

# 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 *not* 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 'Bolotho 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 remifentanyl 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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