

Drug errors and awake paralysis



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HEADLINE

13.1. This chapter describes cases of brief awake paralysis reported to NAP5, as a result of drug errors that led to a neuromuscular drug being administered without prior anaesthesia. Although it can be argued that these cases are not technically 'accidental awareness during general anaesthesia' the experiences and consequences for the patient are similar to AAGA. NAP5 received reports of 17 such cases. It is notable that the distress during the patient experiences and the subsequent psychological distress was of a greater severity than all other cases of AAGA.

BACKGROUND

13.2 An early landmark study of human error as a cause of untoward anaesthetic outcomes was published by Cooper et al. (1978). At that time, a syringe swap or the unintended administration of an incorrect drug was the third most common cause of anaesthetic critical incident (human error involving disconnection of circuit or inadvertent changes in gas flow being the two commonest). Syringe swaps now account for an even higher proportion of critical incidents in anaesthetic practice because, over time, the latter two have been virtually eliminated. Osborne et al. (2005) reported that of 4,000 reports received by the Australian Incident Monitoring Study (AIMS), there were almost as many cases of awake paralysis due to syringe swaps as awareness during anaesthesia.

13.3 More recent incident reporting studies suggest a rate of drug error of 1 every 140 anaesthetics (Webster et al., 2001; Zhang et al., 2013). This is almost certainly an underestimate as many unrecognized errors are not reported. Given these

odds, it is almost inevitable that an anaesthetist will make drug errors during their career; yet many practitioners remain in a state of denial that they could make such an error, preferring to believe that they are less fallible than their colleagues (Evley et al., 2010).

13.4 Many errors are due to slips or lapses in concentration that occur in the multi-tasked setting in which anaesthetists work. It is important that the broader environment in which anaesthetists work, is not forgotten as a source of contributory factors to drug error: the likelihood of a final slip or lapse may be increased by many 'latent factors' (see Chapter 23, Human Factors). At an individual level, haste, inattention and distraction are likely to increase the risk of drug errors. The practice of anaesthesia involves continuous vigilance, and that may be impaired by the effects of fatigue.

13.5 Reason's classic 'Swiss cheese model' of human error in medical care explains that the coincidental lining up of 'holes' or faults in the protective

barriers in the environment is what allows errors to manifest as patient harm (Reason, 2000).

- 13.6 During syringe swaps patients are likely to have the distressing experience of total paralysis (perhaps including painful fasciculations with suxamethonium) in the absence of any anaesthetic agent that reduces consciousness. Patient experiences include awake-paralysis, distress, fear of dying and that paralysis may be permanent. PTSD may follow. As both a feeling of paralysis and distress at the time of awareness are associated with worse psychological sequelae after AAGA (Samuelsson et al., 2007, Ghonheim, 2009) it is not surprising that these cases are associated with a high rate of severe psychological sequelae (Mihai et al., 2009).
- 13.7 There have been several solutions suggested to reduce the incidence of drug errors in anaesthesia and other branches of medicine. These include checking drugs with another person before administration ('two person checking' or 'double checking') and also the use of technology (bar code scanning). Both systems have been trialled in anaesthesia (Evley et al., 2010).
- 13.8 While double checking of drugs has an appeal, there are recognised problems with it as a solution. To be effective, the double-checking must include all phases of drug administration (drawing up, drug selection and drug administration). A recent UK study found it was impractical due to the inability to ensure two individuals were present whenever drug administration was required (Evley et al., 2010). The evidence from other areas of medicine that double checking reduces drug error is limited. A systematic review identified a single RCT which reported that it reduced ward-based drug error from 2.98 to 2.12 per 1000 drug administrations (one error prevented in every 1,162 drug administrations, Alsulami et al., 2012), which the authors described as of 'unclear clinical advantage'. Toft has described 'involuntary automaticity' as an explanation of why double (or even multiple) checking may still enable errors to occur (Toft & Mascie-Taylor, 2005). There is a tendency to 'see what you expect to see' and while there may be mechanisms to reduce its effect it may not be entirely avoidable.
- 13.9 Bar-code scanning also appears to be a reliable solution but previous studies have identified many shortcomings with currently available systems and there are important cost implications (Evley et al., 2010). In order to prevent scanning of a syringe that in fact contains the wrong drug, bar-code scanning systems for drugs ideally need to be combined with systematic use of pre-filled syringes. Such systems have been trialled with evidence of modest benefit in reducing drug error but no clear evidence of patient benefit (Merry et al., 2011).
- 13.10 At the time of writing neither two-person checking nor scanning-based systems are in routine use, nor widely recommended in anaesthetic practice.
- 13.11 While litigation as a result of drug errors causing permanent harm in anaesthesia appears rare, drug errors from syringe swaps leading to awake paralysis is prominent in these claims (Mihai, et al. 2009). Such claims are almost invariably judged to represent sub-standard care and litigation is almost invariably successful (see Chapter 22, Medicolegal).
- 13.12 There are several separate problems:
- a *syringe swap* occurs when a drug error occurs because drug from the wrong syringe is administered;
 - a *drug labelling error* occurs when the contents of the syringe are different to that indicated on the label, either because drug was drawn up from the wrong ampoule or the wrong label was applied;
 - a *drug omission* occurs when the intended drug is omitted due to failure to draw up a drug in a dilutant.
- 13.13 We used Class G of the AAGA reporting system as a miscellaneous category. This rapidly filled predominantly with syringe swaps and drug error; of which there were 17. These cases equal 1 in 8 of all definite and probable cases reported to NAP5. The 17 UK cases comprised 11 syringe swaps, five drug labelling errors and one omission error. There was suspicion of omission errors (either no drug given, or partial mixing) in several other cases not included here. Fifteen of 17 drug errors occurred at induction of general anaesthesia; two occurred due to accidental injection of neuromuscular blocking drug or local anaesthetic during intended regional anaesthesia.
- 13.14 Thus, three difficult-to-classify cases originally in this class are not considered further in this chapter. One was an awareness of inhalational induction in a child; one was awareness of cricoid pressure and one was likely partial paralysis in recovery.
- 13.15 The demographic characteristics of the patients in this group were similar to the patients in the Activity Survey: median age 36-40, median weight 70kg, median BMI 26kg/m², and this suggested that all types of patient were susceptible to syringe swaps.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

- 13.16 Most cases were ASA 1 or 2, and most events occurred during daytime hours. Thus it did not appear to be the case that these events were related to out-of-hours or emergency surgery.
- 13.17 Most events were reported immediately, except one case which was reported after several years.
- 13.18 The median perceived duration of the paralysis was very short, 60 (10-180 [5-900]) sec. One case where the experience was very long did not appear to have been administered any anaesthetic during the episode, perhaps because the syringe swap was not recognised and the diagnosis was initially unclear.

A young, anxious patient was undergoing elective orthopaedic surgery. To alleviate anxiety, the anaesthetist planned to give midazolam 2mg but the patient became unresponsive and was hand ventilated via a face mask. Two consultant colleagues arrived to help and it was later observed that the patient was behaving similarly to an inadequately reversed patient. Reversal was given and the patient started responding again. The patient was later able to give a detailed description of being paralysed and unable to respond to the anaesthetist's commands (to take deep breaths and opening eyes). There was fear of death. The episode lasted 15 min. The patient developed unpleasant dreams, nightmares and flashbacks, and symptoms of PTSD. The patient received counselling for this. A formal complaint was received by the trust.

- 13.19 All cases except one occurred on induction, before surgery started.
- 13.20 Most patients (15, 88%) experienced paralysis but two patients did not experience this sensation despite the drug error and experienced only tactile or auditory sensations. Pain was uncommon, (1 of 17, 6%) arising only once and that was in conjunction with paralysis. The majority (11 of 17;

65%) experienced distress at the time of the event. Distress was more common during brief awake paralysis than in definite and probable cases of AAGA (Table 13.1).

Table 13.1. Comparison of the immediate impact (Michigan D denoting distress) and longer term impact (Wang scale and modified NPSA score >2; i.e. moderate or severe) for Class A and B (Certain/probable) versus G (awake paralysis). In all categories, the impact of the last appears more adverse

NAP5 Class	Michigan D	Wang 5	NPSA >2
Definite/probable Class A	54%	35%	24%
Possible Class B	36%	36%	16%
Awake paralysis Class G	65%	47%	41%

- 13.21 Three (18%) of the drug error cases led to a formal complaint or initiation of legal action at the time the case was reported to NAP5, a little higher than was the case with Certain/probable cases (16% in Class G vs 11% of all Class A/B cases).
- 13.22 The Panel judged that all cases of awake paralysis caused by drug error were preventable, and therefore, the quality of clinical care was generally deemed to be poor in the period leading up to AAGA. In contrast, quality of care after the event was frequently good (77% cases), largely because the event was promptly recognised and well managed (Table 13.2).
- 13.23 The majority of syringe swaps that led to AAGA in NAP5 were due to events that led to administration of a neuromuscular blockade without being preceded by a hypnotic agent (Table 13.3). In one case lidocaine was given instead of an antibiotic which led to cardiovascular and respiratory collapse and need for resuscitation. The patient recalled events during the resuscitation.

Table 13.2. Panel judgements on quality of care and preventability for each of the Class A and B (certain/probable) versus Class G (awake paralysis). Notwithstanding the inherent difficulties of the judgement (discussed in Chapter 5, Methods), quality of care before AAGA was always judged poor in Class G and always judged preventable

AAGA Class	Quality of care before AAGA			Quality of care after AAGA			Preventable
	Good	Mixed	Poor	Good	Mixed	Poor	
Certain/probable, Class A	26%	31%	39%	70%	7%	14%	73%
Possible, Class B	29%	32%	29%	55%	10%	17%	29%
Awake paralysis, Class G	0%	23%	77%	77%	6%	12%	100%

Table 13.3. Drugs involved and psychological impact of ten syringe swaps. (NMBD: unidentified neuromuscular blocking drug)

Drug Given	Drug intended	Michigan	NPSA score
Suxamethonium	Anti-emetic	4D	Severe
Atracurium	Saline flush	4D	Severe
NMBD	Midazolam	4D	Severe
Suxamethonium	Fentanyl	4	None
Suxamethonium	Fentanyl	2	None
Lidocaine	Antibiotic	1	Moderate
Atracurium	Saline flush	4D	Severe
Rocuronium	Midazolam	4D	Severe
Rocuronium	Midazolam	4	Moderate
Cefuroxime	Thiopental	4D	Low

13.24 The psychological sequelae of AAGA for the patient in this setting can be particularly severe. Of note: the severity does not appear to be related to duration of experience and even a few seconds of unintended paralysis can lead to prolonged psychological sequelae (also see Chapter 7, Patient Experience).

General anaesthesia was planned for a middle-aged obese patient for drainage of an abscess. The anaesthetist intended to give an anti-emetic before the induction dose of propofol, but mistakenly gave suxamethonium. The error was recognised immediately. The patient was aware for 30 seconds. The patient was extremely distressed in recovery and reported to staff that they had been paralysed, unable to breathe and felt they were going to die. In the post-operative period the patient was very angry and litigation was started.

13.25 The risk of a drug error is logically reduced by avoiding giving unnecessary drugs at the time of induction.

A young patient undergoing emergency surgery was anaesthetised out-of-hours by two trainees planning to undertake a rapid sequence induction. Suxamethonium was given instead of fentanyl while the patient was awake. The mistake was recognised quickly and the patient was anaesthetised with propofol. The patient had recall for a few seconds but no pain or discomfort and was generally unconcerned by the whole event.

Swaps involving larger syringes, such as in induction agent and antibiotic, also led to paralysis and AAGA, as the antibiotic was mistaken for induction agent. Perhaps understandably, this did occur with thiopental and antibiotic (but just one case). Equally understandably, no drug error arose with propofol.

In some of these cases poor communication within the team involving more than one anaesthetist led to these errors. Identifying and agreeing the roles of each anaesthetist in such teams is likely to reduce error.

A patient undergoing an urgent laparotomy for bowel obstruction was under the care of three anaesthetists on an emergency list; the plan was to administer fentanyl followed by thiopental and suxamethonium. Unfortunately, cefuroxime was mistaken for thiopental and administered instead. The patient’s trachea was intubated but the patient became markedly tachycardic and hypertensive. The error was then realized and thiopental was administered. Post-operatively the patient recalled the sensation of being unable to breath, the discomfort of cricoid pressure and an unpleasant sensation of a tube being passed into the back of their throat. This experience lasted for a maximum of two minutes. The patient was not overly concerned about this event and overall hospital experience was very positive.

The similarity of appearance of thiopental and cefuroxime in close proximity



13.26 Seven drug preparation errors were reported (six of labelling error and one drug omission): and all led to awake paralysis and severe psychological sequelae. (Table 13.4).

Table 13.4. Drugs involved and psychological impact of six ampoule-labelling and one drug-omission error. (*there was a suggestion that parexocib was also intended)

Drug Given	Drug intended	Michigan	NPSA score
Atracurium	Midazolam	4D	Moderate
Suxamethonium	Fentanyl	4	Low
Suxamethonium	Ondansetron	4D	Low
Atracurium	Midazolam*	4D	Low
Cefuroxime	Thiopental	2	None
Water	Thiopental	4D	Severe
Suxamethonium	Fentanyl	4D	Severe

13.27 The fundamental cause of most cases of wrong labelling or incorrect preparation appeared task-related. Distractions and perceived time pressures during the drawing up of drugs may lead to errors.

A middle aged patient was due to undergo elective shoulder surgery. The anaesthetist intended to sedate the patient before performing an interscalene block and then induce general anaesthesia. Atracurium 10mg was injected instead of the intended midazolam. The patient recalled feelings of panic, acute distress and the awareness of a very rapid heart rate. The anaesthetist quickly recognised that a muscle relaxant had been administered, and anaesthesia was induced within a few minutes. Whilst drawing up drugs in preparation for the case, the anaesthetist had been distracted by the ODP's request to leave the anaesthetic room to fetch equipment from a nearby store room. On return to the original task, atracurium was inadvertently drawn up into the syringe labelled as midazolam. Both ampoules were of similar size and nearly similar colour. The anaesthetist's explanation to the patient in recovery post-operatively was graciously accepted, and no formal psychological support or treatment was required.

Illustration of the similarity of labelled syringes for midazolam and atracurium left in close proximity



An anxious young patient was due to undergo general anaesthesia for minor surgery. Spontaneous respiration was planned. The patient remembered the anaesthetist's reassuring words that they would soon be asleep, then remembered their arm 'dropping' and being unable to hear their breathing. The consultant anaesthetist immediately realised that suxamethonium had been given instead of fentanyl, and administered a dose of propofol whilst continuing to reassure the patient. A single loose ampoule of suxamethonium had been placed lying close to the fentanyl and other induction drugs in the tray. This arose because the hospital had instituted a policy preventing the entire box of suxamethonium being removed from the fridge (to avoid room temperature degradation). Instead, the ODP had placed a single ampoule of suxamethonium on the tray. The patient was supported, a full explanation offered, and they suffered no long term impact.

An example of a single loose ampoule of suxamethonium and how easily it might be drawn instead of (in this example) ondansetron



13.28 Preparation error accounted for a minority of the drug error cases reported to NAP5. A common thread between them was pre-existing organisational elements that were likely to have increased the chance for error to be introduced (i.e. latent errors).

13.29 The practice of having a delay between drawing up a dilutant into a pre-labelled syringes and then later mixing/adding the active drug led to AAGA through drug omission.

A middle-aged patient required a general anaesthetic for expedited surgery. After induction the anaesthetist noticed greater than expected fasciculations in the patient. Following intubation, a volatile agent was immediately commenced. At this point the anaesthetist realised that no induction agent had been administered, only suxamethonium. In that hospital, thiopental was kept in a central store, so was not immediately available for mixing. After finishing the previous case, the anaesthetist forgot that the thiopental had not been mixed and proceeded with a rapid sequence induction. The patient was induced with a syringe containing only water (but presumably labelled as thiopental). In recovery, the patient reported experiencing paralysis and was clearly afraid: "I thought I might not make it through the operation". The patient was aware of being intubated and was unsure how long it would last but soon after lost consciousness. The patient developed a new anxiety state, flashbacks and possible PTSD. The patient subsequently had meetings with the clinical director and counselling was arranged.

DISCUSSION

- 13.30 The cases in this chapter are perhaps more accurately termed 'unintended awake paralysis', but are perceived by the patient as 'accidental awareness'. The adverse impact is commonly severe. This underlines the reality that paralysis whilst conscious is a potentially harmful experience. Of note: the impact of paralysis in generating distress and longer-term harm, which is also emphasised elsewhere – Chapters 6, Results; 8, Induction; 9, Maintenance; 10, Emergence; and 19 NMB.
- 13.31 The majority of drug errors causing awareness in this category are due to simple syringe-swaps of similar sized syringes, or similar coloured fluids, such as suxamethonium vs. fentanyl or ondansetron (all normally drawn in 2ml syringes); non-depolarising drugs vs midazolam (both normally in 5 ml syringes); or antibiotics vs thiopental (both usually in 20 ml syringes). Indeed, not a single error was reported for dissimilar sized syringes (Tables 13.3 and 13.4).
- 13.32 However, the overall incidence of drug error related to neuromuscular blockade must be regarded as low. The Activity Survey indicates ~2.8 million general anaesthetics per year, with 44.8% (~1.25 million) involving neuromuscular blockade. This represents one report of accidental paralysis for every 70,000 general anaesthetics involving neuromuscular blockade.
- 13.33 Recurring themes in the details of the cases were mention of staff shortages, a pressured environment with 'busy' lists. Some hospital policies for the storage and preparation of drugs appeared misguided and themselves were contributory to error (see Chapter 23, Human Factors).
- 13.34 Distractions during critical moments can have very serious consequences. Jothiraj et al. (2013) reported that other anaesthetists and circulating nurses are the most common causes of distractions. In terms of individual conduct, it seemed that a lack of vigilance and having several similar sized syringes on the same drug tray may be contributory.
- 13.35 Although checking ampoules and labels with a second person is theoretically attractive, the evidence base for checking with a second person before drawing up or giving a drug is weak. Although double-checking is accepted as necessary in other familiar settings (e.g. the administration of blood products), the value of checking routinely administered drugs in the anaesthetic context is more controversial.
- 13.36 When two people are responsible for the same task, neither person is truly responsible. There are several examples of this phenomenon in this report, where two anaesthetists have been present during a case, yet perhaps nobody was truly leading the team. Paradoxically, the introduction of double-checking for routine drug administration could worsen 'involuntary automaticity' and reduce, rather than increase, patient safety.
- 13.37 A technical solution to the problem would involve use of pre-prepared drug syringes and use of scanning technology to 'check' drugs before administration. Any method would need to accommodate the need for rapid response to a changing situation during surgery, and hence the need to have a range of drugs immediately available whose use was not anticipated.
- 13.38 Short of such technology, anaesthetists need to accept that they are all prone to making errors and should therefore, develop robust individual mechanisms to protect themselves. The anaesthetist needs to recognise their vulnerability to these potentially very serious incidents, and develop layers of defence to prevent drug errors; particularly those involving the unintended administration of neuromuscular blocking drugs. In this context the NAP5 data suggests several strategies that could reduce error.
- 13.39 Anaesthetic departments should work with pharmacy departments to take ampoule

appearance into proper consideration when choosing suppliers and should avoid frequent, changes of drug suppliers. If this is unavoidable, then it must appear on the hospital risk register.

- 13.40 Individual strategies that may be helpful include reserving 5ml syringes for neuromuscular blockade only, double-labelling of these syringes or, if available, using coloured syringes or different syringe types.
- 13.41 Although often relegated to being a routine, perhaps subconscious task, anaesthetists should appreciate that preparing drugs is a potentially high risk activity and so be careful to avoid all distractions during this period. The need to read all ampoules and use labels is self-evident, but any doubt or concern or distraction should lead to consideration that the wrong drug may have been prepared.
- 13.42 Perhaps greater attention is also needed to organising the anaesthetic workspace, with attention to detail on where and how the most potentially 'dangerous' drugs (i.e. the neuromuscular blocking drugs) are kept and handled (e.g. in separate trays). Part of this is the need to avoid unnecessarily complicated anaesthetic techniques and avoid the administration at induction of drugs not directly necessary (e.g. anti-emetics, which can often safely be administered later).
- 13.43 After an error had happened, the patient experience appeared greatly influenced by anaesthetic conduct. In some cases hurried efforts were made to reverse paralysis without attending to the patient's level of consciousness, while in others reassurance of the patient and ensuring comfort was prioritised. In the latter group, it seemed that patients, on understanding events, appeared to have considerably more benign experiences and fewer or no sequelae.
- 13.44 Where a drug error leading to accidental paralysis has occurred there are three priorities, in order: first, immediately reassuring the patient that they are safe, whilst second, inducing anaesthesia promptly to mitigate continued adverse impact (including airway management) and last, to consider reversing the paralysis at an appropriate time (e.g. guided by nerve stimulator monitoring).

IMPLICATIONS FOR RESEARCH

Research Implication 13.1

Further research is needed into issues relating to the cause and prevention of drug error in anaesthesia. Relevant questions include: Whether errors are more frequent when drugs are prepared by anaesthetists vs assistants vs double checking? Which strategies for double checking might reduce error? What sort of psychology is involved when teams double-check drugs?

Research Implication 13.2

The design of technical solutions to minimise drug error offers large scope for further research, to establish how the right drug is given at the right time to the right patient. This might include further analysis of interventions involving barcoding, or pre-prepared drugs, or drugs released from fridges or cupboards only on specific request.

RECOMMENDATIONS

RECOMMENDATION 13.1

Hospitals should take ampoule appearance into account to avoid multiple drugs of similar appearance. Hospital policies should direct how this risk is managed. This may require sourcing from different suppliers.

RECOMMENDATION 13.2

The relevant anaesthetic organisations should engage with industry to seek solutions to the problem of similar drug packaging and presentation.

RECOMMENDATION 13.3

Anaesthetists should develop clear personal strategies in the preparation of drugs that minimise or avoid scope for drug error. This includes the recognition that preparation of drugs for use is a potentially high risk activity, in which distractions should be avoided. This applies particularly to neuromuscular blocking drugs.

RECOMMENDATION 13.4

Where a drug error leading to accidental paralysis has occurred there are three priorities, in order: first, immediately reassuring the patient that they are safe, whilst second, inducing anaesthesia promptly to mitigate continued adverse impact (including airway management) and last, to consider reversing the paralysis at an appropriate time (e.g. guided by nerve stimulator monitoring).

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