
Reports of Investigation

Adverse drug errors in anesthesia, and the impact of coloured syringe labels

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Purpose: To describe the frequency and pattern of drug errors in clinical anesthesia, and to evaluate whether a change to colour coded syringe labels, along with education, could reduce the problem of drug errors.

Methods: We prospectively recorded anesthesia-related information from all anesthetic cases for 36 mo, totally 55,426 procedures. Intraoperative problems, including drug errors, were recorded. After eighteen months we changed to colour coded syringe labels, and the effect of this change and education on drug errors was assessed. Errors were divided into four groups: syringe swap, ampoule swap, other 'wrong drug' errors, and wrong dose errors. The problems were graded into four levels, according to severity.

Results: A drug error was recorded in 63 cases (0.11%). There were 28 syringe swaps, and muscle relaxants were erroneously given in 15. There were nine ampoule swaps. There were eight 'other wrong drug' cases, and 18 cases where a wrong dose of the correct drug was given. Three of the drug errors were classified as serious, and 27 were of moderate severity. We found no differences between the two periods except for decreased number of ampoule swaps ($P = 0.04$).

Conclusion: Drug errors are uncommon, and represent a small part of anesthesia problems but still have the potential for serious morbidity. Syringe swaps occurred most often between syringes of equal size, and were not eliminated by colour coding of labels. As muscle relaxant drugs are most commonly involved, and can cause lasting morbidity, special preventive measures should be taken for this group of drugs.

Objectif : Décrire les erreurs de médicaments en anesthésie clinique selon leur fréquence et leur nature et évaluer si une modification de la couleur des étiquettes codées des seringues pouvait, avec une certaine formation, résoudre ce problème.

Méthode : On a enregistré, lors d'une étude prospective, les informations reliées à tous les cas d'anesthésie, 55 426, pendant 36 ms. ainsi que les problèmes peropératoires, y compris les erreurs de médicaments. Après 18 ms, on a introduit des étiquettes de couleur codées et évalué l'effet de ce changement et de l'information donnée sur les erreurs de médicaments. On a divisé les erreurs en quatre catégories : échange de seringue, échange d'ampoule, autre «médicament incorrect» et erreurs de doses, et classé les problèmes selon quatre niveaux de sévérité.

Résultats : Il y a eu 63 cas d'erreurs de médicaments (0,11 %). On a noté 28 échanges de seringues et 15 cas ont reçu des myorelaxants par erreur. De plus, 9 échanges d'ampoules ont eu lieu, 7 cas d'«autres médicaments incorrects» et 18 cas d'erreurs de doses pour le médicament requis. Parmi ces erreurs, 3 étaient sévères et 27 étaient modérées. Il n'y a pas eu de différence entre les deux périodes, sauf en ce qui concerne la baisse d'échanges d'ampoules ($P = 0,04$).

Conclusion : Les erreurs de médicaments sont rares et ne représentent qu'une petite partie des problèmes anesthésiques, mais elles sont toujours potentiellement dangereuses. Les échanges de seringues surviennent le plus souvent entre seringues de même taille et ils ne sont pas réduits par les étiquettes de couleurs codées. Les myorelaxants, le plus souvent en cause, peuvent entraîner une morbidité résiduelle. Des mesures préventives spéciales devaient être envisagées dans ce cas.

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Accepted for Publication June 28, 2000.

ADVERSE drug errors are among the most frequent adverse events in hospitalised patients, and may have serious consequences.¹⁻⁴ The practice of anesthesia has a large potential for drug error as it involves frequent injection of potent intravenous drugs. Published studies on drug errors in anesthesia have not classified the type of drug errors,⁵ been small in numbers, or based on voluntary anonymous incident reports.⁶⁻⁸ This latter method of study has been shown to capture only a small fraction of adverse drug events.⁹⁻¹¹ Thus, the real magnitude, or incidence, of drug errors in anesthesia practice is not known.

Human error is often involved in a 'wrong drug' incident.^{6,12-14} The problem of similarities in drug packaging and ampoule design have been addressed in studies from adverse drug events in hospitals and in anesthesia.^{6,15} In anesthesia, the drugs are often prepared and drawn up in syringes some time before they are to be used. This gives the possibility of choosing the wrong ampoule, as well as choosing the wrong syringe, or 'syringe swap'. Consequently, reports on drug error in anesthesia have addressed the issue of colour coding of ampoules and syringe labels. The addition of colour to a label is thought to be an additional visual and psychological cue for choosing the right ampoule or syringe.¹⁶⁻¹⁹ The effect of 'colour coding' has not been tested, and has been challenged.²⁰

The aim of our study was to describe the frequency and pattern of drug errors in clinical anesthesia. Our secondary aim was to study the impact of a quality improvement (QI) effort on the incidence of drug error. The major QI intervention was changing to colour coded syringe labels, along with an educational focus on the problem of drug error.

Material and Methods

In 1985, our department established a computer-based system for routine recording of anesthetic-related information on all patients given anesthesia.²¹ Specific data fields are included on the anesthetic chart. One of the fields is related to the occurrence of intraoperative problems. A checklist of the most common problems is printed on the anesthetic chart, and one of the check-boxes on the checklist is marked 'Drug error / Syringe swap' (Figure). In addition, information about the patient, the surgery, timing of events, and the anesthetic is recorded. Our system is designed to add minimal workload, as no additional form is needed. The data from the anesthetic charts are entered into a database. A copy of the anesthetic chart is stored in the department.

An 'intraoperative problem' is defined as 'an event that requires one or more measures either to prevent

<input type="checkbox"/>	Uneventful
<input type="checkbox"/>	Laryngeal spasm
<input type="checkbox"/>	Bronchospasm
<input type="checkbox"/>	Aspiration
<input type="checkbox"/>	Hypertension > 30%
<input type="checkbox"/>	Hypotension > 30%
<input type="checkbox"/>	Arrhythmia / ECG change
<input type="checkbox"/>	Perforation of the dura
<input type="checkbox"/>	Convulsions
<input type="checkbox"/>	Tooth Injury
<input type="checkbox"/>	Allergic reaction
<input type="checkbox"/>	Hypothermia < 35.5 °C
<input type="checkbox"/>	Hyperthermia > 39.0 °C
<input type="checkbox"/>	Bleeding > 20%
<input type="checkbox"/>	Difficult emergence
<input type="checkbox"/>	Inadequate anesthesia/analgesia
<input type="checkbox"/>	Equipment failure
<input type="checkbox"/>	Cardiac arrest / CPR
<input type="checkbox"/>	Oxygenation problems / Hypoxemia
<input type="checkbox"/>	Hypercapnia
<input checked="" type="checkbox"/>	Drug error / Syringe swap
<input type="checkbox"/>	Other

2 **Severity of problem**

FIGURE Checklist as printed on the anesthetic chart. If a problem occurs it is indicated as to type and severity, as here a drug error of severity 2. In addition a short description of the problem is written on the anesthetic chart.

further complications, or to treat a situation that is currently or potentially serious, and does not routinely occur during the conduct of anesthesia'. When a problem occurs it is also graded according to severity, using a scale from 'grade 1' to 'grade 4'. 'Grade 1' is a trivial problem, easily dealt with and not affecting the patient's condition. 'Grade 2' is a moderately difficult problem, with some effect on the patient, but of a low severity. 'Grade 3' is a serious situation that either proves very difficult to treat, or causes a serious deterioration in the patient's state. 'Grade 4' problems are associated with a fatal outcome. The anesthesiologist involved writes a short description of the problem on the anesthetic chart. The charts are quality controlled by a consultant before data entry. Over the years much effort has been put into educating the staff to fill in the records accurately, and to create an atmosphere of 'confidence and openness' regarding problem occurrence and recording, which is a prerequisite for user compliance and the quality of such data.^{13,22}

In Norway the anesthesiologist works in co-operation with a qualified nurse anesthetist. The nurse has 18 mo post-graduate education in anesthesiology, and is qualified both to give anesthesia, and to administer anesthetic drugs under supervision of an anesthesiologist. The nurse works eight-hour shifts, and the doctor is on call for 18-hr shifts and does not work the day after call. The standard drugs for anesthesia are normally prepared by the nurse before the patient arrives in the operating theatre. The drugs are drawn up in syringes, and marked with labels with printed drug names. There are no formal procedures for double-checking when the drugs are drawn up or during the administration of drugs to patients.

We implemented colour coded syringe labels in our department in April 1998. Before this, we were using white labels with black printed letters. The labels were placed in 'dispensers' in every anesthesia equipment trolley, and in locations where syringes were prepared. All labels were replaced with labels of similar size and print, but coloured according to the standard D4774-94 by American Society of Testing and Materials (<http://www.astm.org>). At the same time, we had educational department meetings and audits focussing on the problem of 'drug error', partly as case presentations and partly as discussions of the mechanisms behind errors and mishaps.

We chose a 36-mo study period, 18 mo before and 18 mo after implementation of the colour coded syringe labels. Our department gives about 18,000 anesthetics per year, and at Trondheim University Hospital (970 beds, annual admission rate 42,000 patients) most types of surgery are performed. During the study 55,426 anesthetics were given, and in 63 records the checklist had been marked for 'Syringe Swap / Medication Error'. The 'drug error' anesthesia charts were retrieved from our department archives and analysed according to type of error, severity, drug involved and contributing factors.

We used a chi-square test or Fisher exact test for categorical data, and two-tailed t test for continuous data. A $P < 0.05$ was considered statistically significant. Power analysis was obtained comparing two binomial proportions using a two-sided test.

Results

Incidence

In total 55,426 anesthetic procedures were recorded from September 1996 to October 1999 (Table I), and a total of 8,300 (15%) problems were recorded in the study period (Table II).

A drug error was recorded in 63 cases (0.11%, 1:880). Forty-five patients received a 'wrong drug'

TABLE I Demographic data

	Period 1	Period 2	Total
All cases	28,971	26,455	55,426
ASA 1-2	22,451 (77.5%)*	20,167 (76.2%)	42,618
ASA 3-5	6,520 (22.5%)*	6,288 (23.8%)	12,808
General anesthesia	19,313 (66.7%)	18,154 (68.6%)	37,467
Regional anesthesia	9,658 (33.3%)	8,301 (31.4%)	17,959
Age \pm SD)	42.2 \pm 24.1	42.5 \pm 24.4	42.4 \pm 24

Decreased proportion of ASA 1-2 vs ASA 3-5 and increased use of general anesthesia vs regional anesthesia from period 1 to period 2 (* $P < 0.001$).

TABLE II Distribution and severity of all recorded problems during the two periods

Problems	Period 1	Period 2	Total
All problems	4,285 (14.8%)	4,015 (15.2%)	8,300 (15.0%)
Severity 1	3,135 (10.8%)	2,901 (11.0%)	6,036 (10.9%)
Severity 2	1,012 (3.5%)	988 (3.7%)	2,000 (3.6%)
Severity 3	112 (0.4%)	110 (0.4%)	222 (0.4%)
Severity 4	26 (0.0%)	16 (0.0%)	42 (0.0%)

(0.08%, 1:1230). Fifty-six drug errors occurred during general anesthesia (0.15%, 1:660) and seven during regional anesthesia (0.04%, 1:2560). Of the general anesthesia errors two occurred during preparation for anesthesia, 39 during induction, nine during maintenance, and six during emergence. Fifty-six of the drug errors occurred during the day (08-16), six during the evening (16-24), and one during the night (00-08).

Type of problem

Of the 63 drug errors 28 (44%) were syringe swaps, nine (14%) ampoule swaps, eight (13%) 'other wrong drug' cases, and 18 (29%) cases where a wrong dose of the correct drug was given (Table III).

In syringe swaps the most common drugs erroneously given were non-depolarising relaxants (n=9) and depolarising relaxants (n=6) (Table IV). In 27 of the 28 syringe swaps, the swaps were between syringes of equal size. In one case albumin was mistaken for thiopental, the drugs being in syringes of equal size, and the content of the same yellow colour. There were no cases of syringe swap between drugs with the same label colour in period 2 (for instance succinylcholine and pancuronium, both red labels). The drugs most commonly intended to be given in syringe swaps were opioids (n=12), non-depolarising relaxants (n=4), and

midazolam (n=3). Other drugs were swapped only once. In ten cases, relaxants were given when opioids were intended.

In ampoule swaps, the most common drug erroneously given was glycopyrrolate/neostigmine (n=4); other drugs were given only once (Table IV). Four of nine ampoule swaps were between glycopyrrolate and glycopyrrolate/neostigmine. These ampoules came from the same manufacturer, and were of equal size, and with very small and similar writing on the ampoule. The drug that was most commonly intended to be given in ampoule swaps was glycopyrrolate (n=3), other ampoules were swapped only once.

Other 'wrong drug' errors included two cases where the patient was given one hundred percent nitrous oxide, using old anesthesia machines where a minimum FiO_2 was not guaranteed (Table IV). In another two cases, the vaporiser was left 'on' by mistake after a routine check of the apparatus, and the patient was given

an inhalation agent when the intention was to give oxygen by nasal catheter. Other examples included patients who received drugs, to which they were supposedly allergic, or drugs that were inappropriate according to the patient's medical condition.

The 'wrong dose' errors recorded most commonly involved non-depolarising relaxants (n=5), thiopental (n=3) and local anesthetics (n=3). Other drugs were recorded as wrongly dosed only once.

No contributing factors other than similarity of syringe size and colour, could be identified. When dose calculation errors were made, single examples of contributing factors were recently introduced drugs, new staff, and pediatric patients. No errors were committed because of lack of knowledge about the proper indication for the drug. The errors were detected either by some physiological reaction by the patient, or the mistake was detected by the anesthetist after the drug had been given.

TABLE III Distribution of type and severity of drug errors

<i>Drug Errors</i>	<i>Period 1</i>	<i>Period 2</i>	<i>Total</i>
All	40	23	63
Syringe swaps	16	12	28
Ampoule swap	8*	1*	9
Other wrong drug	4	4	8
Wrong dose	12	6	18
Drug errors Severity 1	22	11	33
Drug errors Severity 2	16	11	27
Drug errors Severity 3	2	1	3

No statistically significant difference between periods using Fisher exact test, ampoule swap* ($P = 0.04$).

Severity

Three problems were judged to be serious, 27 moderate, and the other 33 problems were of minor severity (Table III). There was no mortality caused by drug errors.

Three patients were in danger because of the medication error. In two patients the lungs were ventilated with N_2O 100% instead of oxygen. In both, desaturation was rapid, and the errors were detected by pulse oximetry, with lowest saturation values of 42 and 50% respectively. The errors were corrected by changing to oxygen, and both patients rapidly improved. One child received succinylcholine mistakenly for saline during preparation for anesthesia in the

TABLE IV Wrong drug given to patient, by type of drug error

<i>Wrong drug given</i>	<i>Period 1</i>			<i>Period 2</i>		
	<i>Syringe Swap</i>	<i>Ampoule Swap</i>	<i>Other Wrong Drug</i>	<i>Syringe Swap</i>	<i>Ampoule Swap</i>	<i>Other Wrong Drug</i>
Nondepolarising Relax	6	1	1	3		
Succinylcholine	4			2		
Glyco/Neost	1	3			1	
Inhalational agent / N_2O			2			2
Antibiotic			1			2
Ketamine		1		2		
Atropine	1	1				
Local anesthetic	1			1		
Analgesic	1			1		
Midazolam				2		
Glycopyrrolate	1	1				
Dextran		1				
Ephedrine				1		
Albumin	1					
TOTAL	16	8	4	12	1	4

MRI unit. The patient was not monitored by pulse oximetry, and the mistake was detected by appearance of apnea and cyanosis, and rapidly corrected by controlled ventilation with oxygen.

Twenty-seven errors were judged to be 'Severity 2'. Of 18 syringe swaps in this group, 12 patients were given muscle relaxants by mistake when awake. The four patients who received succinylcholine when awake reacted with stress and anxiety, and remembered the incident afterwards, otherwise there were no postoperative sequelae in any patients. Two of eight patients who received non-depolarising muscle relaxant when awake, had noticeable effects before the mistake was identified, but general anesthesia was induced before they were severely paralysed. Three ampoule swaps, three wrong doses and three other wrong drug errors were judged to be of moderate severity.

Impact of colour labels and education

There was a small difference in case mix between the two periods, as there was an increase in the number of ASA 3-5 patients and an increase in the use of general anesthesia from period 1 to period 2 (Table I). There was no difference in age (Table I) or incidence of overall problems (Table II) from period 1 to period 2.

There was a tendency towards reduced total incidence of drug errors ($P = 0.07$). The rate of drug errors in period 1 was 40 errors in 28,971 cases, which was reduced to 23 errors in 26,455 cases in period 2. The decrease was not statistically significant ($P = 0.07$). A power calculation of the statistical analysis using a two sided test, with these proportions, and a chosen level of statistical significance at $\alpha = 0.05$, results in a power of 0.43.²³

There was no reduction in number of wrong drug errors, or number of wrong dose errors between the two study periods, but there was a reduction in number of ampoule swaps (Table III). The severity of problems did not change between the two study periods (Table III).

Discussion

We found that drug errors occurred in 0.11% of anesthetic cases. Drug errors represented 0.8% of all anesthetic problems recorded. Our QI intervention with colour coded syringe labels and education gave no proven reduction in incidence of drug errors.

Incidence and severity

In our study we found a total problem incidence of 15%, and a drug error incidence of 0.11%. This is comparable to the results in a study by Cohen *et al.*, where they used self reporting of problems, and completed a

form concerning intraoperative variables for every anesthetic case.²⁴ They found a 10.6% chance of an intraoperative problem, and 0.18% drug complications in the last part of their study (1978-83), but no classification of drug errors was provided. A study by Spittal *et al.* was based on self reporting of problems, but forms were filled in only when a problem had occurred. From 5,056 cases they received 6.7% incident forms. A 'wrong drug' incident occurred in 0.08%, and 0.16% had a 'wrong drug or dose' incident.²⁵

In our study, the drug errors represented 0.8% of all the problems we recorded. This is comparable to 1.5% by Cohen.²⁴ and 2.4% by Spittal.²⁵ Other studies, based on voluntary reporting of incidents, but without knowledge of the total number of cases, have found large variations in drug errors, from 7.2%⁶ to 22%⁸ of all incidents. However, as the total number of cases is not known in these studies, and the study design is different, comparison is difficult.

We recorded drug errors in 63 cases, and a 'wrong drug' error in 45. Of these, 12 patients were erroneously given a muscle relaxant when awake. Although these are small numbers, this suggests that, in our department, on average one patient each month received an unintended drug, and every three months one patient received a muscle relaxant when awake. The potential for serious morbidity exists, as 27 drug errors were judged to be of severity 2, and three patients became seriously hypoxic as a consequence of the drug errors. Seven of the 12 patients who received muscle relaxants when awake were partly or completely paralysed before induction of general anesthesia. This is a frightening experience, and predisposes the patient to problems with anxiety postoperatively.^{26,27}

A weakness in our study is the possibility that a drug error remains undetected. If there is no physiological response from the patient, and the mistake is undetected by the anesthetist, the error will remain undetected, and - unrecorded. This problem is common to all manual recording systems, but as the undetected problems did not cause marked changes in the patient's condition, they are probably also of minor severity.

Impact of intervention

We expected a reduction in drug errors after our intervention with colour coded labels and general educational sessions, but the reduction was not statistically significant ($P = 0.07$). Our sample sizes were large, but the incidences of drug errors were very low. With a level of statistical significance at $\alpha = 0.05$, a power calculation results in a power of 0.43 to our analysis. This means that if there was a difference between the periods, we only had a 43% chance of detecting it, and

consequentially a 57% chance of not detecting it (Type II statistical error).

Thus, it is a possibility that there was a reduction in drug errors after our intervention, and that a change to colour coded labels and education had an effect, but that it was not detected by our study because of a statistical Type II error.

The major expected effect of our intervention would be a reduction in the incidence of total drug errors and 'syringe swaps', but we found no changes in their occurrence. The possibility of improvement in anesthetic care resulting from a critical incident reporting programme have also been studied by Short *et al.*²⁸ They found no change in ampoule or syringe swaps, or general pharmacological incidents after increased awareness of problems at QA meetings and written reports, using a qualitative study design. It seems that the addition of 'visual and mental cues' is not strong enough alone to correct the mistakes. Indeed, the value of colour coding has also been questioned. Nunn and Baird discussed the possibility for colour coding as a too easy mental short cut for identification of a drug, without reading the label, and that 'it is therefore both fallible and dangerous to ascribe a value to colour'.²⁰ There is no supporting evidence for this, and if colour had replaced the name as a drug identifier in our study, we would have expected syringe swaps between drugs with the same colour, for example succinylcholine mistaken for pancuronium (both red labels). However, all our syringe swaps were between syringes with different colours, meaning that the mistakes involved both the name of the drug and the colour.

Quality of reporting

Critical incident reporting is usually based on an anonymously submitted written report when an incident occurs. Underreporting is a known problem using this technique. Cullen *et al.* found that of the errors observed by a nurse case investigator that only 6% were reported in incident forms.⁹ Similarly Jayasuriya found that of the events reported in a simple routine form, completed for every patient, only 24.8% were reported in the traditional four-page incident report.¹¹ However, for the more serious incidents the compliance was nearly 100%. Under-reporting is probably mostly caused by the added workload represented by filling in separate forms, and a belief that reporting is of little value as the feedback to those supplying the report data may be lacking. Other factors are fear of a disciplinary action or lack of understanding of what types of incidents should be reported.

We have tried to increase reporting compliance by making data recording a routine in all cases, integrat-

ing the data fields into the anesthetic chart, eliminating the need of an additional form, and thereby reducing extra workload.²¹ We have emphasised feedback to anesthesia personnel, and we have also tried to create an atmosphere of 'openness' and 'confidence' about recording problems, and have avoided every aspect of 'inspection' and 'control'.

The incidence of problems recorded in our system is similar to studies where greater resources have been put in.^{5,24,29-31} This makes it likely that our method of recording gives a good reflection of the occurrence of intra-operative problems. Our simple method of problem recording can be a valuable tool for quality assurance, where a useful method for the evaluation of corrective strategies is often missing.

Preventative strategies

In anesthesia, as in hospitals, most drug errors are totally or partially attributed to human error.^{2,6,32} Error making is an inherent part of human psychology and activity, and the occurrence of error can possibly only be reduced, not eliminated.¹³ Examples of psychological factors which increase the possibility of a human error are 'inattention', 'haste', 'communication problems', and 'fatigue'.^{13,33,34} Preventative strategies should aim to reduce these psychological factors, but must also aim at reducing the possibility for error caused by non-psychological factors. This means that the environment, or 'system', in which the anesthesiologist is working must also be the target for corrective strategies. This strategy must try to reduce both the occurrence and the consequences of errors.¹³

Standardisation and visual cues

Standardisation is an important example of a 'system based' approach.^{6,13,17,32} Standardisation can be done by the selection of drugs in the department, by defining drug preparation routines, and by the layout of drug trolleys. National standardisation of syringe labels were recommended by Radhakrishna, as he found a great variation in colour coding between hospitals in UK.³⁵ Ampoules and syringe labels should have large letters, but neither large letters nor colour coding seem to be a strong enough visual cue to prevent errors. Almost no swaps occurred between drugs in syringes of different sizes in our study and the AIMS study.⁶ If one size of syringes was used for only one group of drugs, this might be a strong enough visual cue for reduction of syringe swaps.

Checking

The aviation industry has extensive standard operating procedures for double-checking. Similarly, less reliance

on short-term memory and vigilance, and addressing the potential for reducing errors through the use of well thought-out checklists and computerised decision aids, are recommended for the medical profession.^{1,3} Double-checking of ampoules as the drug is drawn up into the syringe, and checking the label on the syringe as the last procedure before giving the drug to the patient, should be strongly recommended.

Conclusion

We recorded a low incidence of drug errors, and drug errors represented a small part of all anesthesia problems. The implementation of colour coded drug labels did not eliminate the problem of syringe swap. In the line of defences against drug errors, system improvements, better visual cues, and better checking procedures are needed. Reading the label before giving the drug to the patient is still the last in the line of multiple defences against the problem of drug error. As muscle relaxant drugs seem to be most commonly involved, and have a potential for lasting morbidity, special preventive measures should be taken to reduce errors in this group of drugs.

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