.

23.16 Several studies exploring the epidemiology of AAGA have commented in some manner on human factors in their genesis.

23.17 Sandin et al. (2000) described seven (37%) of 19 cases of AAGA as having contribution from HF, including failure to fill a vaporiser, administering a muscle relaxant before induction agent, administering inadequate drug doses, backflow of induction agent up a giving set, failure to administer extra anaesthetic agent during difficult intubation and allowing emergence before surgery had finished. In the remaining cases, causes were 'uncertain' in two and 'no cause found' in ten.

23.18 Errando et al. (2008) reported a 'human error' contribution in 15 (68%) of 22 cases of AAGA, including absolute or relative hypnotic drug dosage errors and problems with difficult intubation. There were two cases of equipment failure and five in which no cause was identified. Paech et al. (2008) reporting on AAGA in obstetrics, reported two cases (100%) in a series of 753 to be as the result of HF – one lapse and one situational violation.

23.19 In contrast, Sebel et al. (2004) described 25 cases of AAGA and, while providing descriptions of anaesthetic type and drug use, made no comment on human error or HF. Similarly the many studies on the impact of depth of anaesthesia monitors on AAGA make no comment and describe no cases of AAGA due to slips, lapses, violations or similar.

23.20 So these studies could be interpreted as reporting HF as contributory in anything from 0–100% of cases of AAGA. It is, however, notable that all these analyses focus only on the active failures as causes of AAGA and none on the latent factors that surround the case. The analyses must therefore be considered superficial at best.

23.21 In the context of AAGA, HF is therefore not restricted to anaesthetists making 'errors' that lead to the administration of too little drug or the wrong drug but, on first principles, could also include issues such as:

- **Organisational**

a) Duty rotas and times of rest.
b) Operating list structure and organisation.
c) Anaesthetic assistance.
d) Theatre flow (e.g. scheduling, use of anaesthetic rooms or not).
e) Anaesthetic room design, theatre design (e.g. anaesthetic room lay out, theatre size and lay out).
f) Drug supply and packaging.
g) Machine design and interfaces, default alarms etc.
h) Design, availability and reliability of anaesthetic equipment (e.g. airway devices, intravenous access, vaporisers TIVA pumps and giving sets).
i) Fitness for purpose of equipment (e.g. depth of anaesthesia monitoring).
j) Lighting and noise levels.
k) Control of distractions and interruptions.
l) Rest periods, food breaks.
m) Organisational communication.
n) Organisational and immediate safety culture.
o) Horizontal/vertical hierarchy in the operating theatre.

- **Individual**

a) Quality of patient assessment.
b) Professionalism (including personal organisation, knowledge, application etc).
c) Faculties (cognition, hearing, sight etc).
d) Communication skills.
e) Concentration skills vs distractibility.
f) Personal attitudes to patient safety and risk.
g) Response to time pressures and adaptability.
h) Attentiveness.
i) Health.
j) Personal stressors.

HF and NAPs

23.22 The nature of the remote, web-based data collection used by NAPs is not ideally suited to collecting HF data. The NAP4 report (Cook et al., 2011) found that 40% of reports included some HF contribution and that in one quarter of these (10% of all reports) such factors were a major contributor to poor outcome. However, in the follow-up study by Flin et al. (2013), telephone interviews with a small cohort of reporters to NAP4 identified this to be a considerable underestimate with HF contribution in 100% of reports with a median of 4.5 HF contributory elements identified per report (range 1–10 per case).

23.23 The commonest HF elements reported by anaesthetists involved in major airway complications were, using the HFIT classification: situation awareness (failure to anticipate, wrong decision); job factors (task difficulty, staffing, time pressure); person awareness (tiredness, hunger, stress).

23.24 In order to extract some useful HF data, specific questions about the contribution of HF to events were included in the NAP5 case report data collection form. As in NAP4 we also used the NPSA classification of contributory factors to patient safety incidents (NPSA 2004) to evaluate each report (Table 23.1).

23.25 NAP5 has been designed in a way that almost inevitably misses much of the HF contributing to AAGA in reported cases. These factors were not actively sought by the data collection process, and may have been overlooked or omitted by the reporter and Local Co-ordinator, who of course have only their own perspective on the events that took place. It is likely that a formal interview using tools such as the Human Factors Interview Tool or in-depth analysis with the Yorkshire Contributory Factors Framework is needed to extract detailed HF coding. Therefore this chapter is principally illustrative and descriptive. The quantitative analysis is indicative of the types and perhaps distribution of HF contributions to AAGA, but will underestimate their frequency. Excerpts from other chapters have been included to illustrate how HF impacts on most analyses within NAP5.

(Dis)organisation of work spaces was associated with drug errors leading to AAGA

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

23.26 Using the NPSA classification, all 110 Certain/ probable (Class A) reports (i.e. those reports with the most complete data available) were judged by the Panel to have contributory factors (median number of factors 3, range 1–7), with the commonest being medication, patient and education/training (Table 23.2).

Table 23.2. NPSA classifications of patient safety incidents for 110 Certain/ probable (Class A) reports of AAGA in NAP5

Factors	Contributory/ Causal/ Mitigating	Contributory or Causal; %
Communication	19 / 0 / 0	17.3
Education and training	58 / 6 / 1	58.2
Equipment and resource factors	33 / 4 / 0	33.6
Medication	66 /20 / 0	78.2
Organisation and strategic	23 / 0 / 0	20.9
Patient	75 / 2 / 0	70.0
Task	27 / 8 / 0	33.6
Team and social	20 / 0 / 0	18.2
Work and environment	27 / 0 / 0	24.5
Other	11 / 0 / 0	10.0

23.27 The Panel judged cases according to quality of care and preventability (Table 23.3). However, AAGA was judged preventable in almost three quarters of Certain/probable reports. In only 1 in 9 cases was care judged good and the AAGA not preventable while in only 1 in 11 reports was no cause found for AAGA (Table 23.3).

Table 23.3. NPSA classifications of patient safety incidents for 110 Certain/probable (Class A) cases

	n in NAP5 (%)
Quality of care	
Good	28 (25.5)
Mixed	34 (30.9)
Poor	43 (39.1)
Preventable	81 (73.6)
Quality of care good and not preventable	13 (11.8)
No cause found	10 (9.1)

23.28 In Chapter 12 (Sedation) the authors concluded that '*miscommunication was the main contributory or causal factor in 81% of reports*'.

23.29 Those reporting cases identified HF in 61% of Certain/probable reports and their causes are listed in Table 23.4.

Table 23.4 Reporters assessment of human factors in Certain/probable (Class A) reports to NAP5; n=104

	n in NAP5 (%)
Judgement	28 (26.7)
Communication	17 (16.2)
Education	9 (8.6)
Tiredness	7 (6.7)
Distraction	4 (3.8)
Theatre design	3 (2.9)
Organisation	3 (2.9)
Decision making	2 (1.9)
Other	11 (10.5)
None	41 (39.0)

Induction

23.30 Human factors contributing to AAGA at induction included (but were not limited to) the following (Reason's error types are in parentheses for illustration):

- Drug errors from mislabelling, failure to mix drugs, omission of drugs or syringe swaps (slips and lapses).
- 'Mind the gap errors' – delayed or omitted maintenance drugs (routine and optimising violations).
- Inadequate dosage of induction agents due to errors of knowledge (knowledge based violation) or judgement (situational violation).

Contributory factors included (The Yorkshire Contributory Factors Framework factors are in parentheses for illustration):

- Ampoule label design (equipment and supplies).
- Errors of judgement or knowledge (training and education).
- Difficult airway management and obesity (patient factors).
- Distraction by colleagues – talking, teaching, interruptions etc. (individual factors/team factors/communication systems).
- Distraction by unexpected difficulty – failed airways, failed vascular access, other unexpected patient complications, equipment failure, (task characteristics, staff workload).
- Busy lists with multiple changes (scheduling and bed management, safety culture).
- Tiredness (individual factors, staff workload).
- Rushing (individual factors, team factors, safety culture).
- Lack of clarity of roles in the anaesthetic room (lines of responsibility).
- The need for rapid sequence induction (task characteristics, patient factors).
- Lack of availability of extra drugs due to local policy (design of equipment and supplies, support from central functions/safety culture).
- Junior trainees working unsupervised (supervision and leadership).

Just prior to induction, because of a history of reflux, the consultant changed the anaesthetic plan to include tracheal intubation. The consultant drew up atracurium while watching the assistant place the IV cannula. When the cannula proved difficult the consultant placed the atracurium on the work surface (unlabelled) and helped with cannulation. The cannula was then flushed but rather than the intended saline flush atracurium was administered. This was promptly recognised and general anaesthesia was induced with propofol. Post-operatively the patient reported an experience of respiratory difficulty, paralysis and a feeling of dread and of death. In the following weeks, severe psychological symptoms were judged to be consistent with PTSD.

During RSI for an urgent procedure, the anaesthetist noticed greater than expected fasciculations after induction. After intubation, a volatile agent was immediately commenced. The anaesthetist then realised that no induction agent had been administered, only suxamethonium. In that hospital, thiopental was kept in a central store, so was not immediately available for mixing. After finishing the previous case, the anaesthetist forgot that the thiopental had not been mixed and proceeded with RSI. The patient was aware of being intubated and was unsure how long it would last but soon after lost consciousness. The patient developed a new anxiety state, flashbacks and possible PTSD.

While the senior trainee anaesthetist was waiting for the patient, the theatre co-ordinator changed the vaporiser for a new 'trial vaporiser' without informing the anaesthetist. Meanwhile the anaesthetist was called to an emergency. On returning, anaesthesia was induced without a further machine check. Following uneventful induction a regional block was performed and the heart rate and blood pressure were observed to be elevated, so more opioid was administered. At incision, heart rate increased further, and at this point the vaporiser was checked and found to be empty. Midazolam and propofol were immediately given to deepen anaesthesia and the vaporiser filled. The patient reported hearing voices, being unable to move and feeling someone "…cleaning their tummy and then a tube going in…"

23.31 Certain phrases and patterns seemed to recur in the reports. Chapter 8 (Induction) reported "*several cases where AAGA had arisen at induction/transfer, apparently because of distraction, fatigue and organisational issues (i.e. a desire to increase rapid turnover of cases, or last minute changes in list order or operating theatre) Five cases (7%) occurred when the induction agent went back up the intravenous line or when the cannula 'tissued'. In two cases the report suggested that the neuromuscular blocking drug had been given too early in the induction process. In neither case was the drug suxamethonium*".

...distracted by ODP leaving to get supplies
...emergency suxamethonium ampoules lying next to general anaesthesia drugs
...ACCS trainee drew up drugs and mislabelled
...thiopental stored out of theatre

23.32 Chapter 16 (Obstetrics) noted "*both syringe swap cases involved antibiotics. In one, a recent change of policy led the anaesthetist to change practice and draw up the antibiotic before delivery, making the possibility of syringe swap more likely. In the other case, the urgency of the case was a distracting factor.*"

23.33 Chapter 11 (Risk Factors) reports "*a disproportionately high proportion of evening and nighttime operating in Class A reports of AAGA compared to the Activity Survey general anaesthetics p<0.0001. There was a disproportionately high proportion of urgent and emergency anaesthesia in Class A reports of AAGA compared to the Activity Survey general anaesthetics p<0.0001. There was a disproportionately high proportion of very junior anaesthetists in Class A reports of AAGA compared to the Activity Survey general anaesthetics p=0.003.*"

Multiple drugs used at induction may increase the risk of slips

Maintenance

23.34 Human factors contributing to AAGA during maintenance included (but were not limited to):

- Under-dosing to maintain cardiovascular stability.
- Under-dosing to lessen risk to a fetus.
- Under-dosing due to inattention or judgement errors.
- Termination of anaesthesia too soon before surgery had finished.

An elderly patient returned to theatre two days after cardiac surgery for management of bleeding. The anaesthetist deliberately used reduced doses of induction drugs and maintenance agents, but also monitored anaesthesia with a BIS monitor (charted as <60 throughout). During repositioning in theatre, the blood pressure and heart rate rose and the anaesthetist administered additional anaesthetic agents. The patient reported brief AAGA the following day, describing awareness during positioning and hearing a discussion about this. The patient could not communicate awareness to the team and this led to moderate psychological distress.

23.35 In Chapter 9 (Maintenance) it was noted "*vaporiser errors included being left switched off after transfer (10 instances (20%), an empty vaporiser unnoticed (two cases) or incorrectly mounted (one case)). Distraction was specifically cited as contributing to vaporiser errors in four (8%) reports.*"

23.36 Human factors contributing to AAGA at emergence included (but were not limited to):

- Turning anaesthetic agents off because of poor communication.
- Turning anaesthetic agents off because of poor understanding of offset times of newer volatile agents.
- Rushing.
- Mistiming, overdosing or unnecessary use of muscle relaxants.
- Failure to monitor degree of residual neuromuscular blockade or the effects of reversal agents.

A patient underwent an emergency operation, and immediately reported having heard the stapling of the skin whilst paralysed. The patient also recalled a discussion about 'sweating'. The experience lasted ~30 minutes. There was distress, sleep disturbance and unpleasant dreams. The anaesthetist had mistakenly turned off the vaporiser prematurely at the end of surgery.

23.37 In Chapter 10 (Emergence), it was noted "*of the 26 cases, 23 (88%) were judged preventable. One was deemed not preventable, and in two cases, poor charting prevented a judgement. In 11 cases (42%) the absence of, or failure to use, a nerve stimulator was identified by the Panel as contributory or causal. In six patients (23%) the Panel judged that the neuromuscular blocker had been administered too close to the anticipated end of surgery, had been ill-chosen for the duration of the procedure, or had been given in too great a dose for the procedure. In another six, reversal appeared to have been given only after the patient exhibited signs of residual paralysis.*

In eight patients (30%) communication between anaesthetist and patient, between anaesthetist and surgeon or between two or more anaesthetists, was assessed as causal/contributory to the episode of AAGA. In one case, the surgeon informed theatre staff that the operation was 'finished' when in fact the operation continued; in another, an anaesthetic trainee felt that the consultant had given instruction to reduce the anaesthetic delivery early towards the end of the case. Apparent unfamiliarity with the speed of offset of short acting agents (e.g. desflurane) was cited in four cases and distraction (from handovers or from involvement of other anaesthetists present) in another four."

Management of AAGA

23.38 When AAGA occurred, HF sometimes contributed to poor quality care during or afterwards. This seemed to exacerbate the adverse experience or potentially contribute to sequelae. Examples included:

- Incomplete communication to patients pre-operatively about the risks of AAGA, especially when the risk was increased (e.g. difficult airway management anticipated, awake extubation planned, relative under-dosing planned due to patient instability).
- Not communicating with patient while AAGA was suspected to be occurring.
- Not deepening anaesthesia when there were signs of inadequate anaesthesia.
- Not adding or deepening anaesthesia when awake paralysis was detected at induction or emergence.
- Not acknowledging, empathising, believing or apologising when patients reported AAGA (including anaesthetists, nurses, surgeons).
- Poor documentation of anaesthetic conduct (including occasional factual inaccuracy).

A patient recalled a burning pain, feeling like a cut, then pulling. The patient was seen by the same anaesthetist afterwards who, the patient felt, did not believe their account and suggested that it had been a dream. The patient was very angry about how the incident had been handled... The anaesthetic record indicated immediate initiation of volatile agent after induction, but the automated machine log showed a gap of several minutes before the vaporiser was turned on.

A patient was upset that they did not get support from the nursing staff in recovery and on the ward...that they were told they had a bad dream and there was nothing to worry about. It was only when the patient spoke to the anaesthetist and recounted what happened that they felt they were believed. On the ward the patient felt they were on a 'conveyor belt' getting ready to go home and that the nurses were not sympathetic to their experience.

A patient was very upset by a member of the surgical team who was trying to defend their view that the patient was not aware and that the event was patient imagination.

23.39 There were equally examples when behaviours contrasting to those above appeared to mitigate patient experience and sequelae when AAGA occurred or was reported.

The patient remembered the anaesthetist's reassuring words that they would soon be asleep, then remembered their arm 'dropping' and being unable to hear their breathing. The consultant anaesthetist immediately realised that suxamethonium had been given instead of fentanyl, and administered a dose of propofol whilst continuing to reassure the patient. A single loose ampoule of suxamethonium had been placed lying close to the fentanyl and other induction drugs in the tray. This arose because the hospital had instituted a policy preventing the entire box of suxamethonium being removed from the fridge (to avoid room temperature degradation). Instead, the ODP had placed a single ampoule of suxamethonium on the tray. The patient was supported, a full explanation offered and they suffered no long term impact.

A patient was given suxamethonium before induction inadvertently. The anaesthetist immediately recognised the error and induced anaesthesia. The patient experienced paralysis, was afraid they were dying from a stroke and had flashbacks for 2–3 days afterwards. However, the patient was very reassured by the anaesthetist's immediate explanation, "I know what's happening and I can fix it", during the critical event and had minimal long-term sequelae.

23.40 Excerpts from comments made by Local Co-ordinators offer some insights.

Excerpts from reporters reflections on cases. Classifications are the reporters' and inevitably some overlap with other categories.

Communication

... locum Anaesthetist – ? not familiar with surgeon/surgery;
... two junior anaesthetists of similar grade with no-one taking complete control;
... apparent lack of effective explanation given to patient by medical staff pre-operatively.

Judgement

... about adequacy of induction agent and administration of muscle relaxant before confirming loss of reflexes;
... possibly underestimated the airway difficulty and might have summoned senior assistance;
... in retrospect the anaesthetic was too light and too much reliance was placed on the BIS monitor;
... inadequate time between last dose of muscle relaxant and attempt at reversal.

Education

... possible that trainee was not aware of need for sedation for transfer;
... failure to appreciate that difficulty with the airway, may lead to inability to maintain inhalational anaesthesia;
... CT1 not aware of guidelines/recognition of signs required for adequate reversal of NMB during emergence;
... understanding of the pharmacokinetics of propofol.

Organisation

... consultant not present in the room at the time. Consultant covers a cardiac list simultaneously with the oncology list;
... lack of trained assistance at induction and throughout anaesthesia process;
... anaesthetist helping with application of tourniquet to aid theatre efficiency;
...staff over-stretched. To avoid any delays in the through-put in the list, the patient was brought into the anaesthetic room while still operating on the previous one, with only one anaesthetist working. Another anaesthetist was asked to come from other theatre to take over the care of patient in the theatre. The main anaesthetist started the care of the said patient.

Theatre design

... anaesthetic room small/narrow- allows probably one anaesthetist (from the head end) to keep an eye on the monitors – could have helped if the anaesthetic room design was better and bigger;
... ASA 3 case scheduled for day-case theatres with inadequate drug stocks;
...thiopentone in a central store so not immediately available for mixing.

Distraction

... a complicated day, with complex cases, list changes (patients and order) and we had swapped theatre to do this case...
... recent bereavement (anaesthetist);
... surgeon had agreed early start with anaesthetist the day before, but team were half an hour late sending because waiting for estates staff to repair equipment (which should have been done after early finish previous day). The pointed discussion audible from theatre as anaesthetist was drawing up was reported by him to be distracting, as was the presence of a brand new FY1. In a break with normal routine, the ODA had given him remifentanil and morphine instead of remifentanil and fentanyl;
...anaesthetist said he was busy in the anaesthetic room drawing up some antibiotics for the next case when the patient moved;
... rushing through the list. Issues in recovery with previous patient. Staff changeover;
... solo anaesthetist. Late start of busy list with difficult cases;
... patient was hypotensive, the vaporiser was turned off, then desaturated which became the focus of the anaesthetists attention – diagnosing and managing an endobronchial intubation in a prone patient at high risk of accidental extubation. The patient had previously had an accidental extubation under general anaesthesia in the prone position.

Tiredness

...anaesthetist had a 2-week old baby at home. The procedure was at night.

Guidelines

... although we have a transfer guideline which includes guidance on sedation it is not explicit that the patient must have an effective form of sedation provided. The transfer checklist provided as part of this guideline was not used.

Other

... the anaesthetist who performed the operation has limited UK experience, however he/she had overseas experience;
... failure to have cannula/arm on display at all times.

All or most of the 'human factors' listed above 'COULD' have some relevance...

DISCUSSION

23.41 HF is considered separately in many individual chapters, directly or in passing. Here we make some more broad comments. Similarly many chapters have recommendations relating to HF.

23.42 NAP5, despite its limitations in terms of detection of HF, has enabled a greater analysis of latent factors than many previous reports on AAGA, which have tended to focus solely on the final 'action errors'.

23.43 As NAP5 and NAP4 share methods in terms of HF analysis, some comparison between projects is relevant. Overall, HF was detected as a contributory or causal factor in NAP5 more often, and as a mitigating factor less often, than in NAP4. While the distribution of contributory factors had similarity between projects (patient and education/training being prominent in both) there were also notable differences (although medication was predictably higher in NAP5, so too was work/environment and task). Quality of care was judged 'poor' in NAP5 almost exactly as often as in NAP4. Finally, HF in NAP5 included issues around airway assessment and management as contributors to AAGA, showing overlap between the two projects.

23.44 It is notable from the vignettes, reporters' comments and chapter excerpts included in this chapter that latent factors play an important part in the genesis of action errors leading to AAGA. Indeed almost every factor listed in para 23.21 is identifiable in reports to NAP5.

23.45 In the case of drug errors leading to AAGA (see Chapter 13, Drug Error) latent factors were identified in every case. These contributory factors and their potential solutions should be considered both by organisations seeking to prevent drug errors leading to AAGA, and in investigations of such events.

23.46 Organisational contributory factors were prominent in reports of AAGA to NAP5, and included staffing, theatre scheduling, busy disorganised lists and communication (all 'threats' in the HFIT model). These raised concerns over safety culture in some cases and indicate that AAGA should not simply be considered to be caused by human errors.

23.47 Individual contributory factors that were prominent in reports were education, judgement (decision making) and distraction ('threats' and 'situation awareness' in the HFIT model).

23.48 Rushing – whether caused by organisational or individual failings – was prominent in the genesis of some cases of AAGA. Prevention of AAGA likely requires that the organisational and individual circumstances that lead to rushing are addressed.

23.49 In Chapter 13 (Drug Error) 'the authors reported *"recurring themes in the details of the cases were mention of staff shortages and a pressured environment with 'busy' lists. Some hospital policies for the storage and preparation of drugs appeared misguided and themselves were contributory to error. ...Distractions during critical moments can have very serious consequences. ...Other anaesthetists and circulating nurses are the most common causes of distractions. In terms of individual conduct, it seemed that a lack of vigilance and having several similar sized syringes on the same drug tray may be contributory."*

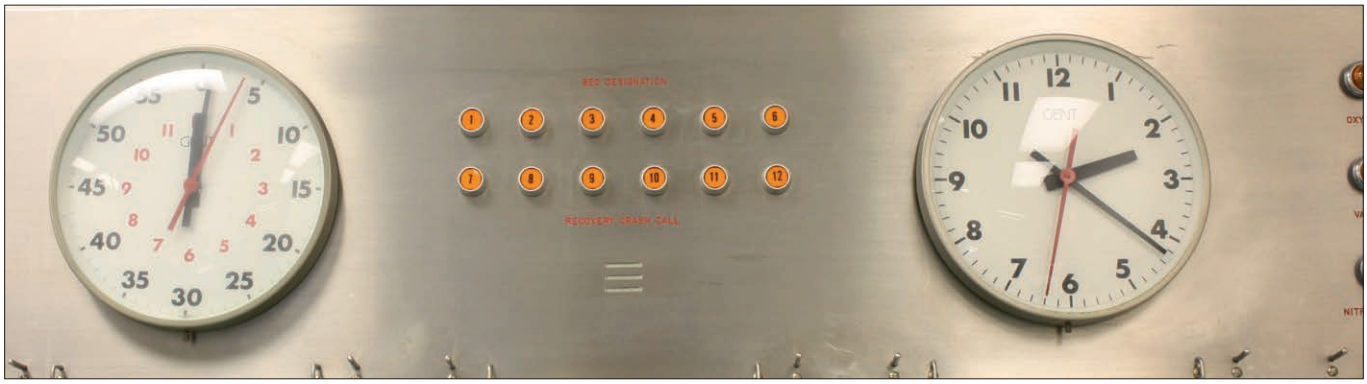
23.50 Checklists are a method to improve reliability of complex or time-sensitive tasks. In Chapter 8, Induction, a very simple ABCDE checklist is proposed to address what we term the 'Mind the Gap' problem – which describes failure to maintain anaesthetic drug concentrations soon after induction, and which may be caused by any one of a large number of organisational or individual HF. This and other checklists – for instance, those to be used at emergence in paralysed patients, or prior to transferring critically ill patients – might be developed and tested.

23.51 Technology may also be used to reduce error/harm from HF. For example, studies have demonstrated that monitoring of end-tidal anaesthetic concentrations (ETAC) can be as effective as specific depth of anaesthesia monitors (BIS) in the prevention of AAGA (Avidan et al., 2011; Mashour et al., 2012). However, this was best achieved when ETAC alarms were activated, audible and backed up by a text message to the anaesthetist alerting them to the alarm (Mashour et al., 2012). Chapter 8 (Induction) notes *"that it was surprising that several reports of AAGA during maintenance were associated with vaporiser problems that went undetected, despite end-tidal monitoring."*

23.52 Anaesthetic machines are now available with smarter anaesthetic gas delivery and monitoring. These include anaesthetic gas delivery systems that guarantee a specified ETAC, and these may have a role in future prevention of AAGA.

23.53 Similarly some machines now have 'single touch' operations that will pause fresh gas and volatile administration but only for a brief period (e.g. one minute) and need only a single touch to restart it. This might reduce the risk of volatile omission after events such as patient repositioning or difficult airway management.

Time pressures and rushing contributed to drug errors and other slips causing AAGA



23.54 Technical solutions such as drug scanning systems that may reduce HF-caused drug errors (timing errors, syringe swaps etc) are also available, but require further development and research. Investment would also be required to see their widespread introduction into practice.

23.55 Solutions do not always need complex technology and, as an example, drug errors due to confusion between ampoule appearances would likely be reduced by improved communication between theatre and pharmacy departments and drug suppliers. This could be extended to national efforts to set minimum standards for drug packaging and ampoule labelling and, even a colour scheme similar to that currently used for anaesthetic syringe labelling.

23.56 In addition to technical solutions, anaesthetists (and those who manage them) need to accept that they are all prone to making errors and should therefore, develop robust individual mechanisms to protect their patients, themselves and their colleagues. The anaesthetist needs to recognise their vulnerability to errors of judgement, knowledge and memory, and that their vulnerability is likely to be increased by tiredness, distraction, hunger etc. All need to contribute to developing environments, equipment and systems of work which minimise the risk of error, and which enable errors to be detected and remedied before harm results.

23.57 Human factors – or even simple 'humanity' – have a role to play in mitigating the effects of AAGA when it occurs. When AAGA occurred, the response of carers at the time AAGA was taking place (explanation and reassurance – or lack of it) and afterwards (empathy, apology and support – or lack of it), appeared to impact on patient experience and the longer term sequelae. In Chapter 13 (Drug Error) for example, the authors stated "*After an error had happened, the patient experience appeared greatly influenced by anaesthetic conduct. In some cases, hurried efforts were made to reverse paralysis without attending to the patient's level of consciousness, while in others, reassurance of the patient and ensuring comfort was prioritised. In the latter group, it seemed that patients, on understanding events, appeared to have considerably more benign experiences and fewer or no sequelae.*"

IMPLICATIONS FOR RESEARCH

Research Implication 23.1
The extent to which Human Factors play a part in the genesis, experience and sequelae of episodes of AAGA could usefully be further explored using HF research methodology. Large registries such as the ASA Awareness registry and that proposed by NAP5 would be useful starting points.

Research Implication 23.2
The apparent overlap between the role of human factors described in NAP5 and those previously described in NAP4, suggests that the themes discussed are generic. Further research into HF leading to AAGA will therefore likely be potentially relevant to a wider area of anaesthetic practice.

Research Implication 23.3
Further research into human error (active failures) in the genesis of AAGA events should also focus on broader contributory factors (latent failures).

Research Implication 23.4
Further research would be valuable to determine which of the several HF classifications and models for investigating healthcare patient safety incidents is or are best suited specifically to the investigation of AAGA events.

Research Implication 23.5

Further research into innovative methods to reduce both latent factors and action errors that increase the risk of AAGA would be of value. This might include investigation of: (a) the role of checklists in improving reliability of care delivery; (b) the impact of technologies (such as drug scanners, anaesthetic machine alarms and anaesthetic gas delivery systems) in reducing the risk of AAGA, and (c) whether individuals can learn 'safer practice'.

Research Implication 23.6

Qualitative research might examine how best to manage the tension between the drive to increase operating theatre productivity whilst maintaining the quality and safety of anaesthesia.

RECOMMENDATIONS

RECOMMENDATION 23.1

All anaesthetists should be educated in human factors, so they can understand their potential impact on patient care and how environments, equipment and systems of work might impact on the risk of, amongst other things, AAGA.

RECOMMENDATION 23.2

Investigation of and responses to episodes of AAGA – especially those involving drug error – should consider not only action errors, but also the broader threats and latent factors that made such an event more or less likely.

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CHAPTER
24

NAP5 in Ireland


Wouter R Jonker


Ellen P O'Sullivan


Jaideep J Pandit

HEADLINE

24.1 The 5th National Audit Project (NAP5) received eleven reports of accidental awareness during general anaesthesia (AAGA) from Ireland. The smaller size of NAP5 in Ireland compared to the UK project, means that numerical analyses are associated with large confidence intervals. Notwithstanding this, the numerical analyses and thematic patterns in NAP5 in Ireland are remarkably similar to those in NAP5 in the UK. The Irish data, in addition to its own merit, provides some validation of the UK data.

BACKGROUND

24.2 Through the involvement of the Association of Anaesthetists of Great Britain and Ireland, Ireland joined the United Kingdom for NAP5. Although there are some similarities with respect to content of training and a common language, the health service structure is very different in Ireland. There is therefore potential, to this limited extent, to assess variations in incidence or presentation and outcome of AAGA in different healthcare systems.

24.3 All 46 acute public hospitals in Ireland took part in the NAP5 project, and infrastructure were as that for the UK, as described in Chapter 5, Methods.

24.4 Approval in Ireland was received from the Department of Health, and the project was endorsed by the Health Service Executive (HSE) National Quality and Patient Safety Directorate. The requirement for ethical approval was waived.

24.5 The NAP5-Ireland baseline survey (Jonker et al., 2014) elicited eight new reports of AAGA in 2011. The estimated number of general anaesthetics in Ireland from an Irish Activity Survey (Jonker et al., 2014) was ~187,000, and this yielded an annual incidence of AAGA of ~1:23,000 general anaesthetics. Taking into account the (Poisson) confidence intervals, this was comparable to the ~1:15,000 estimated during the UK Baseline survey (Pandit et al., 2013 a and b).

24.6 We are not aware of any previous studies of AAGA in Ireland.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

24.7 There were 11 cases of AAGA reported in Ireland: five in Class A (Certain/probable) and one in Class B (Possible), two cases involving drug errors (Class G), one case of Sedation (Class C) and two Statement Only cases.

24.8 Specific depth of anaesthesia monitoring was used in ~9% of general anaesthesia cases in the Activity Survey, but none was used in any of the AAGA reports in Ireland.

Certain/probable and Possible (Class A and B) reports

24.9 Six reports were classed as Certain/probable or Possible AAGA. All but one (a report of possible AAGA in a child <5yrs) were reports from adults.

24.10 Two cases occurred during or soon after induction: one after a rapid sequence induction with thiopental for an elective Caesarean section (after failed attempts at neuraxial blockade), and the other due to failure to turn on the vaporiser to maintain anaesthesia after intravenous induction.

24.11 Four reports were of patient experiences of AAGA after surgery had commenced.

24.12 Neuromuscular blockade was administered to five of the six patients (83%). The patient that did not receive neuromuscular blockade was reported to have not moved during the procedure.

24.13 Three cases involved experiences of paralysis and distress (Michigan 4D), one pain and distress (Michigan 3D; a patient who received no NMB) and two of tactile perceptions (Michigan 2) of which one was with distress and another without.

24.14 None of the AAGA cases involved TIVA.

24.15 Human factors (as described in Chapter 23) contributed to AAGA in four of the Certain/probable and Possible cases. Reason's error-types (Reason 1995) are in parentheses for illustration.

- 'Mind the gap' errors – delayed or omitted maintenance drugs (routine and optimising violations).
- Inadequate dosage of induction agents due to errors of judgement (situational violation).
- Under-dosing during maintenance due to inattention or judgement errors with contributory factors of supervision and staff experience.

A patient undergoing an elective procedure, was intubated and ventilated, but the anaesthetic trainee forgot to turn on the inhalational agent. After some time the patient started bucking and the airway was suctioned during surgery before the trainee realised the mistake and turned on the volatile.

A patient underwent an urgent operation and later recalled having their eye examined, being paralysed, and being unable to communicate. The Local Co-ordinator suggested that a relatively low dose of propofol had been used for induction.

A patient undergoing an elective Caesarean section with general anaesthesia after a failed attempt at regional anaesthesia, reported she was aware of: something in her mouth, taping of eyes, draping and muffled voices. She was unable to move, her arms were strapped down, and she could not see.

A child described having pain during lumbar puncture and bone marrow aspiration, and was upset at the thought of having the procedure again on a subsequent visit by the same anaesthetist. The consultant was not present in the room at the time of procedure and cited the inexperience of the trainee in paediatric anaesthesia as a contributory cause.

Class G reports: Drug Error

24.16 There were two reports of drug errors that resulted in reports of AAGA. Human factors were involved in both: an unwanted syringe of suxamethonium that had been left on the work surface by another anaesthetist in one, and distraction due to teaching of junior staff cited in another.

24.17 The theme of prompt communication with the patient to provide reassurance was evident.

24.18 In one case, a neuromuscular blocker was inadvertently administered instead of a non-steroidal anti-inflammatory via intravenous infusion. The anaesthetist noticed when the patient went to recovery, that the patient's breathing was irregular and that they could not follow commands. The anaesthetist concluded that the patient was accidentally given a neuromuscular blocker towards the end of surgery and stopped the infusion that was on-going at the time.

24.19 In both cases patients experienced paralysis and distress but had low, long-lasting sequalae (modified NPSA 1).

A patient was given suxamethonium in error (instead of fentanyl) for a procedure planned to be done under sedation. The anaesthetist immediately recognised the problem and reassured the patient, stating words to the effect "I know what has happened and I can fix it". The patient experienced paralysis and a fear of dying – in fact, of having had a stroke. The patient suffered flashbacks over the next couple of days, but overall psychological impact has been low. No formal support was needed and the patient was especially grateful for communication during the episode.

Class C: Sedation

24.20 One patient stated that they 'woke up' briefly in the middle of surgery performed with regional anaesthesia and sedation. The patient felt anxious but settled after the anaesthetist explained that they shouldn't be unconscious. Communication was pointed out as main reason for the difference between the patient's expectation and the anaesthetic plan.

Statement Only

24.21 Two reports of AAGA were made without any documentation or further information. One report was 45 years after the incident and the patient still experienced fear of hospitals.

Summary of incidences

24.22 Table 24.1 illustrates the various incidences based on reports of AAGA that can be estimated, notwithstanding the very low overall numbers. Note that the upper limit of the Poisson confidence interval for n = 1 is n = 5, so these incidences are, at worst, five times higher than those quoted. The upper limit of the confidence interval when n=5 or 6 is n = 12 or 13, so these respective incidences are at worst, approximately doubled. These incidences by themselves, based on very small numerators (and hence wide confidence limits), have limited value but comparison with the UK data has merit (Chapter 6, Results).

DISCUSSION

24.23 There were too few reports of AAGA in Ireland to examine detailed sub-correlations with age, sub-specialties, phase of anaesthesia, etc. to make firm recommendations.

24.24 Nonetheless, the six reports of Certain/probable or possible AAGA in Ireland yield an estimate for incidence of reports of AAGA that is comparable to the UK (see Chapter 6; Results).

24.25 The overall incidences in Table 24.1 above perhaps seem to suggest that AAGA is a little less common than in the UK, but the Poisson confidence intervals are much wider, making comparisons of unlikely statistical significance.

For example, the 95% upper confidence limit of Certain/probable and Possible AAGA is 1:14,400, very similar to the UK incidence of 1:19,600 (see Chapter 6, Results).

24.26 There are however, other possible reasons why the estimate of incidence of AAGA may be lower than in the UK:

(a) The Irish data includes only the public hospitals, but 39% of surgical cases are undertaken in the independent/private sector, a much higher proportion than in the UK (Jonker et al., 2014). If there is unequal distribution of AAGA reports across the public and private sectors, this might make the data in Table 24.1 under-estimates.

(b) All of the Irish AAGA reports were made to anaesthetists, and in contrast to the UK, none to other healthcare workers such as General

Table 24.1. Estimated 'incidences' for reported AAGA arising out of reports to NAP5 in Ireland. The first column shows the n from NAP5; the second column shows the relevant n from the Irish Activity Survey

	Irish Activity Survey estimate, n	Incidence	%
Incidence of AAGA of all types of reports to NAP5 (n=11)*	219,700	1: 20,000	0.005
Incidence of AAGA Certain/probable (n = 5)	187,000	1: 37,400	0.003
Incidence of AAGA Certain/probable or possible (n = 6)	187,000	1: 31,200	0.003
Incidence of AAGA when NMB used** (n = 5)	77,115	1: 15,500	0.006
Incidence of AAGA when no NMB used** (n = 1)	109,885	1:110,000	0.001
Incidence of AAGA reports that were during sedation by anaesthetists (n = 1)	32,700	1: 32,700	0.003
Incidence of AAGA with Caesarean section (n = 1)	17,400	1: 17,400	0.005
Incidence of AAGA in cardiothoracic anaesthesia (n = 1)	5,200	1: 5,200	0.020
Incidence of AAGA in paediatric anaesthesia (n = 1)	46,100	1: 46,100	0.002

* includes all categories of AAGA
** includes all Certain/probable and Possible cases, and cases of syringe swaps or drug error

Practitioners or psychiatrists/psychologists. This may indicate under-reporting in the Irish database.

(c) It appears that use of TIVA (albeit non-TCI techniques) is associated with a higher incidence of reported AAGA (Chapter 18, TIVA). Only 2.3% of general anaesthetics in Ireland (Jonker et al., 2014) are conducted using TIVA, compared with 7.5% in the UK.

(d) The use of specific pEEG based depth of anaesthesia (DOA) monitoring is three times as high in Ireland (7.7% of all general anaesthetics) as in the UK (2.9%). There were no cases of AAGA in the Irish data where DOAs had been used, and it could be argued that this is because their use was generally sufficiently high to be preventative.

24.27 However, many of the themes identified in UK NAP5 report were also present in the Irish cases, namely: rapid sequence induction, use of neuromuscular blockade and 'mind the gap' events.

24.28 In summary, the smaller number of general anaesthetics in the public sector in Ireland, coupled with the paucity of AAGA cases makes numerical analysis limited, but many similar themes are evident as in the UK and the numerical analyses are entirely consistent with UK findings, each providing a degree of validation.

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CHAPTER
25

Inadmissible, Statement Only and Unlikely reports of AAGA

Jaideep J Pandit

HEADLINE

25.1 This chapter presents, for completeness, a summary of the reports submitted to NAP5 that were judged Inadmissible, or Unlikely to be AAGA. Also presented are the Statement Only cases for which there were no details available from case notes. Although these cases form perhaps the weakest in terms of levels of supporting evidence, aspects of the vignettes are recognisable in other categories of cases presented elsewhere in the NAP5 Report. Although the median reporting delay in Statement Only cases was ~31 years, longer-term adverse psychological impact was still evident in more than one-third of cases – but at 38% was less prevalent than in those cases reported earlier. This seemed to be associated with distress felt at the time of the AAGA. Clearly medical records are essential to full interpretation of the AAGA, but these reports produce data that remain largely consistent with the more robust AAGA reports.

BACKGROUND

25.2 To our knowledge there are no specific studies of patients who report AAGA but in whom it cannot be verified.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

Inadmissible reports

25.3 Of the 321 reports filed to the website, 21 (6.5%) were judged inadmissible by the Panel after review. The reasons included: not a first report; surgery in non-NHS hospital; report made outside the reporting period; patient did not complain of 'awareness' but of 'pain' or other discomfort, at a time when they did not expect to be unconscious. There were several reports that raised interesting issues as to how unexpected awareness during anaesthesia should best be defined.

25.4 In one case, it was not clear if the weakness related to a prolonged partial paralysis resulting from the effect of the patient's electrolyte disturbance on neuromuscular blockade. Because the patient did not express the view that they should have been unconscious this was classed as inadmissible.

A middle-aged patient with a complex medical history of disease involving the kidneys that produced electrolyte imbalance underwent elective eye surgery. The anaesthetic appeared uneventful, consisting of thiopental, remifentanil, NMB and tracheal intubation. A nerve stimulator was used for neuromuscular monitoring and blockade reversed with neostigmine. However, the patient (fully awake) complained of some weakness of the legs and arms during the recovery period that lasted ~12 hours. The patient was very distressed and experienced sleep disturbance for several weeks. At no time did the patient express an expectation to be unconscious during this time.

25.5 There were several instances during anaesthesia where the patient moved (sometimes the anaesthetist noticed low or absent vapour delivery), and anaesthesia was promptly deepened. In these cases, the anaesthetists questioned the patients afterwards, but there was no report of awareness. Although this indicated a degree of responsiveness (and in some cases likely wakefulness) at the time of the movement, because there was no report from the patient, the Panel judged these cases inadmissible.

An elderly patient underwent an elective general surgical operation. Anaesthesia provided by a consultant seemed uneventful (propofol, fentanyl, NMB – monitored by a nerve stimulator – tracheal intubation and isoflurane) until dramatically, the patient suddenly sat up in the middle of surgery. Anaesthesia was deepened, but no cause was found for this event, and the patient had no recollection of it later.

25.6 One case involved residual neuromuscular blockade in the dead space of an intravenous cannula, that was flushed several hours after surgery was complete, on the ward, resulting in accidental paralysis, followed by resuscitation. Although this was a serious event, there was judged to be no report of 'accidental awareness' or an expectation of unconsciousness before or at the time of the event. While there are elements of this case similar to Category G (Drug Errors) as it did not occur close to a time of intended anaesthesia it was deemed inadmissible.

Several hours after uneventful general surgery, the ward nurse started to administer intravenous antibiotic to a middle aged patient, who suddenly became unresponsive. The nurse promptly called for help and the patient's lungs were ventilated (bag and mask) with cardiac massage for a few minutes, after which spontaneous breathing returned. The patient reported being unable to move or breathe, and had recall of the resuscitation.

25.7 It appeared that NAP5 coincided with a post-operative questionnaire of patients after cardiac surgery, conducted in some hospitals. The questionnaire had included the questions 'Do you recall a tube in your throat after surgery' and 'Do you recall being conscious between going to sleep and waking after surgery'. A small number of patients had ticked 'yes' to these questions, but there were no further details and no follow up. The Panel concluded that the questions asked were not sufficiently precise, and the period covered by such a question might include both surgery (intended anaesthesia) and intensive care (intended sedation); the Panel had no access to further information and judged the reports inadmissible.

25.8 In one case, a patient suffered a cardiac arrest during a long operation, but the 'recall' was judged to be a description of an out-of-body experience, or a dream, and there was no sense that the patient had experienced awareness of events.

An elderly patient underwent complex general surgery. After several hours of surgery, the patient suffered a cardiac arrest (ventricular fibrillation) of uncertain cause which required several minutes of cardiac massage and resuscitation (during which time the anaesthesia was reduced). There was an uneventful recovery but the patient reported 'having seen himself from above, surrounded by people working a machine'. There was no other report of sensations or conversations.

25.9 In summary, several of these inadmissible cases were focuses of interesting debate, and reflect the genuine difficulty of classifying some reports as 'awareness' or not.

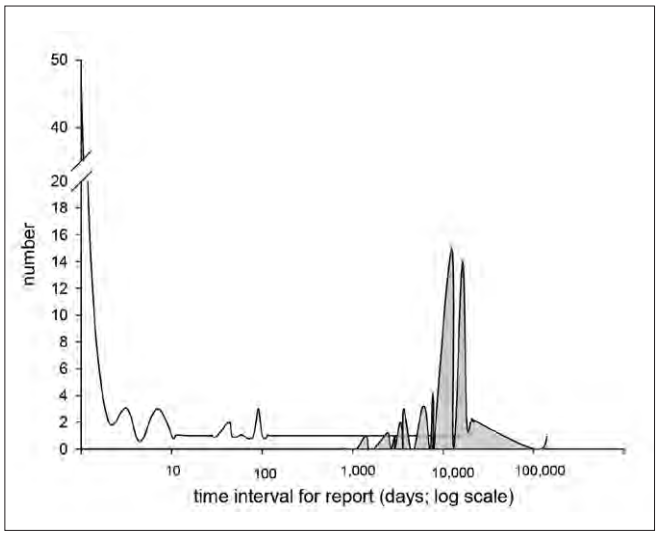
Statement Only cases

25.10 There were 70 (23% of admissible cases) Statement Only cases, with no medical or anaesthetic record to analyse further details.

25.11 The striking difference between these cases and the Certain/probable or Possible cases was the time interval between AAGA event and reporting (Figure 25.1). The time interval was unknown (but likely very long) in five cases, and for the remainder the median was 11,315 (7,300 – 15,248 [1,163 – 22,630]) days (i.e. a median of ~31 years with an upper limit of 62 years (almost to the start of the NHS) – the shortest interval in this group being ~3 years).

25.12 Some reports were extremely sparse in detail, such that it was impossible to know what could have happened, either in terms of anaesthetic detail or patient experience.

Figure 25.1. Time interval for first report of AAGA in Statement Only cases (shaded) versus Certain/probable or Possible reports (line)



A patient recalled being wheeled through some hospital doors many years ago. The patient could not recall the operation or the date or any other details but had felt this was during anaesthesia.

After ~60 years, an elderly patient reported AAGA during tonsillectomy as a child. There were no details of the experience, simply the patient felt they were 'awake'.

After a delay of 62 years, a patient reported AAGA during surgery as a child. The patient felt they could not move but could hear, but could not provide any further details of what the operation was.

25.13 Some reports seemed very implausible in their detail, if taken at face value, and might indicate altered memory for detail of what happened, or splicing of some memory from later events during the hospital stay.

After a delay of 42 years a patient reported AAGA during an urgent appendicectomy, where the patient sat up in the middle of surgery and recalled an amused expression from theatre staffs' faces, then a feeling of a face mask applied.

Many decades after a surgical operation (unknown which type) as a teenager, the patient reported feeling at the time that their 'memory had been stolen'. The patient attributes poor academic performance and now poor memory to AAGA.

After a delay of 46 years, a patient reported being awake and screaming throughout their tonsillectomy surgery as a child.

It was unclear in some reports – especially obstetric and Caesearean section cases – whether a general anaesthetic had been administered, or if the case might have plausibly been conducted under regional anaesthesia.

After a delay of over 40 years, a patient reported pain during the incision of Caesearan section and the surgeon speaking. The patient simply focussed later on looking after the baby and thought nothing of this incident. The details of anaesthetic are unknown.

After a delay of over 30 years a patient reported paralysis and pain, and an inability to talk or call out during her Caearean section. The patient had experienced psychological problems since, and a fear of anaesthetics such that operations had been delayed as a result, but subsequent anaesthetics had been uneventful. It is unclear why there was delay in reporting, and the details of anaesthetic technique are unknown.

25.14 Several patients reported multiple experiences of AAGA on different occasions.

Incident 1. After a delay of 20 years, a patient reported hearing a dentist speaking a sentence during surgery. No details of the anaesthetic technique were available, but the patient believed it to have been a general anaesthetic.

Incident 2. After several years, a patient reported AAGA for a second time during an urgent abdominal operation. The patient heard the surgeon speaking. Neither incident caused distress.

Incident 1. After a delay of over 60 years, a patient recalled AAGA during tonsillectomy, with the sensation of what sounded like a Boyle-Davis gag and of bright lights overhead.

Incident 2. After a delay of 30 years the same patient reported a feeling of her legs in stirrups during a gynaecological operation, some pressure and hearing voices. There was no distress, but for a while the patient experienced recurrent dreams of these events.

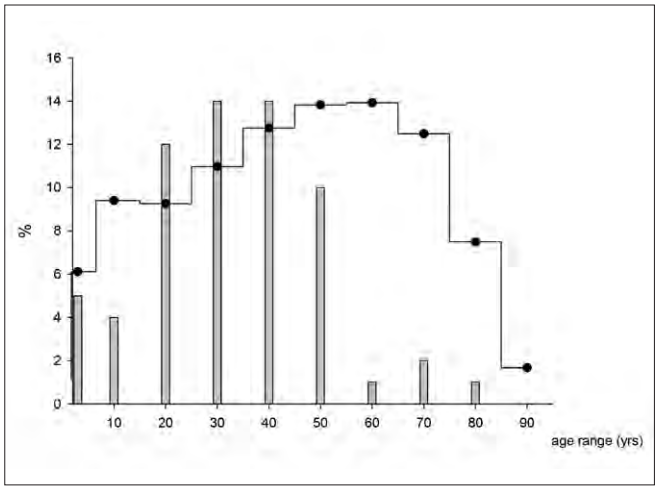
25.15 Several reports, however, were quite detailed, even after considerable time intervals, and recurrent themes included the recall of events at induction (tubes in the mouth or throat) and a feeling of paralysis.

Fifteen years after orthopaedic surgery, a patient remembered an injection in their hand, then a tube being put into their throat, and being unable to move or speak, feeling very anxious about this. The patient was left with a fear of facemasks.

After a delay of five years, a patient reported AAGA during emergency surgery. The main sensation was paralysis with no ability to communicate and the patient was distressed. "I counted to ten as I fell asleep but then was aware of a tube in my throat. I could not move, then recall being moved. There were bright lights, even though my eyes were shut and I thought to myself "Oh no, I am going to be awake and feel the surgery happening."

25.16 Figure 25.2 shows the estimated age distribution of these cases (the estimated age at which the AAGA occurred, not the age at which the report was made to NAP5) for patients where this was known. There are fewer older patients making Statement Only reports than undergo anaesthesia in the general population (this is expected as these are historical cases when the very elderly have not survived to make a report).

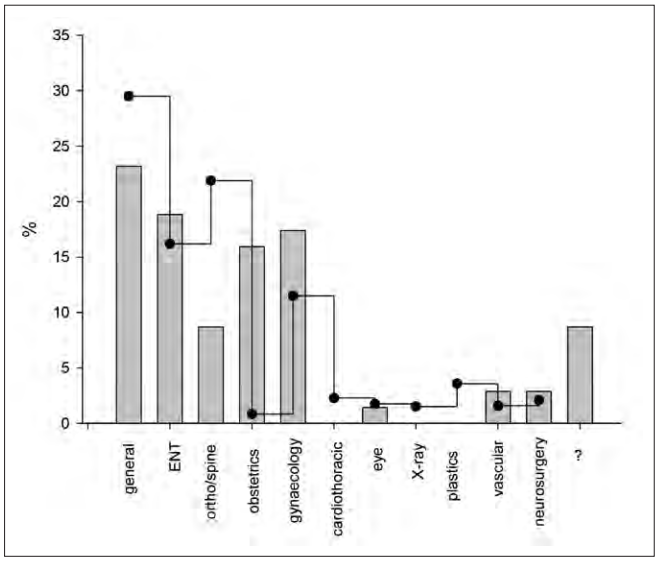
Figure 25.2. Histogram of age at AAGA event for Statement Only cases (bars) and that of general anaesthetic cases from the Activity Survey (lines with dots). Age ranges are in deciles, with the smallest being <5 yrs and the highest being >90 yrs



25.17 Body habitus at time of report was largely unknown.

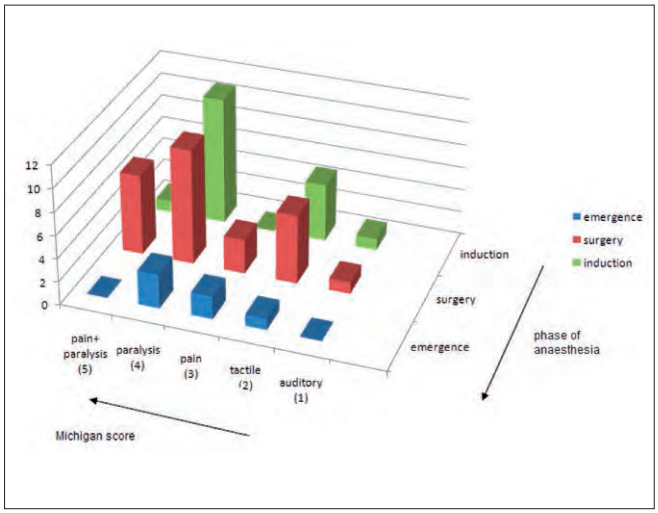
25.18 Figure 25.3 shows the distribution in terms of closest specialty. As with the Certain/probable and Possible cases (Chapter 6, Results), there was over-representation of reports from obstetrics, and to an extent, gynaecology (but notably, not cardiothoracics). However, as with the Certain/probable and Possible cases there was an under-representation in AAGA cases of orthopaedics/spine/trauma and plastics. However, the 'don't know' category was marked in the Statement Only cases.

Figure 25.3. Distribution of Statement Only AAGA cases (bars) and in the Activity Survey (dots and line). The specialties are ordered as the respective figure(s) Chapter 6, Results. ENT – ear, nose, throat and dental and maxillofacial surgery; ortho/spine includes orthopaedics, trauma and spinal surgery; eye is ophthalmology; X-ray is radiology



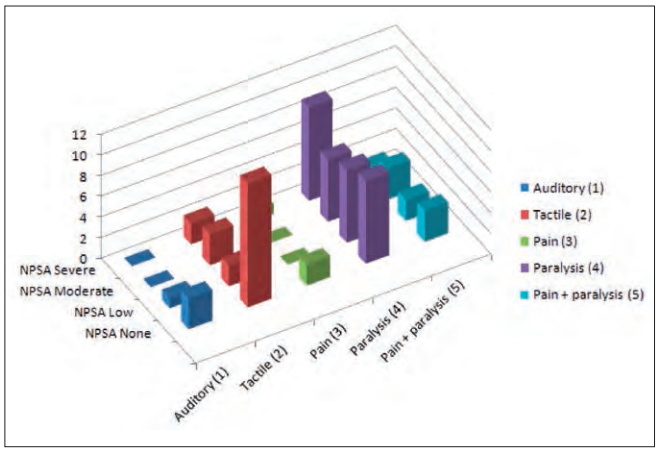
25.19 It was possible to estimate the timing of the AAGA experience in 51 patients (74%). In contrast to the Certain/probable and Possible cases, the majority of experiences were recalled as likely being during surgery, in the maintenance phase (53%), rather than at induction (35%) or at emergence (12%). Paralysis (47%), sometimes with pain (16%), was the commonest experience recalled, whereas pain alone (20%) or tactile (23%) were less frequent. Just 4% of patient had auditory recall alone (Figure 25.4).

Figure 25.4. Distribution of the Statement Only cases (excluding unknowns) by phase of anaesthesia (AAGA more common in at surgery > induction > emergence) and by symptoms (by Michigan classification



25.20 Just as for the Certain/probable and Possible cases (Chapter 6, Results) paralysis alone or with pain had the highest proportion (~50%) of important, longer term sequelae (i.e. moderate or severe modified NPSA scores). These occurred in fewer of those experiencing auditory or tactile sensations (~26%). However, there was considerable heterogeneity in NPSA scores by type of experience (Figure 25.5).

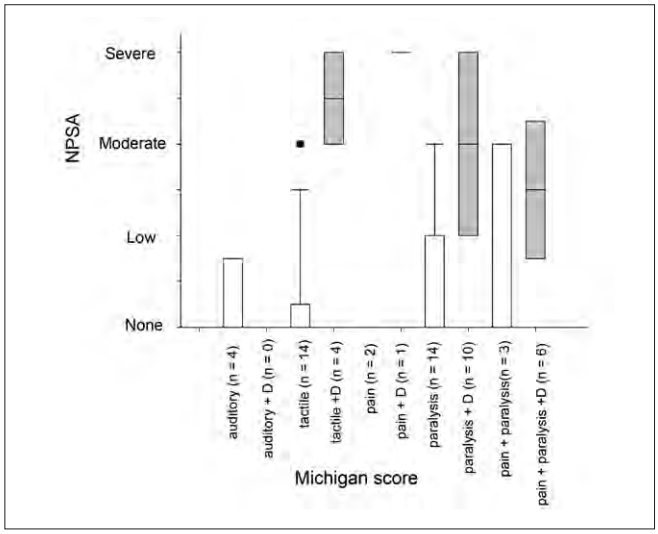
Figure 25.5. Distribution of the Michigan score by NPSA impact (excluding unknowns) for Statement Only cases



25.21 Overall, 36% of patients were distressed at the time, the highest proportions being those who sensed paralysis (42% of those paralysed) and paralysis with pain (67% of those in this category).

25.22 As with the Certain/probable and Possible cases (Chapter 6, Results), the perception of distress at the time of the AAGA (regardless of type of experience) appeared influential in determining longer term impact as assessed by modified NPSA score (Figure 25.6).

Figure 25.6. Statement Only cases: boxplots for modified NPSA score by Michigan score (n) with or without distress (D). White boxes – no distress and shaded boxes – distress. There is a clear association between distress and longer term sequelae

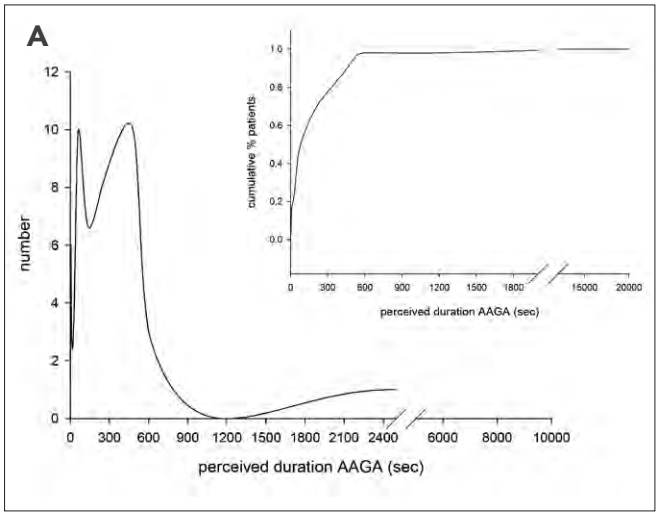


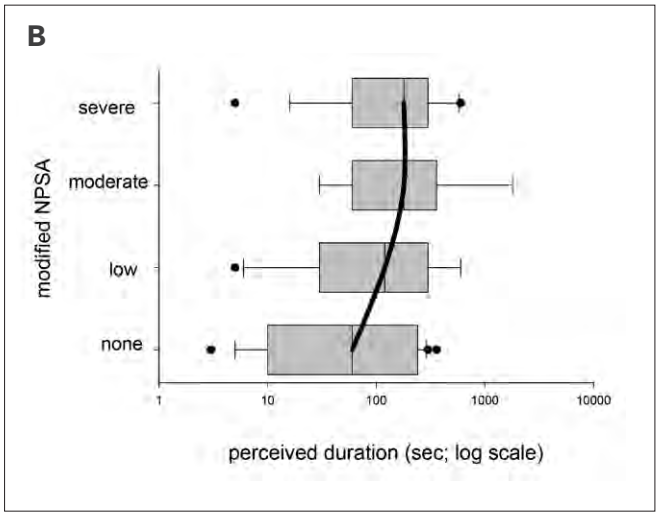
25.23 The perceived duration of the AAGA experience in the Statement Only cases was short (Figure 25.7A). Seventeen patients could not recall how long their experience might have lasted, and the median of those that could was 120 (60 – 300 [5 – 1,800]) sec (i.e. 2 min with an interquartile range of 1–5 min; the longest experienced judged at half-an-hour).

25.24 Despite this generally short perceived duration – and the considerable heterogeneity of impact – the longer-term impact was marginally influenced by duration, such that longer experiences of AAGA appeared to have slightly more adverse impact (Figure 25.7B).

25.25 The relationship in Statement Only cases between distress and sequelae and between duration of AAGA and impact is broadly similar to that observed in Certain/probable and Possible cases (Chapter 6, Results).

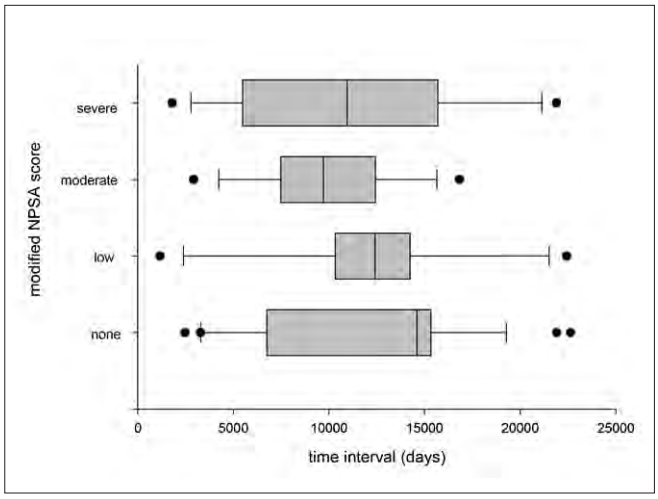
Figure 25.7. Statement only cases: (A). Main panel: distribution of perceived duration of experience; Inset: cumulative distribution. (B). Boxplot of relationship of perceived impact of AAGA by modified NPSA score. The solid bold line joins the medians of boxplots to give a visual impression of relationships





25.26 There was no apparent relationship between the longer term impact of AAGA and the time delay in reporting (Figure 25.8).

Figure 25.8. Statement Only cases. Boxplot demonstrating the lack of relationship of the modified NPSA score with delay in reporting.



Unlikely reports

25.27 There were 12 (4% of admissible) reports in whom there was access to medical records that were judged unlikely AAGA.

25.28 The reasons for this judgement included: where contents of the report that could not, or unlikely could not, have occurred during the course of surgery; where the patient-story was directly contradicted by the evidence, where an anaesthetist provided care, but not anaesthesia or sedation.

25.29 There was one instance where the surgical team encountered a complication related to inadequate muscle relaxation and coughing, and later informed the patient that they had been 'aware under the anaesthetic'. The patient had experienced severe pain when awake post-operatively but interpreted this as being part of the awareness and of the complications.

25.30 There were three reports to NAP5 based on post-operative satisfaction questionnaires that included questions on possible awareness. Two were judged Unassessable, but in only one was the patient followed up, and this revealed the original responses had been incorrect.

A middle-aged patient suffered brief asystolic cardiac arrest during general surgery, with a good outcome. The patient later reported hearing a conversation related to this resuscitation, but no recall of any events during surgery. It seemed likely that this was a conversation at handover in recovery.

An elderly patient was scheduled to undergo urgent surgery but was noticed to be in an arrhythmia, which was treated with magnesium in the anaesthetic room. The patient became flushed and dysphoric. After a period of time, when stable, anaesthesia was induced uneventfully (no neuromuscular blockade; spontaneous breathing via a supraglottic airway). The patient later reported AAGA, having recalled the word 'magnesium'. It was felt that this related to the period of resuscitation, rather than the period of anaesthesia.

In response to a satisfaction questionnaire related to cardiac surgery, a patient indicated awareness on entering the operating theatre, after induction, and awareness between induction and awakening. However, on later contacting the patient it was clear that there had been no AAGA and the first recall was on the intensive care unit.

An elderly patient reported that they had experienced AAGA during a general surgical operation, describing specific comments and conversations and saying that they had suffered a myocardial infarction as a result of this. In fact, the patient had not undergone an operation, which had been abandoned soon after anaesthetic induction because the patient developed an arrhythmia. This had been appropriately treated, and later cardiac review excluded a myocardial infarction. The anaesthetic had involved a propofol TCI technique, no neuromuscular blockade, and a BIS monitor had been used during resuscitation, with readings <40 throughout. The details of conversations reported were refuted by staff.

SUMMARY

25.31 In the Statement Only group, the interval for reporting was very long, often years or decades. One difference between this group and the Certain/probable or Possible group was that the main phase of anaesthesia in which AAGA was recalled was maintenance (rather than the dynamic phases).

25.32 The incidence of longer term psychological impact (or distress recalled at the time) differed little from the Certain/probable or Possible group.

25.33 However, there was an association (as with the Certain/probable or possible group) of distress at time of AAGA with longer term adverse harm. Distress was, again, most commonly associated with sensations of paralysis.

25.34 Experiences recalled many years later in the Statement Only group were no longer in perceived duration than the Certain/probable or Possible group, and there was no clear relationship between perceived duration and longer term psychological impact.

CHAPTER
26

NAP5 Baseline Survey in the UK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HEADLINE

26.1 We issued a questionnaire to every Consultant and Staff/Associate Specialist anaesthetist in the United Kingdom. The survey was designed to ascertain the number of new cases of accidental awareness which became known to them in 2011, for patients under their direct or supervised care, and also to estimate how many cases they had experienced during their careers. The survey also asked about use of monitoring designed to measure the depth of anaesthesia. All Local Co-ordinators responsible for each of 329 hospitals in the UK responded, as did 7125 anaesthetists (82%). There were 153 new cases of accidental awareness notified to respondents in 2011; an estimated incidence of 1:15,414, lower than the 1-2:1,000 previously reported in prospective clinical trials. Almost half the cases (72, 47%) occurred at or after induction of anaesthesia but before surgery, with 46 (30%) occurring during surgery and 35 (23%) after surgery before full recovery. Awareness during surgery appeared to lead more frequently to pain or distress (62% vs 28% and 23% for experiences at induction and emergence, respectively). Depth of anaesthesia monitors were available in 164 (62%) of centres, but routinely used by only 132 (1.8%) of anaesthetists.

The contents of this chapter have been published as Pandit JJ, Cook TM, Jonker WR, O'Sullivan E. A national survey of anaesthetists (NAP5 Baseline) to estimate an annual incidence of accidental awareness during general anaesthesia in the UK. *Anaesthesia* 2013;**68**:343–53 and as Pandit JJ, Cook TM, Jonker WR, O'Sullivan E. A national survey of anaesthetists (NAP5 Baseline) to estimate an annual incidence of accidental awareness during general anaesthesia in the UK. *British Journal of Anaesthesia* 2013;**110**:501–509. This chapter should be referenced as such. All figures in this chapter are reproduced with permission, and any portions of text reproduced with permission of the NAP5 Publications and Dissemination Panel, which includes the editors-in-chief of the respective journals, the *British Journal of Anaesthesia* and *Anaesthesia*.

BACKGROUND

26.2 As a prelude to the prospective NAP5 study, we administered a baseline survey to all consultant and career grade (Staff and Associate Specialist, SAS) anaesthetists working in NHS hospitals. The focus of our interest was to assess how many cases of AAGA had come to the knowledge of the senior UK anaesthetic community during the preceding calendar year. These data were essential to the design of the prospective phase of NAP5. Additionally, we wished to estimate the historical experience of AAGA cases during respondents' anaesthetic careers and also to ascertain some demographic data about years of senior practice. Finally, we wished to know about the availability and use of depth of anaesthesia monitors.

METHODS

26.3 Each of the 329 identified centres in the UK volunteered a Local Co-ordinator (LC) who distributed a data collection form (Figure 26.1) to all consultant and SAS anaesthetists in their institution. LCs then collated responses and populated a data summary form (Figure 26.2), which was returned to the NAP5 team. LCs could contact the NAP5 clinical lead for further advice (which was also provided via the NAP5 website), and in turn, the clinical lead could contact the LCs for clarification of data entries. Questions asked included: the department's total number of consultants and SAS staff and their years of experience as seniors; the number of new cases of AAGA (under their direct or supervised care) of which they were notified during 2011; availability and use of depth of anaesthesia monitoring; and whether the hospital had policies for prevention or management of AAGA.

26.4 Since there was no hypothesis test, there were no statistical comparisons, but continuous data were described as median, interquartile range and categorical data with 95% confidence limits for binomial or Poisson distributions, as appropriate. Poisson and binomial distributions were almost identical so only the Poisson is included. Where illustrative, the goodness of fit of the data to a Poisson distribution was estimated by the least squares regression of actual vs modelled data.

Figure 26.1. Abridged version of Form 1 as sent to individual anaesthetists. The consultant returned this form to their Local Co-ordinator for collation. AAGA was defined as any instance of recall of intra-operative events during general anaesthesia, induction or emergence that occurred with administration of anaesthesia.

1. During 2011, how many new instances of accidental awareness during anaesthesia have you personally had to deal with for patients under your care or care of someone you were supervising?

a) What was the approximate age range of these instances?

Approx age	0-15	16-24	25-44	45-64	>65
Number					

b) How many of these were reports volunteered by the patient vs ascertained only on questioning?

Approx age	0-15	16-24	25-44	45-64	>65
Number volunteered					
Ascertained on questioning					

c) How many of these were brief periods of awareness before surgery (e.g. due to difficult intubation, syringe swaps, drugs given in wrong order, etc), awareness of intra-operative events, or awareness of events on emergence?

Approx age	0-15	16-24	25-44	45-64	>65
Recall of events during induction and before surgery					
Recall of events during surgery					
Aware after surgery and before full emergence					

d) How many of these cases of awareness also involved physical pain or psychological hurt?

Approx age	0-15	16-24	25-44	45-64	>65
Number					

e) How many of these reports led or is leading to a formal complaint to the hospital or litigation?

Approx age	0-15	16-24	25-44	45-64	>65
Formal complaint					
Litigation					

2. Do you use any depth of anaesthesia monitors and if so, which?

	BIS	Evoked potential	Entropy	Narcotrend	Isolated forearm	Other
Routinely						
Selected cases						
Never						

3. Approximately how many cases of accidental awareness occurring directly under your care (including supervising a trainee) as consultant/career grade during your career in UK practice have you experienced?

Yrs of anaesthesia practice (as consultant, including locum or as non-consultant career grade)	Yrs
Total no. of cases of accidental awareness	N =

Figure 26.2. Abridged version of Form 2 as completed by Local Co-ordinators using individuals Form 1 returns, and submitted to NAP5.

Question 1:

- How many consultant anaesthetists (incl. locums) are there in your department?
- How many have responded to the individual questionnaires?
- How many SAS doctors are there in your dept?
- How many have responded to the individual questionnaires?
- Over this last year 2011, how many instances of accidental awareness during anaesthesia have been reported by (i) consultants/ SAS alone or supervising trainees (ii) unsupervised trainees

Question 2: What was the approx age of the patient in these reports?

Approx age	0-15	16-24	25-44	45-64	>65
Number					

How many of these were reports volunteered by the patient vs ascertained only on questioning?

Approx age	0-15	16-24	25-44	45-64	>65
Number volunteered					
Ascertained on questioning					

How many of these were brief periods of awareness before surgery (e.g. due to difficult intubation, syringe swaps, drugs given in wrong order, etc), awareness of intra-operative events, or awareness of events on emergence?

Approx age	0-15	16-24	25-44	45-64	>65
Recall of events during induction and before surgery					
Recall of events during surgery					
Aware after surgery and before full emergence					

How many of these cases of awareness also involved, physical pain or psychological hurt?

Approx age	0-15	16-24	25-44	45-64	>65
Number					

How many of these reports led or is leading to a formal complaint to the hospital or litigation?

Approx age	0-15	16-24	25-44	45-64	>65
Formal complaint					
Litigation					

Question 3: Do you have any depth of anaesthesia monitors available for use in your hospital?: If yes, how many (n) consultants and career grades use the following?

	BIS	Evoked potential	Entropy	Narcotrend	Isolated forearm	Other
Routinely						
Selected cases						
Never						

Question 4: Consultant/career grade anaesthetic experience of those who have responded to Form 1:

	Sum of yrs experience	Mean (sum divided by n responding)	Range of experience (min yrs – max yrs)
Years of experience			

Question 5: How many consultants/SAS doctors in your department have ever personally identified or witnessed a case of accidental awareness during anaesthesia, under their care, during their consultant/career grade careers in UK practice?

	0 cases	1 case	2 cases	3 cases	4 cases	5 cases	6 cases	7 cases	>7 cases
No. of respondents									

Question 6: Trust/Board Policies – please provide copies if 'yes':

To **prevent** awareness (e.g. identify high risk patients, use of monitors or specific drugs?	Yes/No
To **manage** awareness if reported?	Yes/No

NAP5 RESULTS AND NUMERICAL ANALYSIS

26.5 All LCs replied on behalf of their centre, and collected data from a total of 7125 (82%) anaesthetists (Table 26.1).

26.6 Figure 26.3 shows the demography of staffing across centres: in 12 of 265 (5%) of centres, the number of SAS doctors was equal to or greater than consultant anaesthetists.

26.7 There was a variety of experience in terms of years worked by respondents (Figure 26.4); the crude sum of years' experience was 81 147 years.

26.8 A total of 153 new cases of AAGA were reported in the year 2011 to the anaesthetists who responded to this survey. Most patients experiencing AAGA were young or middle-aged adults (Figure 26.5A); the details of more than twice as many cases were volunteered to anaesthetists by patients (114, 75%), compared to those established by direct questioning (39, 25%, Figure 26.5B). Most cases related to experiences of AAGA at or soon after induction of anaesthesia but before surgery commenced (72, 47%: Figure 26.5C), followed by experiences of AAGA during surgery (46, 30%) and lastly, by reports of awareness after completion of surgery but before full emergence (35, 23%). Indeed, the combined total for experiences during induction and emergence (i.e. the 'dynamic phases' of anaesthesia) was twice as high (107, 70% of cases) as for experiences during surgery (the 'static phase'; 46, 30%). A minority (58, 38%) of cases of AAGA suffered pain or distress as part of their experience, and even smaller proportions went on formally to complain (29, 19%) or begin legal proceedings (6, 4%; Figure 26.5D).

Figure 26.3. Demography of staffing in UK hospitals.Top panel: histogram of number of SAS, consultant and total anaesthetists across hospitals (trusts); middle panel: SAS anaesthetists as % of consultants across hospitals (trusts); bottom panel: absolute number of SAS vs consultant anaesthetists across hospitals (trusts)

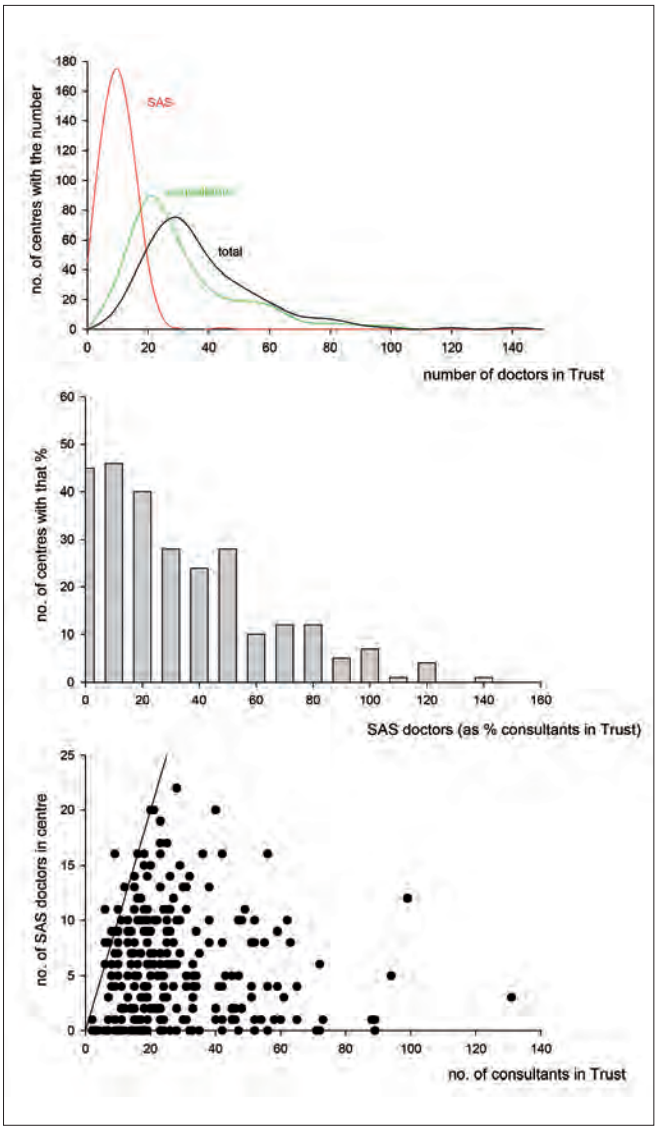
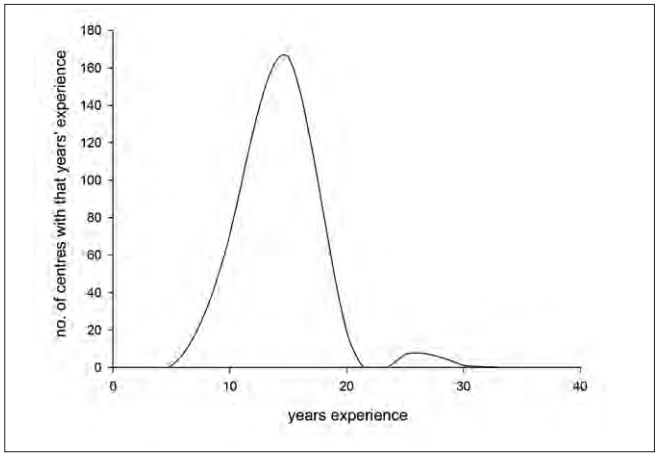


Table 26.1 Response rates from 265 Local Co-ordinators (responsible for 329 UK hospitals; 100% response rate). All centres had consultant staff, so the data for consultants use 265 as denominator; *45 centres had no Staff and Associate Specialist (SAS) anaesthetists, so the denominator used here is 220. Values are median (IQR [range])

	Consultants		SAS*		Total senior staff	
Totals	Total (n = 7,140)	Responding (n = 5,951; 83%)	Total (n = 1,532)	Responding (n = 1,174; 77%)	Total (n = 8,672)	Responding (n = 7,125; 82%)
Staff response/ centre*; n	22 (15-33 [2-131])	19 (13-28 [2-101])	5 (1-9 [0 - 22]	4 (1-7 [0 - 20])	28 (20-42 [2-134])	25 (16-34 [2-103])
Response rate/ centre*; %		94 (78-100 [18-100])		91 (60-100 [0-100)]		92 (76-100 [17-100])

Figure 26.4. Distribution of mean years' experience of senior staff



26.9 Proportions of patients volunteering their experience compared to those responding to direct questioning were broadly similar across the age groups (Figure 26.6A). The distribution of awareness experienced by phase of anaesthesia/surgery was also similar across the age groups (Figure 26.6B), and there were no striking age-dependent influences upon the degree of pain or distress or the likelihood of formal complaint (Figure 26.6C).

Figure 26.5. (a) Distribution of AAGA reports by age. (b) Proportions where reports were volunteered by the patient vs established by direct questioning. (c) Distribution of reported experiences by phases during anaesthesia and surgery. (d) Patients' experiences that included pain or distress, resulting in a formal complaint or in legal proceedings (as a proportion of total cases of AAGA)

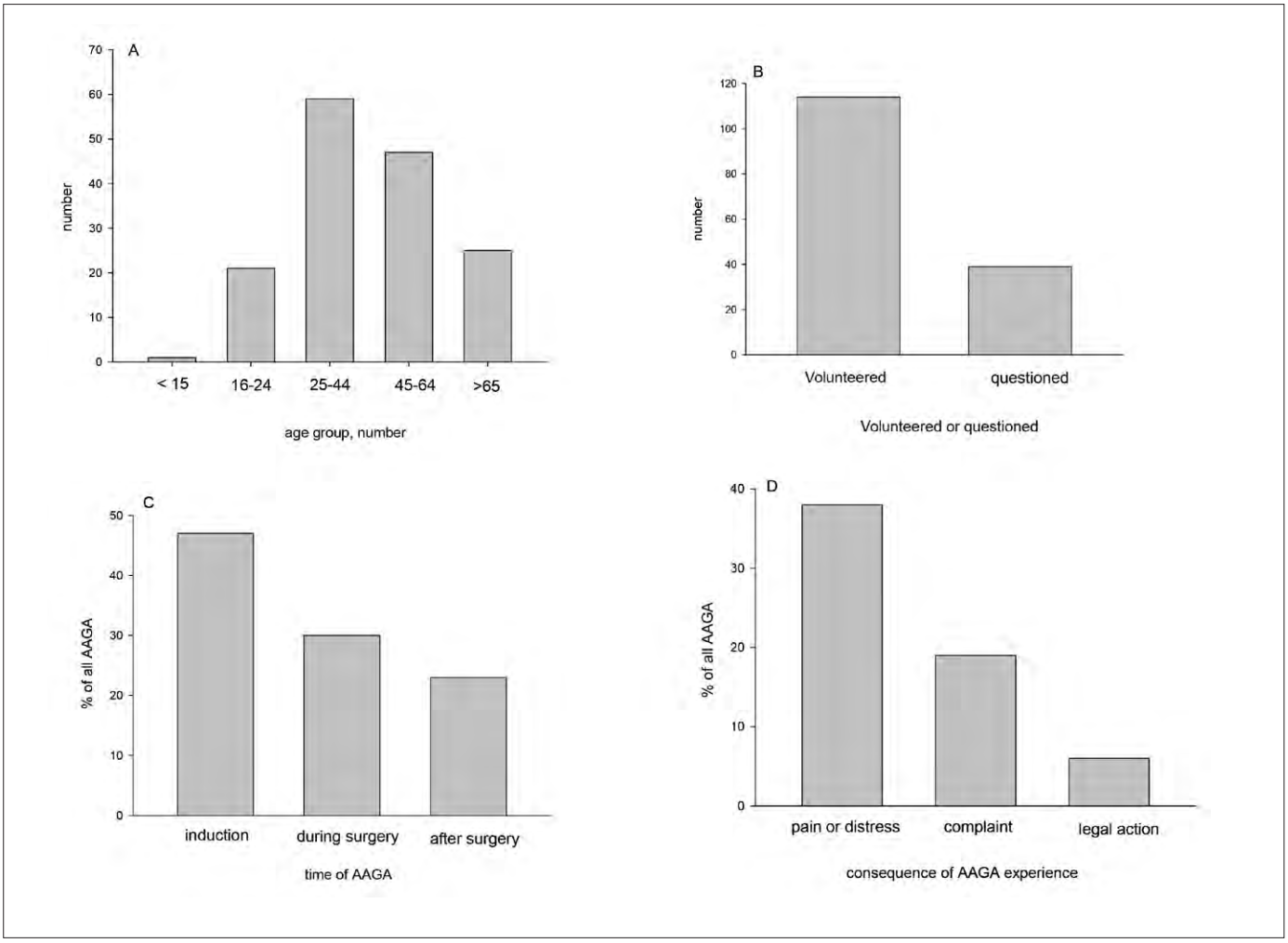
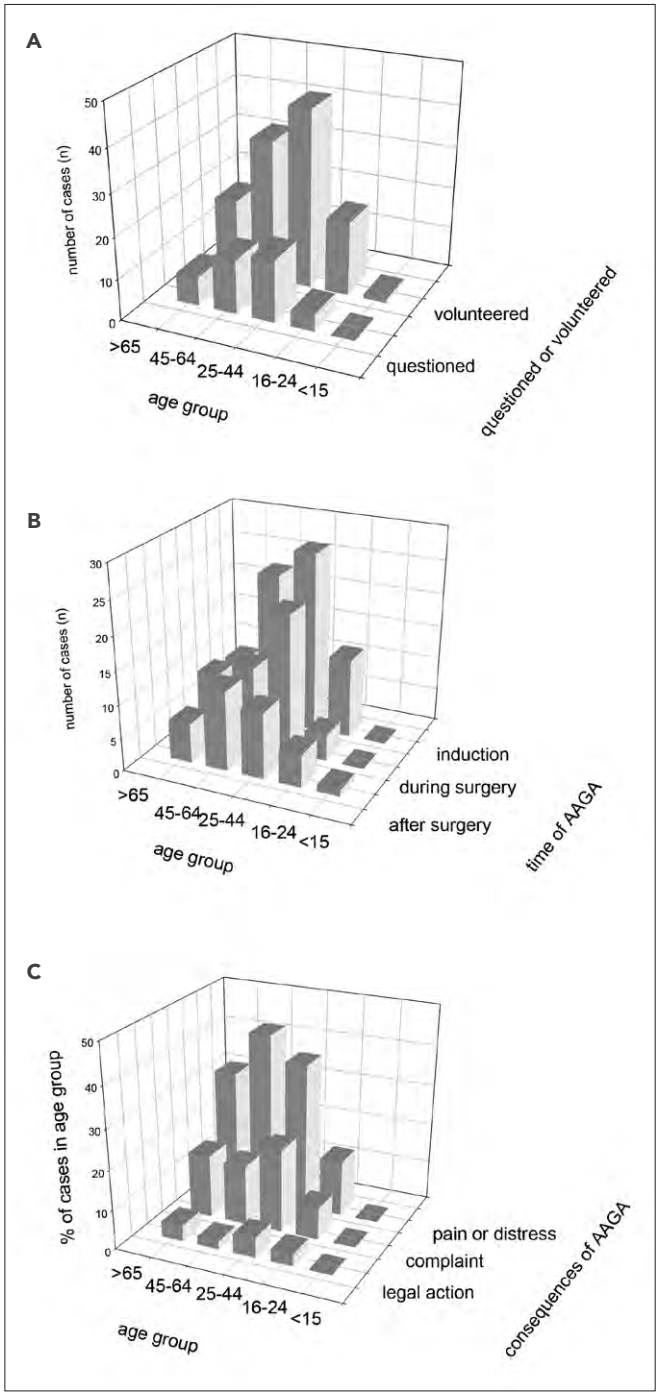
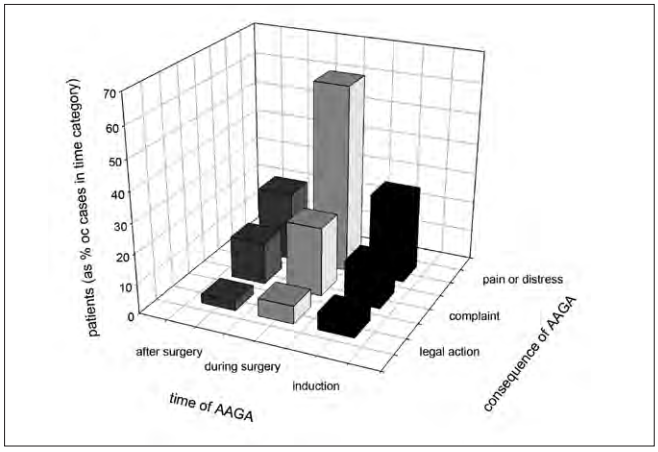


Figure 26.6. (a) Distribution of volunteered reports vs those established by questioning by age. (b) Lack of influence of age on when AAGA was experienced (c) Lack of influence of age on pain or distress, or issuing a complaint or legal proceedings



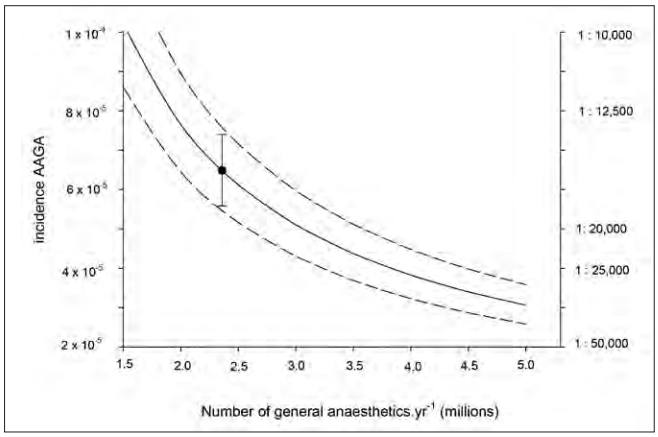
26.10 However, AAGA experienced during surgery appeared more likely to result in pain or distress than did that experienced in the dynamic phases (induction and emergence) of anaesthesia (Figure 26.7).

Figure 26.7. Influence of when during anaesthesia/surgery accidental awareness during general anaesthesia was experienced on whether pain or distress resulted, or if a complaint or legal proceedings were issued



26.11 Using a denominator for the number of general anaesthetics administered in the UK (obtained from the 4th National Audit Project (Woodall & Cook 2011) and adjusting this figure by the number of respondents, we estimated the incidence of AAGA known to anaesthetists in the year 2011 to be approximately one case for every 15,414 general anaesthetics (Table 26.2). As the denominator value may have changed since NAP4 (which we consider to be unlikely given the relatively short time interval involved), the calculated incidence may vary depending on the actual denominator (Figure 26.8). The effect of relatively large changes in the denominator (plus or minus one million) can be seen to be relatively small, leading to a range of 1:12,500 to 1:20,000. Subsequently, we undertook the Activity Survey which confirmed the accuracy of the denominator.

Figure 26.8. The influence of denominator value (number of general anaesthetics administered annually) on the estimated mean incidence (solid line) of AAGA (± 95% Poisson CI, dotted lines), given our data of 153 instances of AAGA in one year. The incidences are shown as absolute values (left y-axis) and as ratios (right y-axis). The point represents the value assuming the NAP4 estimate of denominator is correct (adjusting for non-responders in this survey) ± 95% Poisson CI



26.12 These data imply that just one senior anaesthetist out of around 47 will know of a new case of AAGA each year (Table 26.3). The median (IQR [range]) number of new cases per centre was 0 (0–1 [0–4] (Figure 26.9). Over the course of an anaesthetic career, we estimate that a senior anaesthetist will have personal experience of one case of AAGA every 36 years (Table 26.2). The vast majority of anaesthetists reported never having had direct experience of a case of AAGA (Figure 26.10).

Figure 26.9. Distribution of AAGA cases by centre. The data could be fitted by a Poisson distribution with a covariance r2 > 0.997

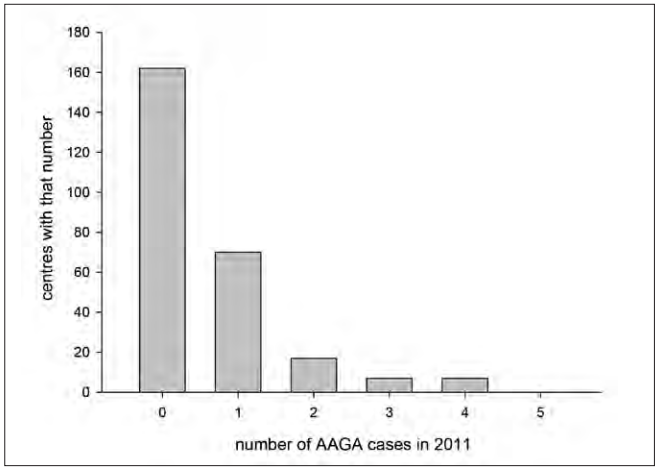
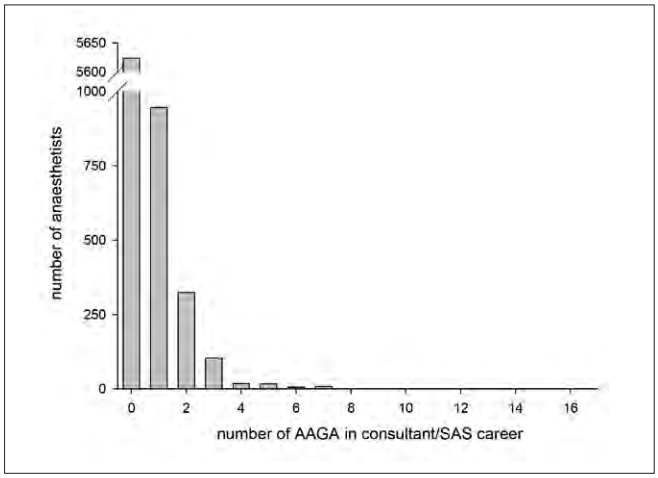


Table 26.2. Number of cases of AAGA known to senior anaesthetic staff over their careers and incidence (total yrs of service 81 147). The binomial and Poisson estimates are almost identical; the binomial are presented

Descriptor	Incidence
Cases; n	2280 (2190 – 2353)
Incidence; cases/senior staff/yr	0.028 (0.027 – 0.029)
Cases: yrs of senior practice	1:35.6 (1:34.5 – 1:37.0)

Figure 26.10. Distribution of the number of cases of AAGA experienced by senior staff in their careers. The spread of values is 0 (0–0 [0–16]), and the data can be fitted by a Poisson distribution with covariance r2 > 0.997. The x-axis extends to 17 as there was one respondent who had personal experience of 16 cases in his/her career (the data point cannot be seen due to the size of the y-axis scale)



26.13 Approximately two-thirds of centres reported the immediate availability of depth of anaesthesia monitors (Table 26.3), with their routine use practiced by 132 (1.8%) respondents.

26.14 Twelve centres (4.5%) reported the existence of a policy to prevent or manage awareness. Two of these used their general critical incident policy, with no specific reference to AAGA. The policies ranged from very general, brief or mini-reviews of AAGA to somewhat more comprehensive suggestions (see Appendix).

Table 26.3. Access to and use of depth of anaesthesia (DOA) monitoring in the 7,125 senior staff who responded. Values are number (proportion). BIS, bispectral index; EP, evoked potential monitoring; IFT, isolated forearm technique; 'other' included mention of the Vigileo flotrac as a haemodynamic monitor of awareness, the Cerebral Function Analysing Monitor (CFAM), or a targeted end-tidal volatile agent algorithm, or was not specified

Centres with DOA	Anaesthetists using DOA in selected cases only	Anaesthetists using DOA routinely	Type of DOA used (as % of those using DOA) n=1904					
			BIS	Entropy	EP	Narcotrend	IFT	Other
163/263 (62%)	1,772 (25%)	132 (1.8%)	1,442 (76%)	332 (17%)	90 (4.7%)	6 (0.3%)	14 (0.7%)	20 (1%)

DISCUSSION

26.15 The striking finding of this survey is that the incidence of new cases of AAGA as notified to anaesthetists in the year 2011 of approximately 1:15,000 is much lower than the incidence previously published, which was ascertained through direct patient questioning, of approximately 1–2:1,000. If both sets of data are valid, then it means that for approximately every 15,000 general anaesthetics administered, the anaesthetist may learn of just one case of AAGA, while up to around 30 other patients will experience AAGA but not report it. Interestingly, the incidences in Table 26.2 are very similar to those described by Pollard et al. (2007) who reported (also by direct questioning) an incidence of 1:14,500.

26.16 Full reasons for the discrepancy have been discussed elsewhere (Pandit et al., 2013a and b; Avidan & Mashour, 2013a and b) and in earlier chapters of this report. The possible reasons for disparity are summarised in Table 26.4. Nevertheless, it is notable that the incidence anticipated by the survey is borne out by the prospective NAP5 study (see Chapter 6, Results).

26.17 Also presaged by this Survey were the findings that adverse consequences for the patients who experienced AAGA seemed more modest than perhaps others have reported. In two-thirds of the AAGA cases reported, patients felt no pain or distress (compare with Chapter 7, Patient Experience), and only a fraction resorted to complaint or legal action (compare with Chapter 22, Medicolegal).

Table 26.4. Possible reasons for disparity between our reported incidence and any hypothetical 'true' incidence of AAGA

Reasons for disparity

- Anaesthetists forgot the number of cases of AAGA they were involved with.
- Unlike surgeons, anaesthetists generally do not routinely see post-operative patients at an interval after surgery in a clinic. As some patients only become aware of their experience of AAGA after a time interval, they have no direct opportunity to communicate this to their anaesthetist.
- Governance and reporting systems in hospitals may not be conducive to patient reporting of their complications; patients may be reporting their experience to surgeons (or other medical staff) but this is then not passed on to the anaesthetic department staff.
- The majority of patients consider their experience to be too trivial to report and are not harmed or affected by it, consistent with our finding that two-thirds of those experiencing AAGA did not find it distressing or painful (Figure 26.D). However, this interpretation is at odds with some findings that in fact, a high proportion of patients in prospective studies experience psychological symptoms, including post-traumatic stress after AAGA.
- AAGA patients may exhibit anxiety-fuelled avoidance and frank phobic reactions to hospitals and doctors arising as a direct result of the AAGA trauma. The most adversely affected patients experiencing AAGA are less likely to volunteer their experiences, which would bias the reported cases towards those of lesser psychological impact.
- Since patients may delay reporting AAGA for some time after their surgery and as we conducted this survey in March–April 2012 (asking about knowledge of reports made in 2011), we may have missed a large cohort of cases. Balanced against this is the likelihood that some cases first presenting to anaesthetists in 2011 underwent anaesthesia before 2011, including in some cases many years previously.
- Trainees did not complete a questionnaire (see text for fuller discussion).
- 'Over-reporting' if false memories or dreaming by patients were erroneously classified as AAGA by doctors, or if cases were reported twice or from private sector (see text for fuller discussion).

Why our reported incidence may be accurately reflect a 'true incidence'

- Some previous suggestions of a high incidence may themselves be flawed: study consent processes may make it more likely that patients respond affirmatively to a direct question. While most studies employing the Brice protocol seek to confirm that a report of AAGA is verifiable against the medical case notes, this is not universal.
- The UK population, which might be more susceptible to hypnotic effects of anaesthetic agents, or more resilient in their psychological response to an experience of AAGA (see text for fuller discussion).
- UK clinical practice differs to an extent that makes AAGA less common, e.g. (a) greater use of supraglottic airways, with avoidance of neuromuscular blockade (the laryngeal mask airway being a British invention that was standard practice in the UK long before other countries; or (b) in the UK, anaesthesia is a purely medical specialty and further, in recent years has been an increasingly consultant-delivered service.

26.18 Also, two-thirds of AAGA reports in this Survey described experiences during the 'dynamic' phases of anaesthesia (especially at or immediately after induction), anticipating the findings reported in Chapters 8 (Induction) and 10 (Emergence).

26.19 With regards to the use of depth of anaesthesia (DOA) monitoring, the survey anticipated the low use of DOAs as confirmed in the Activity Survey. In this survey, we found that almost three-quarters of senior anaesthetists never used a DOA monitor, despite two-thirds of centres possessing such equipment. Thus even in those centres with equipment available to them, only a minority of practitioners employ it even for selected cases. We did not ask how many monitors were available in each centre, so it is possible that there is not enough equipment to service each operating theatre or, that consumable costs are constraints. However, some comments written on survey returns suggest otherwise (e.g. "the monitor is locked in a cupboard and nobody uses it" or "we have a monitor, but it has stopped working and nobody has serviced it"). In this respect, our survey results differ from those of Lau et al. (2006), who found 85% of anaesthetists would use a depth of anaesthesia monitor if it were available (21% would use it routinely). Being a much smaller study with a lower response-rate, the respondents to Lau et al.'s study may have been enthusiasts of DOA monitoring, or may have been those more likely to have experienced a case of AAGA. This last is certainly possible, as they reported 33% of anaesthetists had experienced a case of AAGA; whereas our data suggests only 21% have ever done so. Or, as Lau's study was conducted in 2005, perhaps the passage of time has since made anaesthetists more (rather than less) sceptical of the benefits of existing DOA monitors.

26.20 Our finding that so few centres have developed any protocols for either the specific prevention or management of AAGA is notable, and is now specifically addressed by the NAP5 Awareness Support Pathway presented in Chapter 7, (Patient Experience).

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Excerpts from policies for managing AAGA

Below are listed extracts of policies from the few centres that had a policy to manage AAGA, highlighting some comments that are of interest, or may require further discussion. Taken from different centres, some of the comments are contradictory. They are used to illustrate the limitations of many of the policies in existence.

"The defence organisations (unfortunately) say that failure on the part of the anaesthetist is the most common cause of awareness."

"Virtually all of cases of light anaesthesia will be detected, long before awareness occurs, by the usual signs of tachycardia, rising blood pressure, sweating, dilated pupils etc. Sadly there have been a very few cases where awareness has occurred without any of these signs occurring."

"Awareness" is a "NEVER" event, i.e. one which should NEVER occur."

"Minimum Alveolar Contractions [sic] (MAC) requirements to prevent awareness have been delineated."

"In the unstimulated patient 0.45 MAC is sufficient. 0.75 MAC is probably adequate to prevent intra-operative awareness. The administration of 1.3 MAC in non-paralysed patients is likely to prevent movement and awareness."

"MAC 0.8 or more should be sufficient for majority of patients requiring muscle relaxation."

"Lower MAC than 0.8 might be tolerated under depth of anaesthesia guidance and in certain circumstances."

"The Isolated Forearm Technique (IFT) is the only method available to directly detect intra-operative wakefulness."

"It is very unusual for claims of awareness to be entirely fabricated."

"A handwritten record, not backed up with a printout, is of minimal medicolegal value since the anaesthetist may have recorded what s/he things [sic] is being given rather than what is actually being given."

"Some studies quote as high as 1:1000 (but there is a much lower incidence locally)."

"After a patient report of awareness, the anaesthetist should be relieved from clinical duties in view of the stress of the situation and need to care for the patient. Obviously the list must cease until another anaesthetist or machine can be found."

"ASA 3-5 patients are twice as likely to have awareness than ASA 1-2."

"The monitors such as Bispectral Index (BIS) were initially criticised because of manufacturers' claims that by titrating the anaesthetic to a certain monitored level of EEG, less agent could be used, and the patient woke up quicker. How could this then be used to prevent awareness if in fact less anaesthetic was being given?"

CHAPTER
27

The NAP5 Activity Survey


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Jaideep J Pandit

HEADLINE

27.1 Details of current UK anaesthetic practice are unknown, and were needed for interpretation of reports of accidental awareness during general anaesthesia (AAGA) within NAP5. We surveyed NHS anaesthetic activity to determine numbers of patients managed by anaesthetists and details of 'who, when, what and where': activity included general anaesthesia, local anaesthesia, sedation or patients managed fully awake. Anaesthetists in NHS hospitals collected data on all patients for two days. Scaling enabled estimation of annual activity. Response rate was 100% with 20,400 returns. The median hospital return rate was 98% (IQR 0.95–1). Annual numbers (% of total) of general anaesthetics, sedation and awake cases were 2,766,600 (76.9 %), 308,800 (8.6 %) and 523,100 (14.5%) respectively. A consultant or a career grade anaesthetist was present in over 86% of cases. Emergency cases accounted for 23.1% of workload, 75% of which were undertaken out of hours. Specialties with the largest workload were orthopaedics/trauma (22.1%), general surgery (16.1%) and gynaecology (9.6%): 6.2% of cases were non-surgical. The survey data describe: who anaesthetised patients according to time of day, urgency and ASA grade; when anaesthesia took place by day and by weekday; the distribution of patient types, techniques and monitoring where patients were anaesthetised. Nine patients out of 15,460 receiving general anaesthesia died during the procedure. Anaesthesia in the UK is currently predominantly a consultant-delivered service. The low mortality rate supports the safety of UK anaesthetic care. The survey data should be valuable for planning and monitoring anaesthesia services.

This chapter is reproduced, in part, as a summary paper and should be quoted or referred to as: Sury MRJ, Palmer JHMacG, Cook TM, Pandit JJ. The state of UK anaesthesia: a survey of National Health Service activity in 2013. *British Journal of Anaesthesia* 2014 doi: 10.1093/bja/aeu292. All figures in that paper are reproduced with permission of the Editor-in-Chief of the *British Journal of Anaesthesia*, Oxford University Press.

BACKGROUND

27.2 The main focus of the NAP5 project was the collection of new patient reports of AAGA over one year in the UK, and separately in Ireland. This registry provides a numerator. In order to estimate the incidence of reports of AAGA, the denominator number of general anaesthetics administered was needed. Moreover, to best interpret the AAGA reports an analysis of current anaesthetic practices was required.

27.3 There are several potentially useful estimates of anaesthesia-related activity available. In England and Wales, national data are collected by Hospital

Episode Statistics (HES, 2013 a,b and c) but these lack detail of whether or not anaesthesia was involved. The number of procedures lasting >30 min has been estimated by the National Institute for Health and Care Excellence (NICE), using HES data, to be just over two million per year (NICE, 2014). HES data also has details of anaesthesia for maternity services; there were an estimated 671,255 deliveries in NHS hospitals (in England) in 2012–13 (92% of all births (Statistical Bulletin, 2012), of which a little less than two-thirds (63%) required anaesthetic intervention.

27.4 In 2008, the census phase of the NAP4 project estimated the number of general anaesthetics administered over a two-week period (Woodall & Cook, 2011). Data were collected locally and then pooled centrally. The number of general anaesthetics per year was estimated to be just under three million (2,872,600). Although the NAP4 census had data on airway management, it did not provide details of anaesthetic practices or patient demographic characteristics which would be pertinent to NAP5.

27.5 The National Enquiry into Peri-operative Deaths (NCEPOD) surveyed the seniority of anaesthetists (and surgeons) and when operations were carried out; the so called 'Who Operates When?' or 'WOW' studies. WOW1, in 1995/6 (NCEPOD, 1995–6) took data from hospitals over randomly allocated 24h periods, and WOW2 in 2002 (Martin, 2013) collected data over a whole week. Ninety-seven percent of NHS hospitals participated, but only surgical cases were included (cases in radiology suites, and all others outside operating rooms were excluded). No scaling factor was applied to calculate an annual workload, and details of anaesthesia management were not obtained.

27.6 In 1988, more than 500 volunteer anaesthetists recorded data from approximately 25 consecutive anaesthetics for a Survey of Anaesthetic Practice (SOAP), organised by the Association of Anaesthetists (AAGBI, 1998). Its output does not enable estimation of total workload, and no record of the surgical procedure was made, but it does contain data that estimates the proportion of patients who received specified anaesthetic techniques.

27.7 In the absence of relevant and recent data, a survey was designed to help interpret NAP5 AAGA reports. The survey aimed to not only determine the number of general and other anaesthetics conducted in the UK, but also to provide detailed information about patient characteristics, the procedures they underwent, their management (including timing and seniority of the anaesthetist), the drugs and techniques used, and specifically for AAGA, the use of monitors of depth of anaesthesia (DOA).

METHODS

27.8 All hospitals, Trusts and Boards in the UK that took part in the NAP5 project were identified and represented by 267 Local Co-ordinators (LCs). Participating LCs coordinated a survey within their own hospital or hospital group on every patient who underwent a procedure under the care of an anaesthetist. Only NHS patients managed in NHS hospitals were included.

27.9 Anaesthesia activity was defined as any surgical, diagnostic or interventional procedure where an anaesthetist (of any grade) was responsible for patient care. The type of care could be general anaesthesia (GA), sedation, local anaesthesia (LA), or with the patient awake and the anaesthetist providing monitoring only ('managed anaesthesia care'). It included general anaesthesia or central neuraxial blockade for Caesarean section or assisted delivery and epidurals performed for labour pain relief, but it did not include sedation delivered by non-anaesthetists or specialist interventional pain procedures where the anaesthetist undertook both sedation and the procedure.

27.10 It included patients on the intensive care unit (ICU) in whom unconsciousness was induced or maintained for any surgical procedure, whether in theatre (e.g. transferred for laparotomy) or at the bedside (e.g. tracheostomy) or for a diagnostic or interventional procedure (e.g. CT scan) but it did not include ICU management with sedation. It also included emergency department (ED) cases such as cases of trauma where an anaesthetist secured the airway and transferred the patient to a site of a procedure (e.g. CT scan or operating theatre).

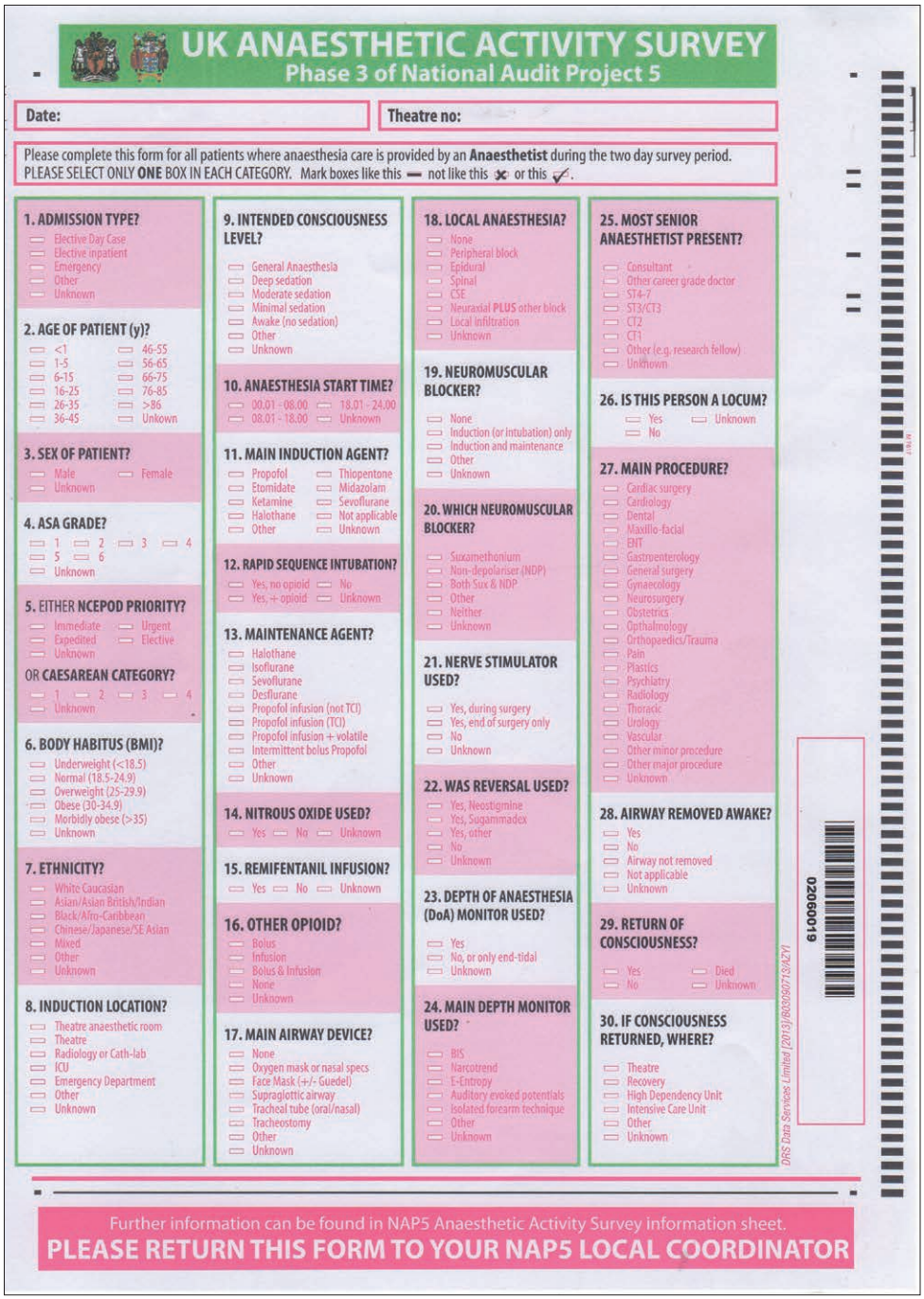
27.11 The data was captured on a paper questionnaire designed to be read automatically by 'optical character recognition' (OCR) technology (DRS Data & Research Services plc. Milton Keynes, Buckinghamshire, UK). The questionnaire was made up of 30 questions on one side of A4 paper (Figure 27.1). Each question could be answered by choosing only one option from a list which included the options 'unknown' and 'other'. All LCs were asked to provide a 'return rate' i.e. their estimate of the proportion of all cases which had been reported in their hospital(s).

27.12 The survey period chosen was Monday 9 September 2013 to Monday 16 September 2013.

No bank holidays or school holidays fell between these dates. Data collection over a whole week was considered both too burdensome and too costly, and therefore the activity during the week was sampled by randomising each LC to two consecutive days within the chosen week. Specialist hospitals (Paediatric, Cardiothoracic and Neurosurgery) were randomised separately to avoid unequal allocation of collection days.

27.13 A scaling factor was used to convert the number of forms returned from two days into the estimated number of cases for a whole year (annual workload). The scaling factor had three components: conversion of two days to a week (3.5), the number of working weeks in 2013 (50.59, see Appendix) and the median return rate from LCs (0.98). The scaling factor was 180.68 (= (3.5 x 50.59)/0.98). Annual caseload estimations were rounded to the nearest 100. All calculations were made using Microsoft Excel 2010 and the 'PivotTable' facility. In interpreting results, it is therefore notable that an estimated annual caseload of 200 or 400 represents 1 or 2 returns respectively, and that, inevitably, such small numbers are less reliable than larger numbers.

Figure 27.1. Survey questions



UK ANAESTHETIC ACTIVITY SURVEY
Phase 3 of National Audit Project 5

Date:

Theatre no:

Please complete this form for all patients where anaesthesia care is provided by an **Anaesthetist** during the two day survey period.
PLEASE SELECT ONLY **ONE** BOX IN EACH CATEGORY. Mark boxes like this — not like this ✗ or this ✓.

1. ADMISSION TYPE?
Elective Day Case
Elective inpatient
Emergency
Other
Unknown

2. AGE OF PATIENT (y)?
<1 | 1-5 | 6-15 | 16-25 | 26-35 | 36-45 | 46-55 | 56-65 | 66-75 | 76-85 | >86 | Unkown

3. SEX OF PATIENT?
Male | Female | Unknown

4. ASA GRADE?
1 | 2 | 3 | 4 | 5 | 6 | Unknown

5. EITHER NCEPOD PRIORITY?
Immediate | Urgent | Expedited | Elective | Unknown
OR **CAESAREAN CATEGORY?**
1 | 2 | 3 | 4 | Unknown

6. BODY HABITUS (BMI)?
Underweight (<18.5)
Normal (18.5-24.9)
Overweight (25-29.9)
Obese (30-34.9)
Morbidly obese (>35)
Unknown

7. ETHNICITY?
White Caucasian
Asian/Asian British/Indian
Black/Afro-Caribbean
Chinese/Japanese/SE Asian
Mixed
Other
Unknown

8. INDUCTION LOCATION?
Theatre anaesthetic room
Theatre
Radiology or Cath-lab
ICU
Emergency Department
Other
Unknown

9. INTENDED CONSCIOUSNESS LEVEL?
General Anaesthesia
Deep sedation
Moderate sedation
Minimal sedation
Awake (no sedation)
Other
Unknown

10. ANAESTHESIA START TIME?
00.01 - 08.00 | 08.01 - 18.00 | 18.01 - 24.00 | Unknown

11. MAIN INDUCTION AGENT?
Propofol | Etomidate | Ketamine | Halothane | Other | Thiopentone | Midazolam | Sevoflurane | Not applicable | Unknown

12. RAPID SEQUENCE INTUBATION?
Yes, no opioid | Yes, + opioid | No | Unknown

13. MAINTENANCE AGENT?
Halothane
Isoflurane
Sevoflurane
Desflurane
Propofol infusion (not TCI)
Propofol infusion (TCI)
Propofol infusion + volatile
Intermittent bolus Propofol
Other
Unknown

14. NITROUS OXIDE USED?
Yes | No | Unknown

15. REMIFENTANIL INFUSION?
Yes | No | Unknown

16. OTHER OPIOID?
Bolus
Infusion
Bolus & Infusion
None
Unknown

17. MAIN AIRWAY DEVICE?
None
Oxygen mask or nasal specs
Face Mask (+/- Guedel)
Supraglottic airway
Tracheal tube (oral/nasal)
Tracheostomy
Other
Unknown

18. LOCAL ANAESTHESIA?
None
Peripheral block
Epidural
Spinal
CSE
Neuraxial **PLUS** other block
Local infiltration
Unknown

19. NEUROMUSCULAR BLOCKER?
None
Induction (or intubation) only
Induction and maintenance
Other
Unknown

20. WHICH NEUROMUSCULAR BLOCKER?
Suxamethonium
Non-depolariser (NDP)
Both Sux & NDP
Other
Neither
Unknown

21. NERVE STIMULATOR USED?
Yes, during surgery
Yes, end of surgery only
No
Unknown

22. WAS REVERSAL USED?
Yes, Neostigmine
Yes, Sugammadex
Yes, other
No
Unknown

23. DEPTH OF ANAESTHESIA (DoA) MONITOR USED?
Yes
No, or only end-tidal
Unknown

24. MAIN DEPTH MONITOR USED?
BIS
Narcotrend
E-Entropy
Auditory evoked potentials
Isolated forearm technique
Other
Unknown

25. MOST SENIOR ANAESTHETIST PRESENT?
Consultant
Other career grade doctor
ST4-7
ST3/CT3
CT2
CT1
Other (e.g. research fellow)
Unknown

26. IS THIS PERSON A LOCUM?
Yes | No | Unknown

27. MAIN PROCEDURE?
Cardiac surgery
Cardiology
Dental
Maxillo-facial
ENT
Gastroenterology
General surgery
Gynaecology
Neurosurgery
Obstetrics
Opthalmology
Orthopaedics/Trauma
Pain
Plastics
Psychiatry
Radiology
Thoracic
Urology
Vascular
Other minor procedure
Other major procedure
Unknown

28. AIRWAY REMOVED AWAKE?
Yes
No
Airway not removed
Not applicable
Unknown

29. RETURN OF CONSCIOUSNESS?
Yes | No | Died | Unknown

30. IF CONSCIOUSNESS RETURNED, WHERE?
Theatre
Recovery
High Dependency Unit
Intensive Care Unit
Other
Unknown

02060019

DRG Data Services Limited (2013)(80090718/427)

Further information can be found in NAP5 Anaesthetic Activity Survey information sheet.
PLEASE RETURN THIS FORM TO YOUR NAP5 LOCAL COORDINATOR

27.14 Some responses were missing, and because question choices included 'other' or 'unknown', we combined all these uninterpretable answers (the sum of the missing, 'other' and 'unknown') and expressed them as a percentage. These uninterpretable answers were discarded when calculating proportional results, so all percentages quoted in results relate only to interpretable forms. For questions relating to general anaesthesia (e.g. technique and monitoring), estimations of numbers and percentages were made only on forms indicating that general anaesthesia was the prime mode of anaesthesia (i.e. answering 'GA' to Q9).

NAP5 ACTIVITY SURVEY RESULTS AND NUMERICAL ANALYSIS

Returns by LCs

27.15 All 267 LCs took part in the survey (100% response rate) and a total of 20,400 forms were returned. The median number of returned forms per LC was 60: 75% of LCs returned fewer than 100 forms (Figure 27.2). Three LCs reported that their hospital had no cases in the reporting period. The median return rate was 98% (IQR 0.95 to 1, Figure 27.3): 20 LCs did not estimate their return rates. The proportion of unanswered questions was <4% and only two questions had >20% of 'unknown' answers (Q20 (Which neuromuscular blocker was used?) and Q24 (Main depth monitor used?) (Table 27.1). The estimated annual caseload was 3,685,800. The caseload was broadly similar for the weekdays except Monday and Tuesday, which had slightly lower rates of activity, and there was an appreciable nadir of activity over the weekend (Figure 27.4).

Figure 27.2. Distribution of Local Co-ordinators (LCs) by number of returned forms

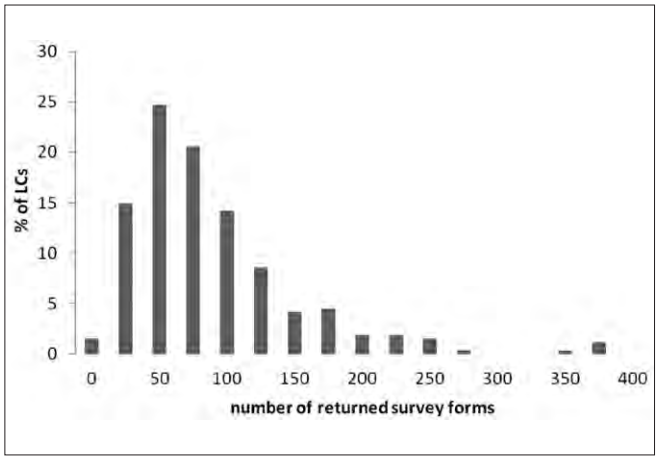


Figure 27.3. Distribution of Local Co-ordinators (LCs) by estimated percentage return rates. Completion rate = number of returned forms/estimated workload during the survey period

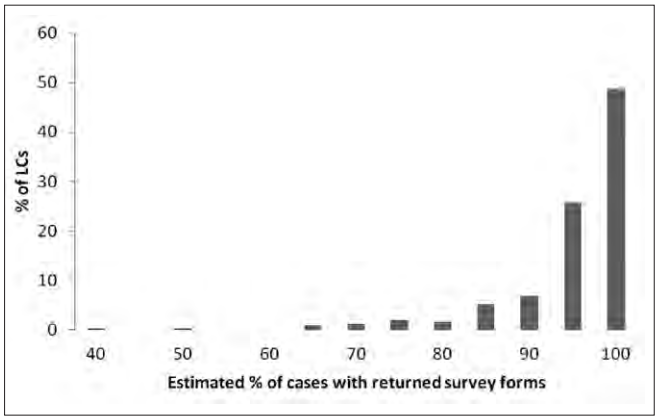
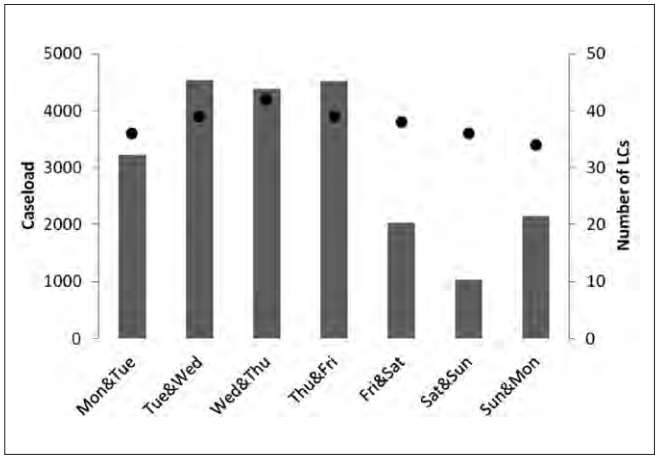


Table 27.1. Uninterpretable answers

	% of forms with answers:		
Questions	Unknown	Other	Blank
1. Admission type	0.75	3.02	0.71
2. Age of Patient	0.79		0.38
3. Sex Of Patient	1.29		0.14
4. ASA Category	1.81		0.27
5. NCEPOD Priority of Surgery	5.18		3.12
6. Body habitus	4.91		0.43
7. Ethnicity	1.39	0.93	0.13
8. Induction location	2.26	4.60	0.38
9. Intended conscious level	0.94	0.26	0.19
10. Anaesthesia start time	1.56		0.38
11. Main induction agent	4.53	14.26	1.59
12. Rapid sequence intubation	7.12		0.25
13. Maintenance agent	15.27	5.25	0.82
14. Nitrous oxide used?	7.80		1.31
15. Remifentanil infusion?	9.25		0.93
16. Opioid	7.24		0.61
17. Main airway device	3.04	0.61	0.77
18. Local anaesthesia	2.41		1.85
19. Neuromuscular blocker	4.10	0.61	0.69
20. Which neuromuscular blocker?	30.47	0.27	1.29
21. Nerve stimulator used	11.83		0.29
22. Was reversal used?	14.38		0.33
23. Depth of anaesthesia monitor?	7.74		0.49
24. Main depth monitor used?	86.22	11.48	0.13
25. Most senior anaesthetist present?	0.78		0.37
26. Is this person a locum?	2.33		0.23
27. Main procedure	0.99		0.35
28. Airway removed awake?	4.61		1.50
29. Return of consciousness?	12.64		0.30
30. If conscious returned, where?	13.27	2.52	0.85

Figure 27.4. Distribution of caseload and number of Local Co-ordinators (LCs) by two-day randomisation. Caseload and number of LCs according to allocation of two-day period of survey. Columns = caseload. ● = number of LCs



Patient characteristics

27.16 Figure 27.5 shows the distribution of caseload by specialty: the three specialties with the largest workload were orthopaedics and trauma (22.1%), general surgery (16.1%) and gynaecology (9.6%). Non-surgical specialties (Cardiology, Gastroenterology, Pain, Psychiatry and Radiology) accounted for 6.2% of all activity. Obstetric cases accounted for 8.9% of all activity (326,500 per year) of which only 10% involved GA. Most ophthalmology cases (72.7%), managed by anaesthetists, were performed without GA.

27.17 The patients age-group with the highest caseload was 26-35 years (Figure 27.6). In all subsequent figures and tables the age-groups have been combined into 4 broader age-groups: children (<16 years), adults (16 – 65 years), elderly (>65 years) and all patients. In respect of major sex differences, more young women than young men (75:25%, 16-25y), and more boys than girls (60:40%, 1-5y) had anaesthesia care (Figure 27.6). Of all procedures in women, 15.5% were obstetric and 14.7% were gynaecological. Obstetric cases accounted for 60.4% of anaesthesia care in women aged 26-35 years. Urological procedures accounted for 14% of anaesthetic activity in males and 3% in females.

Figure 27.6. Annual caseload according to age group: with sex ratio. Estimated annual caseload, according to age group (top chart) with percentage male (M ~ blue) or female (F ~ pink) (bottom chart)

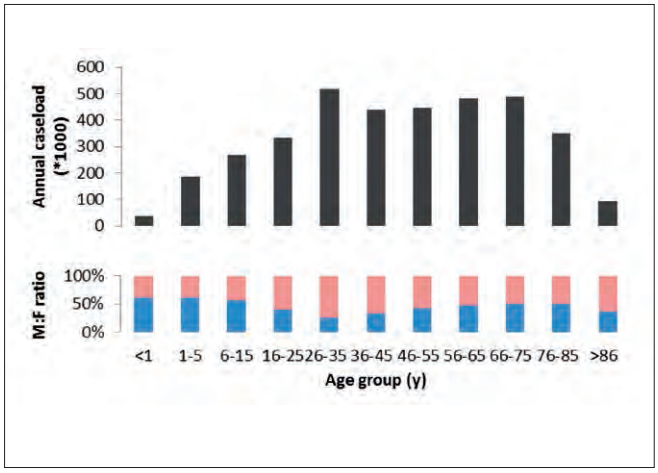
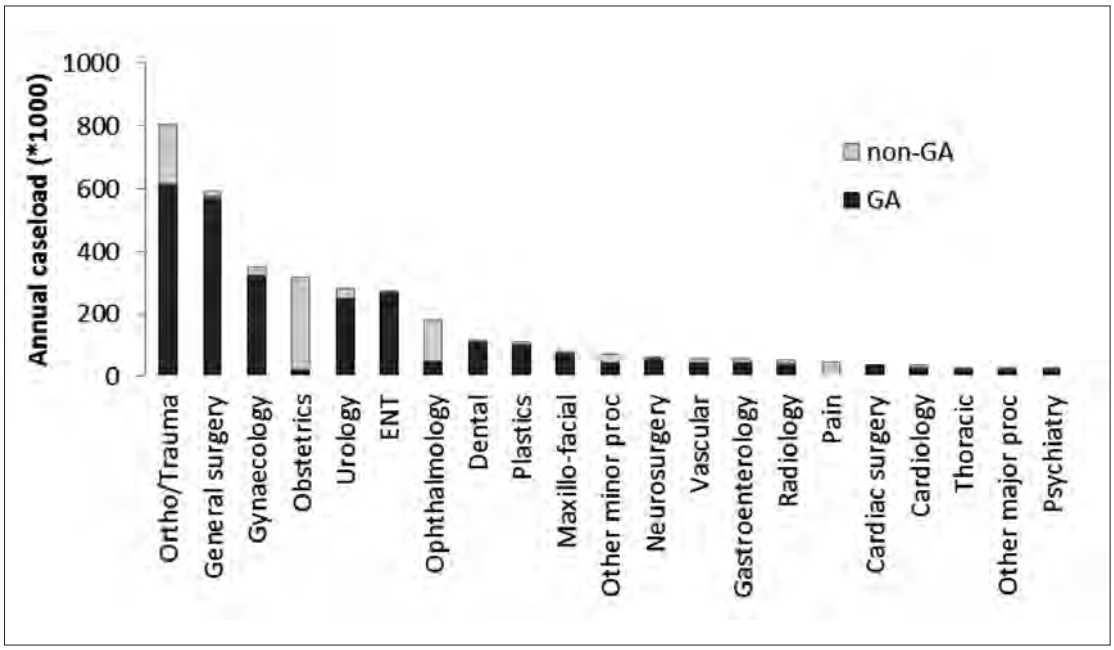


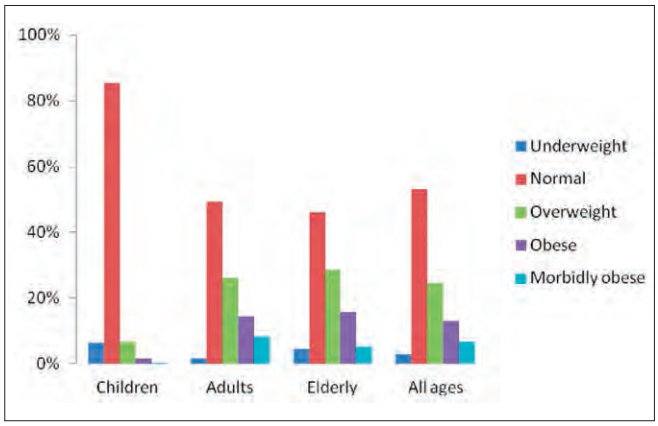
Figure 27.5. Estimated annual caseload according to specialty, and separated into general anaesthesia (GA) and non-GA activity



27.18 Table 27.2 shows the spread of the urgency categories across ASA grades separately for both NCEPOD (NCEPOD, 2004) and Caesarean section (RCOG, 2010; Lucas et al., 2000) categories.

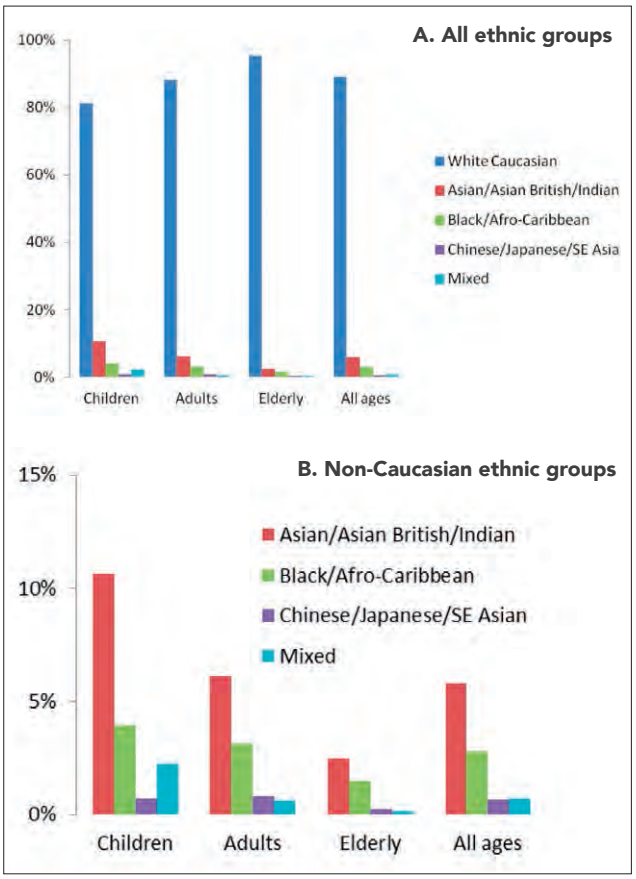
27.19 In all patients over 16 years, the percentage of underweight, normal, overweight, obese and morbidly obese patients were 2.5, 48.4, 26.9 , 14.8 and 7.4 respectively (Figure 27.7).

Figure 27.7. Body habitus and age. Percentage of patients, within age group, with body habitus



27.20 Figure 27.8 shows the distribution of ethnicity according to age group.

Figure 27.8. Ethnicity and age. Percentage of patients, within age group, according to ethnicity. Panel A: with all ethnic groups; panel B, with white Caucasian excluded, for clarity



NCEPOD category						
ASA	Immediate	Urgent	Expedited	Elective	Total	%
1	33,600	281,900	68,500	845,900	1,229,900	38.00
2	17,000	199,600	66,300	1,019,000	1,302,000	40.23
3	9,400	156,600	51,900	386,500	604,400	18.67
4	18,400	40,500	11,900	19,200	90,000	2.78
5	7,000	1,800	400	400	9,600	0.30
6	400	–	–	200	500	0.02
Total	85,800	680,400	198,900	2,271,100	3,236,300	
%	2.65	21.03	6.15	70.18		
Caesarean Section category						
ASA	1	2	3	4	Total	%
1	6,100	25,500	8,300	20,800	60,700	66.27
2	4,000	11,400	2,200	11,000	28,500	31.16
3	500	900	500	–	2,000	2.17
4	–	–	200	200	400	0.39
5	–	–	–	–	–	0.00
6	–	–	–	–	–	0.00
Total	10,700	37,800	11,200	32,000	91,600	
%	11.64	41.22	12.23	34.91		

Table 27.2 ASA and Urgency. Estimated annual caseload according to American Society of Anaesthesiologists (ASA) status versus National Confidential Enquiry into Patient Outcome and Death (NCEPOD, 2004) and Caesarean Section (RCOG, 2010) categories. Totals take into account unknowns

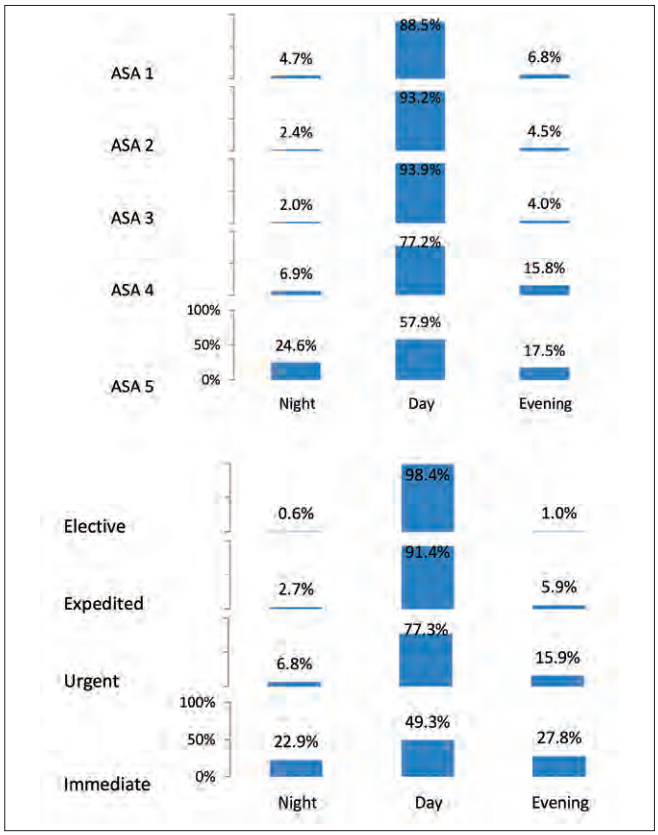
Admission type, urgency and timing of anaesthesia care

27.21 Across all specialties (Table 27.3), 73.9% of admissions were elective (47.4% day case and 26.6% inpatient), and 23.1% (n = 838,300) were emergency. Ninety one percent of all NCEPOD classified cases started between 08:00h and 18:00h but 25% of ASA 4 and 5 cases and 50% of immediate and 25% of urgent cases started between 18:00h and 08:00h (Figure 27.9). Of all activity started between midnight and 08:00h 59.2% were obstetric (n = 72,600), and of these cases 88% were awake, having had neuraxial blockade (23% of these were Caesarean sections).

Table 27.3. Admission type. Estimated annual caseload according to admission type

Admission type	Annual caseload	%
Elective Day Case	1,716,800	47.3
Elective inpatient	965,200	26.6
Emergency	838,300	23.1
Other	111,500	3.0

Figure 27.9. Time of start of anaesthesia care versus ASA grade and Urgency of procedure. Proportion of cases, within ASA grade (top panel A) or Urgency (bottom panel B), versus time of starting anaesthesia care. Each vertical axis represents percentage of cases within either ASA or NCEPOD class (tick marks 0, 50 and 100%). Night = 00:01-08:00. Day = 08:01-18:00. Evening = 18:01-24:00



27.22 The estimated annual caseload was highest during the middle of the week and lowest at weekends (Figure 27.10). The majority of weekend caseload was ASA 1, 2 and 3 patients but activity in ASA 4 and 5 patients varied little across the week. ASA 4 and 5 patients were combined because there were few ASA 5 returns: 530 and 61 respectively. Few elective cases were performed on weekend days (1.7% of elective caseload). The number of immediate cases was similar across the week (Figure 27.11).

Figure 27.10 ASA grade and day of the week. Estimated annual caseload across the week according to the ASA grade

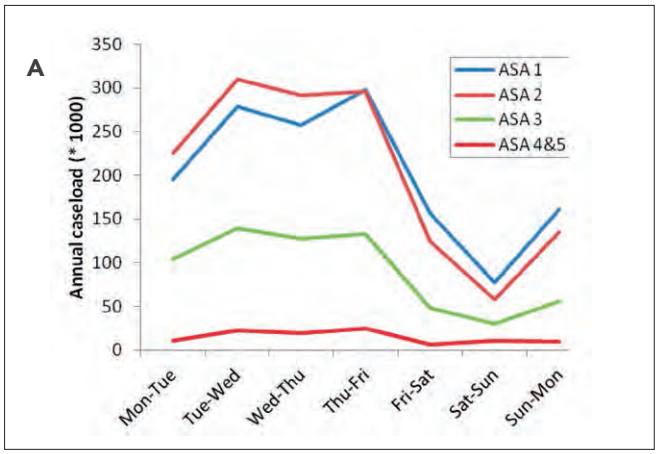
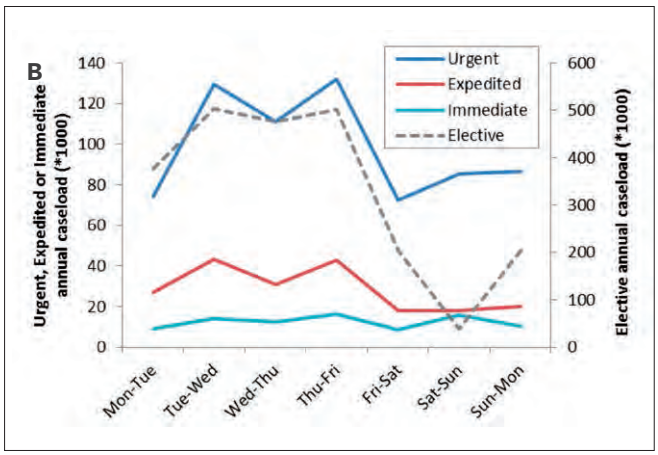


Figure 27.11. Urgency and day of the week (excluding Caesarean sections). Estimated annual caseload across the week according to NCEPOD category (NCEPOD, 2004). N.B the elective caseload (dashed line) is plotted against the right hand vertical axis



Staffing

27.23 Overall, a consultant or career grade doctor was the most senior anaesthetist in 86.2% of cases (71.7% and 15.5% respectively, see Table 27.4), and whatever the ASA grade of the patient, either a consultant or a career grade anaesthetist was present in over 75% of cases (Figure 27.12). A trainee was the most senior anaesthetist for a minority of ASA 4 and 5 patients (18.1%, and 23% respectively). A trainee was the most senior anaesthetist present for a minority (28%) of immediate or urgent cases (Figure 27.13). However, in obstetrics, trainee-led activity was notably higher (41.7% of non-elective Caesarean sections, see Figure 27.14). For all ASA 4 or 5 patients (obstetric and non-obstetric combined) a consultant was present for 80.6% of cases between 08:00h to 18:00h and 51.4% of cases outside these hours (Figure 27.12), and over 70% of cases during the week compared with 46.6% of weekend cases (Figure 27.15).

Table 27.4. Distribution of caseload according to most senior anaesthetist present. Estimated annual caseload according to the most senior anaesthetist present. Overall proportion of locum = 7.2%

Grade	Caseload	% of total	% locum
Consultant	2,562,900	71.65%	7.6%
Other career grade doctor	555,900	15.54%	
ST4-7	303,700	8.49%	3.9%
ST3/CT3	77,300	2.16%	
CT2	43,000	1.20%	
CT1	2,900	0.08%	
Other (e.g. research fellow)	31,400	0.88%	

Figure 27.12. ASA grade and most senior anaesthetist present. Top chart shows estimated annual caseload according to ASA grade. Bottom chart shows % of patients, within each ASA grade, according to most senior anaesthetist present

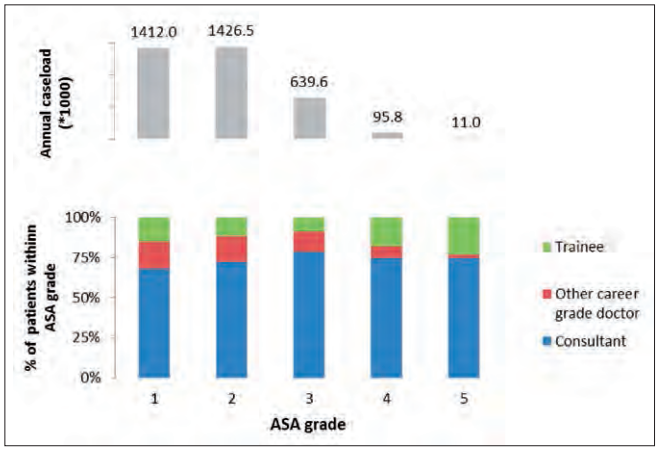


Figure 27.13. NCEPOD urgency and most senior anaesthetist present. Top chart shows estimated annual caseload according to NCEPOD urgency category. Bottom chart shows % of patients, within each category, according to most senior anaesthetist present

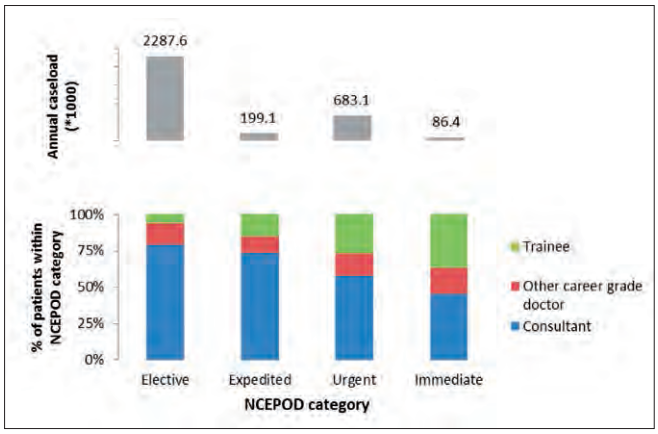


Figure 27.14. Caesarean section category and most senior anaesthetist present. Top chart shows estimated annual caseload according to Caesarean section category (RCOG, 2010). Bottom chart shows % of patients, within each category, according to most senior anaesthetist present

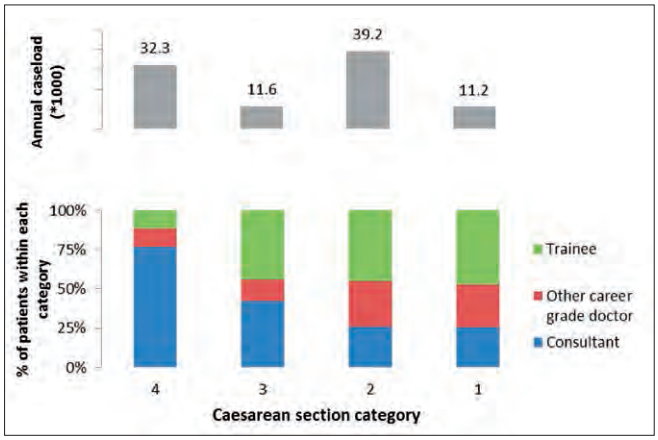
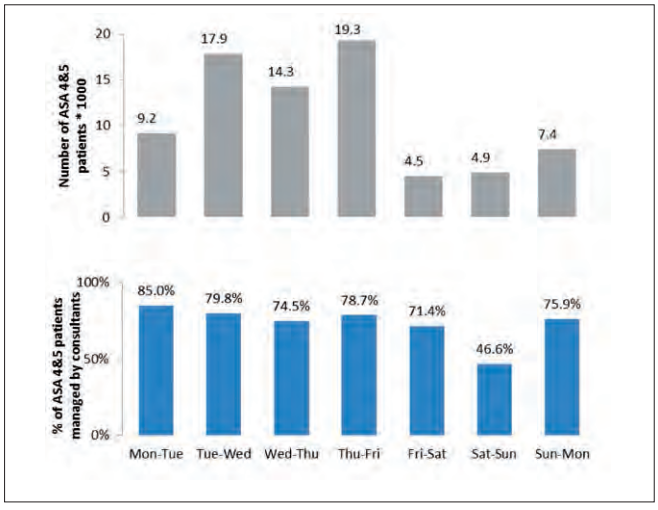


Figure 27.15. Sick patients: day of week and most senior anaesthetist present (non-obstetric and obstetric data combined).

Top chart shows number of ASA 4&5 patients versus days of week. Bottom chart shows proportion of patients, within each day category, managed by a consultant anaesthetist



Anaesthetic conduct

Conscious level

27.24 The estimated annual numbers (with percentage of all cases) of GA, sedation (of any level) and awake cases were 2,766,600 (76.9%), 308,800 (8.6%) and 523,100 (14.5%) respectively. The percentage of patients, by age range, managed according to the intended level of consciousness, is shown in Figure 27.16. As patient age increased there was a trend for sedation to be used more frequently. Of all sedation cases, 50% were orthopaedic and trauma cases (Figure 27.17). A high number (970 of 1,028; 94%) of awake women aged 26–35 years were having obstetric procedures.

Figure 27.16 Percentage of patients, within age range groups, according to intended level of consciousness

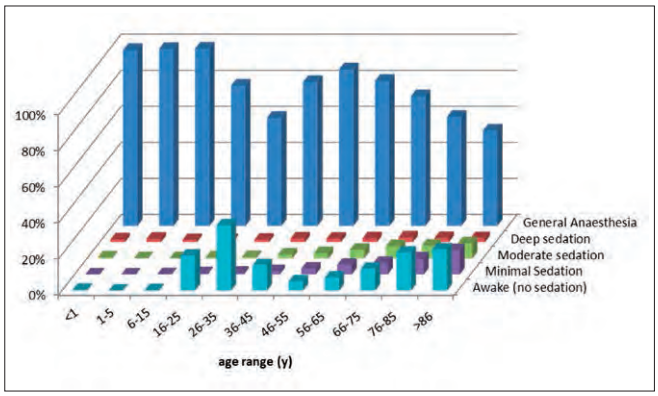
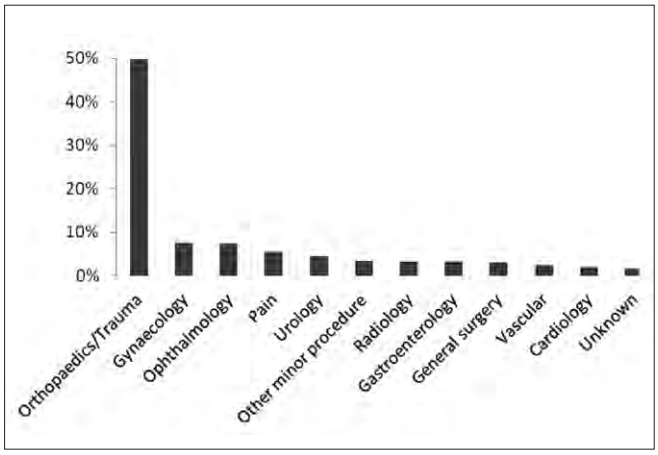


Figure 27.17. Sedation workload. Percentage of sedation cases by specialty; e.g. almost 50% of all sedation cases were in orthopaedics and trauma. Specialties contributing less than 2% of the total not included. All levels of sedation (deep, moderate or minimal) are combined



Local anaesthesia (central neuraxial block)

27.25 The number and percentage of cases in which a central neuraxial block was used are shown in Table 27.5. Central neuraxial block was involved in 28.7% of non-obstetric cases compared with 93% of obstetric activity. In non-obstetric cases, GA was administered in 87% of patients having an epidural and 20% of those having a spinal technique. In contrast, GA was used in only 8% of obstetric cases having a central neuraxial block. Almost 90% (89.2%) of all Caesarean sections were performed with epidural or spinal anaesthesia without GA.

A: Non-obstetric cases

	Epidural	Spinal	Combined spinal and epidural	CNB + other block	Any CNB technique	None
General Anaesthesia	56,700 (87%)	43,200 (20%)	500 (10%)	7,600 (38%)	108,000 (35%)	2,564,200 (89.1%)
Deep sedation	200 (0%)	12,800 (6%)	500 (10%)	1,100 (5%)	14,600 (4.7%)	48,800 (1.7%)
Moderate sedation	500 (1%)	54,400 (25%)	2,000 (38%)	6,500 (32%)	63,400 (20.6%)	43,400 (1.5%)
Minimal Sedation	900 (1%)	59,100 (27%)	1,400 (28%)	3,400 (17%)	64,900 (21%)	56,400 (2%)
Awake (no sedation)	7,000 (11%)	48,200 (22%)	700 (14%)	1,600 (8%)	57,600 (18.7%)	165,700 (5.7%)
Total	65,400	217,700	5,200	20,200	308,500	2,878,400

B: Obstetric cases

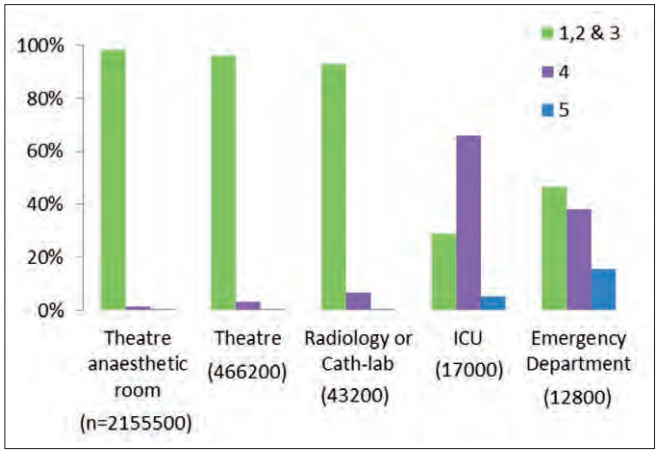
General Anaesthesia	3,100 (8%)	1,600 (1.5%)	400 (2.3%)	0	5,100 (3%)	16,300 (75.6%)
Sedation (deep, moderate or minimal)	700 (2%)	1,100 (0.3%)	0	0	1,800 (0.6%)	400 (1.7%)
Awake (no sedation)	121,600 (90%)	137,000 (98.2%)	17,900 (97.7%)	400 (100%)	276,800 (96.4%)	4,900 (22.7%)
Total	125,400	139,700	18,200	400	283,700	21,500

Table 27.5. Central neuraxial block techniques and intended level of consciousness. Estimated annual caseload in which a central neuraxial block (CNB) was used, presented according to intended level of consciousness in non-obstetric (A) and obstetric cases (B). Obstetric cases include Caesarean and non-Caesarean section activity. Epidural category includes caudal, lumbar, thoracic or cervical techniques. 'None' includes cases in which only local infiltration or peripheral nerve block was used. Caseloads are to the nearest 100: n.b. 200 represents only one report. Percentages are of the total number of cases having each technique

Location

27.26 The theatre anaesthetic room was the most common site of induction of GA (78.7% of all GA cases). Anaesthesia was induced in theatre in 17%, in radiology or catheter laboratory in 1.6%, in the ICU in 0.6%, and in the ED in 0.5% of all GA cases (Figure 27.18). For Caesarean sections, anaesthesia was induced in theatre in 87% cases. More than 50% of GA cases induced in the ICU or ED settings were ASA 4 or 5.

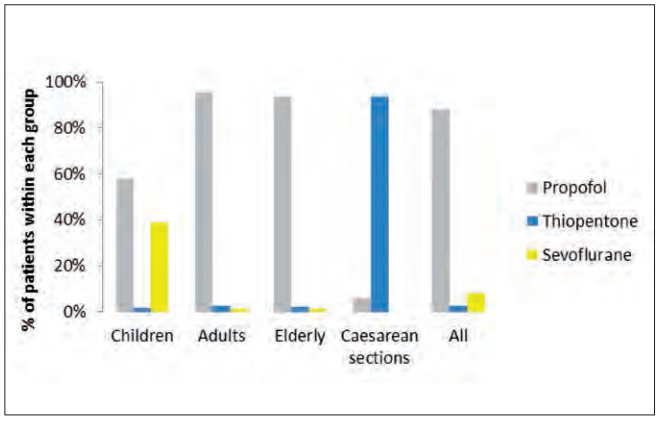
Figure 27.18. Induction location and ASA grade. Percentage of patients undergoing GA, by induction location, according to ASA grade. Number under location is the estimated annual GA caseload (all ASA grades) for the location



Induction agent

27.27 The main induction agents for GA cases were propofol (88%), sevoflurane (7.9%) and thiopental (2.9%). Etomidate (0.2%), midazolam (0.2%) and ketamine (0.25%) were used much less frequently. Halothane was not used. Almost 40% of children received sevoflurane induction and 97% of Caesarean section GA cases received thiopental (Figure 27.19).

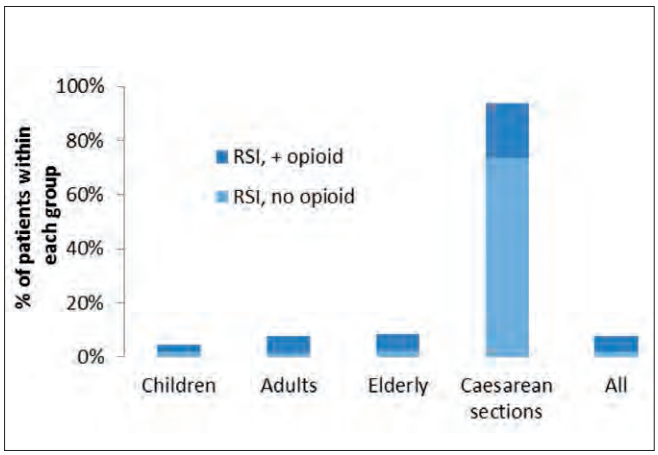
Figure 27.19. Induction agent. Percentage of patients undergoing anaesthesia receiving common induction agents



Rapid sequence induction

27.28 Rapid-sequence induction (RSI) was used in 7.4% of non-Caesarean section GA cases and, of these, propofol was used in 69.1%, thiopental in 27.9%, suxamethonium in 66.2% and an opioid in 75.8% (Figure 27.20). Almost all (92.2%) Caesarean section GA cases included RSI, and of these, thiopental and suxamethonium were used in 100% and an opioid in 23.4%. RSI accounted for 87.3% of all cases induced with thiopental.

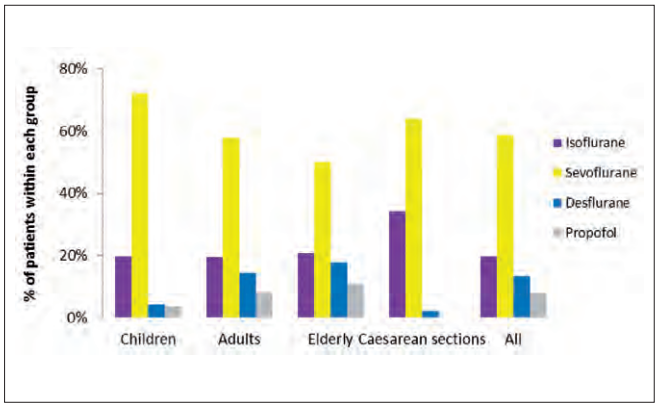
Figure 27.20. Rapid sequence induction. Percentage of patients undergoing anaesthesia receiving rapid-sequence induction



Maintenance agent

27.29 A vapour was used in the maintenance phase of GA in 92% of all cases, and, irrespective of age (Figure 27.21), sevoflurane was the most common agent (58.5%). Propofol Total Intravenous Anaesthesia (TIVA: including all infusion or intermittent bolus techniques) was used in 8% of all cases. 63% of all TIVA with propofol was by Target Controlled Infusion (TCI). Use of TCI varied according to location: 80% in theatre cases and 17% in cases induced in radiology, Cath-lab, ICU or ED.

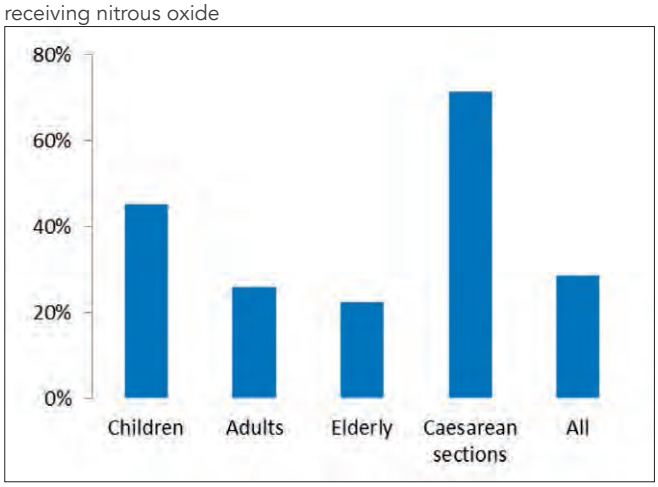
Figure 27.21. Maintenance agent. Proportion of patients undergoing anaesthesia receiving each maintenance agent. The propofol column represents any infusion or intermittent bolus technique



Nitrous oxide

27.30 Nitrous oxide was used (during GA) in approximately 25% of adult and elderly patients, 45% of children and 71.4% of Caesarean sections (Figure 27.22): overall use was 28.7%. Nitrous oxide was used in 4% of propofol TIVA cases.

Figure 27.22. Percentage of patients undergoing anaesthesia receiving nitrous oxide



Opioids

27.31 Remifentanil was used in 10.7% of all cases, 3.4% of children, 11.6% of adults and 13.9% of elderly patients having GA: it was not used in any Caesarean sections. Opioids, other than remifentanil, were used in 86.7% of patients. 10.8% of GA cases received no opioids.

Main airway device

27.32 Airway management is summarised in Table 27.6. A tracheal tube was used in 44.6% (1,147,300 cases) and a supraglottic airway in 51.3% (n = 1,319,100) of all GA cases. Over 80% of these two devices were removed when the patient was awake.

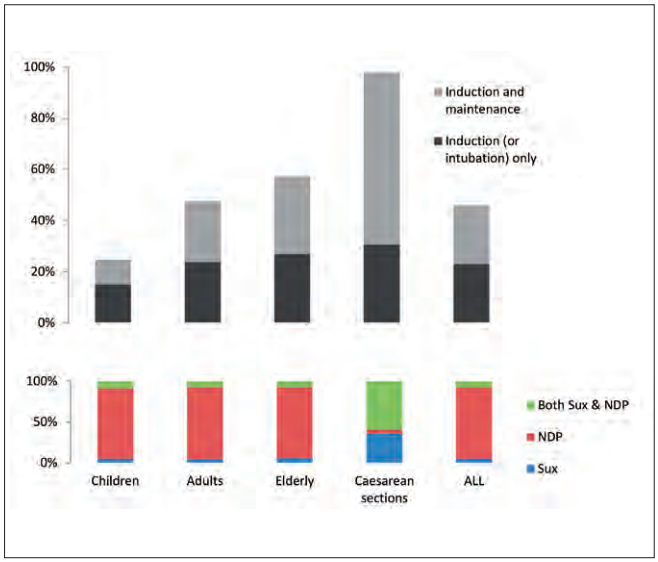
Table 27.6. Main airway device. Main airway device used during general anaesthesia

Airway device	Caseload	(%)	Removed awake
None	8,300	0.3%	
Oxygen mask or nasal specs	11,400	0.4%	
Face Mask (+/- Guedel airway)	77,300	3.0%	
Supraglottic airway	1,319,100	51.3%	84.5%
Tracheal tube	1,147,300	44.6%	83.2%
Tracheostomy	10,700	0.4%	

Neuromuscular blockade, monitoring and reversal

27.33 Neuromuscular blockade (NMB) was used in 46% of all patients receiving GA. Within age groups, NMB was used in 24.7% of children, 47.6% of adults and 57.3% of elderly patients (Figure 27.23). Suxamethonium was used in almost all (92%) Caesarean section anaesthetics but only 13% of other cases in which NMB was used. In cases involving a non-depolarising NMB a nerve stimulator was used in 38% and reversal was used 68% (Sugammadex in 1.5%).

Figure 27.23. Use of neuromuscular blocker. Percentage of patients, within each age group (and Caesarean section group) receiving neuromuscular blockade



Depth of Anaesthesia monitoring

27.34 DOA monitoring of any type was used in 2.8% of GA cases: processed EEG monitoring (including BIS, Narcotrend or E-Entropy) was used in 2.75% and Auditory Evoked Potentials was used in 0.03% (Table 27.7). The isolated forearm technique was reported in only five patients (0.03%). The use of DOA monitoring varied with the anaesthetic technique: DOA was used most often (23.4%) with TIVA anaesthetics in which NMB was used, and least often (1.1%) with volatile based anaesthetics without NMB (Table 27.8). DOA use was greatest in the elderly (5.5%) compared to adults (2.4%) and children (0.5%).

Table 27.7 Use of depth of anaesthesia monitors during general anaesthesia. Percentage of anaesthetised patients, according to age group, having depth of anaesthesia monitoring. * Processed EEG includes BIS, Narcotrend or E-Entropy

	BIS	Narcotrend	E-Entropy	Processed EEG *	Auditory evoked potentials	Isolated forearm technique
Children	0.42%	0.04%	0.04%	0.49%	0.00%	0.00%
Adults	2.01%	0.11%	0.29%	2.41%	0.00%	0.04%
Elderly	4.65%	0.18%	0.66%	5.48%	0.12%	0.03%
All ages	2.31%	0.11%	0.33%	2.75%	0.03%	0.03%

Table 27.8 Use of depth of anaesthesia monitoring (DOA) according to maintenance agent and neuromuscular blockade (NMB). Use of any dedicated DOA monitor in patients undergoing GA, according to maintenance anaesthetic technique and use of NMB. TIVA = propofol infusion (TCI and non-TCI combined) or intermittent propofol technique

	No NMB	% using DOA	NMB	% using DOA
Volatile agent	1,357,600	1.1%	1,095,100	3.5%
TIVA	95,200	7.8%	109,100	23.4%

Return of consciousness

27.35 Overall only 1% of patients recovered in a high dependency unit or ICU setting. Twenty patients were reported to have died: nine deaths occurred during GA, two during deep sedation and two during moderate sedation (in seven patients the intended conscious level was unspecified). The cause of death was not captured in the survey, but of the nine GA patients all were ASA 3, 4 or 5 (three in each category) and aged over 55 years (three were aged 56-65 years, three 66-75 years, two 76-85 years, and one >86y); the main procedure was general surgery in three, vascular in two, an unspecified major procedure in three and unknown in one; three were elective and six emergencies. None were caesarean sections. Three had GA induced in the anaesthetic room, one in theatre, one in an ICU, three in an ED and one in an unspecified location: The overall GA death rate was 0.06% (1:1718). If all patients in whom the intended level of consciousness was unspecified received GA, the incidence would be 0.12%.

Table 27.9 Return of consciousness. A: % of patients undergoing GA according to the site of their return of consciousness. B: % of patients undergoing GA who did not regain consciousness (at the time of the completion of the survey form), according to age group. The number of deaths is of deaths reported during the anaesthetic procedure

A: Site of return of consciousness	
Theatre	35.2%
Recovery	63.6%
High Dependency Unit	0.3%
Intensive Care Unit	0.9%

B: Patient group	% who did not regain consciousness	% who died	Number of deaths
Children	1.9%	0.00%	0
Adults	1.6%	0.04%	3
Elderly	4.0 %	0.2%	6
All	2.2%	0.06%	9

DISCUSSION

27.36 This is not the first survey of its kind, but we believe it is the most comprehensive national picture of anaesthesia practice to date. Clergue and colleagues conducted a national survey of anaesthesia activity in France in 1996 (Clergue et al., 1999). This had less detail than ours and was not intended to relate to AAGA or intended conscious level. Data was collected over three consecutive days from 98% of hospitals (public and private) and 62,415 cases were analysed. Their estimated annual national anaesthesia workload was 7,937,000 of which 77% were GA or sedation cases. As part of

NAP5, a similar survey to ours was undertaken in Ireland, and collected data from public and private hospitals (Jonker et al., 2014).

27.37 We considered running the census over an entire week. However, we judged that it would present an unreasonable burden on staff, and ultimately would lead to a lower response rate. Although the previous NAP4 survey (Woodall and Cook; 2011) was undertaken over two weeks, the data required for each case was much less, and we did not think the UK anaesthetic community could sustain a detailed survey over this period. A shorter sampling time yields smaller numbers and results in higher Poisson 'noise' (Fried, 1974), but a longer sampling time, although giving larger numbers, could lead to a higher error in terms of incomplete reporting. On balance, it is more important to reduce the incomplete reporting error (Ɛ) than it is to obtain a larger sample size, because the upper 95% confidence interval of the fractional error = $\sqrt{(\varepsilon^2 + 1/N)}$ where N is the number of cases collected and Ɛ is the reporting error (e.g. 0.1 for a 10% reporting error). Simple plots reveal that where $N >$ ~10,000 there is more gained by keeping Ɛ lower than by further increasing N. That 100% of NHS centres responded to the survey, and the median return rate was 0.98, represents excellent compliance. However, even with a two-day survey, some centres struggled to capture all their data, confirming to us that a longer survey period would only have increased the error rate.

27.38 Randomisation of hospitals to two-days had the potential problem of misrepresenting activity of specialist hospitals if their allocated days were skewed. We tried to minimise this problem by randomising specialist hospitals separately. The two-day collection period also meant that calculation of activity for individual days was not possible. The large size of our sample dataset means that we can be confident that we have a true representation of the 'big picture' and that it is reasonable to scale-up the two-day sample data to estimate the annual workload. However, where the sample size was small, variations in data captured or missed would have a proportionately larger impact on annual estimates, so these data should be treated more circumspectly.

27.39 Extrapolating sample data to annual activity is always at best an estimate, especially as a true annual figure takes into account seasonal variations. Our choice of a time period that avoided school holidays, bank holidays or major conferences may have avoided skewing our data, but equally in some respects 'maximised' the returns since at other times, activity might be expected to be lower than we report – however our scaling factor does account for the effect of Bank holidays on activity, treating them as weekend days. Further, our results are broadly in line with estimates using other sources. Our reported estimate of 2,766,600 general anaesthetics is in very close agreement with the NAP4 estimate (using a two-week long survey in 2008) of 2,872,600 (Woodall & Cook, 2011). Our estimate of 308,800 cases of sedation and 523,100 awake cases (with or without local anaesthesia), gives a total of total of 831,900, which is also in close agreement with NAP4's estimate of 700,000 cases (Cook et al., 2011). The distribution of uses of airway devices in this survey is also similar to that reported in NAP4: the proportion of cases managed with facemask/Hudson mask, supraglottic airway or tracheal tube/tracheostomy for NAP5 were 3.4%, 51.3% and 45% vs 5.3%, 56.2% and, 38.4% for NAP4. The estimated number of Caesarean sections however, performed with GA was 9,200, compared to an estimate of 11,278 by Murdoch et al., (2013). Moreover the HES data (corrected for the UK population) estimates the number of Caesarean sections with general anaesthesia to be 11,687 per year which suggests that our data underestimate the true number (HES, 2013). See also Chapter 16 Obstetrics.

27.40 An advantage of pivot tables is the ease with which large datasets can be analysed by their constituent factors, but one limitation is that the results of pivoting are influenced by the order of application of certain 'filters' that organise the dataset. Therefore, some small variation in estimates is obtained depending upon the method of pivoting the same dataset. For example in respect of Caesarean sections, if the only filter is 'Caesarean Section category', the annual estimate is 91,600. However, if the primary filter is 'Obstetric procedure', followed by a secondary filter of 'Caesarean Section', then an estimate of 92,160 is obtained. Such a variation however, is too small to affect the main conclusions.

27.41 This survey shows that NHS anaesthetists not only deliver approximately ~2.8 million general anaesthetics in a year, but also that there is a substantial additional workload when sedated and awake patients are added. Non-GA anaesthetic activity accounts for approximately 25% of all Anaesthetic activity, and this figure is consistent with previous estimates in NAP4 (Woodall & Cook, 2011). Activity was spread over a wide range of

surgical and non-surgical specialties. In respect of AAGA, for which the survey was primarily intended, the annual number of general anaesthetics of 2,766,600 has been used to estimate the incidence of reports of AAGA to NAP5.

27.42 Our data show that the majority of patients are managed by consultants, irrespective of the patient's ASA grade. In respect of urgent and immediate cases, consultants were present in fewer, but still a majority, 57%. However, consultant presence at category 1 and 2 Caesarean sections was low (26%) and Consultant presence for ASA 4 and 5 patients was approximately 50% outside daytime operating hours compared to 80% during the daytime, and 47% during weekends compared with 70% at other times of the week (see 'Staffing' section, above). Thus, while consultant anaesthetist presence is generally high, there is scope to increase the presence out of hours and at weekends, and for Caesarean sections. The nature of Category 1 Caesarean sections and the quantity of such work performed out of hours makes this a particular challenge.

27.43 The survey data can be presented in many ways and used to answer many questions. For example, the data could be used as denominator data for a variety of calculations performed by research groups studying the incidence of various events or complications associated with anaesthesia care. We emphasise however that the data should be used to compare groups of patients cautiously and not to make inferences about causation. Instead it could help to generate hypotheses and questions that should be answered by appropriately designed trials.

27.44 The survey has important data regarding the planning for, or impact of, seven-day working (Figures 27.10 and 11). If it is planned that the caseload during weekend days becomes similar to weekday days, then we estimate that the NHS needs to find capacity for about one million extra surgical anaesthetic cases annually (an increase of ~33% on current figures). If, on the other hand, it is planned that existing caseload is simply redistributed to weekends, then each weekday's work will need to reduce by approximately 200,000 cases annually to fill the weekend capacity. It is also possible that it is envisaged seven-day working will involve a smoother distribution of emergency cases across the working week, thereby releasing weekend capacity for elective cases. However, Figures 27.10 and 11 show that in fact, there is relatively little variation in the number of emergency surgical procedures across the week and certainly not to an extent that a reduction in weekend emergencies will free up spare capacity. Our data therefore bring into sharp focus the basis of planning for seven-day services in the NHS.

27.45 The low mortality rate (0.06% or 1 in 1,718) occurring during surgery is notable. Many patients are 'scared of anaesthesia', and this figure can only be reassuring for them. During the period of time when they are cared for by anaesthetists the risk of death is low indeed. This low mortality rate is in marked contrast to the report by EuSOS of an overall 4% (1 in 25) mortality rate for inpatient major elective surgery (Pearse et al., 2012). These differences highlight the potential impact that advances in peri-operative care – by anaesthetists, surgeons and intensivists – might have on overall mortality rates after surgery.

27.46 In planning an anaesthetic service for a large population, datasets such as ours are likely to be valuable. That there have been few such national surveys, may relate to the practical difficulties in collecting data from large numbers of patients by busy clinicians. We hope that universal adoption of electronic records will help in future. If major changes in anaesthesia are planned, we propose that another census should be undertaken to determine its effects.

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APPENDIX

Scaling factor

Number of weeks in the year

The weekly caseload may not be multiplied by 52 to estimate an annual caseload because several weeks have Bank Holidays. Assuming that the activity on a Bank Holiday is similar to a weekend day the 'effective' number of weeks can be calculated. For 2013, the number of weeks used as a scaling factor to estimate annual activity was 50.59 (see below).

There were 365 days in 2013, and 52.14 weeks (365/7 = 52.14).

Using the number of weekdays, a scaling factor x, and y as the number of 'effective' weeks in 2013:

5/7 * x = 52.14 and 253/365 * x = y

Therefore x = 7*52.14/5 = y*365/253

And y = (7*52.14*253) / (5 * 365) = 50.59

Return rate

LCs were asked to estimate their site's return rate, either by using their own hospital data or by choosing one of the following ranges: <50%, 51–75%, 76–90%; 91–99%; 99-100%. The median return rate was 0.98 for the entire sample (where the LC quoted a range, the middle rate was used e.g. a rate of 95% was used instead of 91-99%).

Multiplication factor

Number of returns in a week = number of returned forms *3.5

Number of returns in a year (2013) = returned forms *3.5 * 50.59

Estimated annual caseload = (returned forms * 3.5 * 50.59) / 0.98

Multiplication factor = (3.5 * 50.59) / 0.98 = 180.6786

CHAPTER
28

NAP5 Baseline Survey in Ireland


Wouter R Jonker


Ellen P O'Sullivan


Tim M Cook


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HEADLINE

28.1 We issued a questionnaire to every consultant anaesthetist in each of the 46 Public hospitals in Ireland (represented by 41 Local Co-ordinators). The survey ascertained the number of new cases of accidental awareness during general anaesthesia (AAGA) becoming known to them, for patients under their care or supervision for a calendar year, as well as their career experience. Consultants from all hospitals responded, with an individual response rate of 87% (299 anaesthetists). There were eight new cases of accidental awareness that became known to consultants in 2011; an estimated incidence of 1:23,366. Two of the eight cases (25%) occurred at or after induction of anaesthesia but before surgery, four cases (50%) occurred during surgery, and two cases (25%) occurred after surgery was complete but before full emergence. Four cases were associated with pain or distress (50%), one after an experience at induction and three after experiences during surgery. There were no formal complaints or legal actions that arose in 2011 related to awareness. Depth of anaesthesia (DOA) monitoring was reported available in 33 (80%) of departments, while 184 (62%) of consultants used such monitoring, of which 18 (6%) used it routinely. None of the 46 hospitals had a policy to prevent or manage AAGA. Similar to the results of a larger survey in the United Kingdom, the disparity between incidence of awareness as known to anaesthetists and that reported in trials warrants explanation. Also similar is the dearth of policies to prevent or manage awareness. Compared with United Kingdom practice, there appears greater use of depth of anaesthesia monitoring in Ireland, though this is still infrequent.

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BACKGROUND

28.2 NAP5 is a partnership between the Association of Anaesthetists of Great Britain and Ireland (AAGBI) and the Royal College of Anaesthetists (RCoA) and, through the involvement of the AAGBI, also covers Ireland. Although there are some similarities in content of training and a common language, the health service structure is very different in Ireland. We therefore wished to know if the incidence of AAGA reported to anaesthetists was as low in Ireland as it appeared to be in the UK. We also wished to ascertain if clinical practice in relation to DOA monitoring differed.

28.3 No similar survey of AAGA has been conducted in Ireland.

METHODS

28.4 The NAP5 project in Ireland received approval from the Department of Health and was endorsed by the Health Service Executive (HSE) National Quality and Patient Safety Directorate. The Department of Health's Bioethics Office categorized the project as a clinical audit rather than research and as such did not require research ethics approval.

28.5 A Local Co-ordinator (LC) was established in each of the 41 anaesthetic departments that cover 46 public hospitals with surgical services. The LC distributed a survey form (Figure 28.1) to all consultant anaesthetists in their hospital. Each LC collated responses and populated a second summary form which was returned to the NAP5 team. Compared with the UK survey, there were some differences in design and terminology. Irish consultants often conduct sessions in more than one hospital, so were asked only to complete a form for the hospital/department where they have the majority of their sessions. The survey also determined the number of non-consultant hospital doctors (NCHD) in each anaesthetic department. NCHD is a term used for all non-consultant doctors in the health system in Ireland (training and non-training posts), that require immediate, local or distant supervision by a consultant.

28.6 Briefly, the questionnaires asked about the number of consultant staff and their years of experience as seniors; about the number of new cases of AAGA that became known to them (under their direct care or the care of those they supervised) during 2011 (and some relevant case details) as well as during their career as a consultant in Ireland; about the availability and use of DOA monitoring; and whether the hospital had policies for prevention or management of AAGA. LCs could contact the NAP5-Ireland Clinical Lead or the National Co-ordinator for further advice (which was also provided via the NAP5 website at www.nationalauditprojects.org.uk/NAP5_home) and in turn, the Clinical Lead or National Co-ordinator could contact the LC for clarification of data entries.

28.7 Since there was no hypothesis test, there were no statistical comparisons, but continuous data were described as median (IQR [range]) and categorical data with 95% confidence limits for binomial or Poisson distributions, as appropriate. Where illustrative, the goodness of fit of the data to a Poisson distribution was estimated by the least squares regression of actual vs. modelled data.

RESULTS

28.8 Table 28.1 shows the estimated numbers of consultant anaesthetic staff in public hospitals in Ireland, and the generally high proportions responding. The response rate was 100% of departments and 87% of consultants. It also shows the estimated number of NCHDs in Ireland. Median responses per centre were 100%, but in two hospitals where three consultants held the majority of their sessions, only one replied, and in one hospital where seven consultants held the majority of their sessions, only one replied, yielding a rather wide range.

Table 28.1. Estimated numbers of consultants (and NCHDs) and response rates from 41 Local Co-ordinators responsible for the Irish public hospitals (100% response rate). Data reported as median (interquartile range [range]). Note that NCHDs were not asked to respond to the survey

	Consultants		NHCDs
Totals	Total (n = 342)	Responding (n = 299; 87.4%)	Total (n = 430)
Numbers/ centre	6 (4-13 [1-23])	5 (3-9 [1-23])	7 (5-12 [0 - 33])
Response rate/centre (%)		100 (84-100 [14-100])	

Figure 28.1. Survey form distributed by LCs in Ireland to each consultant

NATIONAL AUDIT PROJECT 5
Accidental Awareness during General Anaesthesia

Churchill House 35 Red Lion Square London WC1R 4SG
020 7092 1680 mcenan@nap5.org

FORM 1

NAP5 BASELINE SURVEY OF AWARENESS IN IRELAND– INDIVIDUAL QUESTIONNAIRE – PLEASE RETURN THIS TO YOUR NAP5 LOCAL CO-ORDINATOR

NAP5 is a major project of the RCOA and AAGBI - your response is very important. Please provide the answers to these brief questions.

1. Over approximately this last year 2011, roughly how many instances of accidental awareness during anaesthesia* have you personally had to deal with for patients under your care? ☐

** by accidental awareness we mean any instance of recall of intraoperative events during general anaesthesia, induction or emergence that occurred with administration of anaesthesia under your care or care of someone you were supervising*

2a. What was the approx age range of these instances?

Approx age	0-15	16-24	25-44	45-64	>65
Number					

2b. How many of these were reports volunteered by the patient vs ascertained only on questioning?

Approx age	0-15	16-24	25-44	45-64	>65
Number volunteered					
Ascertained on questioning					

2c. How many of these were brief periods of awareness before surgery (eg, due to difficult intubation, syringe swaps, drugs given in wrong order, etc), awareness of intra-operative events, or awareness of events only on emergence?

Approx age	0-15	16-24	25-44	45-64	>65
Recall of events during induction and before surgery					
Recall of events during surgery					
Aware after surgery and before full emergence					

d. How many of these cases of awareness also involved physical pain or psychological hurt?

Approx age	0-15	16-24	25-44	45-64	>65
Number					

e. How many of these reports led or is leading to a formal complaint to the Trust or litigation?

Approx age	0-15	16-24	25-44	45-64	>65
Formal complaint					
Litigation					

3. Do you use any depth of anaesthesia monitors and if so, which?

	BIS	AEP	SSEPs	Entropy	Narcotrend	Isolated forearm	Other
Routinely							
Selected cases							
Never							

4. Approximately how many cases of accidental awareness occurring directly under your care (including supervising a trainee) as consultant during your practice in **Ireland** have you experienced?:

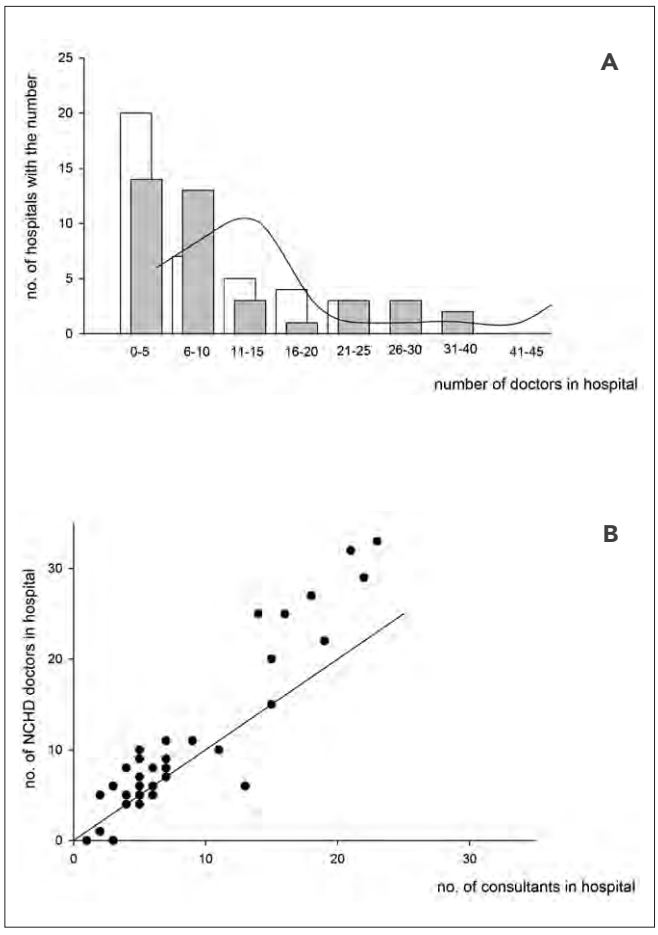
Yrs of anaesthesia practice (as consultant, including locum)	yrs
Total no. of cases of accidental awareness	n=

PLEASE RETURN THIS TO YOUR NAP5 LOCAL CO-ORDINATOR

Fifth National Audit Project of the Royal College of Anaesthetists and Association of Anaesthetists of Great Britain and Ireland:
Accidental Awareness during General Anaesthesia

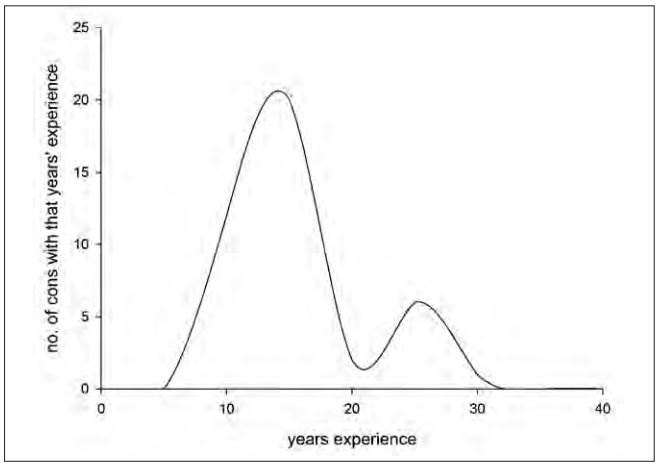
28.9 Figure 28.2 shows the demography of staffing across anaesthesia departments. Many hospitals in Ireland are relatively small. The majority of hospitals (29; 70%) consist of <10 consultants with the majority of their sessions in that hospital. No hospital has >30 consultant anaesthetists with the majority of their sessions in that hospital. In three-quarters of the hospitals (31, 75%), the number of NCHDs equals or exceeds the number of consultants with the majority of their sessions in that hospital (Fig. 28.2B).

Figure 28.2. Demography of staffing. Panel (a): histogram of the number of consultants with most sessions at a given hospital (white bars) and non-consultant hospital doctors (NCHDs) (shaded bars) and total number of anaesthetists (line) by hospital. Panel (b): numbers of NCHDs vs consultants by hospital (the line is the line of identity; note there are some overlapping points)



28.10 Figure 28.3 shows the distribution of mean years of experience of consultants across the hospitals, showing a bimodal distribution with one peak at a mean of ~15 years, and a second peak at mean ~25 years' experience. Notwithstanding less than full time individuals and details of job plans, the crude sum of years' experience as a consultant of those responding to the survey was 3,685 years.

Figure 28.3. Distribution of mean years' experience of consultants across hospitals



28.11 There were eight new cases of AAGA reported to anaesthetists for the year 2011 (Table 28.2). Half were young or middle-aged adults (25-44 years) and half >45 years. Five cases were volunteered by patients and three established through direct questioning by staff. Two cases related to experiences of AAGA at or soon after anaesthetic induction but before surgery commenced, four during surgery and two after completion of surgery but before full emergence. Thus, the combined total for experiences during induction and emergence (i.e. the 'dynamic phases' of anaesthesia) was equal to those experiences during surgery (the 'steady state phase'). Half the patients suffered pain or distress as part of their experience, three during surgery and one for an experience at or soon after induction. The consultants who responded to the survey did not know of any formal complaints or legal proceedings taken during 2011.

Table 28.2. Reports of AAGA and their characteristics

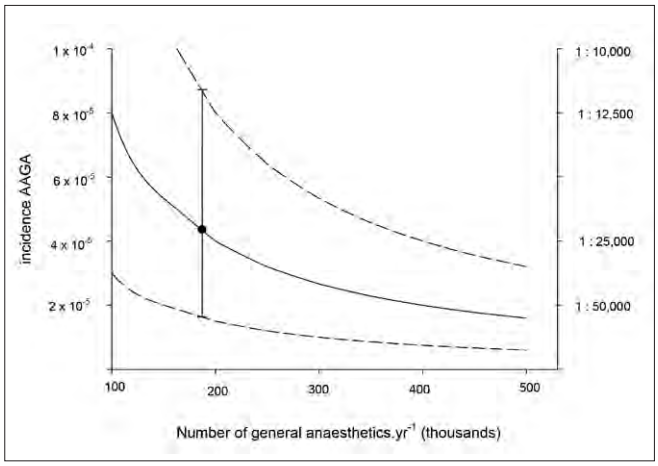
Age range; yrs	How ascertained	Phase of anaesthesia/surgery in which awareness occurred	Pain or distress?
25–44	Volunteered	Surgery	Yes
25–44	Volunteered	Surgery	Yes
25–44	Questioning	After surgery, before full recovery	No
25–44	Volunteered	Surgery	No
45–64	Volunteered	Surgery	Yes
45–64	Volunteered	Induction	Yes
45–64	Questioning	After surgery, before full recovery	No
>65	Questioning	Induction	No

28.12 Using a denominator for the number of general anaesthetics administered in public hospitals in Ireland in one year of 187,000 (rounded to the nearest 100 and obtained from a contemporaneous Irish NAP5 Activity Survey – (see Chapter 29), we can estimate an incidence of AAGA that becomes known to anaesthetists for the year 2011: one case for every 23,366 general anaesthetics (Table 28.3). Even if our method of estimating denominator is inaccurate, Figure 28.4 shows how that the calculated incidence will vary little across a wide range of denominator values.

Table 28.3. Number and incidence of reports of AAGA in 2011 by various descriptors. The binomial and Poisson estimates are almost identical; the Poisson are presented. The denominator used in the calculations is taken from the Anaesthetic Activity Survey in Ireland data of 187,000 adjusted for the non-response rate

Descriptor	Incidence
Cases of AAGA	8 (3 – 16)
Incidence per general anaesthetic	0.0043% (0.0016 – 0.0086%)
Cases : anaesthetic	1: 23,375 (1: 11,628 - 1: 62,500)
Cases per consultant per yr	1: 37 (1: 19 – 1: 86)

Figure 28.4. The influence of denominator (number of general anaesthetics administered annually) on the estimated mean incidence of AAGA (with 95% Poisson CI, dotted lines), given our data of eight instances of AAGA in one year. The incidences are shown as absolute values (left y-axis) and as ratios (right y-axis). The point represents the value assuming the Anaesthetic Activity Survey in Ireland [9] estimate of denominator is correct (error bars = 95% Poisson CI for the point estimate)



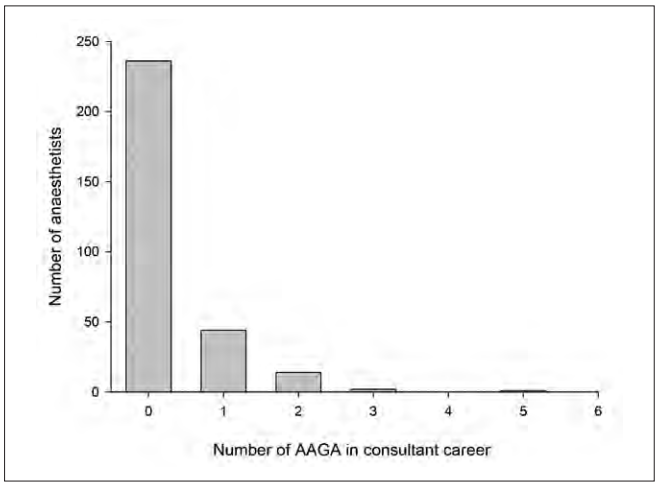
28.13 These data mean that just one consultant anaesthetist out of ~37 will know of a new case each year (Table 28.3).

28.14 The collective career knowledge of AAGA cases personally experienced by consultant anaesthetists is shown in Table 28.4 and the distributions in Figure 28.5. This seems broadly consistent with the experience for 2011, with the likelihood that an individual consultant anaesthetist will have personal experience of an AAGA event just once every ~46 years of their career (i.e. possibly never in their working lives; Table 28.4). The vast majority have never had direct experience of a case for which they were responsible, but one respondent reported having experience of five cases (Fig. 28.5).

Table 28.4. Number of cases of AAGA known to staff over their consultant careers and incidence (total years of service 3,685). The binomial and Poisson estimates are almost identical; the binomials are presented. Incidence is presented by various descriptors

Descriptor	Incidence
Cases; n	82 (65 - 102)
Incidence; cases/consultant per year	0.022 (0.018 - 0.028)
Cases: years of consultant practice	1: 45.5 (1:35.7 - 1:55.6)

Figure 28.5. Distribution of the number of cases of AAGA, known to consultants in their career. The spread of values is median (IQR [range] 0 (0–0 [0–5]), and the data can be fitted by a Poisson distribution with covariance r2 > 0.997



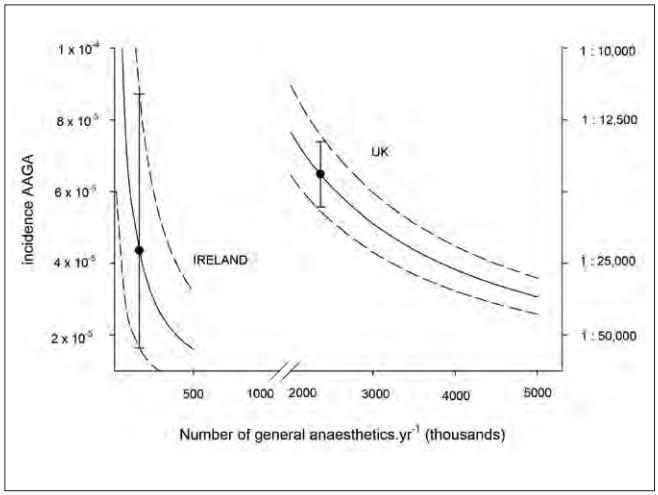
28.15 The access to and use of DOA monitoring is shown in Table 28.5. The majority of Irish hospitals possess DOA monitoring, and almost two-thirds of anaesthetists use it either routinely or in selected cases, with almost 7% using it routinely. The Bispectral Index appears by far the most frequently used, with about two-thirds of those who use any DOA monitoring employing this technique.

28.16 No public hospital in Ireland reported a policy to prevent or manage AAGA.

DISCUSSION

28.17 The results of this Irish survey require interpreting in the light of our recent, similar survey in the UK (Chapter 26). The incidence of new cases of AAGA that becomes known to Irish consultant anaesthetists of ~1:23 000 seems comparable, even a little lower, to that in the UK (~1:15 000), but the wider confidence intervals for the Irish estimate are due to the smaller denominator (Figure 28.6) and encompass the UK estimates. In other words, the incidence of AAGA known to anaesthetists in Ireland is unlikely to be commoner than 1:10,000, and of similar rarity to the rate reported in the UK. The estimated career incidence per year of consultant practice is almost identical to the UK estimate of one case every 36–47 years, underlining the similarity of the data (Chapter 26).

Figure 28.6. The Irish and UK data plotted on the same axes (data taken from Chapter 26). The graph shows the relative influence of the denominator value of the number of general anaesthetics administered annually on the estimated mean incidence of AAGA (±95% Poisson CI), given the instances of AAGA obtained in the two nations, respectively. The incidences are shown as absolute values (left y-axis) and as ratios (right y-axis)



28.18 There were too few cases of AAGA to examine detailed sub-correlations with age, phase of anaesthesia, etc. Nonetheless, two national surveys from different countries now consistently show that estimates using anaesthetists' knowledge of cases are very much lower indeed than estimates obtained from direct questioning in prospective trials (~1–2:1,000), the reasons for which are discussed in Chapter 26 and elsewhere. These broadly relate to possible patient, organisational or methodological factors. Patient factors include such severe psychological trauma that there is a reluctance even to discuss, let alone report the experience. Or, conversely it might be the case that the experience is felt by patients to be so trivial that they omit or forget to report it. Organisational factors include deficiencies in hospital reporting systems or the fact that anaesthetists rarely see patients in outpatient clinics post-operatively, where a report of AAGA might be made. Methodological factors include the different nature of the studies undertaken to produce an 'incidence'.

28.19 One notable feature is the very large difference in size of the anaesthetic communities to which the surveys were directed. A total of just 342 consultant anaesthetists in public hospitals in Ireland (population 4,588,252 in the 2011 census (Central Statistics Office, 2011) is dwarfed by 8,672 consultants and SAS anaesthetists in the NHS hospitals in the UK (population 63,200,000 in the 2011 census, (Office of National Statistics, 2011). The number of senior anaesthetists in Irish public hospitals per head of population is half that for the UK (1:13,415 vs. 1:7,287). See also Chapter 5, Methods for discussion of this.

28.20 Expressed differently, the ratio of public hospital senior anaesthetist per 100,000 population in Ireland and the UK is ~7.45 and ~13.7 respectively.

Table 28.5 Access to and use of depth of anaesthesia (DOA) monitoring. Data are numbers or (%). BIS = bispectral index; EP = evoked potential monitoring; IFT = isolated forearm technique

Centres with DOA	Anaesthetists using DOA monitoring in selected cases and routinely	Anaesthetists using DOA monitoring in selected cases	Anaesthetists using DOA monitoring routinely	Type of DOA monitor used (as % of those using DOA monitors)					
				BIS	Entropy	EP	Narcotrend	IFT	Other
33/41	184/299	164/299	20/299	126/184	42/184	15/184	1/184	0/184	0/184
(80.5%)	(61.5%)	(54.8%)	(6.7%)	(68.5%)	(22.8%)	(8.2%)	(0.5%)	(0.0%)	(0.0%)

This is in part due to the inclusion as seniors of the staff and associate specialist (SAS) and career grade anaesthetists, working in UK NHS hospitals as well as the small independent hospital sector in the UK. The number of public hospital consultants in Ireland identified in this survey correlates well with the estimate of 336 consultant posts, supplied by the Health Service Executive (HSE) to the College of Anaesthetists of Ireland in September 2012 during manpower planning (College of Anaesthetists of Ireland, 2013).

28.21 A separate estimate by the College (using the Professional Competence Scheme database) at the same time, identified 379 consultants practicing in public hospitals and a further 64 solely in private practice. Even taking into account this larger estimate and including those who work solely in private practice, the number of consultants per head of population (1: 10,357) remains lower than for the UK.

28.22 The 430 NCHDs reported to work in the public hospitals by this survey also correlates well with the College's 2012 manpower assessment of 464 NCHD staff (also from the Competence Scheme database). The small difference of 34 might reflect those in full time research as well as those completing fellowships abroad. Of note: the public hospital anaesthetic consultant to anaesthetic NCHD ratio of 1.26 and the consultant to 100,000 population ratio of 7.45, estimated by this survey, falls well short of the recommendations set in the Report of the National Taskforce on Medical Staffing (Department of Health, 2003) of 0.61 and 11 respectively. This raises concerns and challenges for anaesthetic training and service delivery in Ireland.

28.23 This manpower data, coupled with data on activity presented in Chapter 29 might provide opportunity for a more detailed analysis of anaesthetic service issues.

28.24 Another striking contrast between the UK and Irish datasets is the adoption of DOA monitoring. Whereas in the UK, more then one-third (39%) of hospitals possess no DOA monitoring and only a quarter of anaesthetists ever use this technology (Chapter 26), in Ireland 80% of hospitals have access to DOA monitoring and the majority of anaesthetists (62%) use it at some time as part of their practice. (Also discussed in Chapter 27 and 29 regarding UK and Irish Activity surveys).

28.25 The relative proportions using BIS and Entropy are broadly similar (~75% and 69% for BIS vs. ~17% and 23% for Entropy in UK and Ireland, respectively) and perhaps the only minor, but intriguing difference is that whereas 14 (0.7%) practitioners use the isolated forearm technique in the UK (Chapter 26), it is not used at all in Ireland. We can speculate on the causes of these differences. The smaller size of each Irish anaesthetic department (a median of just 6 vs. 27 for the UK (Chapter 26) may lead to greater standardisation such that practice is more homogenous. Fewer monitors are therefore also needed in each hospital for usage to be high as a proportion of theatres/anaesthetists. It is possible that Irish anaesthetists regard AAGA as a more serious problem, to be tackled with greater use of DOA monitoring.

28.26 However, this interpretation is not consistent with the finding that no Irish hospital reported having a policy to prevent or manage AAGA.

28.27 In summary this survey provides important information on staffing and demography of anaesthetic departments in the Republic of Ireland. The annual and career incidence of AAGA that becomes known to anaesthetists is very similar to the incidence calculated using similar methodology in the UK (Chapter 26). This incidence is, however, much lower than reported in prospective trials that use direct patient questioning, and this large disparity warrants further research and explanation.

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CHAPTER
29

NAP5 Ireland Activity Survey


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HEADLINE

29.1 The first phase of NAP5 Ireland consisted of a survey of anaesthetic activity in Ireland. A network of Local Co-ordinators who organised data collection from the anaesthetic departments of 46 public and 20 independent hospitals over seven days. Data on patient demographics, anaesthesia techniques, staffing, admission and discharge arrangements were collected on all cases for which anaesthesia care (i.e. general, regional, local anaesthesia, sedation or monitored anaesthesia care) was provided. A total of 8,049 cases were reported during the survey, giving an annual estimate of 426,600 cases for which anaesthesia care is provided. General anaesthesia constituted 5,621 (69.8%) of total number of cases, regional anaesthesia 1,404 (17.4%), local anaesthesia 290 (3.6%), sedation 618 (7.6%) and monitored anaesthesia care 116 (1.4%). As data collection included both public and independent hospitals the survey provides a unique comparison of caseload – both in terms of activity and case-mix – in Ireland. This survey provides unique data regarding anaesthesia service in public and independent hospitals in Ireland.

The contents of this chapter have been published as Jonker WR, Hanumanthiah D, Ryan T, Cook TM, Pandit JJ, O'Sullivan EP; the NAP5 Steering Panel. Who operates when, where and on whom? A survey of anaesthetic-surgical activity in Ireland as denominator of NAP5. *Anaesthesia* 2014 doi: 10.1111/anae.12763. [Epub ahead of print]. This chapter should be referenced as such. All figures in this chapter are reproduced with permission, and any portions of text reproduced with permission of the NAP5 Publications and Dissemination Panel, which includes the Editor-In-Chief of *Anaesthesia*.

BACKGROUND

29.2 A survey of anaesthetic services (i.e. an Anaesthetic Activity Survey (AAS) was conducted in Ireland to obtain, for the first time, detailed information on anaesthesia services. We contacted all 46 acute public hospitals (Health Service Executive (HSE) and voluntary hospitals) and all 21 acute independent (private) hospitals.

29.3 The primary motivation for this survey was to obtain denominator data for NAP5 in Ireland.

METHODS

29.4 The NAP5 project in Ireland received approvals as documented in Chapter 28. Additionally, approvals for the AAS in the independent hospitals were received from every individual hospital's Ethics or Medical Advisory Committee. The project

infrastructure in Ireland is as that for the UK, as described in Chapter 5, Methods and Chapter 24 NAP5 in Ireland. A team of volunteer consultant anaesthetists was recruited as Local Co-ordinators (LCs), one in each of the identified public and independent hospitals. Information on the AAS was distributed to all anaesthetists through the LCs in their hospital, as well as at AAGBI meetings prior to the survey. The College of Anaesthetists of Ireland provided advertisement and support for the survey through mailshots and information on their website. Instructions on how to complete the AAS Data Collection form (Fig. 29.1) were provided to anaesthetists through an AAS Advice sheet. Data were prospectively collected on all cases for which anaesthesia care was provided over seven days in 2012. The chosen week (from 8:00 on Monday 26 November 2012 to 7:59 on Monday 3 December 2012) was selected to avoid potential factors that could affect activity, e.g. national holidays and anaesthesia/surgical conferences or meetings.

29.5 Anaesthesia care was defined as any procedure or case where an anaesthetist, (consultant or non-consultant hospital doctor (NCHD)) provided general, regional or local anaesthesia, sedation or monitored anaesthesia care for surgery or an interventional procedure. NCHD is a term used for all non-consultant hospital doctors (whether in training or not) in the health system in Ireland, who work under immediate, local or distant consultant supervision. The terms 'surgery' and 'procedure' are used interchangeably to describe any form of intervention for which an anaesthetist provided care, and can cover a range of surgical or obstetric operations or interventional procedures conducted by radiologists or physicians.

29.6 Inclusion and exclusion criterial were as for the UK Activity survey (see Chapter 27). We collected simiilar but not identical data to that collected in the UK. In particular we also collected data on the site of pre-operative assessment and the use of blood transfusion.

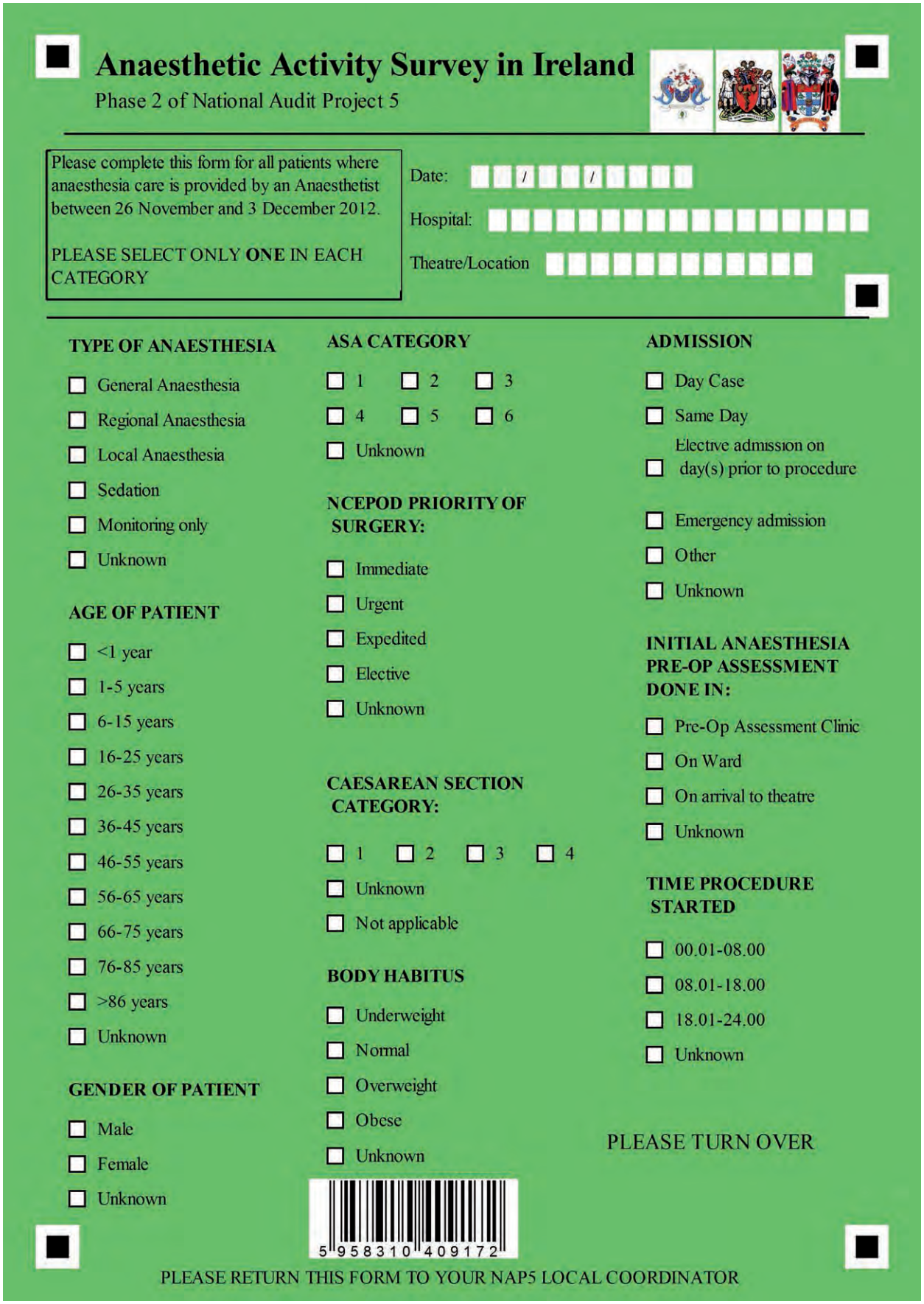
29.7 If a combination of techniques were used, e.g. general anaesthesia combined with a neuraxial blockade, the respondents were advised to select general anaesthesia as the main or primary type of anaesthesia.

29.8 The AAS Data Collection form instructed the anaesthetist to only select one option in each category with the exception of two categories i.e. 'Anaesthesia Agents Used' and 'Type of Regional Anaesthesia' for which more than one option could be selected. This was to accommodate the breadth of procedures and techniques performed during an individual case.

29.9 LCs distributed the AAS Data Collection forms throughout their departments and made local arrangements on collection of forms. The LCs correlated the completed AAS Data Collection forms with theatre-, radiology- or delivery suite registers. If the attending anaesthetist did not capture a case, the LCs were asked to complete a data form from the theatre register. An 'Unknown' option was given in each category. The LCs and other anaesthetists could contact the NAP5-Ireland Clinical Lead, National Co-ordinator for further advice prior to and during the survey. At the end of the survey the LCs graded the accuracy of their data on the four-point scale, i.e. Accurate (0-2% error), Close Estimate (2-10% error), Estimate (>10% error) or a Guess (an estimate without data to support it). Any significant theatre closures during the survey were noted. All data collection forms were returned to the National Co-ordinator and digitally scanned (Informa, Dublin, Ireland) using optical character recognition technology. The scanning operator as well as the National Co-ordinator verified the electronic data. Discrepancies in data, such as data scanning errors or illogical data were corrected, where possible, after evaluating the original data collection form. If correction was not possible the 'Unknown' option was selected in that category.

29.10 Since there was no hypothesis test, there were no statistical comparisons and only descriptive data are presented.

Figure 29.1. Irish Activity Survey data collection form



Anaesthetic Activity Survey in Ireland

Phase 2 of National Audit Project 5

Please complete this form for all patients where anaesthesia care is provided by an Anaesthetist between 26 November and 3 December 2012.

PLEASE SELECT ONLY **ONE** IN EACH CATEGORY

Date: / /

Hospital:

Theatre/Location

TYPE OF ANAESTHESIA

- ☐ General Anaesthesia
- ☐ Regional Anaesthesia
- ☐ Local Anaesthesia
- ☐ Sedation
- ☐ Monitoring only
- ☐ Unknown

AGE OF PATIENT

- ☐ <1 year
- ☐ 1-5 years
- ☐ 6-15 years
- ☐ 16-25 years
- ☐ 26-35 years
- ☐ 36-45 years
- ☐ 46-55 years
- ☐ 56-65 years
- ☐ 66-75 years
- ☐ 76-85 years
- ☐ >86 years
- ☐ Unknown

GENDER OF PATIENT

- ☐ Male
- ☐ Female
- ☐ Unknown

ASA CATEGORY

- ☐ 1 ☐ 2 ☐ 3
- ☐ 4 ☐ 5 ☐ 6
- ☐ Unknown

NCEPOD PRIORITY OF SURGERY:

- ☐ Immediate
- ☐ Urgent
- ☐ Expedited
- ☐ Elective
- ☐ Unknown

CAESAREAN SECTION CATEGORY:

- ☐ 1 ☐ 2 ☐ 3 ☐ 4
- ☐ Unknown
- ☐ Not applicable

BODY HABITUS

- ☐ Underweight
- ☐ Normal
- ☐ Overweight
- ☐ Obese
- ☐ Unknown

ADMISSION

- ☐ Day Case
- ☐ Same Day
- ☐ Elective admission on day(s) prior to procedure
- ☐ Emergency admission
- ☐ Other
- ☐ Unknown

INITIAL ANAESTHESIA PRE-OP ASSESSMENT DONE IN:

- ☐ Pre-Op Assessment Clinic
- ☐ On Ward
- ☐ On arrival to theatre
- ☐ Unknown

TIME PROCEDURE STARTED

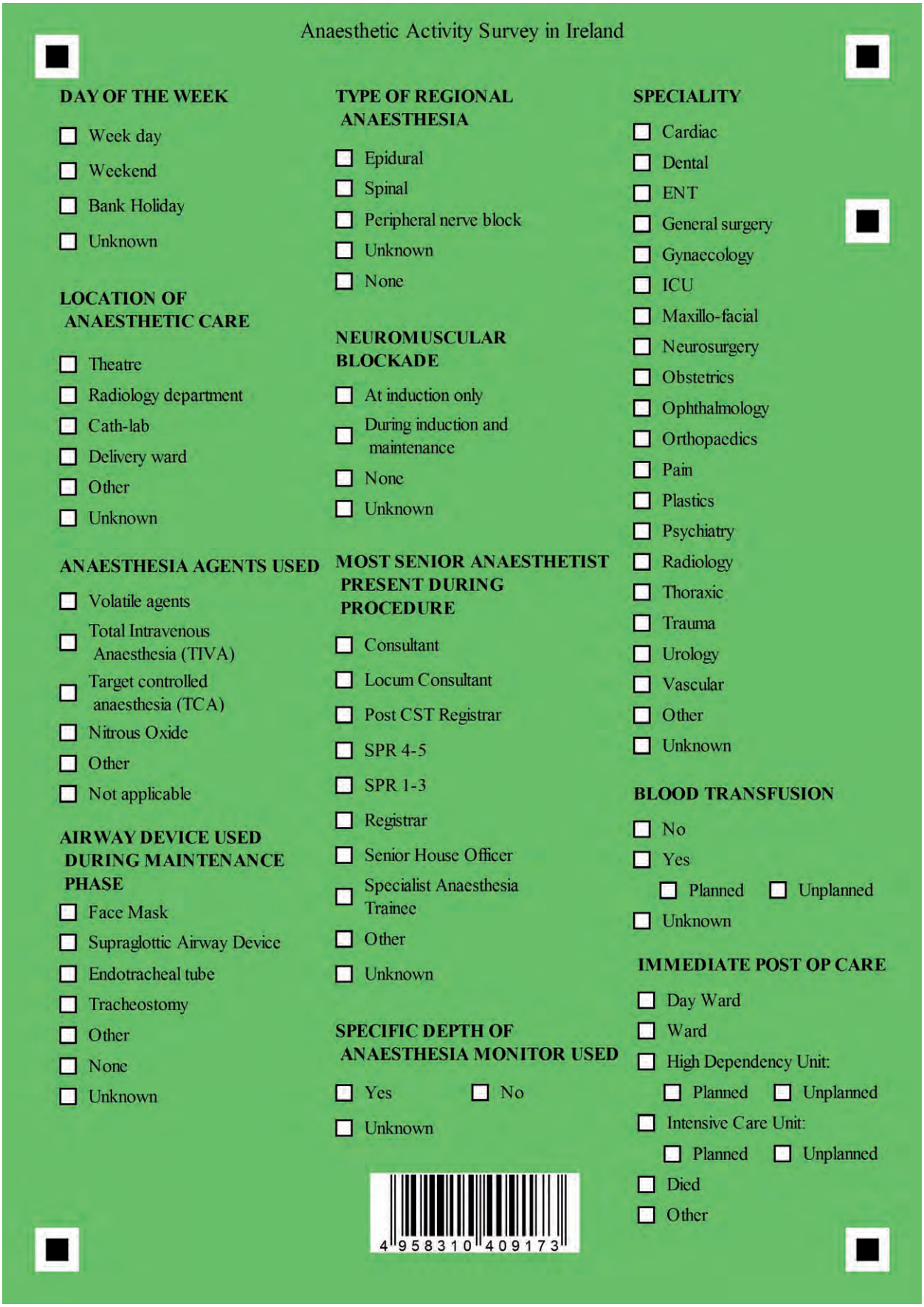
- ☐ 00.01-08.00
- ☐ 08.01-18.00
- ☐ 18.01-24.00
- ☐ Unknown

PLEASE TURN OVER

5 958310 409172

PLEASE RETURN THIS FORM TO YOUR NAP5 LOCAL COORDINATOR

Figure 29.1. Irish Activity Survey data collection form.



Anaesthetic Activity Survey in Ireland

DAY OF THE WEEK

- ☐ Week day
- ☐ Weekend
- ☐ Bank Holiday
- ☐ Unknown

LOCATION OF ANAESTHETIC CARE

- ☐ Theatre
- ☐ Radiology department
- ☐ Cath-lab
- ☐ Delivery ward
- ☐ Other
- ☐ Unknown

ANAESTHESIA AGENTS USED

- ☐ Volatile agents
- ☐ Total Intravenous Anaesthesia (TIVA)
- ☐ Target controlled anaesthesia (TCA)
- ☐ Nitrous Oxide
- ☐ Other
- ☐ Not applicable

AIRWAY DEVICE USED DURING MAINTENANCE PHASE

- ☐ Face Mask
- ☐ Supraglottic Airway Device
- ☐ Endotracheal tube
- ☐ Tracheostomy
- ☐ Other
- ☐ None
- ☐ Unknown

TYPE OF REGIONAL ANAESTHESIA

- ☐ Epidural
- ☐ Spinal
- ☐ Peripheral nerve block
- ☐ Unknown
- ☐ None

NEUROMUSCULAR BLOCKADE

- ☐ At induction only
- ☐ During induction and maintenance
- ☐ None
- ☐ Unknown

MOST SENIOR ANAESTHETIST PRESENT DURING PROCEDURE

- ☐ Consultant
- ☐ Locum Consultant
- ☐ Post CST Registrar
- ☐ SPR 4-5
- ☐ SPR 1-3
- ☐ Registrar
- ☐ Senior House Officer
- ☐ Specialist Anaesthesia Trainee
- ☐ Other
- ☐ Unknown

SPECIFIC DEPTH OF ANAESTHESIA MONITOR USED

- ☐ Yes ☐ No
- ☐ Unknown

4 958310 409173

SPECIALITY

- ☐ Cardiac
- ☐ Dental
- ☐ ENT
- ☐ General surgery
- ☐ Gynaecology
- ☐ ICU
- ☐ Maxillo-facial
- ☐ Neurosurgery
- ☐ Obstetrics
- ☐ Ophthalmology
- ☐ Orthopaedics
- ☐ Pain
- ☐ Plastics
- ☐ Psychiatry
- ☐ Radiology
- ☐ Thoraxic
- ☐ Trauma
- ☐ Urology
- ☐ Vascular
- ☐ Other
- ☐ Unknown

BLOOD TRANSFUSION

- ☐ No
- ☐ Yes
  - ☐ Planned ☐ Unplanned
- ☐ Unknown

IMMEDIATE POST OP CARE

- ☐ Day Ward
- ☐ Ward
- ☐ High Dependency Unit:
  - ☐ Planned ☐ Unplanned
- ☐ Intensive Care Unit:
  - ☐ Planned ☐ Unplanned
- ☐ Died
- ☐ Other

RESULTS

Returns

29.11 All 46 (100%) acute public hospitals and 20 of the 21 (95%) acute independent hospitals in Ireland took part in the survey. A total of 8,058 AAS data collection forms were received. Nine (0.1%) forms were not suitable for scanning because of non-compliance, thus 8,049 AAS data collection forms were included in the analysis. A total of 50 (75.8%) Local Co-ordinators reported their individual hospital's returns to be 'accurate' (<2% error), 15 (22.7%) a 'close estimate' (2-10% error), 1 (1.5%) an 'estimate' (>10% error) and zero (0%) a 'guess' (i.e. an estimate without data to support it). This suggests an overall error rate of ~4%.

29.12 To estimate an annual number of cases, a week-to-year scaling factor was calculated. Using our data collection period (five normal weekdays and two weekend days) we scaled this up to one year of activity (252 normal weekdays, 105 weekend days and nine bank holidays) thereby deriving a week-to-year multiplier of 50.97. This was then multiplied by 1.04 to take the overall average error rate (~4%) into account. A scaling factor of 53 was obtained by this method and is used to calculate annual estimates (expressed to the nearest 100) throughout the report.

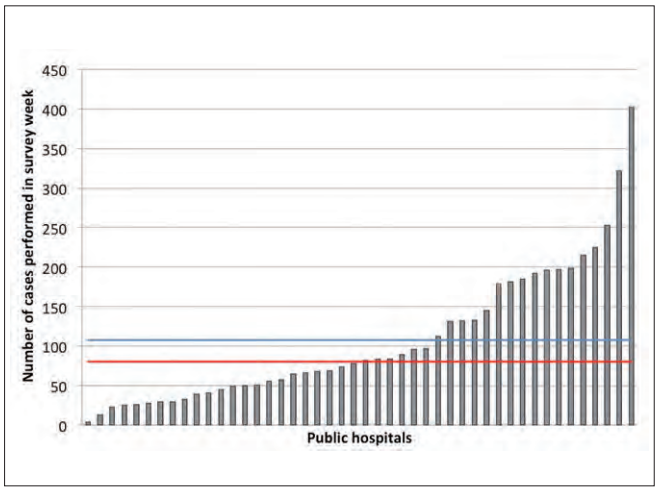
29.13 A total of 4,949 (61%) of cases were performed in public hospitals and 3,100 (39%) in independent hospitals. Using the scaling factor of 53, an annual estimated ~426,600 cases occurred in 2012 in Ireland comprising ~262,300 in public hospitals and ~164,300 in independent hospitals.

29.14 In the main section of this chapter we focus on the results from the public hospitals and present data for the independent hospitals separately, in the Appendix. The discussion highlights differences between public and independent hospital practices. Percentages are expressed as the respective proportion of the total number of cases undertaken in either the public or independent hospitals. Responses marked as 'unknown' are reported in results where relevant.

Distribution of cases by location

29.15 Figure 29.2 shows the distribution of number of cases across the 46 public hospitals. The median number of cases per hospital captured during the survey was 80 (IQR 46-170, Range 4-402). The majority (29, 63%) of hospitals undertook <100 cases, with only 5 (11%) hospitals performing >200 procedures during the one week survey. Nearly a third (14) of the public hospitals were affected by some theatre closure(s) during the survey period.

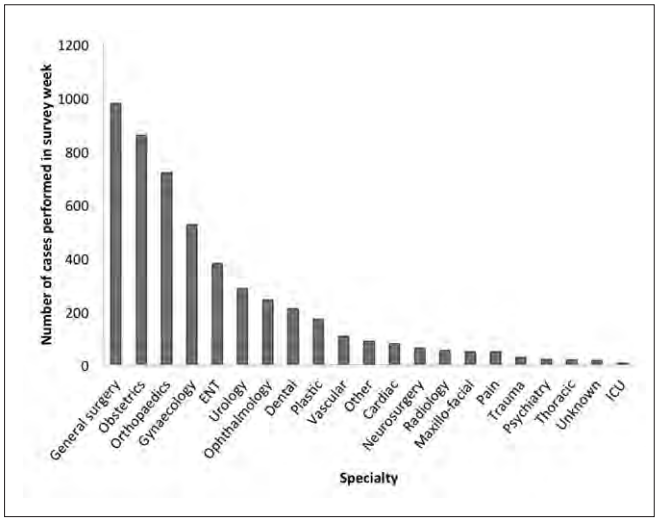
Figure 29.2. Number of cases performed in each of the public hospitals. (Mean=blue, median=red)



Patient characteristics

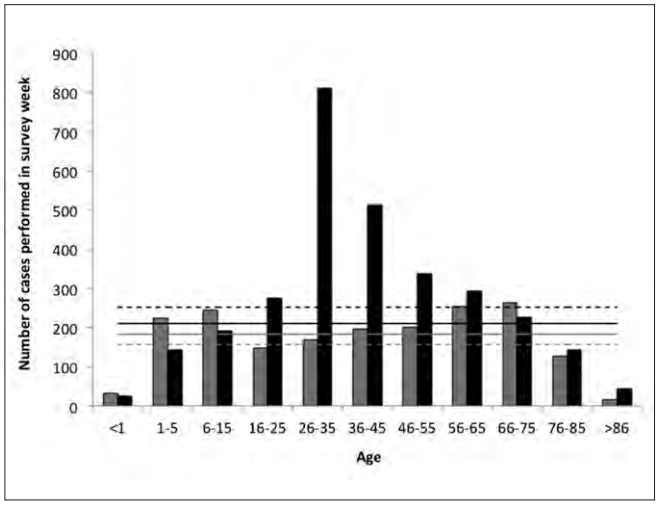
29.16 More than 60% (3,081) of the procedures were in four specialties: general surgery (977, 20%), orthopaedic surgery (720, 15%), obstetric (858, 17%) and gynaecology (526, 11%) (Figure 29.3). The vast majority (98%) of obstetric cases performed nationally occurred in public hospitals. The number of procedures for non-surgical specialties (psychiatry, pain, radiology and others including gastroenterology) was 212 (4.3%).

Figure 29.3. Number of cases performed by specialty in public hospitals. Note that 'ICU' refers to procedures with anaesthetic intervention undertaken in ICU (and not simply patients managed in ICU during survey period)



29.17 Figure 29.4 demonstrates the distribution of cases by age and gender. More women underwent a procedure (3,011, 61%) than men (1,884, 38%; with some unknowns). Obstetric procedures accounted for the majority of procedures performed in younger females: 50% in the age group 16–25 years and 67% in the age group 26–35 years. For men, there was a slight preponderance of elderly patients undergoing procedures (Figure 29.4). The median age of both women and men undergoing procedures in public hospitals was 36–45 years.

Figure 29.4. The number of cases by age and gender in public hospitals. Male (grey) and female (black). Mean number of cases per gender=dashed line, median number of cases per gender = continuous line



29.18 Table 29.1 demonstrates the ASA physical status and NCEPOD classification of cases: 2,990 (60%) were Elective, notably Immediate and Urgent together constituted >25% of the activity. This broadly matches the admission categories (Table 29.2), which shows the majority of admissions are Day-Cases (admissions on day of procedure with a plan to discharge on the same day), Same-Day admissions (admission on the day of the procedure with discharge the following day) and Elective admissions (planned admission on the day(s) before the procedure). Unplanned admissions (i.e. Emergency or Other, including inter-hospital transfer) accounted for one fifth of cases (991, 20%).

Table 29.2. Admission categories in Public hospitals. Values are number (proportion). *to the nearest 100

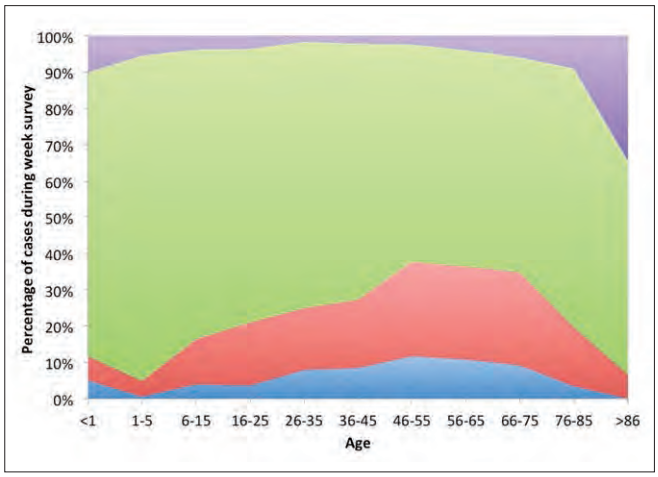
Admission type	Number of cases performed in survey week	Estimated total per annum*
Day Case	1,995 (40.3%)	105,700
Same Day	1,180 (23.8%)	62,500
Elective	752 (15.2%)	39,900
Emergency	839 (17%)	44,500
Other	152 (3.1%)	8,000
Unknown	31 (0.6%)	1,600
Total	**4,949**	**262,300**

Table 29.1 Number of cases in each ASA physical status category and NCEPOD classification of priority of surgery collected during the survey in public hospitals. Values are number (percentage). *To the nearest 100

	Immediate	Urgent	Expedited	Elective	Unknown	Total	Estimated total per annum*
ASA 1	91	622	239	1,386	79	2,417 (48.8%)	128,100
ASA 2	50	311	189	1,212	22	1,784 (36%)	94,500
ASA 3	22	134	99	364	7	626 (12.6%)	33,200
ASA 4	12	24	5	4	3	48 (1%)	2,500
ASA 5	5	4	0	0	0	9 (0.2%)	500
ASA 6	1	0	1	0	0	2 (0.04%)	100
ASA Unknown	2	15	7	24	15	63 (1.3%)	3,300
Total	183 (3.7%)	1,110 (22.4%)	540 (10.9%)	2,990 (60.4%)	126 (2.6%)	4,949	262,300
Estimated total per annum*	9,700	58,800	28,600	158,500	6,678	262,300	

29.19 Body habitus was reported in 4,893 (99%) patients. The distribution of body habitus between the different age groups is illustrated in Figure 29.5. More than a quarter of patients were overweight (905, 18.3%) or obese (350, 7.1%). Nearly a third of patients aged 46–75 were classified as being overweight or obese, contrasting with 33.9% of patients aged >86 years who were classified as being underweight. No patient aged >86 years of age was classified as obese.

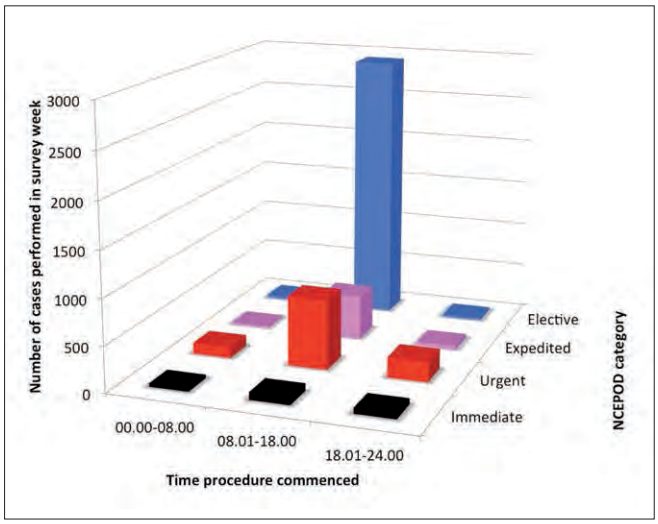
Figure 29.5. Body habitus in each of the age categories for public hospitals. Underweight (purple), normal (green), overweight (red) and obese (blue)



Time of procedure

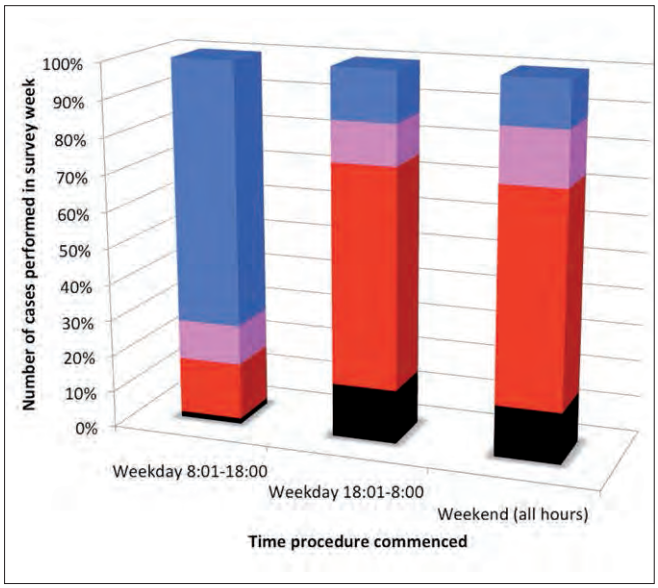
29.20 Almost all (98%) elective procedures commenced during normal working hours of 08:01–18:00 (Figure 29.6). Approximately one in eight (590, 12%) of all the procedures commenced after hours (i.e. between 18:01 and 08:00) consisting of mainly Urgent (343, 58%) and Immediate (100, 17%) NCEPOD category cases.

Figure 29.6. Start time of procedure in Public hospitals by NCEPOD classification of priority of surgery



29.21 Most (4,512, 91%) of cases occurred on a weekday and only 425 (9%) at the weekend. However, 861 (17%) of all cases started during 'non-routine' working hours (i.e. Monday to Friday 18:01 to 08:00 and all hours on the weekend). Figure 29.7 illustrates the proportion of NCEPOD categories for the procedures that occurred during routine and non-routine hours.

Figure 29.7 Time of start of procedure vs NCEPOD category. Routine (weekday 8:01–18:00) and non-routine hours (weekday 18:01–8:00 and all hours on weekend) in public hospitals. Immediate (black), Urgent (red), Expedited (pink) and Elective (blue)



Staffing

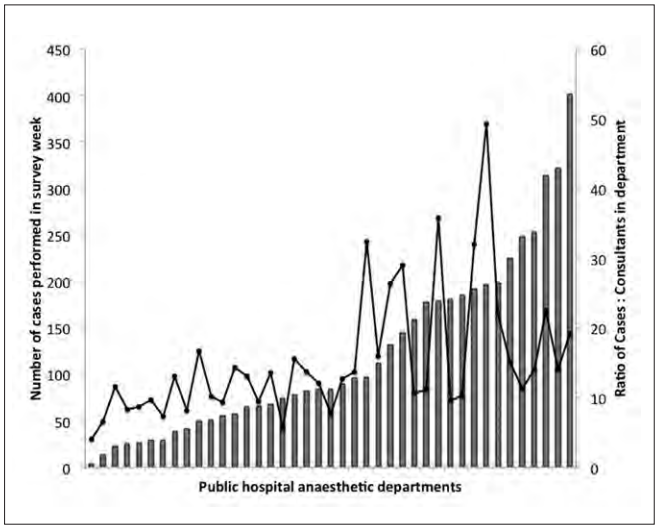
29.22 The most senior anaesthetist present during the procedure was recorded in >99% of cases, and this is presented in Table 29.3. A consultant was the most senior anaesthetist present during the procedure in 3,729 (75.3%) cases: 83.5% (3,390) of procedures that occurred during routine and 38.4% (331) of procedures during non-routine hours. Of the 1,190 (24%) NCHD-led cases, 526 (44.2%) occurred during non-routine hours. Nearly a third (364) involved procedures for labour analgesia on the delivery ward, with this split approximately equally between routine (169, 46.4%) and non-routine (186, 51.1%) hours.

Table 29.3. The most senior anaesthetist present during procedure in Public hospitals. Values are number (%). *To the nearest 100

Staff level		Total during survey	Estimated total per annum*
Consultant	Permanent	3,557 (71.9%)	188,500
	Locum	172 (3.5%)	9,100
NCHD= Non-Consultant Hospital Doctor	Post CST registrar	44 (0.9%)	2,300
	Specialist Registrar Year 4-5	147 (3%)	7,800
	Specialist Registrar Year 1-3	212 (4.3%)	11,200
	Registrar	621 (12.6%)	32,900
	Senior House Officer	156 (3.2%)	8,300
	Specialist Anaesthesia Trainee	10 (0.2%)	500
Other		4 (0.1%)	200
Unknown		26 (0.5%)	1,400
Total		**4,949**	**262,300**

29.23 Figure 29.8 illustrates how anaesthetic activity per consultant anaesthetist per week varied widely across anaesthetics departments (median (IQR) [range]) = 13 (10 –16) [4 – 49]).

Figure 29.8. The number of cases performed by each of the 43 public hospital anaesthetics departments (x-axis), plotted from smallest to largest value (bars; read from left y-axis), and the corresponding ratio of cases performed during survey per consultant in that department (black line; read from right y-axis)



Anaesthetic conduct

29.24 More than one third (1,847, 37%) of patients had their first pre-operative anaesthetic assessment on arrival in theatre (Figure 29.9), which is disproportionately high when compared to the number of emergency admissions (839, 17%). In contrast, more than half of the 753 (15.2%) patients who had their initial pre-operative anaesthetic assessment through a pre-operative assessment clinic (PAC) underwent day case admission and most were ASA 1-3 (Figure 29.10).

Figure 29.9. Location of initial pre-operative anaesthetic assessment in Public hospitals for the different admission categories

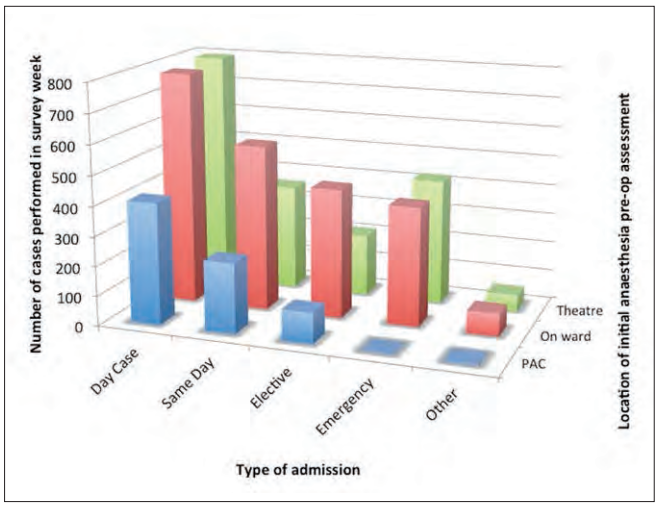
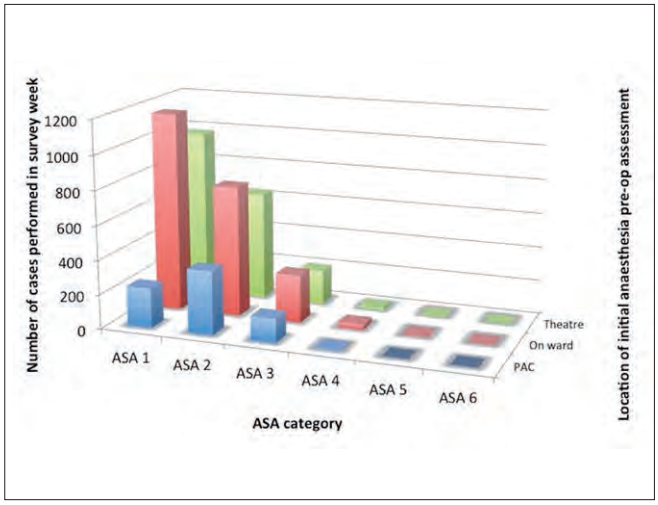


Figure 29.10. Location of pre-operative anaesthetic assessment in Public hospitals for different ASA physical status categories



29.25 Most (4,301, 87%) of the anaesthetic activity occurred in theatre with the remaining activity distributed in the following 'out-of theatre' locations: delivery ward (439, 9%), radiology (71, 1%), cardiology catheterisation lab (17, 0.3%), other (92, 2%) or unknown/undisclosed (29, 0.6%) locations.

29.26 General anaesthesia was administered to 3,527 patients in the public hospitals accounting for 71.3% of anaesthetic activity (annual estimate 187,000). Regional anaesthesia was the primary anaesthetic in 1,143 (23.1%) cases and combined with general anaesthesia in a further 415 (11.8% of general anaesthesia) cases. Sedation, local anaesthesia and monitored anaesthesia care accounted for 138 (2.8%, annual estimate 7,300), 75 (1.5%, annual estimate 4,000) and 66 (1.3%, annual estimate 3,500) cases respectively.

29.27 Table 29.4 demonstrates the breakdown of the most commonly used airway devices as well as techniques used during general anaesthesia. Including the cases not displayed in 29.4 (i.e. those with less frequently used airway devices), volatile agents were used for 3,388 (96.1%) cases, total intravenous anaesthesia (TIVA) for 88 (2.8 %) cases and target controlled infusion (TCI) for 84 (2.4%) cases. Nitrous oxide was administered for 793 (22.5%) cases. In 1,493 (42.3%) cases, a neuromuscular blocking drug (NMB) was administered. Specific DOA monitoring was used in the majority (38, 82.5%) of the public hospitals but in only a minority, 320 (9%) of the patients that received general anaesthesia. DOA monitoring was more prevalent when NMB was employed (~14% of patients with NMB) than when not used (~4% of patients with no NMB), and when TIVA was used: ~24% versus ~9% during volatile anaesthesia. Regional anaesthesia techniques combined with general anaesthesia were: epidural in 101 (2.9%) and peripheral nerve block in 314 (8.9%) cases. Out-of-theatre general anaesthetics comprised 134 (3.8%) cases.

Table 29.4. Most commonly used airway devices and associated techniques during general anaesthesia in public hospitals. Values are number (percentage). †Proportion of general anaesthesia cases. *Estimated total per annum to the nearest 100. Volatile= volatile anaesthetic agent, TIVA= total intravenous anaesthesia, NMB= neuromuscular blocking drug, DOA= depth of anaesthesia monitor

General Anaesthesia											
3,527 (71.3% of all cases) (187,000*)											
Tracheal tube 1,663 (47.2%†) (88,100*)				**Supraglottic airway device** 1,555 (44.1%†) (82,400*)				**Facemask** 240 (6.8%†) (12,700*)			
Volatile 1,629		TIVA 22		Volatile 1,525		TIVA 19		Volatile 186		TIVA 41	
NMB 1,323	No NMB 256	NMB 16	No NMB 6	NMB 79	No NMB 1,342	NMB 2	No NMB 17	NMB 21	No NMB 157	NMB 14	No NMB 27
DOA 181	DOA 7	DOA 6	DOA 0	DOA 8	DOA 57	DOA 2	DOA 2	DOA 6	DOA 4	DOA 0	DOA 0

29.28 Regional anaesthesia was the primary type of anaesthetic in 1,143 (23.1%) cases. Table 29.5 demonstrates the different regional techniques used. Regional anaesthesia for labour analgesia was provided in 434 (8.8% of all anaesthesia cases and 38% of regional anaesthesia cases) and for surgery in 709 (14.3% of all anaesthesia cases and 62% of regional anaesthesia cases) cases. Epidural and spinal anaesthesia were equally prevalent (each 508, 10.3% of all anaesthesia cases and 44.4% of regional anaesthesia cases), with combined spinal epidural techniques less so (17, 0.3% of all anaesthesia cases and 1.5% of regional anaesthesia cases).

29.29 Blood transfusions were administered to 107 (2.2%) patients while undergoing a procedure; in 39 (36% of transfusions) this was unplanned.

Post-operative care

29.30 The location of post-operative care after discharge from recovery or post-anaesthesia care unit was as follows: day-ward 1,825 (36.9%), ward 2,678, (54.11%), high-dependency unit 139 (2.8%), intensive-care unit 112 (2.3%) and unknown in 192 (3.9%). Two patients died before transfer from the theatre complex (excluding the two cases of organ retrieval). Twenty (0.4%) patients during the survey received post-operative care in a high-dependency or intensive-care unit that was not planned prior to the procedure. Nearly three-quarters (40, 70.2%) of the 57 ASA 4 and ASA 5 patients undergoing surgery were admitted to a high-dependency or intensive-care unit post-operatively.

DISCUSSION

29.31 This is the first comprehensive survey of anaesthetic activity in Ireland. The voluntary participation of all the nation's public hospitals and all but one of the independent hospitals reflects their interest and commitment to audit and research. The very high response rate is likely due to a user-friendly form designed to collect a minimum essential dataset. A more detailed form might have provided more information but at the likely cost of a lower response rate.

29.32 Activity rates vary widely across the Irish hospitals, both in terms of total caseload (range 4 – 402 cases per week) and caseload per consultant (range 4 – 49 cases a week per consultant in public anaesthetic departments). Notwithstanding case complexity handled by individual hospitals, it seems reasonable that the feasibility of the smaller units is currently under review by the government's hospital reconfiguration plan (Reilly, 2013).

29.33 With an estimated population of 4,588,252 in the 2011 census (Central Statistics Office, 2011), our data suggest an annual incidence of ~9.3 anaesthetic procedures per 100 population and ~6.5 general anaesthetics per 100 population across public and independent hospitals. This is slightly higher than the 5-5.4 general anaesthetics per 100 population estimated during the NAP4 UK snapshot by Woodall and Cook (2011).

29.34 The public hospitals in Ireland use a Hospital In-Patient Enquiry (HIPE) database to collect data regarding hospital attendance. Unfortunately anaesthesia-related information is captured retrospectively by administrative staff and is limited to ASA physical status and type of anaesthetic (labour analgesia, general anaesthesia, regional anaesthesia or sedation). Our methods were more robust as the primary care providers (i.e. anaesthetists) entered data contemporaneously at the point of care. Of note: the total number of general anaesthetics obtained from HIPE dataset for 2012 (175,961) was approximately 10% less than the estimated total from this survey.

29.5 Techniques used where regional anaesthesia was the primary type of anaesthetic in public hospitals (including obstetric epidurals). Values are number (percentage). †Proportion of regional anaesthesia cases. *Annual estimate to the nearest 100

Regional Anaesthesia 1,143 (23.1% of all cases) (60,600*)						
Epidural	**Spinal**	**Peripheral nerve block (PNB)**	**Combined Spinal and PNB**	**Combined spinal epidural**	**Combined Epidural and PNB**	**Unknown**
508 (44.4%†)	508 (44.4%†)	64 (5.6%†)	30 (2.6%†)	17 (1.5%†)	1 (<0.1%†)	15 (1.3%†)
27,000*	27,000*	3,400*	1,600*	900*	100*	800*

29.35 We considered a number of methods for calculating a scaling factor to derive an annual estimate of anaesthetic activity from our weeklong survey. One method was to use the HIPE data for 2012 and divide it by the number of general anaesthesia cases in public hospitals we obtained for the week, taking into account our overall error of ~4%. This gave us: (175,961 / 3,527) x 1.04 = 51.89. This resulted in our lowest multiplication factor, giving an estimated total of 8,049 x 51.89 = 417,662 cases nationally. This method was rejected because no comparable national data are available for the independent hospitals. Another method was simply to use the number of days in 2012 and divide by the seven days of survey, i.e. 366 / 7 = 52.29) then factoring in the ~4% error rate. This resulted in our highest multiplication factor (i.e. 52.29 x 1.04 = 54.38) giving an estimated total of 8049 x 54.38 = 437,704 cases nationally. However, we also rejected this method as it treats all weeks as identical and makes no adjustment for public/bank holidays. Our method more precisely multiplied the relevant activities by the number of weekdays/weekend days, counting bank holidays as the latter.

29.36 More than a third (3,100; 39%) of procedures took place in the independent hospitals (94% of which were for elective surgery), reflecting the greater private sector contribution to elective surgical services in Ireland as compared with other countries such as the UK (where non-NHS surgical activity accounts for just ~10% of the workload (Laing's Healthcare Market Review, 2012–13). The previously unknown anaesthesia workload division between public and independent hospitals made a national survey highly relevant and informative and may assist in future healthcare planning and audit. Difficult economic circumstances have resulted in a decline in private health insurance holders in Ireland from 50.9% to 45.8% in the period 2008 to 2012 (Health Insurance Authority, 2013). This decrease in membership has directly affected the public hospitals with a 9% decline in the number of private patients discharged from public hospitals and a corresponding increase in public patient discharges. The continued increase in health insurance premiums will most likely increase the reliance on public healthcare.

29.37 In terms of the delivery of healthcare in the public and independent sectors it is notable that all but 2% of anaesthesia interventions for obstetric care take place in the public sector. The single independent hospital that undertook obstetric cases has since closed. A slight majority of anaesthetic interventions for pain management, ophthalmology, urology and neurosurgery take place in the independent hospitals. Independent hospitals and their patients' are far more likely to be admitted for elective procedures (98% vs 79%), less likely to experience emergency admissions (1.4% vs 17%) and undergo far fewer NCEPOD urgent or emergency procedures. Independent hospitals perform proportionately fewer procedures out of hours (6% vs 12%) of which a larger proportion is elective (79% vs 11%). Although the proportion of patients with ASA1-2 physical status differs very little between locations (both ~85%) the public hospitals do the majority (57, 82%) of patients classified as ASA 4-5 nationally. Independent hospitals, patients undergoing anaesthesia interventions are generally older than those in public hospitals (median ages 46-55 and 36-45 years respectively). General anaesthesia in independent hospitals more often, than in public hospitals, involves use of a supraglottic airway device (57.6% vs 44.1%), and less frequently a tracheal tube (33.1% vs 47.2%). TIVA is used slightly more frequently in Independent hospital anaesthesia (5% vs 2.8%) and NMB slightly less frequently (36% vs 42%). independent hospitals perform a much smaller proportion of cases under regional anaesthesia alone (8.4% vs 23.1%), and regional anaestheia is used less overall (15.9% vs 34.9%). When regional anaesthesia is used, epidurals and spinals respectively form a smaller and higher proportion of regional anaesthetic techniques performed there. In independent hospitals anaesthetist workload includes sedation and monitored anaesthesia care more often than in public hospitals (15.5% vs 2.8% of cases).

29.38 It is of concern that so many patients are seen for the first time by an anaesthetist only after they arrive in theatre (50% in independent hospitals and 37% in public hospitals), despite clear guidance that pre-operative evaluation must be performed earlier (AAGBI, 2010). Although evidence regarding the effect of the timing of the pre-operative anaesthetic assessment on patient outcome is not established, identification of inappropriate surgery, optimization of medical conditions and an environment for informed consent are really only possible before arrival in theatre. Furthermore, evaluation in a pre-operative clinic, days or weeks before surgery, is not a substitute for a pre-operative visit by the anaesthetist on the day of surgery. Specific research is needed to establish why anaesthetic practice in Ireland is deviating so much from established guidelines.

29.39 Some other data emerged that may be of interest to anaesthetists as a focus for further research. The overall rate of TIVA seems very low in Ireland, at just ~4% of all general anaesthesia cases (see Chapter 27 for UK). Yet, the highest use of TIVA was reported during facemask anaesthesia (17%). Perhaps this refers to the use of a technique employing intermittent boluses of intravenous agent like propofol, which respondents classed as 'TIVA'. The use of TIVA may have been underestimated, as the question regarding 'Anaesthesia agents used' (i.e. volatile agents, TIVA, TCI, Nitrous oxide and other), was potentially confusing as more than one option could be selected. If the TCI cases without volatile agents is included with TIVA, it only marginally increases TIVA usage to 4.6%.

29.40 The finding that specific DOA monitors were available in 82.5% of public hospitals during this survey correlates with the earlier findings from the NAP5-Ireland baseline survey (Chapter 28) that 80% of the public hospitals have access to DOA monitoring. Yet, this monitoring was used in only a minority (9%) of patients. The use of DOA monitors is much lower (4.8%) in the independent hospitals.

29.41 In conclusion, we undertook a survey of anaesthetic activity in Ireland. An estimated 187,000 general anaesthetics were performed in the public hospitals in 2012 and this was used to calculate the incidence of accidental awareness during general anaesthesia on completion of NAP5. The survey has provided important numerical information on anaesthetic activity and practices in both public and independent hospitals.

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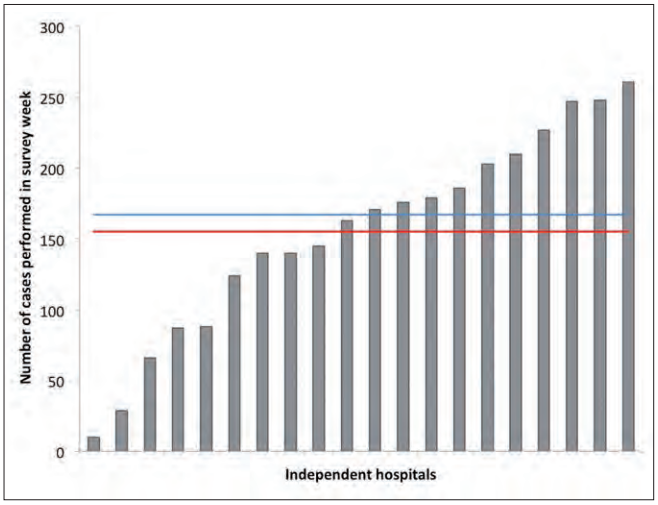
Irish independent hospital activity survey data

29.42 A total of 3,100 procedures took place in the 20 independent hospitals that participated in the anaesthetic activity survey in Ireland. After contacting the single independent hospital that did not take part it was apparent that activity was minimal so this has been approximated to zero.

Distribution of cases by location

29.43 Figure 29.A1 shows the distribution of cases across the 20 independent hospitals. The median number of cases per hospital captured during the survey was 167 (IQR 115–205, Range 10–261). During the one week survey the majority (15, 75%) of hospitals undertook >100 cases, with 6 (30%) hospitals performing >200 procedures. Only 4 (15%) of the Independent hospitals was affected by some theatre closure(s) during the survey period.

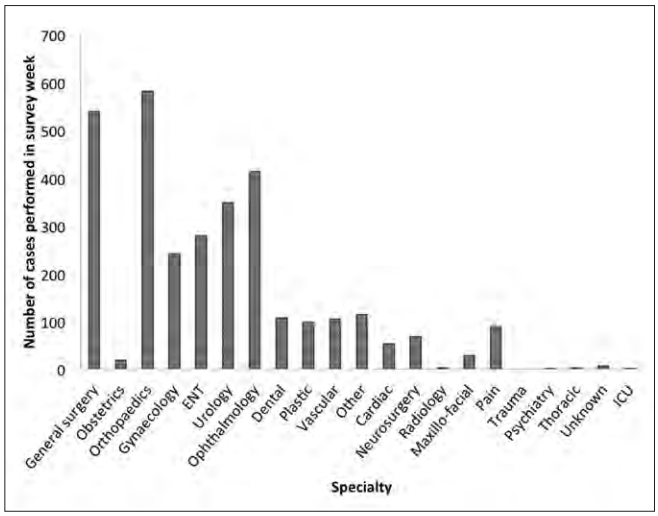
Figure 29.A1. Number of cases performed in each of the Independent hospitals. (Mean=red, median=blue).



Patient characteristics

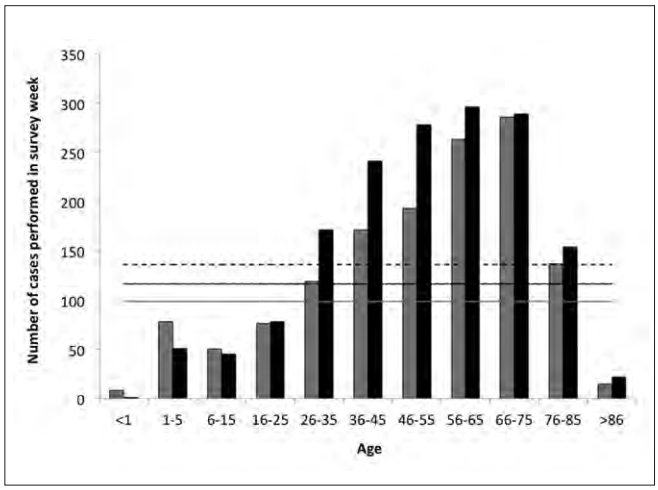
29.44 Figure 29.A2 shows the number of cases in each specialty performed during the AAS in same order as in Figure 29.3. In four specialties the number of procedures exceeded those performed in the public hospitals. These specialties were: Pain, Ophthalmology, Urology and Neurosurgery (64.9%, 63%, 55.1% and 51.5% of national activity respectively). In contrast, only 19 (2.2%) of the obstetric procedures performed nationally during the survey took place in the independent hospitals. The number of procedures for non-surgical specialties (psychiatry, pain, radiology and others including gastroenterology) was 206 (6.6% of independent hospital activity).

Figure 29.A2. Number of cases performed by specialty in independent hospitals. Note that 'ICU' refers to procedures with anaesthetic intervention undertaken in ICU (and not simply patients managed in ICU during survey period). Order on x-axis is same as in Figure 29.3



29.45 Figure 29.A3 demonstrates the distribution of cases by age and gender. More women underwent a procedure (1,634, 52.7%) than men (1,398, 45.1%). There was a slight preponderance of elderly patients undergoing procedures. The median age of women and men undergoing procedures in independent hospitals was 46–55 and 56–65 years respectively.

Figure 29.A3. The number of cases by age and gender in independent hospitals. Male (grey) and female (black). Mean number of cases per gender=dashed line, median number of cases per gender = continuous line



29.46 Table 29.A1 demonstrates the ASA physical status and NCEPOD classification of cases: 2,915 (94%) were Elective, while Immediate and Urgent cases constituted <2.5% of activity. This broadly matches the admission categories (Table 29.A2), which shows the majority of admissions were Day-Cases, Same-Day admissions and Elective admissions. Unplanned admissions (i.e. Emergency or Other, including inter-hospital transfer) were extremely rare (<2%).

Table 29.A2 Admission categories in Independent hospitals. Values are number (proportion). *To the nearest 100

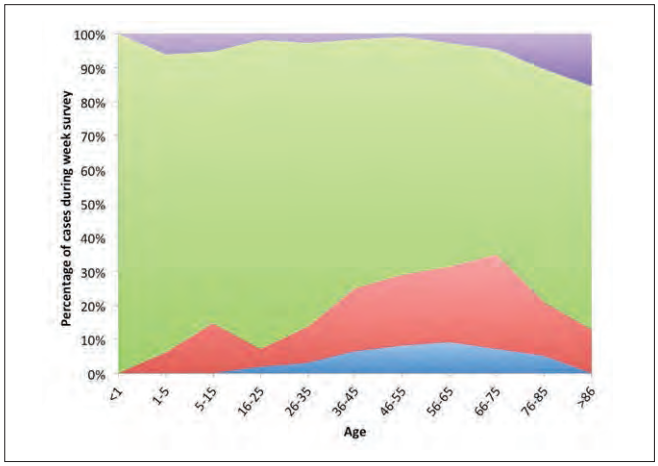
Admission type	Number of cases performed in survey week	Estimated total per annum*
Day-Case	2,093 (67.5%)	111,000
Same-Day	549 (17.7%)	29,100
Elective	390 (12.6%)	20,700
Emergency	44 (1.4%)	2300
Other	18 (0.6%)	1000
Unknown	6 (0.2%)	300
Total	**3,100**	**164,300**

Table 29.A1. Number of cases in each ASA physical status category and NCEPOD classification of priority of surgery collected during the survey in independent hospitals. Values are number (percentage). *To the nearest 100

	Immediate	Urgent	Expedited	Elective	Unknown	Total	Estimated total per annum*
ASA 1	3	23	24	1,316	18	1,384 (44.6%)	73,400
ASA 2	1	20	28	1,252	17	1,318 (42.5%)	69,900
ASA 3	0	24	16	303	3	346 (11.3%)	18,300
ASA 4	0	1	2	8	0	11 (0.4%)	600
ASA 5	0	0	0	1	0	1 (<0.1%)	53
ASA Unknown	0	0	1	35	4	40 (1.3%)	2,100
Total	4 (0.1%)	68 (2.2%)	71 (2.3%)	2,915 (94%)	42 (1.4%)	3,100	**164,300**
Estimated total per annum*	200	3,600	3,800	154,500	2,200	**164,300**	

29.47 Body habitus was reported in 3,068 (99%) patients. The distribution of body habitus between the different age groups is illustrated in Figure 29.A4. Nearly a quarter of patients were overweight (580, 18.7%) or obese (185, 6%). Nearly a third of patients aged 46–75 were overweight or obese, contrasting with 15.4% of patients aged >86 years who were underweight.

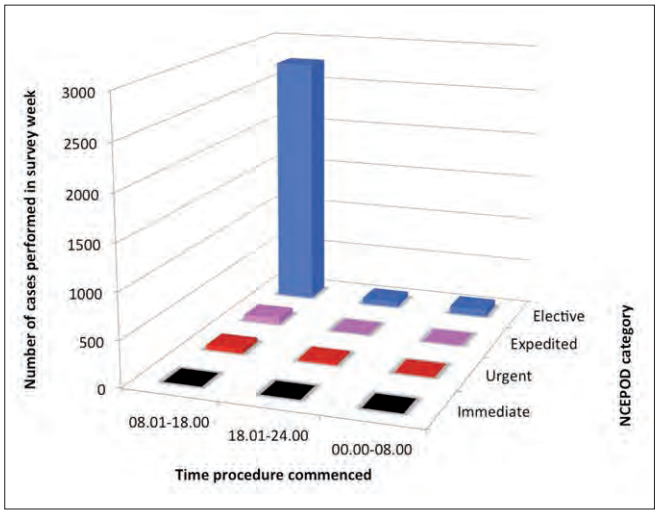
Figure 29.A4. Body habitus in each of the age categories for Independent hospitals. Underweight (purple), normal (green), overweight (red) and obese (blue)



Time of procedure

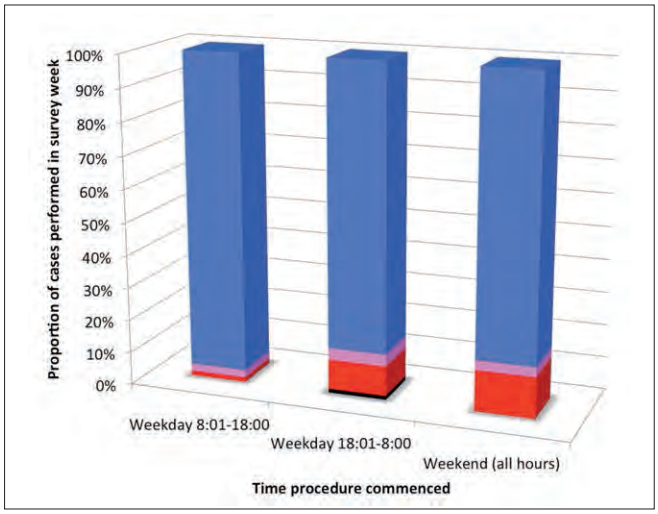
29.48 Almost all (93.8%) elective procedures commenced during normal working hours of 08:01–18:00 (Figure 29.A5). Approximately one in 18 (179, 5.7%) of all the procedures commenced after hours (i.e. between 18:01 and 08:00) consisting of mainly 'Elective' (142, 79.3%) NCEPOD category cases. Start time of cases, outside routine hours, was split evenly between 18:01–00.00 and 00:01–08:00 which likely reflects an earlier start and later finish time of routine lists in independent hospitals.

Figure 29.A5. Start time of procedure in Independent hospitals by National Confidential Enquiry into Patient Outcome and Death (NCEPOD) classification of priority of surgery



29.49 Most (2,990, 96.5%) of cases occurred on a weekday and 103 (3.3%) at the weekend. However, 268 (8.6%) of all cases started outside routine working hours (i.e. Monday to Friday 18:01 to 08:00 and all hours on the weekend). Figure 29.A6 illustrates the proportion of NCEPOD categories for the procedures that occurred during routine and non-routine hours.

Figure 29.A6. Time of start of procedure vs NCEPOD category. (weekday 08:01–18:00) and non-routine hours. Routine weekday 18:01–08:00 and all hours at weekend) in independent hospitals. Immediate (black), Urgent (red), Expedited (pink) and Elective (blue)



Staffing

29.50 The most senior anaesthetist present during the procedure was recorded in >99% of cases, and in 99.1% of cases a consultant anaesthetist was present (Table 29.A3). No data was collected regarding number of anaesthetic staff in the independent hospitals.

Table 29.A3. The most senior anaesthetist present during surgery in independent hospitals. Values are number (proportion). *To the nearest 100

Staff level		Total during survey	Estimated total per annum*
Consultant	Permanent	2,975 (96%)	157,700
	Locum	97 (3.1%)	5,100
Non-Consultant Hospital Doctor	Specialist Registrar Year 1–3	1 (<0.1%)	53
Unknown		27 (0.9%)	1,400
Total		**3,100**	**164,300**

Anaesthetic conduct

29.51 Half (1,555, 50.2%) of patients had their first pre-operative anaesthetic assessment on arrival in theatre (Figure 29.A7), which is disproportionately high as compared with the number of emergency

admissions (44, 1.4%). Nearly two-thirds of the 379 (12.2%) patients who had their initial pre-operative anaesthetic assessment through a pre-operative assessment clinic (PAC) were ASA 1 and 2 patients undergoing day-case admission (Figure 29.A8).

Figure 29.A7. Location of pre-operative anaesthetic assessment in independent hospitals for different types of admission

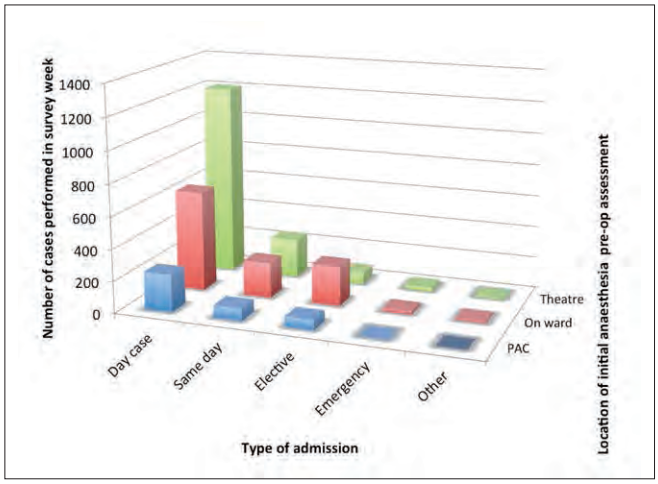
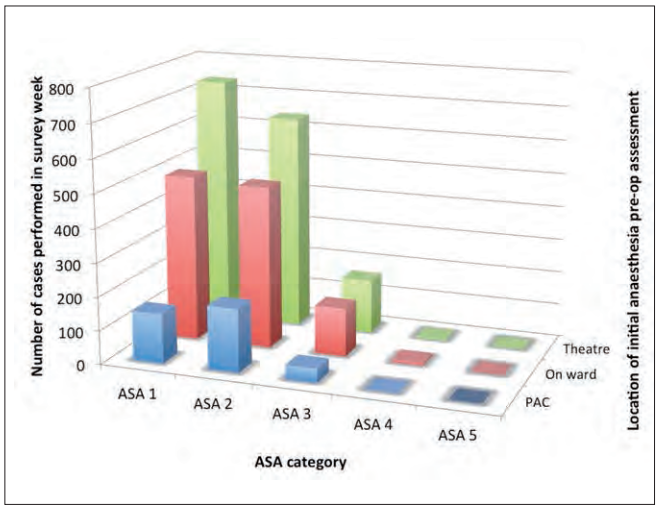


Figure 29.A8. Location of pre-operative anaesthetic assessment in independent hospitals for different ASA physical status categories



29.52 Most (2,801, 90.4%) of the anaesthetic activity occurred in theatre with the remaining activity distributed in the following 'out-of-theatre' locations: delivery ward (9, 0.3%), radiology (5, 0.2%), cardiology catheterisation lab (22, 0.7%), and in other or unknown locations (263, 8.5%).

29.53 General anaesthesia was administered to 2,094 patients in the independent hospitals, accounting for 67.6% of anaesthetic activity (annual estimate 111,000). Regional anaesthesia was the primary anaesthetic in 261 (8.4%) cases, and combined with general anaesthesia in a further 158 (7.5% of general anaesthesia) cases. Sedation, local anaesthesia and monitored anaesthesia care accounted for 480 (15.5%, annual estimate 25,400), 215 (6.9%, annual estimate 11,400) and 50 (1.6%, annual estimate 2,700) cases respectively.

29.54 Table 29.A4 demonstrates the breakdown of the most commonly used airway devices as well as techniques used during general anaesthesia. Including the cases not displayed in Table 29.A4 (i.e. those with less frequently used airway devices), volatile agents were used for 1,925 (92%) cases, total intravenous anaesthesia (TIVA) for 131 (6.3%) cases and target controlled infusion (TCI) for 50 (2.4%) cases (29 of which did not have concomitant use of volatile agents). Nitrous oxide was administered for 744 (35.5%) cases. In 749 (35.8%) cases a neuromuscular blocking drug (NMB) was administered. Specific depth of anaesthesia (DOA) monitoring was used in 9 (45%) of the independent hospitals, but in only a minority, (100 <5%) of the patients who received general anaesthesia. DOA monitoring was more prevalent when NMB was employed (~10% of patients with NMB) than when not used (just ~1% of patients with no NMB), but not when TIVA was used: 5% during volatile anaesthesia and <2% during TIVA. The technique

Table 29.A4. Most commonly used airway devices and associated techniques during general anaesthesia in independent hospitals. Values are number (percentage). †Proportion of general anaesthesia cases. *Estimated total per annum to the nearest 100.

General Anaesthesia 2,094 (67.5% of all cases) (111,000*)											
Tracheal tube 693 (33.1%†) (36,700*)				Supraglottic airway device 1,206 (57.6%†) (63,900*)				Facemask 140 (6.7%†) (7,400*)			
Volatile 688		TIVA 2		Volatile 1,185		TIVA 16		Volatile 44		TIVA 94	
NMB 563	No NMB 114	NMB 2	No NMB 0	NMB 168	No NMB 961	NMB 1	No NMB 15	NMB 7	No NMB 30	NMB 0	No NMB 91
DOA 77	DOA 0	DOA 0	DOA 0	DOA 2	DOA 14	DOA 0	DOA 0	DOA 0	DOA 0	DOA 0	DOA 2

used for regional anaesthesia when combined with general anaesthesia was an epidural in 12 (0.6%), spinal in 17 (0.8%) and peripheral nerve block in 129 (6.2%) cases. Out-of-theatre general anaesthetics comprised 55 (2.6%) cases.

29.55 Regional anaesthesia was the primary type of anaesthetic in 261 (8.4%) cases. Table 29.A5 demonstrates the different regional techniques used. Regional anaesthesia for labour analgesia was provided in 10 (0.3% of all anaesthesia cases and 3.8% of regional anaesthesia cases) and for surgery in 251 (8.1% of all anaesthesia cases and 96.2% of regional anaesthesia cases) cases. Spinal anaesthesia was the most frequently used technique 152 (4.9% of all anaesthesia cases and 58.2% of regional anaesthesia cases).

29.56 Blood transfusions were administered to 31 (1%) patients while undergoing a procedure; in 3 (10% of transfusions) this was unplanned.

Post-operative care

29.57 The location of post-operative care after discharge from recovery or post-anaesthesia care unit was as follows: day ward (2028, 65.4%), ward (957, 30.9%), high-dependency unit (41, 1.3%), intensive care unit (44, 1.4%) and unknown in 30 (1%). Only one patient during the survey received post-operative care in a high-dependency unit that was not planned prior to the procedure. Six (50%) of the 12 ASA 4 and ASA 5 patients undergoing surgery were admitted to an intensive care unit post-operatively.

29.A5. Techniques used where regional anaesthesia was the primary type of anaesthetic in independent hospitals (including obstetric epidurals). Values are number (percentage). †Proportion of regional anaesthesia cases. *Annual estimate to the nearest 100

Regional Anaesthesia 261 (8.4% of all cases) (13,800*)						
Epidural	**Spinal**	**Peripheral nerve block (PNB)**	**Combined Spinal and PNB**	**Combined spinal epidural**	**Combined Epidural and PNB**	**Unknown**
21 (8%†)	152 (58.2%†)	62 (23.8%†)	7 (2.7%†)	2 (0.8%†)	0 (0%†)	17 (6.5%†)
1,100*	8,100*	3,300*	400*	100*	0*	900*

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