

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:
- Issues around consent in NAP5.
 - Highlighting areas where NAP5 results indicate that consent practices can be improved with respect to AAGA.
 - Offer suggestions as to how this can be achieved.
- 21.7 Discussing consent for anaesthesia with a patient, involves:
- A need to provide information about what procedures the patient will undergo.
 - A need for consent concerning specific components of the anaesthetic plan, e.g. central venous epidurals etc.
 - 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 unconsciousness 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:
- 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?
 - How common or rare is the complication?
 - 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:
- Sedation is not general anaesthesia and there is no intention to eliminate sensation.
 - Sedation may calm the patient but not eliminate all anxieties.
 - Sedation may induce a light sleep from which the patient may rouse intermittently.
 - The patient may be aware of surrounding events but may not particularly care or be interested in them.
 - 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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