

Reports of AAGA after sedation



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HEADLINE

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

BACKGROUND

- 12.2 NAP5 focuses on patient reports of AAGA. These reports may arise when a patient has not actually received general anaesthesia. It is well recognised that reports of AAGA may occur after sedation (Samuelsson et al., 2007; Mashour, 2009; Kent, 2013). In the study by Samuelsson et al., 5% of patients reporting AAGA had received intended sedation. In Kent's study of self-reports to the ASA awareness registry, 27 of 83 (33%) patients who reported AAGA had received intended sedation: 50% by an anaesthetist and 50% by a non-anaesthetist.
- 12.3 Indeed one study of >60,000 patients, where patients were asked rather generically 'if they experienced any problems related to anaesthesia', reported no statistically significant difference in the rate of reports of AAGA after general anaesthesia or sedation (0.023% vs 0.03%, $p=0.54$, relative risk of AAGA in general anaesthesia (GA) vs non-GA 0.74 0.28-2.0 (Mashour, 2009).
- 12.4 Reports of AAGA after sedation imply two things: first that the patient does not have a full understanding of the intended level of consciousness, and second that the level of consciousness experienced was likely undesirable.
- 12.5 Esaki et al. (2009) studied 117 patients undergoing regional anaesthesia or 'managed anaesthesia care', and performed a structured interview assessing expected and experienced levels of consciousness. 'Complete unconsciousness' was the state most often expected and also the state most often reported as subjectively experienced. A notable finding in this study was that only 58% of patients reported that their expectations of conscious level for the procedure were set by the anaesthesia provider.
- 12.6 Reports of AAGA after sedation are not trivial. Kent et al. (2013) compared the experiences and sequelae of patients in the ASA awareness registry whose anaesthesia care was intended to be general anaesthesia with those who had

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

Definitions

- 12.7 There is no colloquial or agreed definition of 'sedation' accessible to patients. The online Oxford English Dictionary (2014) defines sedation (self-fulfillingly) as a verb of action; 'The action of allaying, assuaging, making calm or quiet.', Wikipedia (<http://en.wikipedia.org/wiki/Sedation>) defines sedation as '...reduction of irritability or agitation...to facilitate a medical procedure...' whereas older dictionaries refer to alleviation of pain (Baker, 1956; Onions, 1991).
- 12.8 The report of the Academy of Medical Royal Colleges defines levels of sedation (consistent with the terms used by the ASA; Table 12.1) as '...drug-induced depression of consciousness, a continuum culminating in general anaesthesia'.
 - (a) *Minimal sedation* is where the patient responds normally to verbal commands. Cognitive function and physical co-ordination may be impaired, but airway reflexes, and ventilatory and cardiovascular functions are unaffected.
 - (b) *Moderate sedation* is a state where purposeful responses to verbal commands or light tactile stimulation are maintained. Conscious sedation is a term also applied here, which is a degree of depression of the mental state allowing surgery

to proceed where verbal contact is maintained with the patient throughout the period of surgery;

- (c) In *deep sedation* the patient responds purposefully only to repeated or painful stimulation; the patient may have depressed respiration and may need a degree of airway support.
- 12.9 One important limitation of all these definitions in these reports is that sedation is defined by its outcome from the sedationist's perspective, rather than as the actual state of mind the patients might find themselves in as a result of drug administration. Thus from the patient's perspective, responding to verbal stimulation could encompass a wide range of mental states, some of which are acceptable (to the patient) but some unacceptable. Also, these definitions are difficult to use when the conscious level changes rapidly in response to a stimulus or use of a short-acting drug such as propofol (i.e. the definitions lend themselves better to description of a steady state than a dynamic one).
- 12.10 Indeed the literature highlights different perspectives on sedation. Because analgesia is an important goal, patients frequently misunderstand what sedation is (Chatman et al., 2013) and many want to be completely unaware and have no pain or recall (Subramanian et al., 2005). It is not clearly defined what the purpose or endpoint of sedation is for a caregiver, but first principles suggest that the prevention of awareness of unpleasant aspects of the procedure as well as blunting recall of pain are amongst the important aims (Chatman et al., 2013; Kent et al., 2013). From the patient's perspective, the boundary between sedation and general anaesthesia is obscured (Esaki et al., 2009).

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

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

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

Practice

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

Table 12.2. Gloucester comfort score with definitions

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

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

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

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

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

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

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

Numbers

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

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

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

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

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

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

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

Figure 12.1. ASA status of sedation cases

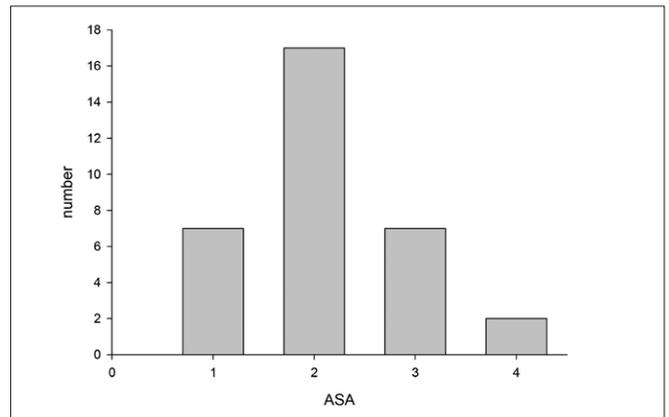
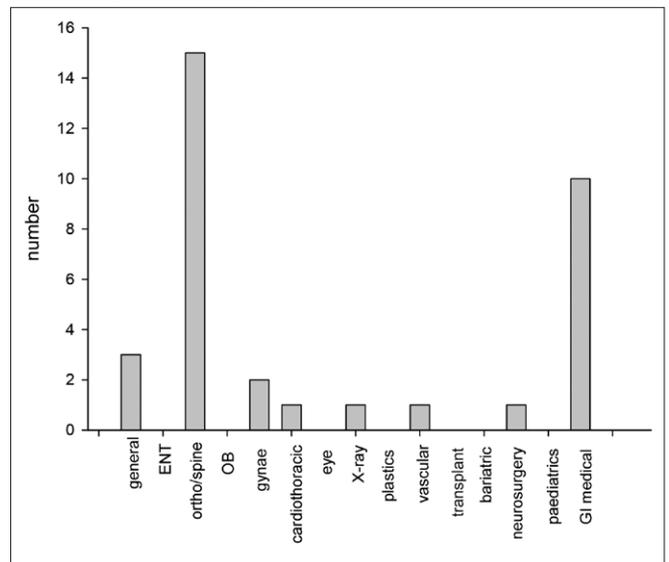


Figure 12.2. Number of sedation cases by specialty. ENT = ear, nose, throat; OB = obstetrics; X-ray = cases in radiology; GI medical = medical gastroenterology



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

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

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

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

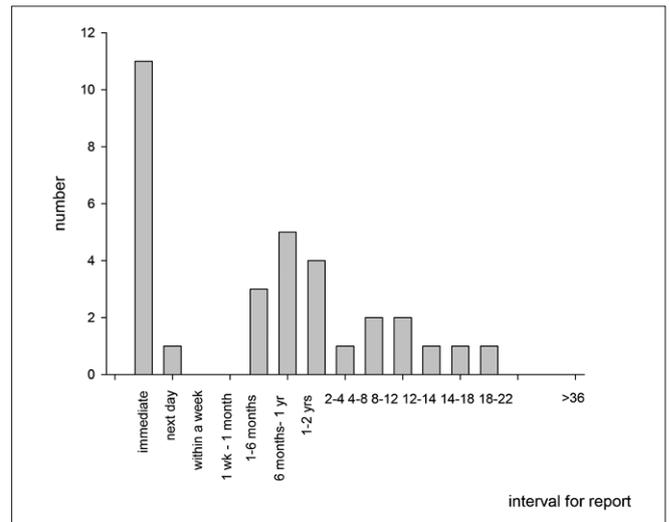
A patient reported: "I woke up and could hear discussion going on around me and the anaesthetist waved his hand in front of me. I was told it would be a light anaesthetic but expected to be asleep. I woke during surgery, heard some hammering and someone saying 'That's a good fit'. I wasn't afraid, and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

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

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

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

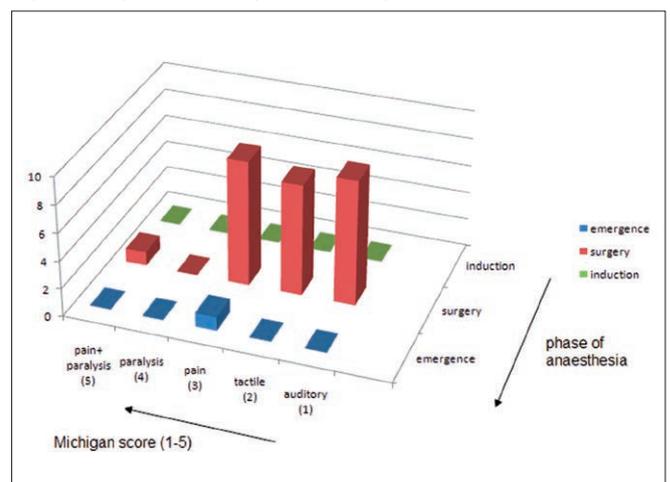
Figure 12.3. Histogram of time interval before sedation cases made a first report of perceived AAGA



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

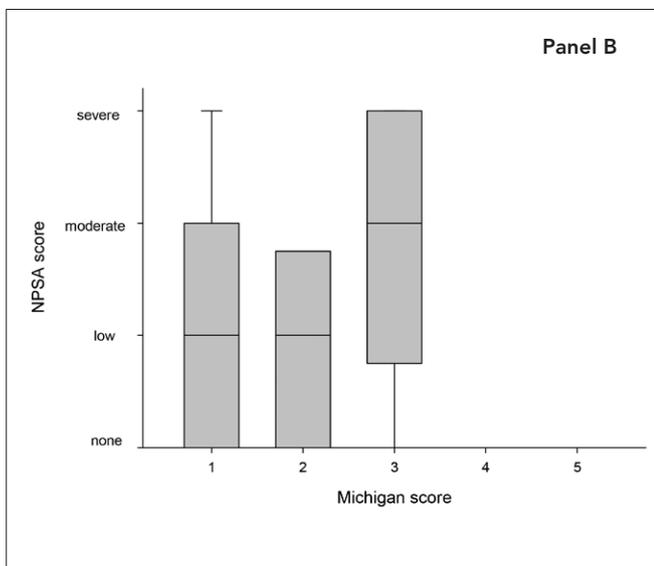
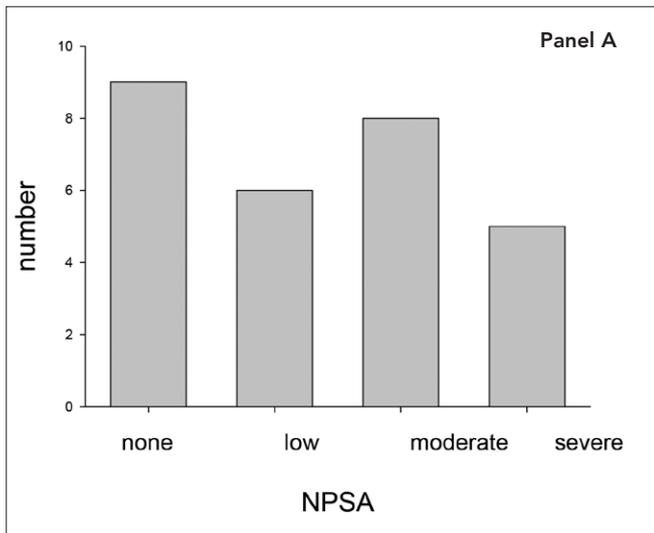
About two-thirds of experiences involved auditory and tactile sensations (i.e. Michigan scores 1 and 2). About a third of patients reported pain, and there was one instance of paralysis plus pain. This last was associated with distress at the time. In total about half the patients (15) reported distress,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

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



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

Figure 12.5. Panel A: Distribution of impact (modified NPSA score); Panel B: Boxplot of the modified NPSA score by patient experience (Michigan scale)



The patient did not like the drape being over their face, nor the sounds of the saw and drilling which they found unbearable. They bit on their fist to stop themselves screaming 'Stop!' during the procedure. They said there was no one to talk to during the operation or to inform that they were not coping and expected to be 'naturally asleep'.

A patient reported that they woke up in the operating theatre three times while under the anaesthetist's care. They reported being able to see the surgeon cutting into their limb. The anaesthetist asked if the patient wanted to go back to sleep and they said 'Yes'. They woke up a further two times during surgery and during a further anaesthetic procedure. The notes recorded a well-documented plan of 'sedation, spinal and nerve block at end' but the patient stated they were promised they would be completely unaware of the procedure. The patient experienced pain during the nerve block and reported that they were 'mentally scarred' and 'phobic of having any more surgery'. The patient was referred to a psychologist.

DISCUSSION

12.31 Patients may report AAGA despite not having a general anaesthetic. The reasons for this are explored in Chapter 21 (Consent). For those patients who do report AAGA after sedation or regional anaesthesia the experiences are not dissimilar to those reported after AAGA and there may be significant psychological sequelae.

12.32 The data from NAP5 reinforces that from Kent et al. (2013). Using a patient registry that recruits self-referred patients, they found that 27 of 80 AAGA cases in fact underwent sedation (31%). The spectrum of symptoms experienced by these patients was broadly similar to our finding in Figure 12.5B. Kent et al. found the incidence of tactile/auditory experiences was ~20%; of pain ~10%; and of distress ~80%. However, they reported a higher incidence of paralysis (~25%) and pain with paralysis (~45%). It is unclear why none of our reports also complained of any 'paralysis' from regional anaesthesia.

12.33 Kent et al. (2013) were able to examine in detail the longer term psychological sequelae, with overall 40-50% of patients experiencing a mix of symptoms including anxiety, flashbacks, nightmares, depression and chronic fear. NAP5 methodology did not have the resolution to explore this level of detail, but our finding that about half of patients experienced moderate or severe impact (Figure 12.5B) is consistent with their results.

12.34 These findings emphasise three points:

- (a) The importance of investigation of all reports of AAGA to confirm, amongst other things, that general anaesthesia was in fact intended (and/ or expected) by the patient.

- (b) The importance of ensuring that both patient and practitioner agree and understand the intended level of sedation when that is intended.
- (c) That reports of AAGA after sedation are not trivial and should be managed as other reports.

- 12.35 From the Activity Survey we estimate that there are ~310,000 anaesthesia-administered cases of sedation (i.e. minimal, moderate or deep sedation) per year. There were 20 reports of AAGA where sedation was administered by anaesthetists. This yields an estimate for perceived AAGA during anaesthetist-administered sedation of ~1:15,500. This seems at least as common as Certain/probable or Possible AAGA reports after anaesthesia (~1:20,000; Chapter 6, Main Results).
- 12.36 The number of sedation cases by non-anaesthetists is unknown. Gavin et al. (2013) estimated ~500,000 colonoscopies and Quine et al. (1995) ~400,000 sedated gastroscopies. It therefore seems likely that well over 1 million sedation episodes take place in the UK each year, with the vast majority of sedated patients managed by non-anaesthetists. We cannot guarantee that NAP5 detected all reports of perceived AAGA that were made to non-anaesthetists and therefore make no effort to estimate an incidence.
- 12.37 Such data would be important to explore the speculation that where an anaesthetist is involved, patients automatically have a greater expectation of 'anaesthesia' (i.e. complete unconsciousness) simply because of the job title of the person involved.
- 12.38 However, Gavin et al. (2013) reported discomfort and pain rates to be ~10% and even if a tenth of these patients expected full unconsciousness and thus report AAGA, this would result in ~500 patients a year perceiving AAGA after sedation for colonoscopy alone. In line with suggestions by Gavin et al. more research is needed on patient experiences after interventions where sedation is undertaken by non-anaesthetists.
- 12.39 Communication with patients undergoing procedures under sedation could be improved. Terms such as 'we'll give something to make you sleep', or 'you won't be aware of anything' should be avoided as they describe a state of anaesthesia or total amnesia and thus misinform the patient. While the only record a patient has of events is their (fragmented) memory, a written signature provides some reassurance (to all involved) that clear information was originally provided. Most sedation cases are elective so there is ample opportunity

for written information to be provided beforehand. This information should, amongst other things, make clear that the patient may retain memory of the procedure. See also Chapter 21, Consent.

Failures of communication were the cause of almost 90% of reports of 'AAGA' after sedation



- 12.40 The Activity Survey estimates about 500,000 patients underwent procedures awake supervised by anaesthetists, but none of these reported AAGA (i.e. patients who were awake, unlike some sedated patients, did not expect to be fully unconscious).
- 12.41 Table 12.3 indicates some useful forms of words that help define sedation from the patient's perspective.

Table 12.3. Continuum of depth of sedation: definition of levels of sedation/analgesia with respect to patient response and intervention required

	What will this feel like?	What will I remember?	What's the risk related to the sedation drugs?
Not sedated; awake	I am awake, possibly anxious. There may be some mild discomfort (depending on the what I am having done)	Everything	Nearly zero
Minimal sedation	I am awake and calm. There may be some mild or brief discomfort	Probably everything	Very low risk
Moderate sedation	I am sleepy and calm but remain in control. I may feel some mild discomfort	I might remember some things	Low risk
Deep sedation	I am asleep. I will not be in control	Probably very little	Higher risk. My breathing may slow when I am asleep – and I may need help to breathe – a tube might be inserted into my nose, mouth or (rarely) windpipe. I will need oxygen and special monitoring
Anaesthesia	I am deeply 'asleep' and unable to respond	Very unlikely to remember anything	Higher risk (but the presence of an anaesthetist increases safety). My breathing may slow or stop and my blood pressure and heart rate may fall. I will need a specialist doctor to look after my breathing and support my blood pressure and heart rate I will need oxygen and special monitoring and equipment

RESEARCH IMPLICATIONS

Research Implication 12.1

More collaborative research between anaesthetists and other specialists involved in sedation is needed on patient experience and outcomes after sedation for interventional procedures, especially where sedation is conducted by non-anaesthetists.

Research Implication 12.2

It would be interesting to compare if patient expectations or recollections differ (regardless of information provided) between sedation conducted by an anaesthetist versus a non-anaesthetist.

Research Implication 12.3

Sedation offers a rich research base for the study of retention of information and memory. This is highly relevant for how best to take consent from patients undergoing procedures under sedation.

Research Implication 12.4

NAP5 received no reports relating to instances of patient-controlled sedation. The efficacy and practicality of patient controlled sedation might be a useful avenue for further research.

Research Implication 12.5

The question whether different drugs used in sedation have differential influences on aspects of the experience of recall is amenable to further research? (i.e., do some drugs tend to impair memory while others impair the perception of noise vs touch, etc?).

RECOMMENDATIONS

RECOMMENDATION 12.1

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

RECOMMENDATION 12.2

On the day of procedure, sedation should be described again from the patient's perspective, using terminology such as that suggested in Table 12.3 as a guide.

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