5th National Audit Project (NAP5) on accidental awareness during general anaesthesia: patient experiences, human factors, sedation, consent, and medicolegal issues†‡


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Editor’s key points

- This paper addresses crucial aspects of accidental awareness during anaesthesia and its consequences.
- Importantly, it highlights that despite short duration of awareness, half of the patients suffer significant distress.
- The patient’s interpretation of what is happening at the time of the awareness seemed central to later impact.

Summary. The 5th National Audit Project (NAP5) of the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland into accidental awareness during general anaesthesia (AAGA) yielded data related to psychological aspects from the patient, and the anaesthetist, perspectives; patients’ experiences ranged from isolated auditory or tactile sensations to complete awareness. A striking finding was that 75% of experiences were for <5 min, yet 51% of patients [95% confidence interval (CI) 43–60%] experienced distress and 41% (95% CI 33–50%) suffered longer term adverse effect. Distress and longer term harm occurred across the full range of experiences but were particularly likely when the patient experienced paralysis (with or without pain). The patient’s interpretation of what is happening at the time of the awareness seemed central to later impact; explanation and reassurance during suspected AAGA or at the time of report seemed beneficial. Quality of care before the event was judged good in 26%, poor in 39%, and mixed in 31%. Three-quarters of cases of AAGA (75%) were judged preventable. In 12%, AAGA care was judged good and the episode not preventable. The contributory and human factors in the genesis of the majority of cases of AAGA included medication, patient, and education/training. The findings have implications for national guidance, institutional organization, and individual practice. The incidence of ‘accidental awareness’ during sedation (≏1:15 000) was similar to that during general anaesthesia (≏1:19 000). The project raises significant issues about

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Accompanying papers detail the method and results of the 5th National Audit Project (NAP5) of the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland. In this paper, we discuss the perspectives from the patient, the anaesthetist, and their interaction. While presenting novel data, this paper is in large part set in context of a review. First is an analysis of the patient experiences of accidental awareness during general anaesthesia (AAGA) with a view to providing guidance to mitigate adverse psychological impact. Next is an analysis of the human factors involved. Third is a very brief discussion of issues related to consent in relation to AAGA. Finally is a summary discussion of medico-legal issues that were raised by AAGA reports. One further set of data germane to this focus on personal perspectives is the group of patients who reported ‘AAGA’ but in fact who had undergone procedures under sedation. Their belief that they had received general anaesthesia—and had been accidentally aware—provides insight into many of the issues discussed. More details are available in the full report of the NAP5 (http://www.nationalauditprojects.org.uk/NAP5_home).

**Patient experiences and psychological consequences of AAGA**

AAGA can be terrifying, with experiences of hearing voices and equipment, vainly trying to move to alert staff, feeling anxious that something has gone wrong; powerlessness; or a fear that things will get worse. Compelling individual descriptions include: ‘I’m going to die’ or ‘...it is one of the worst scares I’ve had...’; seeing silhouettes; and auditory memories. Preoperative concern about AAGA causes anxiety: if the issue is not discussed as part of consent, the tendency to catastrophistic interpretation of the experience may be exacerbated. There are, however, also patients who experience AAGA but are relatively unconcerned by it.

**Anaesthesia and memory**

Anaesthetic drugs can directly abolish memory. Volunteer studies show that post-sedation recall is prevented by anaesthetic doses low enough to permit conversation and voluntary responses.

It is not known how long a stimulus has to be presented in order to be registered as a conscious perception, or if there is any relationship between the duration of consciousness and the likelihood of recall. Memory formation does not happen instantly the moment consciousness returns. Studies using the isolated forearm technique show that patients can respond to complex conditional command intraoperatively but have no explicit postoperative memory of events.

Questioning is therefore a test of memory, which is the basis of the Brice and colleagues interview. Studies using this methodology consistently report the incidence of AAGA as ~1–21000 but estimates still vary considerably from 1:100 to 1:4000. A brief discussion of memory types is relevant:

(i) explicit or declarative memory is that whose content can be articulated. Meaningful or well-organized material is easier to recall;

(ii) trauma memory is a type of explicit memory where the trauma is relived rather than just recalled. Normally, as encoded, memories are stripped of much of their sensory detail, so it is the general ‘gist’ that is recalled. High levels of distress can alter this process, leaving memories that are rich in sensory detail;

(iii) implicit memory is that revealed by experimental paradigms such as those based on responses to word associations but is not discussed further here;

(iv) false memory is also possible. We generally recall things by reconstructing rather than replaying a past event, with a risk of distortion. False memories can be created by inserting false information into the reconstruction process, especially when prompts or leading questions are used (e.g. adults shown fabricated photos of themselves enjoying a hot air balloon ride as children later falsely ‘remembered’ the event). Spontaneous reports of AAGA are, however, unlikely to be false memories because the detailed information to construct such a false memory is not provided. It is unknown, however, whether Brice interviewing ever induces false memories.

(v) source memory refers to recalling where, when, or how we did or learned something, and often fails: we might remember a remark but not who said it or when. In AAGA, the patient might recall intraoperative events but be unable to place when they occurred, compounded if a patient does not understand what is happening. In a compelling personal account, Aaen vividly describes how she forgot that she was having a Caesarean section and thought instead that she was being raped.

Memories of AAGA can emerge gradually. In Sandin and colleagues’ study, only six cases of AAGA were identified in

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**Keywords**: awareness; consent; patient experience; sedation

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the immediate post-anaesthesia care unit; a further five 7–14 days after surgery. This is not unique to AAGA.19 ‘Hypermnesia’ refers to how memories can be overwritten by later events and retrieval impaired until those later memories fade or become less salient.20 Repeated questioning may aid this process (e.g. as in Brice questioning).21

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.22 The relationship of memory and AAGA (or no AAGA) is summarized in Figure 1.

Post-traumatic stress disorder
AAGA can lead to post-traumatic stress disorder (PTSD),23 24 but it is not known in what proportion of patients this happens. In a review, Aceto and colleagues25 reported that an aggregate PTSD rate across a diverse mix of studies of ~15% (range 0–70%); the highest rate in a very small cohort of just five of seven patients.25 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 the incidence of PTSD between self-reported AAGA and that revealed after Brice interview.

Hospital admission, surgery, and anaesthesia can all involve adverse experiences. Avidan and colleagues (2014; personal communication, unpublished results), using a symptoms checklist rather than a formal diagnosis of PTSD, have found symptoms of postoperative PTSD in ~16% of elective surgery cases without awareness and 43% in matched cases with AAGA.

Psychological harm after AAGA is not confined to PTSD: clinical depression or complex phobias may also develop.26 An important element is that the person perceives a threat to their life, which depends on the patient’s understanding and interpretation of what is happening. Neuromuscular paralysis prevents the patient from moving (leading to ‘helplessness’) and can be influential in creating catastrophic interpretations of what is happening.

Psychological experiences and NAP5 results
The Michigan awareness scale27 and a modified National Patient Safety Agency (NPSA) scale1 formed the main tools of assessing psychological impact, along with the patient stories. The Panel applied the Wang scale to the reports, but it was not discriminatory for impact [all reports were grade 4 (65%) or grade 5 (35%)].1 28

Experiences reported to NAP5 in 141 certain/probable and possible reports included: 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%, and dreamlike experiences 5%. Patients reported between 0 (a report of simply ‘being awake’ with no further detail) and 8 of these experiences

Fig 1 General anaesthesia most commonly involves no AAGA and there is no explicit recall or adverse psychological outcome. 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. Recall of AAGA can lead to a neutral or adverse outcome.

AJA
Cook et al.
Although patients sometimes interpreted AAGA as a dream, there was only one assessable case (judged unlikely) where the patient seemed to interpret a vivid dream as AAGA.

During induction (n=59), paralysis (Michigan 4) and tactile and auditory sensations (Michigan 1 and 2) were common. During surgery (n=43), pain with paralysis (Michigan 5) was the most common, followed by paralysis alone (Michigan 4). At emergence (n=23), paralysis was the most striking symptom (Michigan 4; Fig. 2).

About half the reports (47%, 65 of 138 cases with known Michigan scores) were judged not to be associated with distress, including some cases where the patient experienced pain and paralysis. Such neutral reports included a small minority with ‘positive’ aspects where the patient felt thankful for the efforts of staff. The proportion of patients judged to have experienced distress at the time of the AAGA increased with increasing Michigan score (Fig. 3): distress was most common when paralysis was present (61%) or when pain and paralysis were experienced together, 17 of 22 (77%). 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 (3%) specifically mentioned that they feared they were going to die. Two patients thought they were actually dead at the time of the intraoperative awareness episode because of the experience of paralysis.

Overall, 41% of cases were judged to have moderate-to-severe longer term harm and this was more common in patients experiencing paralysis, pain, or both: 51% of these patients reported moderate-to-severe harm compared with 25% of those reporting only auditory or tactile sensations (Fig. 4). There appeared no clear relationship between the experience (classed by Michigan scale) with the longer term impact (judged by the modified NPSA scale), with considerable heterogeneity (Fig. 4). Thus, it was not the case that a particular type of experience (e.g. tactile vs pain) invariably led to a more or less adverse longer term outcome.

Rather, it was distress during AAGA that was strongly associated with longer term sequelae (Fig. 4). Fifty-five of 70 (79%) patients reporting distress had moderate-to-severe longer term impact, compared with only two of 68 (3%) of patients without distress during AAGA, giving an odds ratio of developing longer term sequelae after distress during AAGA of 121. Distress appeared influential on the longer term impact, for any given sensory experience: that is, the interpretation of the experience as one causing distress seemed more impactful than the type of sensations experienced. Severe reactions to the episode of AAGA were characterized 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.

In contrast, 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. Some patients were reported to have become angry or upset by an apparently unsupportive reaction by staff and in some cases, this created greater unhappiness than the actual experience. 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.

The incidence of distress and of the classifications Wang Class 5 and NPSA severe were all higher in the cases of AAGA because of drug errors than in the certain/probable and possible cases. In this group, who experienced awake paralysis without any anaesthesia, 65% experienced distress during the episode and 41% severe longer term sequelae.

The majority of AAGA experiences were brief; in 75% of cases, the patient’s perception of duration of experience was <5 min (Fig. 5). There was no clear association between duration and perceived distress of AAGA; that is, it was not the case that the longer the perceived experience, the greater the distress, across any of the Michigan scores (Fig. 6a). There also was no clear relationship between the perceived duration of AAGA and longer term psychological impact. Brief experiences could be severely distressing (Fig. 6b).

For certain/probable and possible AAGA reports, the most common time to report AAGA was on the day it occurred (34% of reports) with 52% of reports made within a week of surgery. There were also some very long delays in reporting, with one-quarter of cases reported after a year or more (35 of 141 cases). The median time interval for reporting AAGA was 7 [0–364 (0–16 439)] days. Reasons for delay were generally not given, although one patient reported being reluctant to report the incident earlier because of fear of ridicule and not wanting to re-live the incident. 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) (Fig. 7a) or between reporting delay and longer term sequelae (Fig. 7b). So, it did not appear that those patients who delayed reporting did so because of excessive distress.
Summary and conclusions to patient experience

NAP5 has shown that while a substantial number of reports of AAGA are neutral and not associated with longer term sequelae, almost half are associated with distress at the time of the event and a similar number lead to moderate or severe longer term consequences. These consequences include symptoms of PTSD. Features associated strongly with longer term sequelae were a sensation of paralysis during the experience and distress, which were themselves linked. However, even brief experiences of AAGA, without these features can cause longer term sequelae.

The NAP5 Baseline Surveys for both the UK and Ireland confirmed a dearth of policies in hospitals designed to deal with the aftermath of a report of AAGA. To address this, we propose a clear step-by-step guide to support a patient making such a report (Appendix), and further research to assess its utility.

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. An experience of paralysis was important in this respect—more so than pain—in causing patient distress. Conversely, understanding what was happening seemed to be protective. Hearing staff explain the problem while it was happening appeared helpful. Consistent with this conclusion, paralysis in informed volunteers need not be distressing if it is expected and understood, although associated sensations of being unable to breathe do tend to cause distress. 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.

There were occasional descriptions of disembodied experiences that may be interpreted as consistent with several proposals made in the anaesthetic literature on states of mind variously termed ‘cognitive unbinding’, ‘disconnectedness’, or ‘dysanaesthesia’. Or, these may reflect the sensation of paralysis or mis-interpretations by patients of their unusual experiences as dreams. Reports of perioperative dreaming vary considerably from 6% to 50%. These suggestions are amenable to further research.

All reports of AAGA should be treated seriously, even when sparse or delayed, as they may have, or have had, serious psychological impact. Healthcare or managerial staff receiving a report of AAGA should (i) inform the anaesthetist who provided the care; (ii) institute the NAP5 Awareness Support Pathway (or similar system; Appendix).

‘AAGA’ during sedation

Patients may interpret experiences during conscious sedation as AAGA. Of patients in the ASA Awareness Registry whose medical notes were examined, one-third had not received general anaesthesia and consequences were not trivial with ~75% patients distressed. Between 25% and 40% of these patients reported flashbacks, nightmares, anxiety and depression, and chronic fear.

A large number of authoritative and multidisciplinary reports on the management of sedation focus only on the safety and technical aspects of the process, with an inherent...
assumption that both practitioners and patients know what sedation is. They do not address the issues of consent and explanation. Thus, in these reports, sedation is defined by its outcome from the sedationist’s perspective, rather than as the actual state of mind the patient might find themselves in. For a patient, ‘responding to verbal stimulation’ could encompass a wide range of mental states, some of which are unacceptable for surgery. Furthermore, because analgesia is an important goal, patients frequently misunderstand what sedation is and many want to be completely unaware without pain or recall. From the patient’s perspective, the distinction between sedation and general anaesthesia is ambiguous.

Fig 6 (a) Boxplot for certain/probable and possible reports of duration of perceived AAGA by Michigan score: no distress (green bar) and distress (blue bar). Although the pooled durations are little meaningful, for all Michigan scores combined, the median duration for no distress was 60 [15–300 (3–10 800)] (outliers >4000 s not shown) and for distress was 180 [60–360 (5–3600)] s (NS). The vertical line within each box (generally obscured by the axis) is the median, the edges of the box the 25th and 75th centiles, the error bars the 90th centile (the 10th centile obscured by the axis), and dots are outliers. (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 (modest) relationships.
Sedation and NAP5 results

NAP5 received 32 reports of AAGA after intended sedation—equivalent to almost one-quarter of reports of AAGA after intended general anaesthesia. In 20 of these cases, care was provided by an anaesthetist. From the NAP5 Activity Survey, we estimate that there are ≏310 000 anaesthetist-administered cases of sedation per year. This yields an estimate for perceived AAGA during anaesthetist-administered sedation of ≏1:15 500, which is at least as common as certain/probable or possible AAGA reports after anaesthesia (≏1:19 000).2

All but one event arose during the ‘maintenance’ phase of the intervention and none at ‘induction’ (Fig. 8A). About two-thirds (61%) of experiences involved auditory and tactile sensations (i.e. Michigan scores 1 and 2) and about one-third (36%) of patients reported pain. About half the patients (15) reported distress, more so if pain was experienced (eight of the 15) with greater propensity to longer term impact (Fig. 8B). Of these patients, 46% developed moderate or severe longer term psychological sequelae: slightly more than in reports after intended general anaesthesia.
Miscommunication or lack of managed expectations was judged 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. 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.

Summary and conclusions to sedation

Failure to provide patients undergoing procedures under sedation with sufficient information such that they understand the nature of sedation can lead to reports of ‘AAGA’. These are associated with levels of distress and longer term sequelae that are very similar to AAGA after intended general anaesthesia. Prevention of these experiences is likely to depend on clearly communicated information that is provided in both written form and reinforced verbally at the time consent is
Human factors and AAGA

There has been an increasing acknowledgement that the safe delivery of healthcare is affected by the manner in which humans delivering it interact with their environment. Human factors (HF) are not the same as ‘human error’. ‘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’. Studies exploring the epidemiology of AAGA have commented on HF in up to 68% of adverse events, including failure to fill a vaporizer, administering neuromuscular block (NMB) before induction agent, inadequate drug doses, backflow of induction agent up a giving set, failure to administer extra anaesthetic agent during difficulty intubation, and allowing emergence from mislabelling, failure to mix drugs, omission of drugs or syringe swaps, delayed or omitted maintenance drugs, and inadequate dosage of induction agents because of errors of knowledge or judgement. Contributory factors included ampoule label design, errors of judgement or knowledge, difficult airway management and obesity, distraction by colleagues—talking, teaching, interruptions, etc.; distraction by unexpected difficulty—failed airways, failed vascular access, other unexpected patient complications, equipment failure; busy lists with multiple changes; tiredness; rushing; lack of clarity of roles in the anaesthetic room; the need for rapid sequence induction; lack of availability of extra drugs because of local; and junior trainees working unsupervised.

HF contributing to AAGA during induction included drug errors from mislabelling, failure to mix drugs, omission of drugs or syringe swaps, delayed or omitted maintenance drugs, and inadequate dosage of induction agents because of errors of knowledge or judgement. Contributory factors included ampoule label design, errors of judgement or knowledge, difficult airway management and obesity, distraction by colleagues—talking, teaching, interruptions, etc.; distraction by unexpected difficulty—failed airways, failed vascular access, other unexpected patient complications, equipment failure; busy lists with multiple changes; tiredness; rushing; lack of clarity of roles in the anaesthetic room; the need for rapid sequence induction; lack of availability of extra drugs because of local; and junior trainees working unsupervised.

HF contributing to AAGA during maintenance included under-dosing to maintain cardiovascular stability, under-dosing to lessen risk to a fetus, under-dosing because of

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**Table 1** NAP5 suggestion for describing sedation definitions from a patient’s perspective, as part of a process of consent

<table>
<thead>
<tr>
<th>What will this feel like?</th>
<th>What will I remember?</th>
<th>What is the risk related to the sedation drugs?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not sedated; awake</td>
<td>I am awake, possibly anxious. There may be some mild discomfort (depending on what I am having done)</td>
<td>Everything</td>
</tr>
<tr>
<td>Minimal sedation</td>
<td>I am awake and calm. There may be some mild or brief discomfort</td>
<td>Probably everything</td>
</tr>
<tr>
<td>Moderate sedation</td>
<td>I am sleepy and calm but remain in control. I may feel some mild discomfort</td>
<td>I might remember some things</td>
</tr>
<tr>
<td>Deep sedation</td>
<td>I am asleep. I will not be in control</td>
<td>Probably very little</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>I am deeply ‘asleep’ and unable to respond</td>
<td>Very unlikely to remember anything</td>
</tr>
</tbody>
</table>

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Taken. Information should emphasize that during sedation the patient is likely to be conscious, 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. Confirming that the information is understood by the patient is part of taking informed consent. We recommend adopting the terminology in Table 1, which provides descriptors of sedation from the patient’s perspective.

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**Human factors and NAP5 results**

We focus here on the 110 certain/probable reports to NAP5 as being the most robustly amenable to an HF analysis. Using the NPSA classification, all certain/probable reports were judged by the Panel to have contributory factors (median number of factors 3, range 1–7) with the most common being medication, patient, and education/training. AAGA was judged preventable in 73.6% of these reports. In only one in nine cases was care judged good and the AAGA not preventable, while in only one in 11 reports was no cause found for AAGA.

Miscommunication was judged the main contributory or causal factor in 81% of sedation reports. HF were identified by the reporter in 61% of certain/probable reports and their causes are listed in Table 2.

HF contributing to AAGA at induction included drug errors from mislabelling, failure to mix drugs, omission of drugs or syringe swaps, delayed or omitted maintenance drugs, and inadequate dosage of induction agents because of errors of knowledge or judgement. Contributory factors included ampoule label design, errors of judgement or knowledge, difficult airway management and obesity, distraction by colleagues—talking, teaching, interruptions, etc.; distraction by unexpected difficulty—failed airways, failed vascular access, other unexpected patient complications, equipment failure; busy lists with multiple changes; tiredness; rushing; lack of clarity of roles in the anaesthetic room; the need for rapid sequence induction; lack of availability of extra drugs because of local; and junior trainees working unsupervised.

HF contributing to AAGA during maintenance included under-dosing to maintain cardiovascular stability, under-dosing to lessen risk to a fetus, under-dosing because of
inattention or judgement errors, and termination of anaesthesia too soon before surgery had finished.

HF contributing to AAGA at emergence included 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 neuromuscular blocking agents; failure to monitor degree of residual NMB; or the effects of reversal agents.

When AAGA occurred, HF sometimes contributed to poor quality care during or afterwards, exacerbating the adverse experience (Table 3). Examples included incomplete communication to patients before operation about risks, especially when the risk was increased (e.g. difficult airway management anticipated, awake extubation planned, relative under-dosing planned because of 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, empathizing, believing, or apologizing when patients reported AAGA (by anaesthetists, nurses, and surgeons); poor documentation of anaesthetic conduct (including occasional factual inaccuracy).

| Table 2 NPSA classifications of patient safety incidents for 110 certain/probable (Class A) reports of AAGA in NAP5 |
| Factors | Contributory or causal (%) |
| Communication | 19/0/0 | 17.3 |
| Education and training | 58/6/1 | 58.2 |
| Equipment/resource factors | 33/4/0 | 33.6 |
| Medication | 66/2/0/0 | 78.2 |
| Organization 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 |

| Table 3 Quality of care assessment for 110 certain/probable (Class A) cases; n (%) |
| Quality of care | NAPS (%) |
| Good | 28 (25.5) |
| Mixed | 34 (30.9) |
| Poor | 43 (39.1) |
| Unassessable | 5 (4.5) |
| Preventable | 81 (73.6) |
| Quality of care good and not preventable | 13 (11.8) |
| No cause found | 10 (9.1) |

| Table 4 Assessment by reporters of HF in certain/probable (Class A) reports to NAP5; n=104 |
| 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) |
| Organization | 3 (2.9) |
| Decision-making | 2 (1.9) |
| Other | 11 (10.5) |
| None | 41 (39.0) |

Summary and conclusions to HF

The factors listed above and their potential solutions should be considered in investigation of AAGA events and particularly by organizations seeking to prevent drug errors leading to AAGA.

Organizational contributory factors were prominent in reports of AAGA to NAP5 and included (Table 4) staffing, theatre scheduling, busy disorganized lists, and communication [all ‘threats’ in the HF Investigation Tool (HFIT) model].45 These raised concerns over safety culture in some cases and indicate that AAGA should not simply be considered to be caused by human errors.

Rushing—whether caused by organizational or individual failings—was prominent in the genesis of some cases of AAGA. In the analysis of syringe swaps, recurring themes were mention of staff shortages, a pressured environment with ‘busy’ lists. Distractions during critical moments can have very serious consequences. Other anaesthetists and circulating nurses are the most common causes of distractions46 and distractions are most common during transfer into theatre and at emergence.2 In terms of individual conduct, it seemed that haste and a lack of vigilance may be contributory.

Checklists are a method to improve reliability of complex or time-sensitive tasks. The ABCDE checklist described in the accompanying paper should address the common problem of failure to maintain anaesthetic drug concentrations soon after induction or patient transfer.2 Technology (e.g. drug scanning systems) may reduce error/harm from HF but requires development, research, and investment. Alternative solutions such as national minimum standards for drug labelling (including a colour scheme as for drug labelling) might be equally effective in reducing errors.

Anaesthetists need to accept they are all prone to making errors and therefore, develop robust individual mechanisms to protect their patients, themselves, and their colleagues.

HF—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.
Consent in the context of AAGA

NAP5 has raised important issues regarding consent for both general anaesthesia and sedation. Space precludes full discussion of this in this summary paper and readers are referred to the full report for a more detailed analysis and discussion (http://www.nationalauditprojects.org.uk/NAP5_home).

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. Because anaesthesia is a separate intervention, it is logical that some form of separate consent for the anaesthetic is necessary, whether with or without separate written consent. While general principles and consent for anaesthesia have been discussed elsewhere, NAP5 raises two important questions regarding consent: (i) should patients be routinely warned of the risk of AAGA; (ii) what information about that risk should be provided, and how?

Consent and NAP5 results

General anaesthesia

Of the 136 cases of certain/probable and possible AAGA for which data were available, there was a clear record of consent in 60 (44%). There was evidence of a specific preoperative discussion of AAGA in only three (2%) cases. Specific warnings of AAGA did not appear to mitigate adverse psychological impact when AAGA occurred.

Sedation

Failure of the consent process was the main contributory factor in reports of ‘AAGA’ after sedation. It was notable that issues of consent for sedation can evolve into legal action.

Summary: consent for general anaesthesia in context of AAGA

Anaesthetists have a limited time during which to gain consent from patients and this means that the information discussed is inevitably selected in subject and depth. Patient information sheets can provide more comprehensive preoperative information, especially concerning AAGA. NAP5 has shed light on the nature of AAGA and can usefully be referred to in describing what patients might experience during AAGA. This includes the duration (usually very brief), timing (more often before or after surgery than during), likely sensations (touch or sound more than pain), the importance of paralysis (temporary), and the possibility of sequelae (fewer than half of cases).

In terms of quoting incidences of risk, anaesthetists now have several options. Anaesthetists might use statistics from NAP5 (see Table 2 of the accompanying paper) for example, an overall risk of ~1:19 000, ~1:8000 if NMB is used, or ~1:134 000 if not. Alternatively an anaesthetist may quote incidences derived from Brice interview studies (~1:600). Which incidence is quoted is dependent on the anaesthetist’s professional interpretation of the available evidence. Logically, whichever incidence is quoted, it should be qualified: if quoting NAP5, that the incidence relates to patient reports and if quoting Brice data, that this is based on structured repeated postoperative questioning.

Finally, consent might usefully also describe the manner in which the anaesthetist will attempt to mitigate the risk of effects of AAGA—such as the use of volatile monitoring, depth of anaesthesia monitors, or both.

Summary: consent for general anaesthesia in context of sedation

NAP5 has highlighted important areas for discussion around consent for both general anaesthesia and sedation. For the latter, Table 1 serves as a useful guide for appropriate terminology. The topics are discussed in considerably more detail in the full report (http://www.nationalauditprojects.org.uk/NAP5_home).

Medicolegal aspects of AAGA

NAP5 provides important information about complaint and litigation after reports of AAGA. Space precludes full discussion of this in this summary paper and readers are referred to the full report for a more detailed analysis and discussion.

It might be expected that AAGA would invariably lead to both complaints and litigation. An analysis of litigation claims handled by the NHS between 1995 and 2007 suggested that cases of AAGA and ‘awake paralysis’ accounted for 12% of all anaesthetic-related claims and >20% of all claims relating to general anaesthesia (~10 claims per year). These statistics do seem superficially at some odds with the proposal that the true incidence of AAGA is as high as ~1:600. Obstetric claims were perhaps over-represented, comprising 30% of the total. Although small in absolute numbers, a high proportion of AAGA cases (87%) were settled in favour of the claimant, with average cost to the NHS of ~£30 000.

Medicolegal aspects of NAP5 results

It is important not to draw too many medicolegal implications from the NAP5 results, since any standards applied when judging care as ‘good’ or ‘poor’ will not necessarily match those which would be considered appropriate by a court. NAP5 did not have access to the case records and relied only on detail provided by the Local Co-ordinator.

Of 141 certain/probable and possible cases, 14 (10%) submitted a formal complaint to the hospital and a further six (4%) were reported to be involved in some legal action. Of 17 drug error/syringe swap cases, 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.

Summary of medicolegal aspects of AAGA

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 one-fifth of cases resorted to complaint and only 4% to legal action.
AAGA might be considered to be a fundamental failure on the part of the anaesthetist to deliver the care that they have a duty to deliver. It might therefore be considered that a complaint or claim cannot be defended—or in legal terms ‘res ipsa loquitur’ (‘the thing speaks for itself’). However, NAPS provides much evidence as to why this argument should be resisted: AAGA may occur without any cause being found (perhaps because of intrinsic patient resistance to anaesthetic); there is no reliable form of monitoring which constitutes a standard of care; AAGA may be reported when there has been no general anaesthesia, and patients also report AAGA which on investigation is disproven. NAPS not only shows that each report of AAGA benefits from full investigation but also provides a methodology (categorization of type, evidence, and contributory factors) than could be used as a uniform model by organizations and courts investigating claims. All these aspects are discussed in greater detail in the full report.

Some causes of AAGA, notably accidental syringe swap, administration of the wrong drug, failure to turn on a vaporizer or to recognize that it is empty, and disconnection/‘tissuing’ of i.v. infusions of anaesthetic drugs, are likely to be indefensible.

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Declaration of interest

All conflicts of the NAP5 team have been registered at the NAP5 website http://www.nationalauditprojects.org.uk/NAP5_home. T.M.C. is an Advisor on National Audit Projects Royal College of Anaesthetists; J.J.P. is a Clinical Lead, NAP5; Scientific Officer of the Difficult Airway Society, and co-editor of Anaesthesia. T.M.C. and E.P.O’S serve on the Editorial Board of the British Journal of Anaesthesia. M.W. has received honoraria and travel expenses from Abbvie and Abbott pharmaceutical companies.

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Appendix

NAP5 Awareness Support Pathway for AAGA. Detailed notes on the application of the NAP5 support pathway are provided in the full NAP5 Report at http://www.nationalauditprojects.org.uk/NAP5_home.

- Face to face meeting with patient
  - Listen carefully to patient’s story to detail and understand their experience
  - Accept the patient’s story as their genuine experience
  - Express regret that the event has happened (this does not constitute an admission of liability)
  - Consult with local clinical psychologist
- Seek cause of awareness using NAP5 process
  - Check details of patient’s story with monitoring details and with staff
  - Seek independent opinion of analysis
- To detect impact early, in first 24 h check for four cardinal signs of impact: (1) flashbacks, (2) nightmares, (3) new anxiety state, and (4) depression
  - Active follow-up at 2 weeks
  - If impact persists, formal referral to psychiatric/psychological services

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