SPECIAL ARTICLES

5th NationalAuditProject(NAP5)on accidental awareness during general anaesthesia: protocol, methods, and analysis of data†‡


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Editor’s key points

- This paper describes in detail the methodology used for the NAP5.
- NAP5 focuses on the awareness during general anaesthesia spontaneously reported by the patient.
- The methodology is different from that used by previous work in this area.
- The methodology has its own unique context against which the results should be interpreted.

Background. Accidental awareness during general anaesthesia (AAGA) with recall is a potentially distressing complication of general anaesthesia that can lead to psychological harm. The 5th National Audit Project (NAP5) was designed to investigate the reported incidence, predisposing factors, causality, and impact of accidental awareness.

Methods. A nationwide network of local co-ordinators across all the UK and Irish public hospitals reported all new patient reports of accidental awareness to a central database, using a system of monthly anonymized reporting over a calendar year. The database collected the details of the reported event, anaesthetic and surgical technique, and any sequelae. These reports were categorized into main types by a multidisciplinary panel, using a formalized process of analysis.

Results. The main categories of accidental awareness were: certain or probable; possible; during sedation; on or from the intensive care unit; could not be determined; unlikely; drug errors; and statement only. The degree of evidence to support the categorization was also defined for each report. Patient experience and sequelae were categorized using current tools or modifications of such.

Conclusions. The NAP5 methodology may be used to assess new reports of AAGA in a standardized manner, especially for the development of an ongoing database of case reporting. This paper is a shortened version describing the protocols, methods, and data analysis from NAP5—the full report can be found at http://www.nationalauditprojects.org.uk/NAP5_home.

Keywords: AAGA; awareness; consciousness; mechanisms

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Accidental awareness during general anaesthesia (AAGA) is a complication of anaesthesia that is greatly feared by patients and anaesthetists alike. It is perhaps the second most common adverse outcome that concerns patients, after postoperative nausea and vomiting, and both patients and anaesthetists rank it high in outcomes to avoid during anaesthesia.\(^1\)\(^2\)\(^3\)\(^4\)\(^5\)\(^6\)\(^7\) Several studies that included the Brice questionnaire in their methodology\(^8\) reported the incidence of AAGA to be 1--2,000.\(^9\)\(^10\)\(^11\) A method that used Brice-style patient questioning twice over a 48 h period yielded a much lower incidence of 1:14,500.\(^11\)

The effect of different methodologies on the incidence of AAGA has previously been discussed.\(^12\) Case series can be used, such as that of Blusse\(^{\text{a}}\) van Oud-Alblas and colleagues who questioned 928 consecutive paediatric patients for AAGA using a Brice questionnaire repeated three times over a month, reporting an incidence of 0.6%. Other types of case series examine only patients reporting AAGA, to focus on common themes or on the psychological impact.\(^13\)\(^14\)\(^15\) Non-randomized studies usually seek to establish the incidence of AAGA to ascertain influential factors. For example, Sebel and colleagues\(^16\) published a prospective cohort study of just under 20,000 patients using a Brice-style interview repeated twice in a week, and used multivariate logistic regression to identify possible contributory factors, reporting an incidence of 0.13%. Randomized study designs usually seek to assess the impact of an intervention; for example, the impact of BIS monitoring was examined by Myles and colleagues.\(^17\) An example of a randomized study examining the impact of a prophylactic treatment is that of Wang and colleagues.\(^18\) Data registries are, at the simplest level, a collection of case details stored and analysed by later interrogation.\(^19\) Small-scale registries may be assembled by referring to articles in medical journals, also helping to highlight the project to practitioners, the Royal College of Psychiatrists, and national societies of psychological practitioners. Publications, in general medical journals, also helped highlight the project to professionals.\(^20\) Initially, no public announcement or media exposure was actively sought, in case this altered the normal manner in which patients made reports of AAGA. However, publication of the baseline papers in April 2013 was accompanied by widespread media attention.

Any person wishing to file a report of AAGA on his/her behalf or that of another person could do so, or could contact his/her local co-ordinator using an online list. Equally, local co-ordinators could contact each other to exchange information securely. To file a report of AAGA, the local co-ordinator or other person needed login details to the secure site provided by the NAP5 central team. A short set of screening questions was used to filter inadmissible reports, and later on review, some reports that had been filed were deemed inadmissible. To be reportable, a report of AAGA had to be:

(a) a situation where the patient (or his/her representative or carer) made a statement that he/she had been aware for a period of time when he/she expected to be
unconscious. Thus, a complaint of pain or anxiety alone was inadmissible, as was a desire to have been less conscious (as opposed to unconscious) during a procedure;
(b) the first report of AAGA made to the healthcare system;
(c) between 00:00 on June 1, 2012 and 23:59:59 on May 31, 2013 for the first report, regardless of when the actual event occurred;
(d) relating to care in an NHS (UK) or public (Ireland) hospital.

The report related to a specific surgical or medical intervention in which anaesthesia care was provided. Anaesthesia care was interpreted in the broadest sense, ranging from monitored anaesthesia care to sedation to general anaesthesia, given by any type of practitioner. We therefore aimed to capture all new patient reports of AAGA, irrespective of whether the patient’s perception of the event was accurate.

For cases deemed to meet our inclusion criteria, login details and passwords were issued.

Once access information was released, the NAP5 team had no access to data during submission of the report but merely received notification of when the website was first accessed and when the form was completed, to enable progress to be monitored. The website was secure and encrypted. Where there was uncertainty as to whether a case met inclusion criteria, the reporter was directed to determine this by discussion with the NAPS moderator, a consultant anaesthetist entirely independent of the project team, who had no contact with the review panel throughout the project.

The secure reporting site asked for details of the case and conduct of anaesthesia, and local co-ordinators were advised to file the report after reviewing the casenotes. No patient-identifiable data were requested and prompts on the secure site ensured that all potentially identifiable data were removed.

The questionnaire is available in full at http://www.nationalauditprojects.org.uk/NAP5_home. Further, to guarantee anonymity, the NAP5 team had no information as to who had originally filed the report.

The NAP5 panel met monthly to review and discuss all submitted reports. The panel had access to several types of information, including the full patient report from the secure website and a case summary prepared by the NAP5 clinical lead. The panel used these to review cases in a structured manner, and created a standardized output for quantitative analysis of the dataset. Each report was first reviewed by a minimum of four panel members. The report then underwent a second review by a larger group formed by combining several small groups, typically 12–16 members. Each report and its output were presented and this was further reviewed and moderated. At each meeting, some reports were intentionally reviewed by pairs of small groups before large group review as a form of internal control.

In performing reviews, the panel was repeatedly cautioned about: outcome bias, where knowledge of the poor outcome can lead to a retrospective harsh judgement; hindsight bias, an exaggerated belief that a poor outcome would have been predicted; and group-think, where groups make irrational decisions given a subconscious desire to agree with others. The two-stage review process was specifically designed to address the latter bias. Reports were classified into mutually exclusive report classes (Table 1) and by degree of evidence (Table 2).

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

(a) pre-induction of anaesthesia;
(b) induction: at or after induction, but before surgery;
(c) maintenance: during surgery, after incision;
(d) emergence: after surgery was complete but before full emergence (extending to any time after the end of surgery, where the patient reported he/she was awake.

<table>
<thead>
<tr>
<th>Table 1 Classification into types of report. All classes were mutually exclusive, so a patient report could only be classified into one group. AAGA, accidental awareness during general anaesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain/probable AAGA</td>
</tr>
<tr>
<td>Possible AAGA</td>
</tr>
<tr>
<td>Sedation</td>
</tr>
<tr>
<td>ICU</td>
</tr>
<tr>
<td>Unassessable</td>
</tr>
<tr>
<td>Unlikely</td>
</tr>
<tr>
<td>Drug error and miscellaneous</td>
</tr>
<tr>
<td>Statement only</td>
</tr>
</tbody>
</table>
when he/she felt he/she should have been unconscious. Therefore this included cases where drug errors or failure to reverse neuromuscular block caused paralysis and hence a perception of AAGA in the recovery period; (e) other: uncertain time.

We then classified causality, including contributory factors, and preventability. This was based on the NPSA contributory factors framework (see http://www.nrls.npsa.nhs.uk/resources/?entryid45=7560533). We also judged quality of care, both leading up the reported event and after it, as: good; poor; good and poor; or unassessable. Such judgement was made on the basis of consensus of the panel, where possible, making the judgement relevant to standards effective at the time of the report for historical cases. The preventability of each case was classified as: yes, no, or uncertain. Preventability was defined as ‘one or more avoidable actions or omissions outside of standard practice, without which the occurrence of AAGA would have been unlikely’.

The impact on the patient was classified in three ways:

(a) patient experience during the episode, using the Michigan Awareness Classification Instrument34 (Table 3);
(b) intra-operative cognitive state and psychological impact on the patient, using the Wang classification 35 (Table 4);
(c) severity of patient outcome, using a modification of the National Patient Safety Agency classification 33 (Table 5).

Results

The results and analysis of AAGA reports are presented in accompanying papers.36 37 This paper presents only the results relating to the methodology itself.

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

Table 2 Classification by degree of evidence. AAGA, accidental awareness during general anaesthesia

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-quality</td>
<td>Where the report of AAGA was, or could easily be, confirmed by other evidence</td>
</tr>
<tr>
<td>Circumstantial</td>
<td>Where the report of AAGA was supported only by clinical suspicion or circumstance</td>
</tr>
<tr>
<td>Plausible</td>
<td>Where other evidence was available, but this did not shed further light on the matter</td>
</tr>
<tr>
<td>Unconfirmed</td>
<td>This was generally applied to the statement-only cases where there was no evidence other than the patient report</td>
</tr>
<tr>
<td>Implausible</td>
<td>This was generally applied to statement-only reports where there was no evidence other than the patient story and where this was judged implausible</td>
</tr>
</tbody>
</table>

Table 3 Michigan Awareness Classification Instrument (from Mashour and colleagues).34 An additional designation of D was if the panel decided there was distress during the experience

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

Table 4 Wang classification of intra-operative cognitive states.35 PTSD, post-traumatic stress disorder

<table>
<thead>
<tr>
<th>Grade</th>
<th>Intra-operative state</th>
<th>Immediate postoperative state</th>
<th>Late postoperative state (&gt;1 month)</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Unconscious</td>
<td>No signs; no response to command</td>
<td>No recall</td>
<td>Adequate anaesthesia</td>
</tr>
<tr>
<td>1</td>
<td>Conscious</td>
<td>Signs/response to command</td>
<td>No recall</td>
<td>Intra-operative wakefulness with obliterated explicit and implicit memory</td>
</tr>
<tr>
<td>2</td>
<td>Conscious; word stimuli presented</td>
<td>Signs or response to command</td>
<td>No explicit recall, implicit memory for word stimuli</td>
<td>Intra-operative wakefulness with subsequent explicit memory</td>
</tr>
<tr>
<td>3</td>
<td>Conscious</td>
<td>Signs or response to command</td>
<td>No recall</td>
<td>PTSD/nightmares but no explicit recall</td>
</tr>
<tr>
<td>4</td>
<td>Conscious</td>
<td>Signs or response to command</td>
<td>Explicit recall with or without pain</td>
<td>Explicit recall but no emotional sequelae</td>
</tr>
<tr>
<td>5</td>
<td>Conscious</td>
<td>Signs or response to command</td>
<td>Explicit recall with distress, pain, or both</td>
<td>PTSD/nightmares with explicit recall</td>
</tr>
</tbody>
</table>
A total of 471 requests from both UK and Ireland were made for login details to access the website. After screening, 341 were judged admissible and logins issued. However, 20 local co-ordinators did not use their logins, leaving 321 reports filed. Guidelines from the National Institute for Health and Clinical Excellence (NICE) on electronic depth of anaesthesia monitoring and criticisms thereof38 39 were published in November 2012 and February 2013, respectively; the baseline survey of NAP5 was published in March 2013.23 24 None of these appeared to influence the request rate for logins to the website (Fig. 1).

In the majority (314; 98%) of reports, a local co-ordinator was involved in submitting it to the NAP5 website, either alone or with another anaesthetist. In seven reports, an anaesthetist who was not a local co-ordinator filed the report alone. A majority (305; 95%) of reports were made spontaneously by the patient. Otherwise, reports were made by the patient to a friend, who reported it to an anaesthetist (one case), in a legal letter of claim (one case), where the anaesthetist suspected AAGA and initiated the discussion with the patient (six cases), or by a carer or relative (eight cases). In the majority (305; 95%) of reports were made spontaneously by the patient. Otherwise, reports were made by the patient to a friend, who reported it to an anaesthetist (one case), in a legal letter of claim (one case), where the anaesthetist suspected AAGA and initiated the discussion with the patient (six cases), or by a carer or relative (eight cases). In the majority of cases, an anaesthetist received the report of AAGA from the patient (Fig. 2).

Of the 321 reports filed to the website, 21 (6.5%) were reviewed and judged inadmissible by the panel. The reasons included: not a first report; surgery in non-NHS hospital or non-public Irish hospital; report made outside the reporting period; or not a complaint of awareness but rather of pain or other discomfort, at a time when they did not expect to be unconscious. There were several reports that raised interesting issues as to how AAGA should best be defined and this cohort of inadmissible cases were, to some extent, helpful in evolving the process in the methodology. For example, one patient had a complex medical history of kidney disease with electrolyte imbalance; the anaesthetist appeared uneventful and included neuromuscular blocking drugs and a nerve stimulator was used for monitoring. However, when fully awake, the patient complained of leg and arm weakness during the recovery period that lasted ~ 12 h. The patient was very distressed and experienced sleep disturbance for several weeks. At no time did the patient express an expectation to be unconscious during this time and therefore, the NAP5 panel judged this was not a case of AAGA but of prolonged muscular weakness probably induced by electrolyte imbalance.

There were several instances during anaesthesia where the patient moved and anaesthesia was promptly deepened. In these cases, the anaesthetists questioned the patients afterwards, but there was no report of awareness. Although this indicated a degree of responsiveness, and in some cases likely wakefulness, at the time of movement, the panel judged these cases inadmissible because there was no report from the patient.

One case involved residual neuromuscular block in the dead space of an i.v. cannula that was flushed on the ward several hours after surgery, resulting in accidental paralysis followed by resuscitation. Although this was a serious event, and with similarities to syringe swap cases, there was judged to be no report of accidental awareness or an expectation of unconsciousness before or at the time of the event.

It appeared that NAP5 coincided with a postoperative survey of patients after cardiac surgery conducted in a small number of centres. The questionnaire included the questions ‘Do you recall a tube in your throat after surgery?’ and ‘Do you recall being conscious between going to sleep and waking after surgery?’ A small number of patients had ticked yes to these questions, but there were no further details and no follow-up. The panel concluded that the questions asked were insufficiently precise, and the period covered by such a question was likely to include surgeries, intended anaesthesia, intensive care, and intended sedation; the panel had no access to further information so judged the reports inadmissible.

In one case, a patient suffered a cardiac arrest during a long operation, but the report was judged to be a description of an
Fig 1 Monthly request rate for logins to the secure NAP5 website per month. NAP5 commenced on 1 June 2012; the arrows show the times when relevant NICE guidance\textsuperscript{18} and an associated editorial\textsuperscript{19} and the NAP5 Baseline Survey\textsuperscript{24} were published.

Fig 2 Bar chart of to whom the report of AAGA was made. Department, anaesthetic department; GP, general practitioner.
out-of-body experience, or a dream, and there was no sense that the patient had experienced awareness or complained of such.

Another category of report that informed the methodology was those classed as unlikely AAGA (12 cases, 4%). The reasons for this judgement included: could not have occurred during the course of surgery or anaesthesia; the patient’s story was directly contradicted by the evidence; and the anaesthetist had been involved in providing some other form of care such as resuscitation.

There was one instance where the surgical team encountered a surgical complication during anaesthesia, associated with a period of inadequate muscle relaxation and coughing, and later informed the patient that they had been ‘aware under the anaesthetic’. The patient had experienced severe pain when awake after operation but interpreted this as being part of the ‘awareness’ of which they had been informed. The Panel judged this to be unlikely AAGA.

There were three reports based on postoperative satisfaction questionnaires that included questions on possible awareness. In two (classed inadmissible), there was simply no further information available, but in one case (with details from case-notes) the panel was informed that later follow-up revealed the original patient response to the survey had been incorrect.

The methodology yielded 70 (23%) statement-only reports, with no medical or anaesthetic record to analyse further details. The striking aspect of these historical reports was a very long time interval between the primary event and the first report of AAGA. The time interval was unknown, but likely to be very long, in five cases, and for the remainder the median (inter-quartile range [range]) was 11 315 (7300–15 248 [1163–22 630]) days, in other words a median of ~31 yr with an upper limit of 62 yr. Some reports were extremely sparse in detail, such that it was impossible to know what could have happened, in terms of either anaesthetic detail or patient experience. A full account of the inadmissible and unlikely cases is provided in the NAP5 report (see http://www.nationalauditprojects.org.uk/NAP5_home).

Discussion

The study architecture of NAP5 conforms to a registry, but one that is nationwide, separately for the UK and Ireland. Therefore, NAP5 is probably the first national survey of AAGA ever undertaken. Our method of assembling registry cases through local co-ordinators at each hospital appears unique to this topic, though identical to two previous NAPs.\textsuperscript{20–22} Several other features are important: it is a registry of first reports of AAGA, and great care was taken to exclude reports made previously to the healthcare system. No active questioning of patients was required, but naturally, sometimes anaesthetists did question patients whom they suspected of having been aware. Reports elicited in this manner (6, 1.9%) were accepted as being part of routine clinical care rather than excluded as protocol-based interrogation.

It was the intention of the project that the AAGA reports remained anonymous and the regulatory requirements imposed on NAP5 reinforced this necessity. Hence, the NAP5 panel do not know the geographical source of the report, the identity of the local co-ordinator who filed the report, or any patient, hospital or clinician-identifiable details. If, despite this, details provided in this or accompanying papers\textsuperscript{16, 37} appear recognizable to some readers, it is, we believe, because they are very representative of not-infrequent occurrences.

By relying on spontaneous reports, we hoped to receive the most robust reports; that is, those reports unprompted by active questioning. We were confident that our team of local co-ordinators diligently scanned their hospitals on a regular basis, and were actively searching for reports. The 100% response rate provides some evidence that this worked, and indeed reports were received from a variety of sources. The use of strictly defined categories of report was important in this project. We believe our methodology improved the likelihood of correct inclusion and exclusion of reports and made the nature of those reports more explicit, adding to the robustness of the project. We have described those cases that could not be assessed or judged inadmissible here and in the full report to enable others to judge this. The relatively high proportion of statement-only cases, and the strikingly long time intervals for their reporting, might also suggest a diligence of the system in detecting these otherwise long-unreported cases.

The accuracy of our method in detecting all cases of AAGA relies upon the ability of the healthcare system to transmit the report to anaesthetists: as Avidan and Mashour previously commented, we may be ‘under the radar’.\textsuperscript{40} The fact that most reports were made to anaesthetists does not exclude the possibility that reports were made to others, but not transmitted to anaesthetists, and therefore not detected by local co-ordinators. The reports we obtained were several steps removed from the source, the patient themselves. Furthermore, we did not have access to the medical records, but rather the local co-ordinator’s version of the record. There was thus some inevitable loss of detail. On first principles, this potential loss of detail may have affected the reporting of sophisticated outcomes such as psychological detail more than it did objective details such as drugs administered.

The alternative to a reliance on spontaneous reporting is to use active questioning. Although the Brice interview is commonly used in research, we cannot find any previous critique of it; its possible weaknesses appear to have gone unchallenged. It is often described as modified,\textsuperscript{41} but seems identical when used in respect of its key questions to that originally described.\textsuperscript{1} Studies using the Brice questionnaire have often lacked detail as to how the output was interpreted, what other investigation of possible cases was undertaken, and what criteria were used to confirm or refute AAGA. Therefore, for any given group of patients administered the Brice questionnaire, it is not known what proportion of reports initially indicating awareness are later judged by a review panel not to have been certain or possible AAGA. While it seems that up to three Brice-style interviews up to a month after operation yields the highest positive response rate for AAGA,\textsuperscript{12} it is not known if even more questioning yields different rates. Indeed, it would appear likely that several cases that could
something quite different.44 In a more pragmatic sense, the ‘root cause’, the event initiating the causal chain, can be these events do not arise that there is AAGA. The ‘immediate is normally the cause of unconsciousness and it is when so that one event can lead to another. Nor does it encompass causality as a probabilistic analysis. In the study of medical practice in particular, the notion of ‘contributory factors’ is perhaps more meaningful than ‘cause’, and we have adopted this in our methods.

AAGA might equally be viewed as an absence or failure of the normal chain of events that leads to general anaesthesia. In other words, administration of a general anaesthetic drug is normally the cause of unconsciousness and it is when these events do not arise that there is AAGA. The ‘immediate cause’ of AAGA is always inadequate anaesthesia; however, the ‘root cause’, the event initiating the causal chain, can be something quite different.44 In a more pragmatic sense, the cause of AAGA might be broadly summarized as either a failure or interruption of delivery of suitable concentrations of anaesthetic, or an inherent resistance on the part of the patient to the effect of the anaesthetic.

If possibilities like this are to be investigated, an ongoing database of AAGA becomes necessary, as large cumulative databases are the only means to study relatively rare diseases or syndromes.45 Moreover, a more direct clinical relevance of our methodology is that it offers a standardized means to investigate or analyse cases of AAGA as they arise in practice. The use of the classification scheme we have suggested might help standardize some of the terminology. The relevant anaesthetic organizations, working together with the appropriate national patient safety organizations, should consider developing a means by which all incidents of AAGA are properly recorded and entered onto a permanent database, to allow for ongoing learning.

Authors’ contributions
All authors contributed to the study design and creation of tools and methods described. J.J.P. conducted the data analysis. J.J.P. and T.M.C. wrote the manuscript, with all other authors commenting on it, or revising and amending the manuscript.

Acknowledgements
See the NAP5 website and main NAP5 findings paper for full list.36

Declaration of interest
All conflicts of the NAP5 team have been registered at the NAP5 website http://www.nationalauditprojects.org.uk/NAP5_home. Specific to this paper: J.J.P. is Scientific Officer of the Difficult Airway Society and an 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. No other competing interests declared.

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