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ORIGINAL ARTICLE

Patient safety incidents involving neuromuscular blockade: analysis of the UK National Reporting and Learning System data from 2006 to 2008

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Summary

Neuromuscular blockade is a powerful anaesthetic tool that has the potential for significant adverse outcomes. We sought to explore the national picture by analysing incidents relating to neuromuscular blockade in anaesthesia from the National Reporting and Learning System from England and Wales between 2006 and 2008. We searched the database of incidents using SNOMED CT® search terms and reading the free text of relevant incidents. There were 231 incidents arising from the use or reversal of neuromuscular blocking agents. The main themes identified were: non-availability of drugs (45 incidents, 19%), possible unintentional awareness under general anaesthesia (42 incidents, 18%), potential allergic reaction (31 incidents, 13%), problems with reversal of blockade (13 incidents, 6%), storage (13 incidents, 6%) and prolonged apnoea (11 incidents, 5%). We make recommendations to reduce human error in the use of neuromuscular blocking agents and on future incident reporting in anaesthesia.

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Incident reporting is an important process in improving patient safety in anaesthesia. The UK National Patient Safety Agency (NPSA) set up the National Reporting and Learning System (NRLS) to identify and learn from adverse incidents nationally [1]. Since 2006, which was the first year in which all trusts contributed data, the Agency has begun to work more closely with clinicians in an attempt to extract useful lessons for feeding back into practice [2]. Previous analyses of over 12 000 NRLS patient safety incidents in anaesthesia identified some general problems with analysing the database and drew out some themes for further consideration [3]. Although there have been some detailed analyses of more discrete topics within critical care [4–6], these have not so far been attempted in anaesthesia.

Neuromuscular blocking agents are a unique and powerful set of drugs but, like all effective compounds, have undesirable as well as intended effects [7]. There are new developments in both clinical pharmacology [8–10], including as yet-unpublished observations, and in opinion on monitoring [11] of neuromuscular blocking agents, so we felt it was timely to seek data on these agents. Our aim was to explore the national picture by analysing NRLS patient safety incidents relating to neuromuscular blockade in anaesthesia whilst at the same time establishing a methodology for extraction of relevant data in the future.

Methods

The NPSA provided us with a Microsoft Excel® spreadsheet, which contained the anonymised incidents arising from anaesthesia and all surgical specialties in the calendar years 2006, 2007 and 2008. 'Incidents' are as defined by the NPSA (Table 1). We used SNOMED CT® to identify search terms relevant to neuromuscular blockade, listed in Table 2. Using the database's 'Find' function, we searched on those terms sequentially until no further records were found. SNOMED CT® is the Systematized Nomenclature of Medicine, Clinical Terms, which has recently been adopted as the preferred clinical

Table 1 National Patient Safety Agency incident definitions.

Patient safety incident – any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS funded care (this definition incorporates all terms such as adverse incidents, adverse events and near misses)
Prevented patient safety incident – any unexpected or unintended incident that was prevented so no harm occurred
No harm patient safety incident – any unexpected or unintended incident that ran to completion but no harm occurred
Harm – injury, suffering, disability or death

Table 2 Key words used for text search.

Atracurium
Mivacurium
Muscle block
Muscle relax*
Neostigmine
Neuromuscular block
Paraly*
Revers*
Rocuronium
Sux*
Tetanic
Train of four
Vecuronium

where * is a 'wild card' such that the term paraly* would find instances of paralysis, paralysed and paralysed.

terminology of the NHS [12]. It comprises a structured list of terms for describing healthcare and is intended to create a common language for clinicians and researchers. We also randomly selected 1% of the total records for manual review to check search precision.

The free text of the records found was then read directly by the first author and duplicates were discarded. The author then determined if the incident did in fact arise from the use of a neuromuscular blocking agents and if not, the incident was discarded as a false positive. The following data were extracted from relevant incidents: age of patient; location of incident within the hospital; and two fields entered by the reporting clinician, namely originating specialty and degree of harm resulting from the incident (the NPSA's definitions of harm are shown in Table 3). We then classified the results in three ways as determined by the first author: by the stage in the medication process in which the error occurred; by the degree of harm to the patient; and by assignment to a group of common themes developed as the work progressed. Some of these common themes are explored further in our discussion.

The classification by stage of medication process was derived from the work of Thomas [4] on drug errors in intensive care. Two categories were added – 'reaction not communicated to prescriber', where drug reactions were previously described but not known to the prescribing doctor, and 'drug not disposed of', where incidents occurred involving drugs that had been unused and not properly disposed of.

Table 3 National Patient Safety Agency definitions of levels of severity of patient safety incidents.

None – a situation where no harm occurred: either a 'prevented patient safety incident', or a 'no harm patient safety incident'
Low – any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm, to one or more persons
Moderate – any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area and that caused short term harm, to one or more persons
Severe – any unexpected or unintended incident that caused permanent or long-term harm, to one or more persons
Death – any unexpected or unintended incident that caused the death of one or more persons

Results

A total of nearly 200 000 patient safety incidents were reported over the 3 years, with a sharp rise in the number in the third year, as seen in Fig. 1. Incidents classified by the reporting individual as 'anaesthetic' made up 17 179 (8.8%) of this total. Only 231 incidents were determined to be true positives i.e. distinct incidents arising from the use or reversal of neuromuscular blocking agents. The proportion of true positives initially reported as being

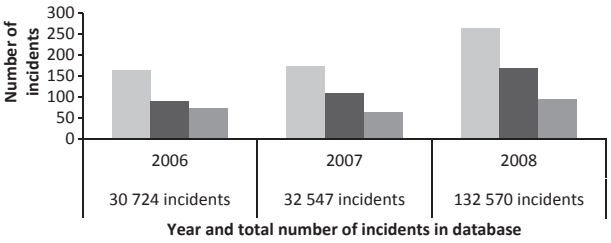

Figure 1 Summary of results identified by search terms (□), false positives (■) and true positives (■).

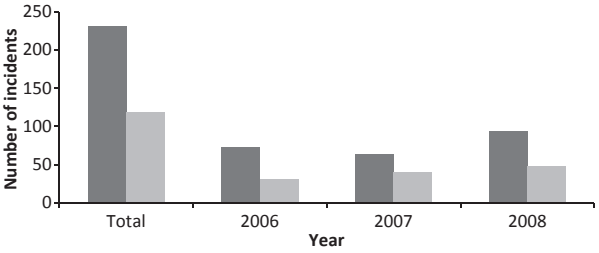

Figure 2 True positives involving neuromuscular blocking agents (■), initially classified as surgical (□).

patient safety incidents due to surgery remained around or above 50% over the 3 years, as shown in Fig. 2.

Outcome of the incidents is shown in Fig. 3, which shows the degree of harm suffered by the patient. There was only one death in the 3 years.

The location in which the incident occurred is shown in Fig. 4, the majority being in the operating theatre.

Table 4 shows the results classified by the stage in the medication process where the error occurred. The most common causes of errors were in supply or storage, administration of the drug especially due to a wrong drug or wrong dose being given, reactions to the drug or problems with monitoring response to the drug.

Broad common themes that we identified in the incidents are listed in Table 5. Non-availability of drugs was the most common, followed by potential awareness and then reactions that could have been caused by drug allergy. Incidents involving emergence included: problems with reversal itself; lack of neuromuscular junction monitoring; and prolonged apnoea. Although incorrect disposal of the drug was noted in seven incidents in the medication stage classification, in three instances anaesthetic drugs including neuromuscular blocking agents were left with the patient. There were two incidents in which malignant hyperpyrexia may have occurred. Illustrative excerpts from the free text fields of selected patient safety incidents are displayed in Table 6.

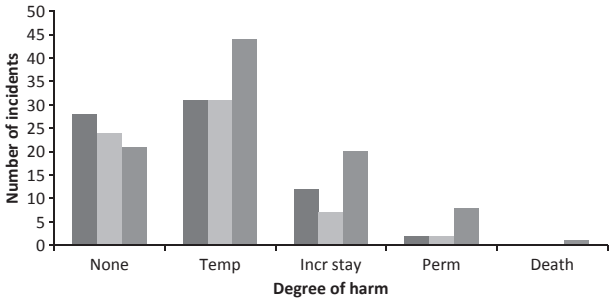

Figure 3 Results by degree of harm for 2006 (■), 2007 (□) and 2008 (▩). Temp, temporary; Incr stay, increased stay; Perm, permanent.

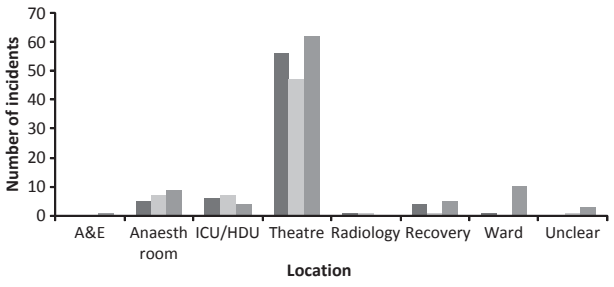

Figure 4 Results by location for 2006 (■), 2007 (□) and 2008 (▩). Anaesth room, anaesthetic room.

Table 4 Results by medication error stage. Values are number of incidents.

	2006	2007	2008	Total
Supply/storage	18	25	20	63
Prescription	2	–	7	9
Allergy known and prescribed	1	–	1	2
Ambiguous prescription	–	–	1	1
Indicated, not prescribed	–	–	1	1
Reaction not communicated*	–	–	3	3
Wrong drug prescribed	1	–	1	2
Preparation (all due to incorrect/ no labelling)	1	2	–	3
Administration	29	23	47	99
Blockage	1	1	–	2
Delay in giving drugs	2	–	–	2
Drug incompatibility	–	2	1	3
Drug not disposed of*	3	–	4	7
Expired drug	–	1	4	5
Extra dose	3	2	3	8
Extravasation	1	1	2	4
Given early	–	1	–	1
Incorrect rate of infusion	1	1	1	3
Leakage	2	–	2	4
Unknown	1	–	–	1
Other infusion device failure	–	–	1	1
Wrong dose given	3	8	7	18
Wrong drug	12	6	21	39
Wrong route used	–	–	1	1
Response to treatment	23	14	20	57
Idiosyncratic reaction	18	11	18	47
Lack of drug monitoring	5	3	2	10

*Category added to original classification.

Table 5 Common themes derived from free text. Values are number of incidents.

	2006	2007	2008	Total
Non-availability of drugs	12	19	14	45
Possible awareness	13	10	19	42
Potential drug allergy	9	7	15	31
Reversal problems	5	3	5	13
Drugs wrongly placed/stored	–	7	6	13
Prolonged apnoea	5	3	3	11
Nerve stimulator not available	5	3	1	9
Drug ineffective	–	2	5	7
Drug left with patient postoperatively	–	–	3	3
Possible MH or risk of MH	–	1	1	2

MH, malignant hyperpyrexia.

Non-availability of drugs was usually cited as being due to inadequate stock in theatre or drugs in theatre having expired. Another commonly occurring event was when locked drug cupboards were not immediately accessible in an emergency. Suxamethonium was the drug most often mentioned in incidents of non-availability, perhaps due to

Table 6 Illustrative quotes from free text of reports.

Non-availability of drugs
'Patient paralysed with muscle relaxant and there was no reversal available in theatre complex'
'A prefilled suxamethonium syringe was requested. An expired syringe was sent. This was reported and a new syringe ordered. The second syringe had also expired. The dispensary manager was alerted and a check showed that suxamethonium stock in the dispensary also contained expired stock'
'Anaesthetist called as patient apnoeic... requested suxamethonium for immediate IV use. I asked Nurse (staff name) to collect from fridge in theatre 11, which is our nearest source. The fridge was locked, so considerable delay...'
Awareness
'Patient reported to recovery staff that she was aware when taken into theatre. Nursing staff have confirmed conversation in theatre remembered by patient indicating that she was aware of surroundings. Patient was terrified as paralysed and unable to indicate awareness'
'Patient came for ptosis repair under local anaesthetic with sedation. Instead of giving midazolam, atracurium was given, both open vials next to each other. Patient unable to breathe'
'Patient in recovery for two hours. Intravenous cannula was flushed prior to returning to the ward. Within five minutes the patient complained of being unable to breathe and saturations dropped to 65%. No reversal given but clinical picture fitted with residual vecuronium in IV cannula'
Suspected allergy to neuromuscular blocking agents
'Severe anaphylactic reaction at induction of anaesthesia... patient developed severe hypotension with rash, was tight to ventilate and suffered PEA cardiac arrest'
'Patient was due to undergo elective right superficial parotidectomy. Subject had an anaphylactic reaction to one of the anaesthetic drugs on induction (ondansetron, fentanyl, midazolam, propofol and atracurium given). Subject developed severe bronchospasm and had cardiac arrest' (this quote from the only death in the series)
Problems at emergence
'No nerve stimulator available... Reversal was given blindly without knowing whether it was too early to work or too late to be necessary'
'Patient unable to breathe adequately shortly after arrival into recovery room. Circuit with positive pressure applied. Reversal required for partial paralysis but had difficulty unlocking cupboard for emergency drugs'
'RSI for emergency exploration of testicle... No respiratory effort at end of case. Nerve stimulator – poor twitch. Patient re-sedated and transferred to PICU with provisional diagnosis of suxamethonium apnoea'

the need for refrigeration coupled with the fact that it is often required in an emergency.

In the 42 incidents of awareness, there were 11 in which awareness was explicitly described by the patient or implied by the free text record (e.g. administration of neuromuscular blocking agents to an otherwise unmedicated patient). The other 31 were incidents in which awareness may have occurred. The most common scenarios were inadequate hypnosis during general anaesthesia or accidental administration of neuromuscular blocking agents to a non-anaesthetised patient. Usually this occurred immediately before anaesthesia but a few incidents mentioned administration of neuromuscular blocking agents in other settings, sometimes thought to be due to residual agent in a cannula or line.

In the 44 incidents involving drug reactions, 13 were specific to neuromuscular blocking agents with 11 involving prolonged paralysis, variously ascribed to mivacurium/suxamethonium apnoea or inadequate reversal, and two involving malignant hyperpyrexia. The remainder were anaphylactic reactions, except for one episode of cardiac arrest due to hypokalaemia and one incident where a dose of suxamethonium failed to produce paralysis.

The 31 incidents of anaphylaxis to neuromuscular blocking agents were always suspected rather than confirmed, as the incident reports were submitted before allergy testing. The single death in the series resulted from anaphylaxis on induction with a group of drugs including atracurium. Otherwise incidents of suspected allergy to neuromuscular blocking agents were described as either hypotension or bronchospasm, with or without rash.

The 37 incidents arising during emergence were often related to non-availability of nerve stimulators (in 10 cases) or neostigmine. Fewer reports cited inadequate reversal or unexpected prolonged apnoea to either suxamethonium or mivacurium.

None of the patient safety incidents randomly selected for review proved to arise from the use of neuromuscular blocking agents i.e. we detected no false negatives.

Discussion

We have identified 231 adverse incidents reported to the NRLS within England and Wales over a 3-year period, directly related to the use of neuromuscular blockade in anaesthetic practice. Errors in prescription or administration of drugs and supply and storage problems were most common. Known complications of neuromuscular blocking agents were also well represented, such as allergic reaction, prolonged paralysis or difficulties in reversal of blockade.

This paper reports the first attempt to gather data relating to neuromuscular blocking agents from the NRLS. This is now a large database of patient safety incidents encompassing the whole of healthcare. A number of points must be noted. First, those reporting an incident allocate the clinical specialty within which the incident is thought to have occurred, and also the degree of patient harm that resulted. The NPSA's own definitions of degree of harm as seen in Table 3 are available to reporters but not always consulted. Our previous pilot work [13] revealed that patient harm was misclassified in one quarter of incidents analysed, with overestimation more likely than underestimation. The free text suggested that this was often due to reporting potential, rather than

actual, harm. Thus there may be some anomalies in the degree of harm allocated, that may need correction. More importantly, many incidents arising from anaesthesia are misclassified into 'surgical specialties', presumably that of the operating surgeon in each case, despite the use of neuromuscular blocking agents being almost entirely the province of anaesthetists. We estimated that about 40% of anaesthetic incidents are misallocated in this way. This may be because it is non-anaesthetic staff who often report incidents; Catchpole and colleagues suggest that it is predominantly nursing staff who report [3]. However, one of the strengths of national systems, as noted by previous authors, is that they provide the large datasets that are necessary to capture infrequent events [14]. Our results reflect this with a low rate of true positives overall. The high proportion of false positives among incidents found with the keyword search reflects the fact that the management of many patient safety incidents in anaesthesia is associated with the use of neuromuscular blocking agents, for instance the use of suxamethonium to manage laryngospasm for example.

Our set of 231 true positives contains both generic medication errors and incidents specific to the use of neuromuscular blocking agents. Generic incidents that might occur with any medication may have unique consequences where neuromuscular blocking agents are involved. An example might be a rapid sequence induction performed where an antibiotic is administered in error rather than thiopentone, resulting in awareness. An example of an incident specific to neuromuscular blocking agents might be prolonged paralysis possibly due to cholinesterase deficiency.

The proportion of neuromuscular blocking agent-related incidents in the total is very low, even when incidents initially classified as 'anaesthetic' are used as the denominator. Although 2006 was the first year in which all trusts in England and Wales reported data to the NRLS, that is not to say that every incident that occurred was reported to the system. In fact, some anecdotal evidence suggests that reporting of anaesthetic incidents became less common when departmental schemes were superseded by hospital-wide risk management systems [15], of which the NRLS is a national extension. It is also well known that underreporting of incidents is usual in a number of contexts [16–19] and this must be contributing to the low rate of true positives in our series. For both these reasons, as well as the lack of denominator data, it is not possible to derive accurate incidence figures for the problems reported.

Indeed, the precise incidence of problems relating to neuromuscular blocking agents is hard to establish. The overall incidence of medication error in anaesthesia was studied by Webster and colleagues, who asked anaesthetists to return a study form anonymously for every anaesthetic, indicating whether or not a drug administration error or pre-error (defined as any incident with potential to become an error) had occurred [20]. From 10 806 anaesthetics, 7794 study forms were returned. The frequency (95% CI) of drug administration error, of any type, per anaesthetic was 0.0075 (0.006–0.009), that is, one in every 133 anaesthetics. The two largest individual categories of error involved incorrect doses (20%) and substitutions (20%) with intravenous boluses of drug. These figures are supported by the work of Yamamoto and colleagues, who performed a retrospective analysis of incident reports relating to medication error during an 8-year period [21]. The total frequency of medication errors in the survey period was 0.175% (48 incidents in 27 454 total anaesthetics given). Medication errors due to overdose were the most frequent (25%), followed by substitution (23%) and omission (21%). Errors due to an incorrect route of administration were rare. The drugs most frequently involved in these errors were antibiotics and neuromuscular blocking drugs. In Orser's questionnaire survey of 2266 Canadian anaesthetists, the commonest drug error or 'near miss' was the administration of a neuromuscular blocker instead of a reversal agent; 'syringe swaps' (70.4%) and the misidentification of the label (46.8%) were common contributing factors [22]. Fasting and Gisvold prospectively recorded data from 55 426 anaesthetics over 36 months. A drug error was recorded in 63 cases (0.11%), of which 22 were related to neuromuscular blocking agents or their reversal, that is, 0.039% of all anaesthetics [23].

Other incident reporting studies have focused on neuromuscular blocking agents. For instance, an analysis of incidents from Pennsylvania from 2004 to 2009 examined 154 reports. Only 22% of these were from anaesthesia or the operating theatre (the rest being principally the emergency department and critical care units). Overall, the predominant error types were wrong-drug errors (37%) followed by wrong-dose/overdosage errors (16.2%) [24]. A 2006 MedMarx study (an anonymous, web-based, medication incident reporting programme linked to the US Pharmacopoeia) examined 599 records involving neuromuscular blocking agents [25]. 'Improper dose/quantity' (28.2%) and 'unauthorised/wrong drug' (27.7%) were the most common types of errors noted. Analysis of the medications the patient was *intended* to receive showed that 47% of the intended medications were *not* neuromuscular blocking agents. For instance, neuromuscular blocking agents were given instead of antibiotics and midazolam. Contributory factors included: unsafe storage (neuromuscular blocking agents held in places they would not be expected to be found), similar product labelling and packaging, similar-sounding names and unlabelled syringes.

Table 7 Recommendations for practice.

Segregated storage may help prevent anaesthetists picking up a neuromuscular blocking agent by mistake; formal organisation of drug drawers and workspaces should be considered
Easily accessible storage for drugs (including refrigeration) must be maintained during temporary rearrangement of theatre spaces to ensure uninterrupted supply
The legibility and contents of labels on ampoules and syringes should be optimised according to agreed standards
Syringes should always be labelled and the label on any drug ampoule or syringe should be read carefully before a drug is drawn up or injected
The availability of all drugs and equipment that may be needed for an anaesthetic should be checked beforehand, including suxamethonium, neostigmine and nerve stimulators
Vigilance for known complications of anaesthetic drugs continues to be important
Intravenous cannulae and lines should be flushed after the last dose of neuromuscular blocking agent has been given, to prevent residual drug entering the circulation after emergence from anaesthesia
Anaesthetists should maintain a low threshold for reversal of neuromuscular blockade before emergence from anaesthesia
Following an anaesthetic, unused drugs should be safely disposed of

Analysis of the reports we have identified underlines existing advice to reduce the incidence of medication error in anaesthesia and our findings support some recommendations to improve safety (Table 7). Multiple strategies to reduce human error in the prescription and administration of drugs in anaesthesia may well produce the most benefit for any given expenditure. This was the most common theme identified and this has been a recognised issue for over two decades [26]. Segregated storage may help prevent anaesthetists picking up a neuromuscular blocking agent by mistake and there is evidence to support the formal organisation of drug drawers and workspaces [27, 28].

Labelling of syringes is already standard practice, and the double-checking of drugs and labels with a second person (or an automated device) before drawing up and administration, preventing their immediate availability is currently the subject of a collaborative project between the NPSA and the Royal College of Anaesthetists [29]. Checking drugs and equipment before the start of anaesthesia is also vital. As nerve stimulators are often first used on an anaesthetised patient just before emergence [30], their absence or malfunction may only be noted at this stage. The Association of Anaesthetists of Great Britain and Ireland recommends that a nerve stimulator should always be available whenever a neuromuscular blocking drug is used, and in fact this is one of the monitoring modalities that should be checked between cases [31, 32]. Likewise, suxamethonium may be needed urgently during a case, and neostigmine required for reversal at the end of anaesthesia, but their availability may not be checked. More difficult to establish is whether suxamethonium has become inactive (usually attributed to interrupted refrigeration). Temporary rearrangement of anaesthetic room and theatre spaces occurs due to maintenance or extra lists and may lead to the placement of drugs in distant or locked storage, preventing their immediate availability. This may also cause suxamethonium to be inadequately refrigerated and rendered ineffective. During rearrangements of the workspace for any reason, care must be taken that drugs continue to be available and pre-anaesthetic checks maintained. Some reports suggested that problems have occurred after emergence, when residual neuromuscular blocking agent was flushed into the circulation. If such a drug has been used, intravenous cannulae should be flushed before emergence in order to avoid this. The choice of whether to reverse neuromuscular blockade must be guided by the clinical situation, but there still appears to be some misunderstanding of the underlying pharmacology [30]. We advise that there should be a low threshold for administering reversal, due to the risk of partial paralysis. This view is supported by the evidence linking reversal of neuromuscular blockade with reduced mortality [33]. Lastly, recommendations such as referring to or labelling neuromuscular blocking agents as 'paralysing agents' [34] may help reduce problems outside the operating theatre but are not necessary for anaesthetists. Such terminology may in fact be inappropriate to use within earshot of patients.

What implications do our findings have for the future use of the NRLS? The system is anonymous, which is essential to gain the trust of its users, respect the confidentiality of patients and facilitate the development of a learning, no-blame culture [16, 35, 36]. However, as incidents are also noted locally before submission to the national database, root cause analysis or other risk assessment exercises based on incident data [37] can be performed. At present, though, there is no mechanism for sharing the results of such analyses more widely through the NRLS. There has also been little direct feedback to trusts and individuals who made the report, though continued feedback is vital to maintain the momentum of reporting [38].

With these factors in mind, and aiming to encourage the specialty of anaesthesia to feel that it has greater control over its reporting system [35], there is now a national specialty-specific reporting scheme for anaesthesia [39] and this should improve the engagement of anaesthetists in incident reporting [29] and avoid some of the difficulties we have encountered in sifting out incidents relevant to anaesthesia from a generic database. Further, the system will allow clinical anaesthetists to see, comment on and spread relevant lessons learned from reported incidents within the specialty. We would recommend that patient safety incidents should be reported by clinical staff, ideally the

anaesthetist involved. The NPSA definitions should be held in mind when reporting, particularly those describing the degree of harm to the patient.

In terms of method, we feel that using keyword searches and then directly reading the free text facilitates an in-depth analysis of the reports. We would argue that a keyword search is only as good as the terms selected, leading us to use SNOMED CT® as an approved NHS standard. Lack of relevant detail has been cited as a problem by previous investigators [3]. Patient safety incidents reported to the NRLS are those involving actual harm or potential harm of enough significance to be reported. Future work may involve using the large numbers generated by a national system to investigate the link between patient safety incidents and the less obvious 'undesirable events' thought to precede them [40].

Competing interests

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