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The Frequency and Nature of Drug Administration Error During Anaesthesia

C. S. WEBSTER*, A. F. MERRY†, L. LARSSON‡, K. A. McGRATH§, J. WELLER**

Departments of Anaesthesia, Green Lane Hospital, Auckland and Wellington Hospital, Wellington, New Zealand

SUMMARY

We aimed to establish the frequency and nature of drug administration error in anaesthesia (a significant subset of error in medicine) at two hospitals.

Anaesthetists were asked 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. Further details were sought if the response was affirmative.

From 10806 anaesthetics, 7794 study forms were returned, representing response rates of 80% from Hospital A and 57% from Hospital B (72% overall). The frequency (95% confidence intervals) of drug administration error, of any type, per anaesthetic was 0.0075 (0.006 to 0.009), of IV bolus errors was 0.005 (0.0035 to 0.006) and of pre-errors was 0.004 (0.003 to 0.005), with no significant difference between hospitals. Overall, one drug administration error was reported for every 133 anaesthetics. The two largest individual categories of error involved incorrect doses (20%) and substitutions (20%) with IV boluses of drug. Of the IV bolus substitutions, 69% occurred between different pharmacological classes. One patient was aware while under muscle relaxation, and two required prolonged ventilation. In addition, 47 transient physiological effects were reported, of which five required intervention.

We conclude that drug administration error during anaesthesia is considerably more frequent than previously reported.

Key Words: ANAESTHESIA: administration, error; COMPLICATIONS: iatrogenic, systems, incident reporting, risk management

Drug administration error during anaesthesia contributes to the problem of iatrogenic harm in medicine[1-6], but there are few data defining its incidence, or the extent of consequent harm.

In general, anaesthetists have recognised the importance of the design of technology in reducing error and of a systems-oriented approach to safety, based on continuous improvement underpinned by information from incident reporting[7-9]. In the case of injectable drug administration, however, anaesthetists have been surprisingly slow to incorporate such techniques, particularly with respect to the lessons from safe-system design[10-12] and the psychology of the mechanisms underlying human error[13,14]. A potentially safer drug administration system based on these considerations is being developed at Hospital A of this study[15]. An important part of any intervention is to evaluate its impact on the problem in question. In particular, it is essential to demonstrate the absence of unintended negative consequences[16]. Therefore, we have undertaken a prospective study to define more accurately the current frequency and nature of drug administration error at two New Zealand hospitals, in order to establish a baseline from which to evaluate the impact of introducing a new system to one of them.

METHODS

This study was accepted as an audit by the regional ethics committee and conducted with the agreement of departmental anaesthetists. Hospitals A and B are both tertiary teaching hospitals in New Zealand. All

* M.Sc.(Hons), Research Fellow, Department of Anaesthesia, Green Lane Hospital and Department of Pharmacology, School of Medicine, University of Auckland, Auckland, New Zealand.

† F.A.N.Z.C.A., F.F.P.M.A.N.Z.C.A., Clinical Associate Professor, Department of Anaesthesia, Green Lane Hospital and Department of Pharmacology, School of Medicine, University of Auckland, Auckland, New Zealand.

‡ R.N., Data Analysist, Department of Anaesthesia, Green Lane Hospital, Auckland, New Zealand.

§ M.Sc.(Hons), Research Officer, Department of Anaesthesia, Green Lane Hospital, Auckland, New Zealand.

** F.R.C.A., F.A.N.Z.C.A., Specialist Anaesthetist, Department of Anaesthesia, Wellington Hospital, Wellington, New Zealand.

Address for reprints: Mr C. S. Webster, Department of Anaesthesia, Green Lane Hospital, Private Bag 92189, Auckland 1130, New Zealand.

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anaesthetics conducted in each hospital during the study period were included, except a small number at Hospital A in which a prototype of a new system of injectable drug administration was used. Anaesthetists were asked to return, anonymously, a study form (attached to the anaesthetic record) for every anaesthetic, indicating whether or not a drug administration error or pre-error (defined as any incident with the potential to become an error) had occurred. If an incident had occurred, anaesthetists were asked to provide additional detail characterizing the event, including contributory factors (Table 1). Explicit negative responses allowed monitoring of the response rate over time. In an attempt to minimize inconsistency in response to the questions in Table 1, our study form also contained definitions of terms and incident types, and lists of common response categories with tick boxes. Anaesthetists, anaesthetic technicians, theatre nurses and other associated staff were briefed on the nature, significance and theoretical background of the problem of drug administration error and on the study. Further presentations during the study provided feedback and sought to maintain the motivation of participants. The returned forms were analysed and the total number of anaesthetics administered during the study period was obtained from the database of each hospital's department of anaesthesia. Data were analysed using the chi squared and Fisher's exact statistical tests in Systat 7.0 (SPSS Inc., Chicago, IL, U.S.A.).

TABLE 1

Questions on the drug administration study form

a. Did you use the new or conventional methods?
b. During this procedure did an error or pre-error occur?
1. Time of day?
2. Was the incident a pre-error or an error?
3. Type of error:
   Omission— drug not given, or nearly not given, or given too late
   Repetition— extra dose of intended drug given/nearly given
   Substitution—incorrect drug given/nearly given instead of desired drug
   Insertion—drug given/nearly given, which was not intended at that time or any stage
   Incorrect dose—desired drug given/nearly given
   Incorrect route—drug given/nearly given
   Other—specify
4. Was the error/pre-error made by you?
5. How many times did the event occur?
6. What was the drug?
7. What was the route of administration?
8. What was the phase of anaesthesia when pre-error/error occurred?
9. What drew your attention to the pre-error/error?
10. What was the duration of the effect of the drug administration error?
11. What was the immediate effect of the drug administration error?
12. What was the final outcome of the drug administration error?
13. What contributing factors were present at the time of the pre-error/error?
14. What was the category of the operation/procedure?
15. What was the primary anaesthetic technique?
16. What was the ASA classification?
17. Major/Minor?
18. Age of patient?
19. Location?
20. Specialty (grade)?
21. Experience in years?
22. Anaesthetic duration (hours)?
23. How long have you been on duty?
24. How long since you last slept?
25. How many hours of sleep (total) did you have in the 24 hours before the incident?
26. How many hours of sleep do you normally need (on an undisturbed night) to feel fully rested?
27. Any other comments about the incident?

RESULTS

In the 18 months from February 16, 1998 to August 20, 1999, 5798 completed study forms were returned from 7286 anaesthetics given at Hospital A, a response rate of 80%. In the latter 12 months of this period, 368 (5%) anaesthetics were conducted at Hospital A with a prototype of a new system of injectable drug administration. These anaesthetics, selected on the basis of availability of the prototype, were excluded from the analysis. Hospital B began collecting data approximately 16 months after Hospital A. In the four months from June 28, 1999 to October 29, 1999, 1996 completed study forms were returned from 3520 anaesthetics at Hospital B, a response rate of 57% (Table 2). On average, 92% of questions were completed on study forms that reported an error or pre-error.

TABLE 2

*Errors and pre-errors reported in relation to drug administration during anaesthesia**

Hospital	A	B	Combined
Anaesthetics, n	7286	3520	10806
Responses (%)	5798 (80%)	1996 (57%)	7794 (72%)
Errors	55	26	81
Pre-errors	31	9	40

*A bolus error made by a nurse in the recovery room has been excluded as this was not an anaesthetic incident. The combined frequency (95% confidence intervals) of all errors per anaesthetic was 0.0075 (0.006-0.009), of IV bolus errors was 0.005 (0.0035-0.006) and of pre-errors was 0.004 (0.003-0.005), with no significant rate differences between hospitals (chi squared, $P > 0.1$).

Respondents and Patients

Anaesthetists who reported errors and pre-errors varied in their years of experience (mode >10 years)

and occupational grade (76 consultants, 35 registrars, 10 jointly reported or unspecified). Error and pre-error reports related to patients aged between two months and 80 years (median 53 years), undergoing a wide range of surgical procedures (Table 3). These patients were evenly distributed across ASA categories 1 to 4, with a single report pertaining to category 5. Four of the patients were also categorized "e" (for emergency).

TABLE 3
Procedure types for which errors and pre-errors were reported

Surgical grade		Surgical category		Anaesthetic class	
Major	65	Cardiothoracic	48	General	105
Minor	48	Otorhinolaryngo-logical	27	General plus regional	11
Unclassified	8	Dental	8	Local with sedation	3
		Vascular	7	Regional alone	1
		Orthopaedic	5	Totally intravenous	1
		General surgical	5		
		Neurosurgical	4		
		Other	17		
Total	121		121		121

Errors

The rate (95% confidence intervals) of drug administration error, of any type, per anaesthetic was 0.0075 (0.006 to 0.009), and for IV bolus error was 0.005 (0.0035 to 0.006). There was no significant difference between hospitals (Table 2).

For the three consecutive six-month periods of the study at Hospital A, the rates of errors reported per anaesthetic were 0.012 (0.008 to 0.017), 0.004 (0.002 to 0.008) and 0.006 (0.003 to 0.009). These differences were significant (chi squared, $P < 0.01$)—the significance being attributable to a reduction in reported error rate between the first and second periods (Fisher, $P < 0.01$), with no significant difference between the second and third periods (Fisher, $P > 0.1$).

Fifty-one (63%) errors involved IV bolus injections, 16 (20%) involved IV infusions, and 12 (15%) involved inhalational agents (Table 4). The two largest individual categories of error were incorrect doses and substitutions with IV boluses of drug, with 16 (20%) reports each—twice as many as any other category. Of the 16 IV bolus substitutions, 11 (69%) involved the administration of a drug belonging to a different pharmacological class from the one intended. Errors involving inhalational agents showed the largest category was that of omission, with six (7%) reports, including three instances in which an anaesthetic vapour was omitted (isoflurane and sevoflurane). There were three instances (categorized under "Other") in which a drug was administered despite a known contraindication.

Procedural problems, such as a failure to check, distraction or communication problems, made up 70% of factors contributing to error overall (i.e., factors 1 to 5 and 9 in Table 5), and comprised five of the top seven factors in rank order. Fatigue was identified as a contributory factor in 11 (9%) of the error reports. There were no differences in the responses to questions specifically related to fatigue (i.e., questions 22 to 26 in Table 1), between the events in which fatigue was identified as a contributing factor and those in which it was not. Inexperience or inadequate knowledge was reported as a contributory factor in only five (3%) error reports.

Pre-errors

Twenty-nine (73%) pre-error reports involved IV bolus injections, seven (18%) IV infusions, three (8%) were unspecified, and one (2%) involved an incorrectly labelled blood product. No pre-error reports involved inhalational agents. Of the IV bolus pre-errors, the largest category was substitutions (18 of 29 reports), followed by IV dosage errors (6 reports), IV insertions (2 reports), IV omissions (2 reports) and one pre-error report of an incorrect route (IV instead of epidural). The seven infusion pre-errors involved three reports of substitution, two of omission, one of an incorrect dose, and one related to incorrect labelling by the anaesthetist (see Question 3 in Table 1 for definitions of incident categories).

Consequences of Errors

No death or permanent injury to a patient was attributed to a drug error during this study. One or more effects from an error were indicated in 50 reports. "Major physiological changes" were reported in seven patients, and "minor physiological changes" in 18. One patient suffered awareness. Five patients had unwanted prolongation of muscle relaxation, and two required unplanned postoperative ventilation in addition to extra time in the operating room. Prolonged unconsciousness was reported in one case. In two patients, intubation of the trachea was attempted in the absence of an intended dose of muscle relaxant (successfully in one, unsuccessfully in the other). Two patients were given IV instead of epidural injections. One of these patients developed tachycardia (after lignocaine and adrenaline injection). In 15 patients, a change in blood pressure was indicated or could be inferred from the study

TABLE 4
*Drugs involved with the 81 errors, by type of error and route of administration**

Error type (type total)	Boluses (freq)	n	Infusions (freq)	n	Inhalational agents (freq)	n
Incorrect dose (26)	Muscle relaxant (4), heparin (3), ephedrine (2), morphine, insulin, fentanyl, midazolam, droperidol, ketamine, cephazolin.	16	Sodium nitroprusside (2), dopamine, nitroglycerine, vecuronium, remifentanil, propofol, unidentified.	8	Nitrous oxide, isoflurane.	2
Substitution (22)	Flumazenil for midazolam, lignocaine for midazolam, morphine for metaraminol, morphine for fentanyl, fentanyl for etomidate, suxamethonium for fentanyl, naloxone for ephedrine, nitroglycerine for ephedrine, flucloxacillin for amoxycillin, augmentin for cefuroxime, thiopentone for cefuroxime, ketamine for remifentanil, atracurium for saline, muscle relaxant for relaxant-reversal drug, mivacurium for unidentified agent, unidentified.	16	Propofol for dopamine, adrenaline for dopamine, calcium for nitroglycerine, insulin for nitroglycerine.	4	Isoflurane for sevoflurane, nitrous oxide for oxygen.	2
Omission (15)	Muscle relaxant (3), antiemetic (2).	5	Remifentanil (2), dopamine, propofol.	4	Isoflurane (2), supplementary oxygen, pre-oxygenation, sevoflurane, nitrous oxide.	6
Repetition/Insertion (9)	Tenoxicam (2), nitroglycerine, dexamethasone, vecuronium, adrenaline, unidentified.	7			Isoflurane, sevoflurane.	2
Incorrect route (2)	Unidentified (1), lignocaine with adrenaline (1)—both IV instead of epidurally.	2				
Other (5)	Tenoxicam to pt on ACE inhibitor, Diclofenac to pt with ulcer history, vancomycin too rapidly (2), cephazolin to endocarditis pt before taking microbiological cultures.	5				
Route Total		51		16		12

*In addition to the 79 tabulated error reports, iodine was used for skin preparation in a patient known to be allergic to iodine and one oral hypertensive agent was substituted for another pre-operatively. Frequency of event is one if not stated in brackets.

form. This was described as "major" or requiring intervention in five. For one patient who was awake, hot flushing was reported. In the remaining cases insufficient detail was reported for classification.

DISCUSSION

This study is the first to estimate the incidence of drug administration error in anaesthesia on the basis of a large, prospective set of data which includes negative responses, an accurate denominator and an identified response rate. It establishes a baseline for the incidence and nature of drug administration error at both hospitals involved, against which future data collected in the same way can be compared.

A drug administration error of some type was reported for every 133 anaesthetics, and one error involving IV boluses of drug was reported for every 200 anaesthetics. As a result of these errors, a number of undesired events occurred; one patient suffered awareness, two required unplanned periods of postoperative ventilation in addition to prolonged time in theatre, and five experienced physiological changes requiring treatment.

Previous research suggests that errors of drug administration occur in a wide range of medical and nursing disciplines in most countries[2-4,17-21], but is relatively unhelpful in identifying the frequency of their occurrence. Two studies have attempted to

TABLE 5
*Factors contributing to the 81 reported errors**

Factor	Number of errors	(%)
1. Failure to check	22	(17)
2. Distraction	21	(16)
3. Inattention	16	(13)
4. Haste or pressure to proceed	15	(12)
5. Communication problem	11	(9)
6. Drug label problem	11	(9)
7. Fatigue	11	(9)
8. Unfamiliar workplace/equipment	9	(7)
9. Staff change/relief anaesthetist	4	(3)
10. Similarity of ampoules	3	(2)
11. Inexperience	3	(2)
12. Inadequate knowledge	2	(1)

*More than one factor may contribute to each error.

estimate the frequency of drug errors in anaesthesia. Chopra's group reported 14 drug errors and two involving giving the wrong blood out of 148 incidents from 113074 anaesthetics over 10 years in one hospital in the Netherlands[17], while Craig and Wilson report 12 drug administration errors from 8312 anaesthetics over a six-month period[22]. These rates are one-fiftieth and one-fifth respectively of that suggested by our data. The difference almost certainly reflects the fact that both previous studies collected positive responses only, and the fact that neither focused primarily on drug administration error.

In our study, reporting was voluntary and vulnerable to bias or to variation in the degree of compliance. Assessment of the incidents was subjective, and therefore an unknown proportion of drug administration errors may have passed undetected by the practitioner concerned, even if every detected error was reported[23]. Nothing is known about the 28% of anaesthetics from which no study form was returned. However, these weaknesses are offset by several strengths. Our audit included explicit negative responses indicating that no error occurred and included all anaesthetics during the survey with a known high (72%) overall response rate. The change in error rate seen over time was not associated with a change in response rate. The participation of two hospitals reduces the degree to which specific errors can be linked to an institution or individual and increases the generalizability of our findings. In addition, ongoing collection from the second hospital may provide control data to facilitate the evaluation of safety interventions planned at the first.

The primary reason for requesting the return of a study form for every anaesthetic was to elicit explicit negative responses and to monitor more accurately the rate of response over time. When calculating the rates of error we have taken a conservative approach and derived the denominator from the total number of anaesthetics given over the study period, rather than from the number of study forms returned. The latter, less conservative approach would have given rates (95% confidence intervals) of drug administration error, per anaesthetic of 0.01 (0.008 to 0.013) overall (i.e., one error per 100 anaesthetics), and 0.007 (0.005 to 0.009) for IV bolus errors (i.e., one error per 143 anaesthetics). The reduction in error rate at Hospital A over the period of the study is of interest. It is possible this was related to an increased awareness of drug error due to the audit, but our data do not permit a firm conclusion.

We were surprised at how few pre-errors were reported (Table 2) as incidents tend to be more common than accidents. It is likely that anaesthetists are less aware of certain types of pre-error than of errors, and that many pre-errors are not reported. For example, picking up the wrong syringe might be thought so commonplace as not to merit reporting.

Given current concern over the harmful effects of fatigue on performance[24], it is interesting that fatigue was identified as a contributing factor in only a minority of the error reports. In this audit, inexperience or inadequate knowledge were uncommon causes of error. In contrast, procedural problems such as failing to check were common (Table 5). Other factors, such as problems with drug labels and similarity of ampoules, are notable because they are amenable to correction[15]. These two contributing factors were associated with 11% of error reports (Table 5).

Giving an incorrect drug belonging to a different pharmacological class from the drug intended is probably riskier, in terms of patient harm, than giving an incorrect drug from the same class as the drug intended. Our data demonstrate that the majority of substitution errors (69%) are of the more dangerous inter-class variety (Table 4). The use of class-specific colour coding for syringe and ampoule labels might not reduce intra-class substitution, but would have considerable potential for reducing inter-class errors[12,15].

It has been estimated from data collected on the hospital ward that only 1% of drug errors actually cause injury[25]. This is consistent with the finding that one of the 81 errors in our study caused important harm (awareness). In New Zealand, many anaesthetists administer approximately 1000 anaesthetics a year[1]. Given one drug administration error per 133 anaesthetics, the "average" anaesthetist would be expected to make approximately seven drug

administration errors a year. If 1% of these errors leads to injury[25], drug error would be expected to injure two patients in the course of a 30-year career in anaesthesia.

The reduction of iatrogenic harm has been recognised as a priority in healthcare[6]. It is important to understand that iatrogenic harm is not a homogeneous problem, but is contributed to by deficiencies in the system within which medical professionals work[6,10,11]. Improvement will follow efforts focused on identifiable weaknesses in individual parts of the system. Drug administration error in anaesthesia is an important subset of drug error in general. The importance of drug error has been emphasized in the Harvard Medical Practice Study[3], the Quality in Australian Healthcare Study[4] and a recent report from the U.S. Institute of Medicine[6]. In the Australian study, drug errors were the fourth commonest category of adverse event (accounting for 10.8%), resulting in permanent disability in 17% and death in 8%. In a recent survey of New Zealand anaesthetists[1], 12.5% reported having harmed patients through drug administration error. A number of fatal drug administration errors, which have come to prominence because of subsequent criminal prosecutions or coroner's inquests, have been reported[26-30]. The significance of a risk relates to its severity as well as to its frequency. The consequences of these fatal errors have been devastating to all those involved and very expensive to society. It is true that many drug errors cause little harm, but it is widely accepted that the key to reducing rare, catastrophic events is to focus on those that are common but less severe, including near misses[11,13]. Our data demonstrate a relatively high rate of drug administration error in anaesthesia, and suggest substantial scope for improvements in safety through better procedures and equipment.

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