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MEDICATION ERRORS IN OPERATING THEATRES IN THE DEPARTMENT OF ANAESTHESIOLOGY AT THE UNIVERSITY OF THE WITWATERSRAND

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine in Anaesthesiology, Johannesburg, 2018

Declaration

I, Janine Claire Vally declare that this research report is my own work.

It is submitted for admission to the degree of Master of Medicine in Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

…….. (signature of candidate)

Signed on this …….. day of …… 2018

Dedication

This MMed is dedicated to all anaesthetists who continually striving to provide excellent and safe care to all their patients and will hopefully be an inspiration on our journey of continued improvement towards better practice.

Abstract

Background

Medication errors occur commonly. They result in preventable morbidity and mortality and increased cost to the health care system. Anaesthetists are at high risk due to the number and potency of medications given in theatre. The occurrence of medication errors in operating theatres amongst anaesthetists at the University of the Witwatersrand is not currently known.

Methods

This is a prospective, contextual and descriptive study. A self-administered questionnaire was completed by anaesthetists at the University of the Witwatersrand (n=128).

Results

Ninety-three percent of participants reported a medication error or near miss event. A total of 231 events were reported. Medications most commonly involved were muscle relaxants, opioids and vasopressors. Substitution was the most common type of error, most often due to failure to check the label prior to administration. Fatigue was an important contributing factor. Events reported were most frequent during general anaesthesia, in adults, ASA I-II, elective patients during normal working hours. Only two cases of major morbidity occurred. No deaths were reported. No differences were found between consultant and junior anaesthetists.

Conclusions

Despite previous recommendations, medication errors and near miss events continue to occur in a similar manner. Negative patient outcomes have occurred with 2 cases of major morbidity reported in this study. Reporting of events remains low, but has improved. Measures should be instituted in order to decrease errors and improve incident reporting rates

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List of abbreviations

ADE:	Adverse drug event
AIDS:	Acquired immunodeficiency virus
ASA:	American Society of Anaesthesiologists'
CAS:	Canadian Anaesthesiologists' Society
HIV:	Human immunodeficiency virus
ICU:	Intensive Care Unit
IOM:	Institute of Medicine
ISO:	International Organization of Standardization
IV:	Intravenous
MeSH:	Medical Subject Headings
SABS:	South African Bureau of Standards
SAJAA:	South African Journal of Anaesthesia and Analgesia
SASA:	South African Society of Anaesthesiologists'
UCT:	University of Cape Town
WHO:	World Health Organization
WITS:	University of the Witwatersrand

Section 1: Literature review

1.1 Introduction

Anaesthetists are involved in providing anaesthesia, peri-operative care, intensive care, emergency care and pain management to patients. They work alongside many medical disciplines in various clinical environments and have a responsibility to provide and improve patient safety and care. (1) Anaesthesia is considered to have a high level of safety as anaesthesia related deaths have declined and are now minimal. One area of patient safety in both general medical practice and anaesthesia is administration of medication. Medication errors, which occur commonly, have a high human and financial cost. (2, 3) Although there is no harm to patients in the majority of cases, there is a minority where serious morbidity and mortality occurs. (3, 4)

Anaesthetists have a unique role and responsibility in patient care. They are involved in prescription, preparation, administration and monitoring of medication and its effects. Unlike in the ward setting, standard safety checks are often bypassed in the theatre environment. (5) It is estimated that the average anaesthetist will administer at least 250 000 medications during their practice. (6) Anaesthetists administer multiple medications of high potency and variety within a short period of time. Patients also use multiple medications in the peri-operative period. (4) It is understandable that errors could occur with negative consequences.

Despite international and national research in multiple centres having demonstrated that medication errors in anaesthesia are common with potentially negative consequences (6), there has been little change in clinical practice to lower of medication error rates and ultimately, enhance patient safety in South Africa. (7)

In order to reduce medication errors, error rates need to be measured, root cause of errors found, potential for harm identified and solutions should be

found and implemented. (5) In South Africa, there is limited data available on medication errors in anaesthesia.

In this literature review, an overview of medical errors and more specifically medication errors will be discussed. The primary focus of the literature review will be on medication errors occurring in theatre during anaesthesia. The following shall be discussed:

- Relevant definitions and classifications
- Patient safety and medical error rates
- Medication errors in medicine
- Medication errors in anaesthesia
- Strategies to decrease medication errors in anaesthesia

1.2 Definitions and Classification

1.2.1 Medical Error

A review by Grober et al. (8) in 2005 suggested medical error is defined as: “an act of omission or commission in planning or execution that contributes or could contribute to an unintended result”. (8) Examples of medical error include incorrect diagnoses, wrong site surgery, patient misidentification and medication errors.

1.2.2 Medication Error (ME)

Medication error is a type of medical error. Multiple definitions are used. Many are long, complex and overlapping. This is problematic as comparison of research results and incident reporting become complex.

For the purpose of this study, medication error is defined as: “any error in the medication process (prescription, dispensing, administration and monitoring) whether there are any adverse consequences or not”. (9) This includes all medications, fluid therapy, medical gases and volatile agents. Of importance

is that the error does not necessarily result in harm to the patient. Medication error is sometimes used interchangeably with the term ‘drug error’. (3)

1.2.3 Near Miss

This is defined by Orser et al. (4) as “an event that did not involve the actual administration of a drug”. However, had the administration of the drug occurred, it would have resulted in an error.

1.2.4 Other important definitions

Omission: “Medication not administered or administered late”
Repetition: “Extra dose of intended medication given”
Substitution: “Incorrect medication administered instead of that intended”
Insertion: “Medication administered which was not intended at that time or at any stage”
Incorrect Dose: “Incorrect concentration, amount, or rate of infusion of the desired medication administered”
Incorrect Route or Inappropriate Drug Administration: “Administered intravenous instead of intramuscular; use of a multi-dose vial on more than one patient”. (9-11)

1.3 Patient Safety and Medical Error

Medical errors pose a significant public health challenge and threaten patient safety. (8) The World Health Organization (WHO) defines patient safety as “the prevention of errors and adverse effects to patients associated with health care”. (12)

In 1999, the report released by the Institute of Medicine (IOM), “To Err is Human: Building a Safer Health System”, highlighted the effects of medical error and initiated a new focus towards improving patient safety. In the United States of America (USA), medical error was found to be a principal cause of death. (13)

1.3.1 International Medical Error Rate

The IOM found that annually at least 44 000 and perhaps up to 98 000 deaths thought to be due to preventable medical error occurred in hospitals in the USA. This exceeded mortality due to trauma from motor vehicle accidents, Acquired Immune Deficiency Syndrome (AIDS) and breast cancer. Examples of medical errors included medication errors, incorrect patient identity, wrong-site surgery and iatrogenic surgical injuries. Medication errors alone accounted for an estimated 7000 deaths per annum. Errors with severe outcomes were more likely to occur in the intensive care unit (ICU), theatre and emergency departments. (13)

Beyond the cost of human life, medical error resulted in a large financial cost. The annual cost due to error was estimated between $17-29 billion per year across the USA. (13) More recently in 2005, Andel et al. (14) found a further increase in preventable deaths (now 200,000 per annum) due to all causes of medical errors in the USA.

1.3.2 National Medical Error Rate

No identified data exists in South Africa for medical error rates. (15) Error rates could be extrapolated from a study conducted in eight developing nations (including South Africa) by Wilson et al. (16) in 2012. A retrospective analysis of medical records from hospital admissions was done. In 8.2% of cases, an average of at least one adverse event had occurred (range 2.5 to 18.4%). Of these errors, 83% were judged to be preventable. (16) Adverse events observed did not specifically identify medication errors.

1.4 Improving Safety

1.4.1 Strategies to improve Patient Safety

Patient safety is being prioritised internationally and measures have been taken to decrease error rates. These include the WHO Surgical Safety

Checklist and incident reporting systems. The aim of the WHO Surgical Safety Checklist is to improve patient safety, decrease morbidity and mortality, and improve communication amongst clinicians and nurses in theatre. (17) The checklist aims to eliminate one possible medication error in theatre by identifying if the patient has any known allergies.

Merry (18) identified the need for a national incident reporting system that would allow anonymous error reporting in anaesthesia. The purpose is to identify key causative factors and increase awareness associated with the risks of providing anaesthesia, including medication errors in theatre. There are many institutions internationally which deal specifically with incident reporting and monitoring in health care. Examples are the National Reporting and Learning System (United Kingdom), Australian Incident Monitoring System and Patient Safety Institute in Canada. (18) There is no national incident reporting and monitoring organisation in South Africa to date.

The Helsinki Declaration on Patient safety in anaesthesiology was released in 2010. The declaration represents the views of and outlines standards that should be met to enhance patient safety during anaesthesia. This includes medication safety practices. It is a requirement that institutions should have specific protocols and necessary facilities to manage checking of medications and syringe labelling. It also states that the WHO Safe Surgery Saves Lives initiatives and Checklist should be supported by all institutions. All institutions should contribute to major audits and critical incident reporting systems. (1)

1.4.2 International Labelling

In anaesthesia, many countries including Australia, Canada, United Kingdom and the USA have adopted an internationally accepted colour-coding system for syringe labelling in theatre. (7, 19) The South African Society of Anaesthesiologist's (SASA) has in conjunction with the International Organization for Standardization (ISO) and the South African Bureau of Standards (SABS), developed a South African standard for colour-coded user applied drug labels (SANS 26825:2009) in anaesthesia. (7) These labels are

only used at some hospitals associated with the University of Cape Town and at Grey's Hospital in KwaZulu-Natal. (7, 20)

After introduction of the above mentioned labels for use in theatre, a reduction in medication errors was reported by Grey's Hospital. The number of medication errors reported over six-month periods before and after introduction of user applied standardised medication labels was examined. It was estimated that if only 10-30% of medication errors are identified and reported, after introduction of labelling up to 70 medication errors may have been prevented over the six month period. (20)

1.4.3 South African Society of Anaesthesiologists (SASA)

SASA has a Practice Guideline (2012), which is available to all members. However, there is no section in the guideline which addresses medication safety and how to avoid medication errors. (21)

1.5 Incidence of Medication Error

It has been challenging to establish an accurate and reliable manner in which to identify medication errors in both hospitals and the theatre environment. (22) Retrospective analysis of cases is limited as it only detects incidents recorded, most likely errors causing harm. Another method of error identification is incident reporting systems. These are commonly used, however unnoticed errors will not be reported. This system is more likely to identify errors that result in harm, an example of reporting bias. (23, 24) Prospective studies rely on self-reporting and there may be under reporting. It has been suggested that observational studies may be the best way to collect the most accurate data, but it is expensive and time consuming. (5, 25-27) One needs to consider the above limitations when reviewing literature on the subject.

1.5.1 Medication errors in Hospitals: International Data

A multinational systematic review conducted by Keers et al. (28) regarding the prevalence of medication errors in the hospital setting showed a high rate of error. A total of 91 studies were included. The median and interquartile range was found to be 19.6% and 8.6-28.3% respectively. The most common errors were found to be wrong timing, omission and incorrect dosage. (28)

1.5.2 Medication errors in Hospitals: South African Data

The only identified data in South Africa is a study conducted by Blignaut et al. (29) in 2015. Direct observation was used as the method to determine the incidence of medication error by nurses. A total of 315 patient medication administrations were observed, with a total of 296 errors occurring. Most frequent errors were incorrect timing (43%) and omissions (41%). Incorrect medications were given in 2% of cases as well as 2% of medications given via the incorrect route. The study did not note any negative outcomes due to the errors. (29)

1.6 Medication errors in anaesthesia occurring in theatre

1.6.1 International Data

Review of American Society of Anaesthesiologist's (ASA) Closed Claims

In 2003 all medication error cases in the ASA Closed Claims Project database were reviewed. Of the total 5803 cases, 3.5% were due to medication errors. The classification of medication errors used in this review was as follows: omission, repetition, substitution, insertion, incorrect dose and incorrect route (refer to section 2 for definitions). "Other" was defined as "a more complex event not fitting into the categories above". (30)

There were a total of 64 cases of incorrect dose (31%), 50 cases of substitution (24%), 50 cases of “other” (24%) and 35 cases of insertion (17%). Only two cases of omission and four cases of incorrect route occurred. (30)

Medication errors in the ASA Closed Claim database frequently resulted in serious problems. Immediate and major physiologic effects occurred in 97 cases (47%). Fifty cases of mortality (24%) were noted and major morbidity in 70 cases (34%). These are much higher numbers than in other studies, likely because they are claims. Errors resulting in no or minor morbidity were possibly not reported. (30)

A wide variety of medications were associated with the errors. The two most common were succinlycholine (17%) and adrenaline (8%). In 12 of the 35 cases associated with succinlycholine, the medication was given to awake patients resulting in awareness. Succinlycholine was given to five patients with a known history of pseudocholinesterase deficiency which resulted in prolonged effects and muscle paralysis. Three patients suffered hyperkalaemic cardiac arrest after it was administered. (30) In the cases involving adrenaline, 11 of the 17 patients suffered death or major morbidity. Adrenaline ampoules were often mistaken for the intended drug. (30)

Reviewers found care to be “less than appropriate” in 84% of medication error claims versus only 35% in non-medication error claims. Payments were made to 72% of claimants for medication errors versus 52% in non-medication error claims. (30)

Prospective Studies

Webster et al. (10) described the frequency and nature of medication errors and ‘pre-error’ (or near miss as defined in this study) in two New Zealand teaching hospitals from 1998-1999. The study was conducted over 18 months. Prospective incident reporting was used. A study form was anonymously completed after each anaesthetic, irrespective if an error or near

miss had occurred or not. If an error or near miss occurred, details of the event were given. (10)

A total of 10 806 anaesthetics were performed with a total of 7794 forms returned (72% response rate). A total number of 121 errors were reported over the 18-month period. Anaesthetists reporting error most commonly had experience of more than 10 years. Errors were not more common in any particular group (e.g. consultants or junior anaesthetists). Age group of patients affected ranged from 2 months to 80 years (median 53 years). Patients affected by errors were evenly distributed across the ASA categories I to IV. Only four of the cases were emergency cases. (10)

The rate of medication error for any type of anaesthetic was 1 in every 133 anaesthetics (0.75%). Fifty-one (63%) errors involved intravenous (IV) bolus injections, 20% IV infusions and 15% related to inhalational agents. The most common types of errors were incorrect dosages, medication substitution (69% of cases a medication from a different class was given) and omission (most commonly occurring with inhalational agents). In three cases a medication was administered despite the patient having a known contraindication. (10)

The most common factors contributing to errors were failure to check, distraction, inattention and pressure to proceed (up to 70% of cases). Fatigue was noted to be a contributing factor in 9% of cases. In 3% of cases, inadequate knowledge or inexperience was a contributing factor. Other contributing factors were: communication problem, medication label problem, unfamiliar environment, staff change and similarity of ampoules. (10)

In this study, no errors resulted in death or permanent injury to a patient. “Major physiological changes” were reported in 7 patients, and “minor physiological changes” in 18 patients. Five patients had prolonged muscle relaxation with two patients needing unplanned post-operative ventilation. This was in addition to prolonged time in theatre. The most significant consequence was one patient who suffered awareness. One patient had

prolonged unconsciousness. Two patients received medication via the IV instead of epidural route. (10)

A noted weakness in the study is that reporting was voluntary, thus compliance was not guaranteed. The assessment of errors was also subjective; some errors may not have been detected. Strengths of the study are that 'negative' responses were recorded and the overall response rate was high (72%). As two institutions were involved, this increases the relevance of results in other settings. Relatively few near misses were reported. This was not expected as they are thought to be more common than errors. It was postulated that anaesthetists were less aware of near misses and those occurring were not reported. (10)

Similar studies have been performed elsewhere internationally. Results obtained are summarised in Table 1 below. (9)

Table 1: Incidence of medication errors in key studies

Study	Study period	No. of anaesthetics	Incidence of error	% of error
Webster et al. (10)	Feb 1998-Oct 1999	10 806	81	0.75
Sakaguchi et al. (31)	1993-2007	64 285	50	0.078
Cooper et al. (32)	Jul 2005-Jan 2006	10 574	52	0.49
Zhang et al. (33)	Mar 2011-Sep 2011	24 380	179	0.73

In Japan, Sakaguchi et al. (31) found the medications most commonly involved in errors were opioid analgesics, inotropes and vasopressors. The most common type of error was 'syringe swop' and less experienced anaesthetists were more likely to make errors. In Canada, Cooper et al. (32) recorded a total of 52 errors, 35 medication errors and 17 near miss events.

Errors were twice as likely to be made by anaesthetists in training and increased in cases where patients were of a higher ASA status. Other contributing factors were distraction (16.7%), pressure to proceed (12.5%) and misreading of labels (12.5%). (32)

The limitations of prospective, self-reporting studies are known. Flynn et al. (25) confirmed low self-reporting rates. Of 456 medication errors found by direct observation, only 34 of those were found retrospectively on examination of the anaesthetic chart and only 1 was reported by the anaesthetist themselves. As validity and reliability of previous studies were of concern, Nanji et al. (5) used primarily direct observation to determine medication error rate and revealed contradicting results.

Nanji et al. (5) used continuous direct observation in theatre as the primary method of data collection. The second method was retrospective chart review. An important difference in methodology to the prospective studies is the manner in which the error rate is calculated. In the prospective studies, error rate is calculated by dividing the total number of errors by the total number of anaesthetic cases done. Nanji et al. (5) calculated the error rate by dividing the total number of errors by the total number of medications administered. (5)

A total of 277 operations were observed on 275 patients with 3671 medications administered. Of the operations observed, 124 (44.8%) included 1 or more medication error or adverse drug event (ADE). General anaesthesia was given in 227 (82%) of cases and sedation only in 37 (13.4%) of cases. Error rates were similar irrespective of the type of anaesthesia. (5)

A total of 211 medication errors and or ADE were noted. The majority were directly observed 171 (81.5%) and only 39 (18.5%) were found during retrospective chart review. Of the 211 events, 18 were excluded, leaving a final sample of 193. Of the events detected 153 (79.3%) were medication errors and 91 (47.2%) were ADEs. A total of 153 events (79.3%) were considered to be preventable with only 40 (20.7%) considered not

preventable. One hundred and four (53.9%) events occurred within 20 minutes of induction. (5)

None of the events resulted in patient mortality, but 1.6% were “life-threatening”, 68.9% “serious” and 29.5% “significant”. The most common type of error was a labelling error (24.2%), wrong dose (22.9%) and omitted medication or failure to act (17.6%). The medications most commonly involved were propofol, phenylephrine and fentanyl. Long cases (> 6 hours) and those where more than 12 medications were given were associated with a higher error rate. (5)

In summary, Nanji et al. (5) are suggesting a much higher rate of 1 in 20 medication administrations resulting in error. In more than 33% of cases harm was observed and in the remaining cases the potential for harm existed. It was suggested that reliance on self-reporting results in not recognizing the majority of medication errors in most settings. This method cannot be used to reliably evaluate this problem. (5)

Survey Study

Orser et al. (4) conducted a survey study of anaesthetists in the Canadian Anesthesiologists’ Society (CAS) in 2000. While it was unable to determine the incidence of drug errors (as in the prospective studies), it identified demographics of practitioners, experience of medication errors, types of errors and consequences, possible causes, contributing factors and reporting behaviours.

All the members of CAS (n=2266) received a self-reporting survey. A total of 687 practitioners responded (30% response rate). At least 1 medication error or near miss had occurred during the career of 85% of participants. An average number of errors per responder were 1.5. A total of 1038 events were described. Most of the respondents were specialist anaesthetists and had been practicing for 5 to 10 years. They mostly practiced in teaching hospitals and more than 75% of time was allocated to clinical work. (4)

Of the 1038 adverse events reported, actual errors and near misses were 61.7% and 9.6% respectively. A total of 103 respondents (14.9%) reported they had never experienced an error. In 95 cases (13.98%), both actual errors and near misses were experienced. The majority of errors resulted in no or minor consequences (57.5% and 35.4% respectively). Major morbidity was caused in 15 cases (1.4%), this included cardiac arrest, stroke or permanent injury. Deaths were reported in 4 cases (<0.4%). The causes of mortality were:

a) an overdose of ketamine after mistaking 50 mg/ml vial for 10 mg/ml
b) noradrenaline given instead of fentanyl for sedation in ICU
c) potassium chloride used to dilute an antibiotic
d) peritoneal dialysate infused IV for volume resuscitation. (4)

The most frequent non-fatal errors were:

a) non-depolarizing muscle relaxant when reversal intended
b) succinlycholine when opioid intended
c) opioid when non-depolarizing muscle relaxant intended
d) inotrope swopped for another inotrope
e) inotrope when anticholinergic was intended. (4)

The most common cause of error was ‘syringe swop’ (70.4%). Other contributing factors were failure to read syringe label (62.9%) and misidentification of the drug ampoule (46.8%). (4)

Respondents identified colour as the most important feature used to identify ampoules and syringes. The drug name and size and shape of the ampoule were less important. When syringes were self-prepared, the syringe size and colour of label were the most important identifying features. Few considered the drug name to be the most important identifying feature. (4)

At the time of the study, use of self-adhesive, user applied drug labels was not standard practice in Canada. Even though 86% of respondents knew about the self-adhesive labels, only 72% of those respondents were using them

regularly. However, 86.9% of respondents believed that self-adhesive labels would decrease the incidence of medication errors. (4)

Of errors reported, 60.1% had not been reported to any authority. Those who had reported had done so to colleagues (10.4%), attending staff at teaching centres (10%) or at meetings and ward rounds (7.5%). None were reported to a provincial or national health agency or regulatory body. The reasons given for not reporting were that errors had been of no clinical consequence (68.3%) and some were not sure where to report the error (18%). Six percent did not report the error due to concern over medico-legal consequences. Most patients (83.5%) were not informed of the error that was made. (4)

Orser et al. (4) admit to the limitations in this study design. In a self-reporting survey participants are self-selected and errors reported may only be those deemed to be of interest or of serious consequence. The authors postulate the number of errors reported was lower than actually occurred. Recall of errors made years prior may have been forgotten. The study highlighted that although error rates are relatively low, rare events were associated with severe consequences and most anaesthetists will have medication errors during their career. As the potential for harm is great, the onus to improve the medication delivery system was felt. They highlighted the importance of targeting both the individual and system to prevent errors from occurring. (4)

1.6.2 South African Data

Prospective Study

One prospective study has been done in South Africa to date. Llewellyn et al. (34) conducted the study in three tertiary South African hospitals from 2005-6. The aim was to determine the incidence of medication errors and near-misses in South Africa. Only survey studies had been done prior to this. Data was collected over a six-month period in each hospital. As in the international studies, an anonymous form was completed for every anaesthetic, noting if an error or near-miss had occurred. Where an incident occurred, further

information was given. All reports were anonymous. Theatre registers were used to determine the total number of anaesthetics given in the data collection period. This number was used as the denominator when calculating the incidence of error. Thus, the minimum incidence was calculated. (34)

A total of 30 412 anaesthetics were given in this period, with a response rate of 53%. All anaesthetics were given by either consultants or trainee anaesthetists. Sixty-six errors and 45 near-misses occurred over the 6-month period. The overall combined incidence of an error or near-miss was 1 in every 274 anaesthetics. One of the hospitals treated only paediatric patients. Here the combined incidence was 1 in 252.

Errors found were most likely to occur during the maintenance phase (51%) of anaesthesia, followed by pre-induction (21%) and reversal (12%). This may reflect that maintenance is the longest phase or practitioners may have increased vigilance during induction and reversal. Unlike the studies by Sakaguchi et al. (31) and Cooper et al. (32) the experience of the anaesthetist did not influence the likelihood of an error occurring. There was no difference in incidence of error between elective and emergency cases. (34)

The most common type of error was substitution (54%). In the paediatric hospital, incorrect dosage (35%) occurred as frequently as medication substitution. This was expected due to weight-related dosing and frequent need for medication dilution. The authors suggested having a weight available for each patient, calculator in theatre, to be meticulous when diluting medications and double checking. In line with international studies the medications most commonly associated with errors were muscle relaxants (25.3%) followed by opioids and vasoactive drugs (13.4% each). No long term sequelae were caused by errors made. In five cases anaesthesia was prolonged between 30-60 minutes. (34)

Errors made were identified in various ways: medication label noted after administration (21%), clinical effects (18%), alerted by another clinician or assistant (23%) or not stated (23%). Error due to ampoule misidentification

occurred in 36.9% of cases. Of these errors, anaesthetists felt it was due to similar-looking ampoules in 64.4% of cases. Syringe identification errors occurred in 21.3% of cases. (34)

Seven (10.6%) of the respondents who reported errors were on medication at the time. Four of these were taking anti-retroviral medication. The incidence of Human Immunodeficiency Virus (HIV) infection in South Africa is known to be high, thus there are likely to be anaesthetists regularly on therapy either as prophylaxis or treatment. Post-exposure to HIV there is a high level of anxiety and this may affect practitioner performance as well as side effects of medication. (34)

Llewellyn et al. (34) reported an incidence of error lower than that of Webster et al. (10) in New Zealand, but higher than that in Japan. A conservative approach was used, as the denominator in the calculations was total number of cases done. If total number of forms returned was used the combined incidence of error would be 1 in 245 cases.

This study highlights that despite increased awareness and efforts to improve safety around medication administration, errors were still common in the study population. As syringe swops were the most common errors, authors suggested clear labelling of syringes and using the international colour-coded labelling system. Hospital A used predominantly colour-coded labels and Hospital B and C used a marker to label syringes. Individual error rates were: hospital A 1 in 320, hospital B 1 in 252 and hospital C 1 in 250 cases. (34)

Ampoule misidentification was also a major cause of error. Authors emphasized the need to address font size, legibility and use of generic names for labelling. It has been proven that humans often use pattern recognition to identify words. Thus, all practitioners need to be educated and ensure they read the label carefully prior to administering medication. Another suggestion made was to have a methodical and systematic system for medication storage and clear organization of syringes in use. The importance of a national incident reporting system was highlighted and authors suggested

such a system should be developed in South Africa. This would allow identification of causative factors in individual institutions. (34)

Survey Studies

Three confidential, self-reporting survey studies have been identified in South Africa to date. These studies are:

- Gordon (35) at the University of Cape Town (UCT) in 2004
- Gordon et al. (36) amongst the members of SASA in 2006
- Labuschagne et al. (37) in 22 public sector hospitals in the Free State in 2011

Table 2 shows the qualifications of the participants, response rates to the survey and medication error rates reported in each study.

Table 2: Nature of participants, response and medication error rates

Study	Participants	Response rate (%)	Medication errors (%)	>3 errors (%)
Gordon (35)	Consultants and registrars	95	93.5	30.6
Gordon et al. (36)	Consultants	18.5	94	22
Labuschagne et al. (37)	Consultants, registrars, MO, CSO and interns	46.3	39	ND

ND, not determined

Gordon et al. (36) included only consultants, most of whom were in full time private-practice, with only 18.8% in academic practice. Participants in the other studies worked in the public sector, some at academic institutions. Similar to the study at UCT, 94% admitted to previous medication error. Thirty respondents (22%) had made errors on four or more occasions.

Labuschagne et al. (37) reported a lower error rate with only 39% of participants involved in at least one medication error. Registrars and specialists reported the most errors. This may imply the probability that more errors will occur with an increased number of anaesthetics administered. It may also imply junior doctors were hesitant to report errors or that they had not noticed an error due to a lower level of knowledge. (37)

The following results found in the South African survey studies have been combined and are shown in Tables 3, 4 and 5 below.

Table 3: Causes of medication errors found in South African survey studies

Study	Syringe swop (%)	Syringe labelling error (%)	Similar syringe/ampoule (%)	Fatigue (%)	Other (%)
Gordon (35)	ND	28.4	11.8	23.5	20
Gordon et al. (36)	40	3.6	27.1	14.1	ND
Labuschagne et al (37)	33	<1	31	25	4

ND, not determined

As in international studies, most common causes included ‘syringe swops’, labelling and misidentification. Examples of ‘other’ factors included inattentiveness, pressure from surgeon or anaesthetic consultant, inadequate lighting and interruption. The causes of fatigue were noted to be inadequate sleep, heavy work overload, exhaustion and alterations in sleep cycles. (35-37)

Sixty percent of participants reported they always read the labels on ampoules before using medications, but 39% reported they only did so ‘most of the time’. (36) A high percentage of respondents felt that standardised colour-coded labels helped or would help to minimize error. (35, 36)

Table 4: Medications most commonly associated with medication errors

Study	Ranking		
	1	**2**	**3**
Gordon (35)	Muscle relaxants (50%)	Adrenaline (9.5%)	Induction agents (8%)
Gordon et al. (36)	Muscle relaxants (50%)	Vasoactive drugs (14%)	Opiates (6%)
Labuschagne et al. (37)	Adrenaline*	Fentanyl*	Succinylcholine*

*No percentages given

Table 5: Outcomes of medication errors

Study	No. of errors	No consequence/minor morbidity	Major morbidity	Death
Gordon (35)	103	NR	2	NR
Gordon et al. (36)	303	NR	3	5
Labuschagne et al. (37)	60	29	1	0

NR, not reported

In the survey by Gordon (35) 17.5% errors were classified as dangerous. This was defined as “able to cause serious haemodynamic or neurological damage”. Erroneous administration of adrenaline was the cause of 2 major morbidities. In one case a patient suffered a myocardial infarction and pulmonary oedema, while the second patient went into ventricular fibrillation which required defibrillation. (35)

Gordon et al. (36), in line with international studies showed that most errors caused no harm. Immediate intervention was needed in 121 cases (41.3%). Serious adverse events were reported; five deaths and three non-fatal cardiac arrests. Clinical effects of errors most commonly noted were: prolonged

paralysis (40%), hypertension (11%), awareness (9%) and tachycardia (4%). In 26.7% of cases the anaesthetic time was prolonged. (36) In Labuschagne et al. (37) only one case of major morbidity was reported, but no fatalities.

Both Gordon et al. (36) and Labuschagne et al. (37) enquired about reporting behaviour of respondents. There was a low percentage who reported errors made. Respondents noted they would be more likely to report errors in future if a central reporting body existed. In one study, only 15% of patients affected were informed of the error. Reasons given for this were that most errors did not result in any clinical effects, poor communication skills of the doctor or fear of litigation. (37)

These three studies indicated that the situation in South Africa was similar to other parts of the world. Almost all anaesthetists had admitted to at least one medication error in their career. Of errors that did occur, only the minority resulted in patient harm, but there was potential for serious consequences. However, in these studies fatigue is highlighted as an important contributing factor to error. All authors suggested standardised syringe labelling, improved ampoule labelling, double checking with two-persons when preparing medications and use of bar-coded ampoules checked with a scanner. (35-37)

1.7 Strategies for preventing medication errors during anaesthesia

Jensen et al. (38) conducted a systematic review of the literature that made suggestions for decreasing medication errors by anaesthetists in theatre for intravenous medication administration. A number of recommendations were made:

Measures *strongly recommended* to be implemented:

- rigorous checking of labels on any medication ampoule or syringe prior to the medication being drawn up or injected
- clear labelling of ampoules, labels easily legible
- standardisation of labelling as agreed upon by relevant standards authority

- clear labelling of all syringes in use
- standard organisation of medication drawers and tidy workspace with clear positioning of ampoules and medications required for emergencies or of extreme danger. (38)

Measures *recommended* to be implemented:

- double checking of all medications prepared or administered, either with a second person or bar code reader
- all medication errors reported via an incident reporting system with regular review of findings
- avoidance of similar packaging resulting in misidentification. (38)

Measures *possibly recommended* to be implemented:

- considering the use of pre-filled and pre-diluted syringes instead of ampoules
- anaesthetist should only used medications prepared and check by themselves
- colour coding according to type of medication as agreed upon by the relevant standards authority. (38)

Most of these strategies do not involve any cost and can be implemented by clinicians. Some do require extra cost (barcode system), but it should be offset by a decrease in the number of medication errors, which have been shown to have a high financial and human cost. (38)

1.8 Summary

Anaesthetists have a responsibility to ensure patient safety; this includes avoiding errors in clinical practice. Medical errors have been shown to have a high human and financial cost. A common type medical error is medication error. Anaesthetists are susceptible to medication errors due to the number of medications administered to each patient and bypass of standard safety checks in the theatre environment.

Despite literature identifying common causes and suggested solutions medication errors still occur commonly internationally and in South Africa. The current experience of anaesthetists at WITS regarding medication errors is unknown. Current experiences need to be explored in order to identify causative factors so that they can be addressed, errors minimised and patient safety improved.

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Section 3: Draft Article

Title: Medication errors in operating theatres in the Department of Anaesthesiology at the University of the Witwatersrand

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Keywords: medical error, medication error, drug error, near miss, anaesthesia

Abstract

Background

Medication errors occur commonly. They result in preventable morbidity and mortality and potential increased cost to the health care system. Anaesthetists are at high risk due to the number and potency of medications given in theatre. The occurrence of medication errors in operating theatres amongst anaesthetists at the University of the Witwatersrand is not currently known.

Methods

This is a prospective, contextual and descriptive study. A self-administered questionnaire was completed by anaesthetists at the University of the Witwatersrand (n=128).

Results

Ninety-three percent of participants reported a medication error or near miss event. A total of 231 events were reported. Medications most commonly involved were muscle relaxants, opioids and vasopressors. Substitution was the most common type of error, most often due to failure to check the label prior to administration. Fatigue was an important contributing factor. Events reported were most frequent during general anaesthesia, in adults, ASA I-II and elective patients during normal working hours. Only two cases of major morbidity occurred. No deaths were reported. No differences were found between consultant and junior anaesthetists.

Conclusions

Despite previous recommendations, medication errors and near miss events continue to occur in a similar manner. Negative patient outcomes have occurred, with two cases of major morbidity reported in this study. Reporting of events remains low, but has improved. Measures should be instituted in order to decrease errors and improve incident reporting rates.

Introduction

Medical error is defined as “an act of omission or commission in planning or execution that contributes or could contribute to an unintended result”.[1] Examples include incorrect diagnoses, wrong site of surgery, misidentification of patients and medication errors.[2]

Medication errors occur commonly and account for up to 34.2% (range of 4-49%) of all medical errors.[3] Medication error is defined as “any error in the medication process (prescription, dispensing, administration and monitoring) whether there are any adverse consequences or not”.[4] “Medication” includes all medications, fluid therapy, medical gases and volatile agents. In contrast, a “near miss” is defined as “an event that did not involve the actual administration of medication”, but if administered would have resulted in an error.[5] Types of errors include omission, repetition, substitution, incorrect dose and incorrect route of administration.

Anaesthetists are involved in providing peri-operative care to patients and have a responsibility to improve patient safety and care.[6] One area of patient safety is administration of medication. Medication

errors have been shown to occur commonly during anaesthesia and have the potential for loss of life and high financial cost.[7,8] Although there is no harm in the majority of cases, there is a minority where serious morbidity and mortality occurs.[5,8] Despite both international and national research into error rates, causes of errors and suggested solutions to the problem, little improvement in error rates has occurred.[9,10]

Avoidance of medication errors has become an important focus of patient safety initiatives. The World Health Organisation (WHO) Surgical Safety Checklist identifies patient allergies prior to administration of medication in theatre. [11] Incident reporting systems are in place in the United Kingdom, Canada, Australia and New Zealand.[12] The Helsinki Declaration on patient safety in anaesthesiology (2010) stated that all institutions should have protocols to manage checking of medications and a standardised system of syringe labelling.[6] Although the use of the WHO Surgical Safety Checklist has been adopted in South Africa, there is no national incident reporting system and only a few hospitals in the Western Cape and KwaZulu-Natal are using user-applied drug labels in theatre.[10,13]

Anaesthetists have a unique role as they are involved in prescription, preparation, administration and monitoring the effects of medication given in the peri-operative period. It is estimated that an anaesthetist will administer at least 250 000 medications during their years in practice.[14] Due to the high number of potent medications given in a short space of time in theatre, it is understandable that errors can occur with potentially serious consequences.[5] Standard safety checks used in the ward environment are often bypassed in the theatre environment.[15]

Medication errors in anaesthesia have the potential for grave consequences. Severe morbidity with permanent damage and mortality can occur.[16-19] Errors involving adrenaline and succinylcholine were more frequently associated with serious morbidity and mortality as reported by the American Society of Anaesthesiologists' (ASA) in the Closed Claims Project review of 2003.[16] In South Africa, two examples described were by Gordon[17] where erroneous administration of adrenaline resulted in the development of myocardial infarction and pulmonary oedema in one patient and ventricular fibrillation requiring defibrillation and resuscitation in another.[17]

International prospective self-reporting studies have shown the incidence of medication errors in theatre by anaesthetists to range from 1 in 133 to 1 in 1285 cases.[20-23] In 2016, Nanji et al.[15] published an observational study in the USA, which suggested that the error rate was much higher. Data was collected by direct observation and retrospective chart review. The error rate observed was one medication error per 20 medication administrations.[15]

A survey study conducted by Orser et al.[5] in Canada found 85% of participating anaesthetists had made at least one error or had a near miss in their career. Errors were more frequently reported than near miss events.[5] In both prospective and survey studies, the most common types of errors were substitution, omission and incorrect dose.[5,21,23] Medications most commonly involved were muscle relaxants, opioids and vasopressors.[5,21,23] Important contributing factors were found to be failure to check the syringe, labelling errors and distraction.[5,23] Low rates of mortality and major morbidity were reported.[5,15,23] Some studies found errors were more likely to occur with junior anaesthetists as compared to consultants.[21,22]

In South Africa, in a prospective, self-reporting study by Llewellyn et al.[24] results showed an estimated medication error and near miss event rate of 1 in 274 anaesthetics administered.[24] Two survey studies by Gordon[17] and Gordon et al.[18] found over 90% of anaesthetists surveyed had made medication errors.[17,18] Types of errors, contributing factors and medications involved in errors were comparable to the international studies.[17-19] In addition, fatigue contributed to errors in 14.1-25% of cases.[17-19] In keeping with international research, rates of major morbidity and mortality were low.[17-19] However, five cases of mortality were reported out of a total of 303 errors in Gordon et al.[18] Examples of morbidity in this study included non-fatal cardiac arrest, prolonged paralysis, awareness, hypertension and tachycardia.[18] In both South African and international survey studies, the rate of error reporting was found to be low.[5,18,19]

It is evident that medication errors occur commonly in the peri-operative period. The potential for serious harm to patients exists and is clearly documented. The occurrence of medication errors in operating theatres amongst anaesthetists at the University of the Witwatersrand (WITS) is currently unknown.

Method

The study was a prospective, contextual and descriptive study. It was conducted on a sample of anaesthetists working in the Department of Anaesthesiology at WITS. The total number of eligible anaesthetists was 202. Departmental members on the postgraduate research committee and those with prior knowledge of the questionnaire were not eligible to participate. Anaesthetists were invited to complete a questionnaire regarding medication errors and near miss events occurring in theatre. There was no time limit as to when events may have occurred. Any errors or near miss events occurring throughout the career of participants were relevant and could have been reported. Data collection took place at departmental academic meetings from April 2017- August 2017. The WITS Medical Human Research Ethics Committee (M170127) granted ethical approval.

Results

A total of 140 questionnaires were distributed. Twelve questionnaires were excluded as they were either blank or partially completed. The final number of questionnaires analysed was 128. The response rate of all eligible anaesthetists at WITS was 69%, thus ensuring validity of the study. The findings are described below:

Characteristics of Respondents

Characteristics of respondents are shown in Figure 1 and 2 below.

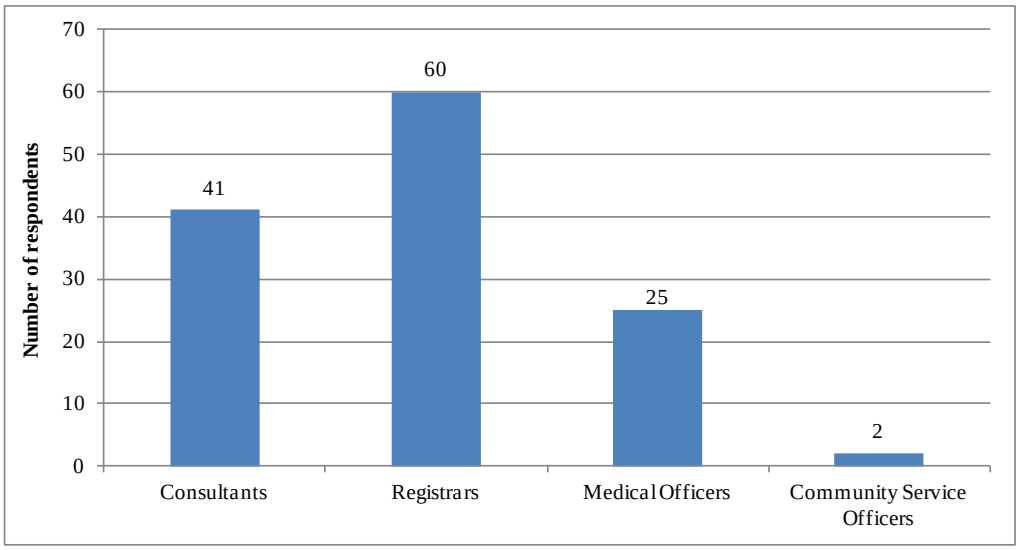


Figure 1: Characteristics of respondents

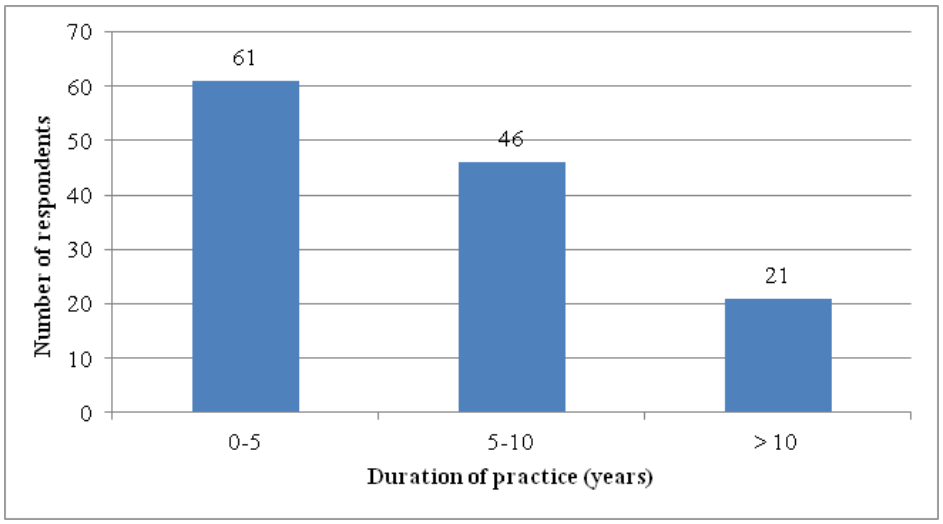


Figure 2: Years of anaesthesia practice

One hundred and two participants (79.7%) spend the majority of their time (76-100%) administering anaesthesia.

Medication errors and near misses reported by respondents

Participants were asked on the number of near miss events and medications errors that they could recall. Each was answered separately. These could have occurred at any point in their anaesthetic career. Thus, a participant may have had only near miss events, only errors, both errors and near miss events or none at all. The results are shown in Figure 3 below.

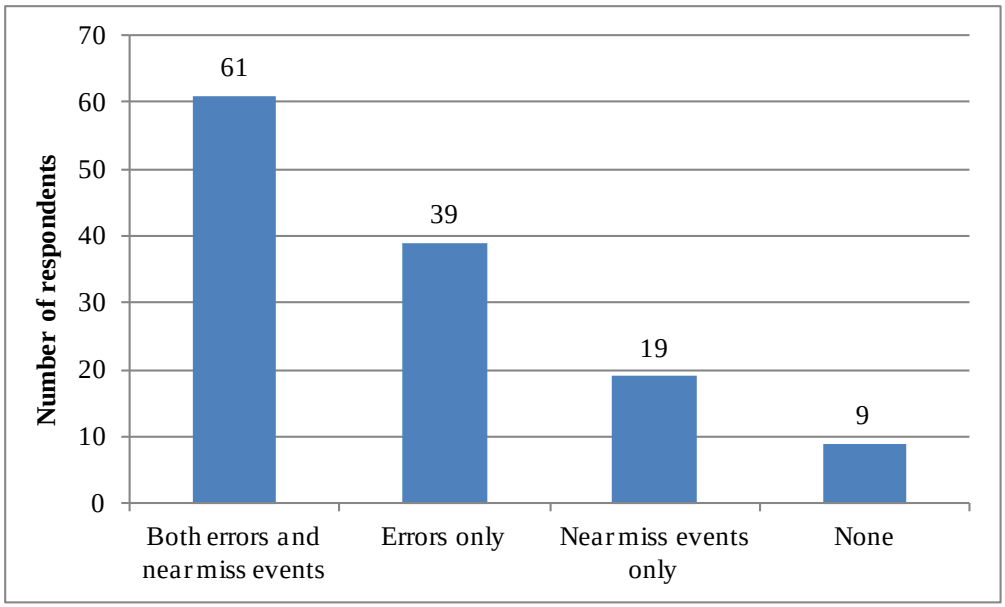


Figure 3: Medication and near miss events reported

Total number of medication errors and near miss events

Many respondents reported multiple errors or near miss events. From the 128 respondents, a total of 231 medication errors and near miss events were reported. Of the total number of events (231) reported, 161 (69.7%) were medication errors and 70 (30.3%) were near miss events. Over half (62.3%) of the reported events occurred within the last three years, 22.5% occurred within the last 3-5 years and only 15.2% having occurred more than five years ago.

Medications associated with medication errors and near miss events

All medications involved in errors or near miss events are shown in Figure 4 below.

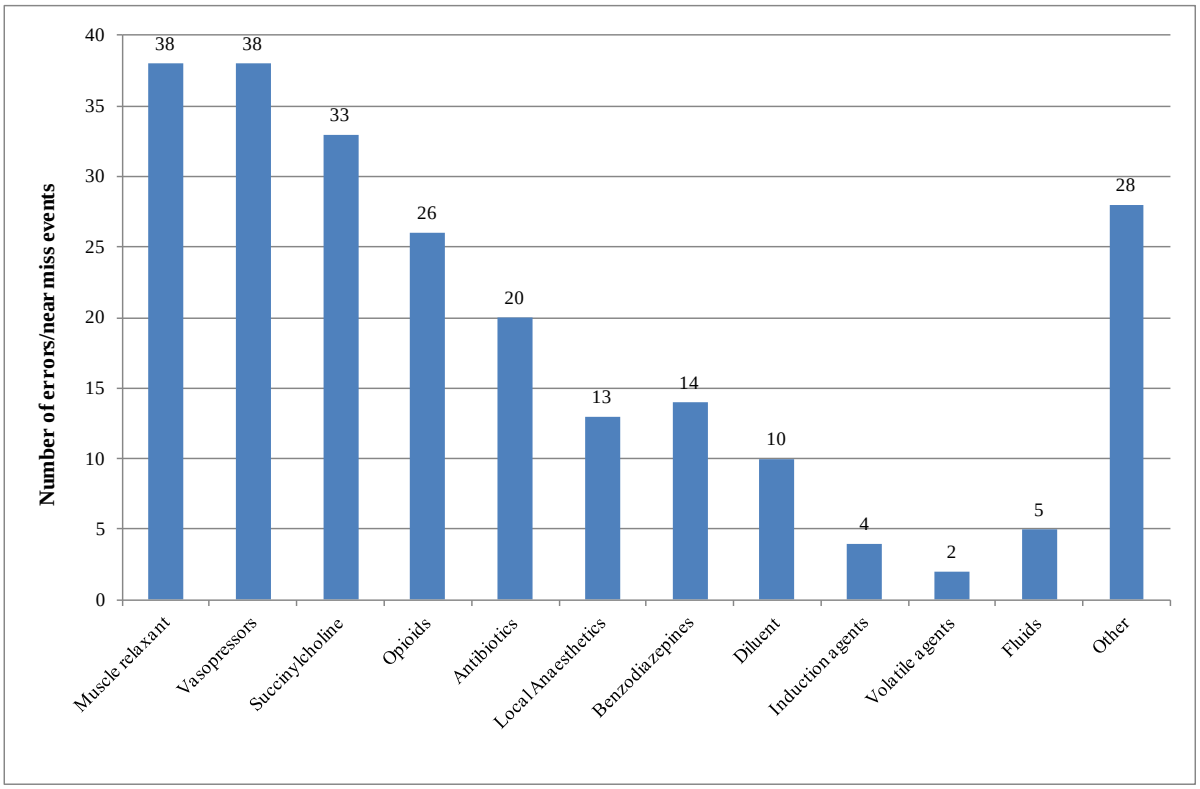


Figure 4: Medications in errors and near miss events

Examples of potentially fatal errors and near misses were: administration of succinlycholine instead of oxytocin, potassium chloride used as diluent, bupivicaine used as diluent, phenylephrine used as diluent, bupivicaine injected intravenously instead of via epidural, inappropriate antibiotics given to allergic patients and adrenaline instead of intended vasopressor. The most frequent errors were giving muscle relaxant instead of an opioid, muscle relaxant instead of reversal agent, and opioid instead of reversal agent. Medications included in the 'other' category were heparin, anti-emetics, corticosteroids, atropine, neostigmine, paracetamol and insulin.

Types and details of errors

Types of errors and near misses are shown in Figure 5 below.

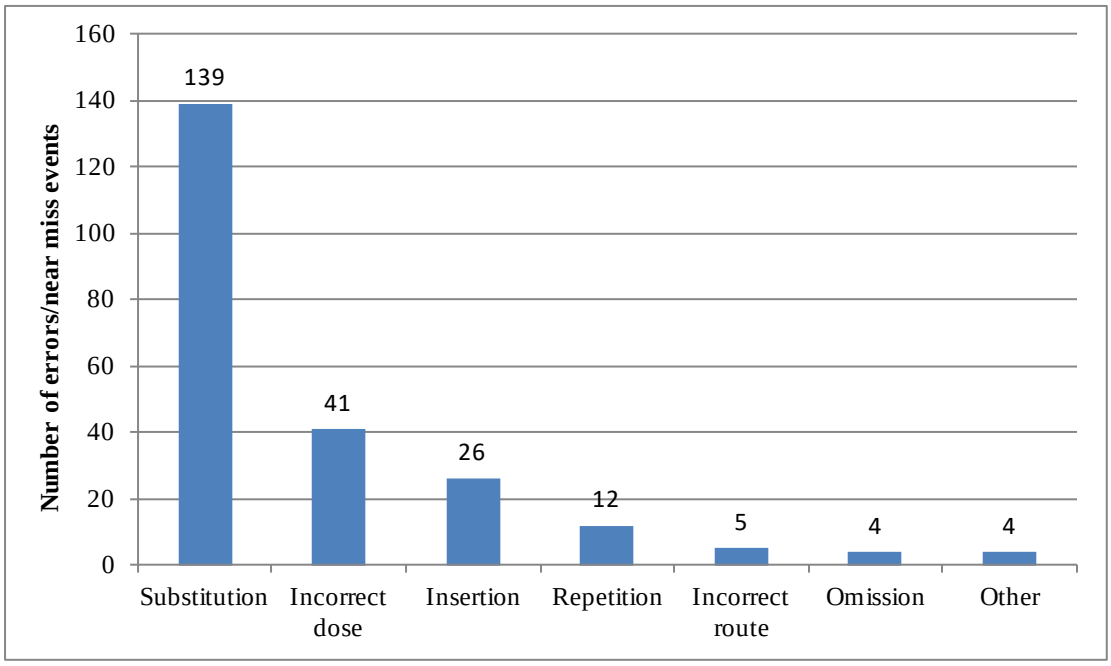


Figure 5: Types of medication errors and near miss events

Other details of errors and near miss events are shown in Table vi below.

Table vi: Details of medication errors and near miss events

Type of Anaesthesia	
General anaesthesia	166 (71.9%)
Regional anaesthesia	55 (23.8%)
Sedation alone	2 (0.8%)
Combination	8 (3.5%)
Phase of anaesthesia	
Maintenance	115 (49.8%)
Induction	90 (38.9%)
Emergence	26 (11.3%)
Time of day	
07:00-16:00	147 (63.6%)
16:00-07:00	78 (33.8%)
Not stated	6 (2.6%)
Urgency	
Elective	125 (54.1%)
Emergency	106 (45.9%)

Patient characteristics and outcomes of errors

Results are shown in Table vii below.

Table vii: Patient characteristics and outcomes of errors

Age of patient	
Adult	166 (71.9%)
Paediatric	15 (6.5%)
Neonate	4 (1.7%)
Geriatric	4 (1.7%)
Not stated	42 (18.2%)
ASA category	
I	85 (36.8%)
II	71 (30.7%)
III	20 (8.7%)
IV	7 (3.0%)
Not stated	48 (20.8%)
Outcome of error	
No clinical effect	151 (65.4%)
Minor morbidity	78 (33.8%)
Major morbidity	2 (0.8%)

Of note, no details of the major morbidities that occurred were given by respondents.

Factors contributing to medication errors

In most cases, respondents reported multiple contributing factors that lead to the error or near miss event. Therefore, the total number of contributing factors (n=391) is greater than the total number of errors or near miss events reported (n=231). The most common reason cited for an error occurring was the label on the syringe or medication ampoule was not read (n=87). Despite this, most participants reported they “always” read medication labels prior to administration of medication (64.1%). All other contributing factors are shown in Figure 6 below.

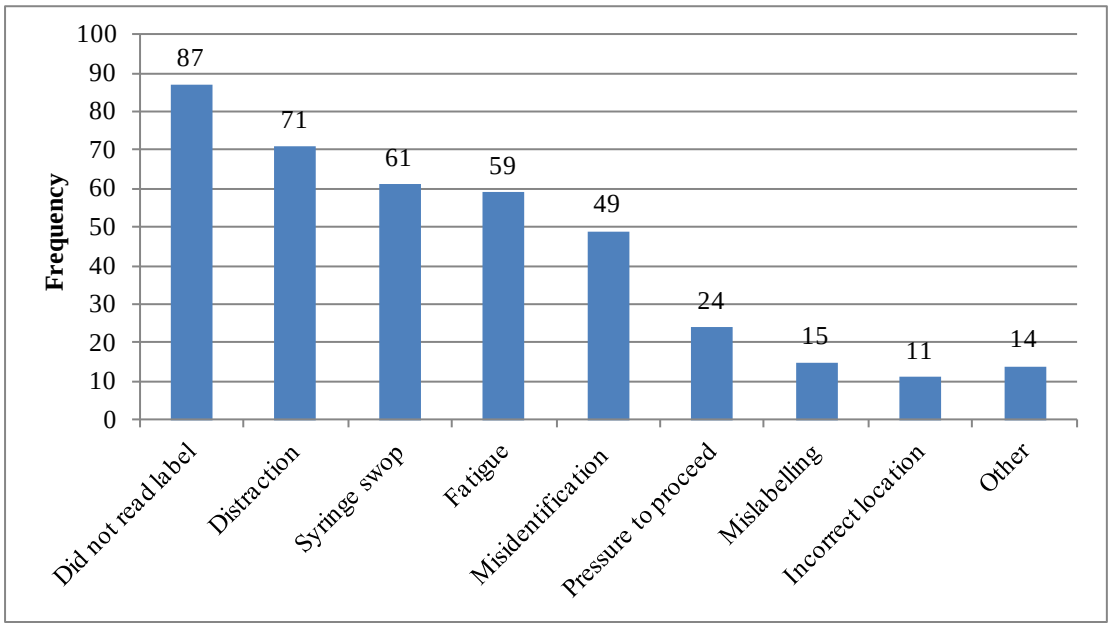


Figure 6: Factors contributing to errors and near miss events

Differences between senior and junior anaesthetists

Of the total 231 events reported, 154 were reported by junior anaesthetists and 77 reported by senior anaesthetists (consultants). A similar proportion of respondents in each group reported errors or near miss events. Of the consultant sub-group, 35 (85.4%) reported errors or near miss events; compared to 77 (88.5%) of the junior anaesthetists sub-group. ($p = 0.7752$). In terms of reporting behaviour, a higher percentage of consultants reported events compared to the junior anaesthetists. Twenty consultants (57.1%) compared to 37 (44.6%) junior anaesthetists reported their errors or near miss events either using the incident reporting systems or to the relevant authority. ($p = 0.2322$).

Reporting behaviours of anaesthetists experiencing medication error

This is shown in Figure 7. Some respondents noted if the event (particularly near miss) was without consequence it was “not applicable” for them to report to any authority.

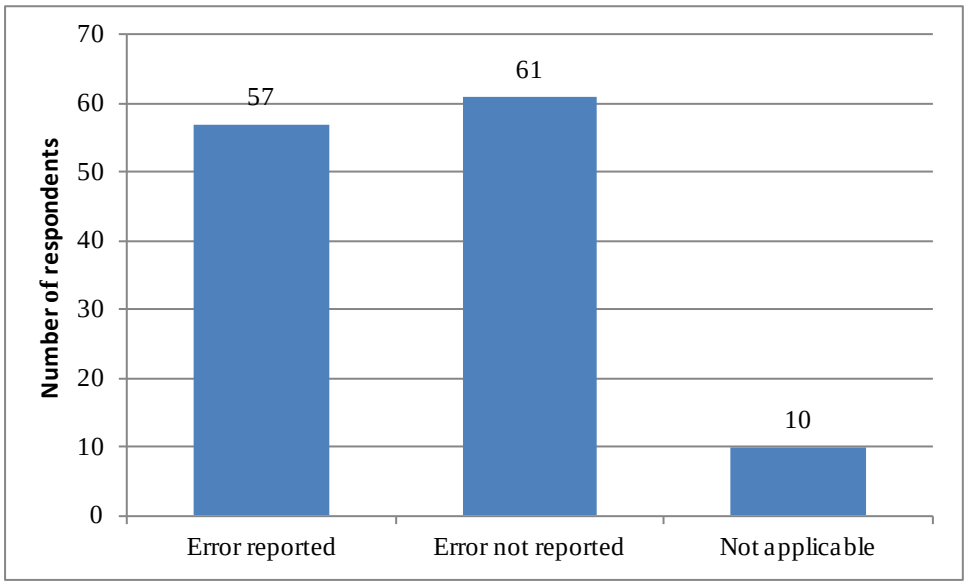


Figure 7: Reporting behaviour of respondents

The majority of events reported were disclosed to "anaesthetic management" n=47 (85.5%). This included the consultant overseeing the list or the senior anaesthetist in charge for that day. The incident reporting systems that are in place were only used in 6 cases (10.9%). Patients were only informed of the error in 29 cases (22.7%). Reasons for not reporting errors are shown in Figure 8 below.

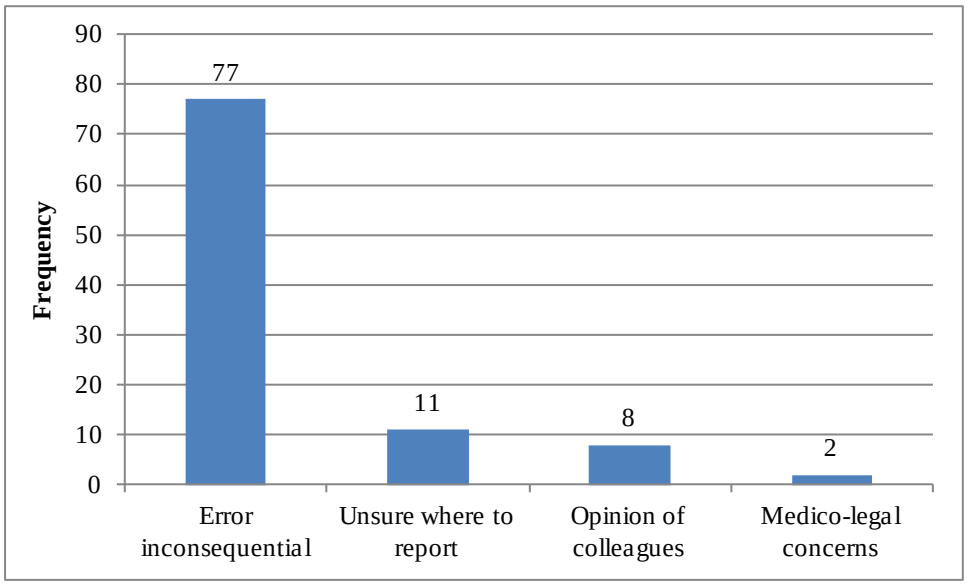


Figure 8: Reasons for not reporting errors

Individual changes made to decrease errors

Most participants (75%) had instituted their own measures to protect against errors from recurring. Thirty one respondents (24.2%) who had made errors in the past had made no changes to their practice despite previously experiencing errors or near miss events. Protective measures instituted by respondents are shown in Figure 9.

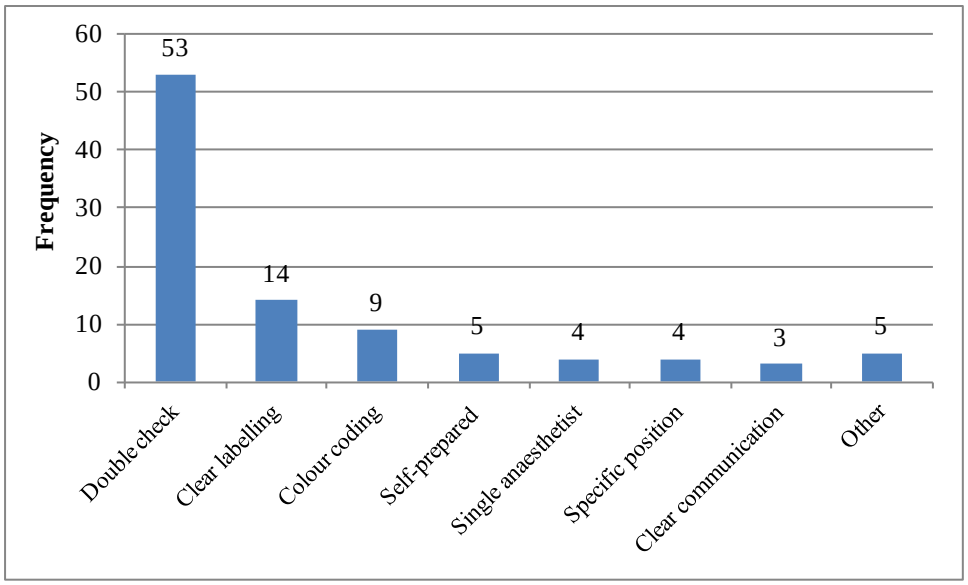


Figure 9: Changes made to decrease errors

Discussion

The response rate to our self-reporting questionnaire was 69%. Although lower than the response rate achieved by Gordon[17], it was higher when compared to other national and international survey studies reviewed.[5,18,19] Both consultant and junior anaesthetists were surveyed.

Although this topic has been researched at WITS previously, this was only done at Chris Hani Baragwanath Academic Hospital 11 years ago, during the period 2005-6 by Llewellyn et al.[24] Results of our study reveal over 84% of events reported occurred within the last five years, thus long after the study by Llewellyn et al.[24] was conducted. This implies errors and near miss events continue to occur in a similar fashion despite findings and recommendations in prior research.

Ninety-three percent of participants reported making either a medication error, having a near miss or both. This was similar to both national and international results.[5,17,18] Sixty-six percent of participants

reported 1-3 errors, whereas only 43% reported 1-3 near misses. An average of 1.8 events per participant was reported for the duration of their anaesthetic career to date. This was higher than the rate of 1.5 per participant in the study by Orser et al.[5] As with both questionnaire and prospective studies, medication errors were more frequently reported than near miss events.[5,23,24]

Some studies showed no increased errors made by junior anaesthetists versus consultants,[23] but Sakaguchi et al.[21] found those with less experience were more likely to make an error. Cooper et al.[22] found junior anaesthetists were twice more likely to make an error than consultants, particularly in patients with a higher ASA status. In South Africa, trainees were not more likely to make an error than a consultant.[24] We found no significant differences between junior anaesthetists and consultants in terms of errors made as well as reporting behaviour.

Medications most commonly implicated in events were comparable with national and international studies.[5,17,18,23,24] These were muscle relaxants (depolarising and non-depolarising), vasopressors and opioids. The medications most commonly associated with closed claims and serious adverse patient outcomes were succinlycholine and adrenaline.[16] In most of these claims patients suffered either death or major morbidity. As both of these medications were frequently involved in events reported in our study, the Department of Anaesthesiology at WITS is also at risk of serious adverse patient outcomes.

The types of medication errors reported were also similar. In this study, the most common type of errors were substitution (60.2%), incorrect dose (17.7%) and insertion of unintended medication (11.3%). In the ASA Closed Claims study medication errors were most commonly due to incorrect dose (31%), substitution (24%) and insertion (17%).[16] Webster et al.[23] found incorrect dose, substitution and omission to be most common.[23] In South Africa, Llewellyn et al.[24] found substitution and incorrect dose (increased in paediatric patients) to be the most common.[24]

Our findings showed that the majority of events reported had occurred in adult patients (87.9%). Most patients were in the ASA I and II category (85%). This was in contradiction to findings by Cooper et al.,[22] where errors were more likely to occur in patients with higher ASA status. Webster et al.[23] found no difference with regards to ASA status and occurrence of errors.

This study found events were more likely to occur during general anaesthesia (71.9%). Events occurred more frequently during the maintenance phase of anaesthesia (49.8%) as opposed to the induction phase (38.9%), which was also found by Llewellyn et al.[24] Events occurred most commonly during cases done within normal working hours of between 07:00 to 16:00. Slightly more events occurred during elective cases (54.1%) versus emergency cases (45.9%). In Webster et al.[23] only 4 of 121 errors occurred during emergency cases whereas Llewellyn et al.[24] found no difference in errors between elective and emergency cases.

This study revealed no clinical effect or harm came to 65.4% of patients. Minor morbidity was reported in 33.6% of cases and major morbidity in 0.8% of cases. No deaths were reported. This was in keeping with both national and international studies.[17-19,23,24] Deaths were reported by Orser et al.[5], as well as Gordon et al.[18] Nanji et al.[15] found the chance of death as a result of error was low, with 1.6% of errors being life-threatening, but of concern 68.9% of errors were found to be serious.

Similar factors contributing to error were identified by participants of this study compared to those in the studies reviewed.[5,17-19,23,24] These were: the label on the medication or syringe was not read prior to administration, distraction, 'syringe swop', fatigue, misidentification of ampoule, pressure to proceed and mislabelling of syringe.[5,17-19,22-24] Fatigue was found to be a more prominent contributing factor in this study, noted in 25% of events reported. This was also found by Gordon[17] and Labuschagne[19] where it was found to be contributory in 23.5% and 25% of cases respectively. However, Webster et al.[23] noted it to be contributory in only 9% of cases. This may highlight it as an important contributing factor in the South African context and could be a factor to address to decrease preventable errors.

Less than half (44.5%) of respondents had reported their errors or near miss events to the relevant authority. Although this may be considered inadequate, it has shown improvement from previous studies conducted in South Africa.[18,19] Our findings were comparable to those by Orser et al.[5] where 39.9% of errors were reported to the relevant authority. In all studies, most of those who did not report noted it was due to the fact that the error or near miss had not resulted in any negative consequence to the patient as well as being unsure where to report and concerns of medico-legal implications. [5] Our findings showed 11 respondents did not know where to report errors and two respondents were

concerned about the opinions of colleagues. Only 22.7% of events were reported to the patients affected in our study, similar to the findings of Orser et al. [5]

Seventy-five percent (n=97) of participants noted that they had made changes to their practice to avoid future medication errors. What is of concern is the 25% of participants who had made errors, but had not made any changes to decrease future errors. This is despite the known risk to patients and the possibility of serious morbidity and mortality. Although this question was included in the survey by Orser et al.,[5] their findings were not included in their results. The issue was not examined by any of the other studies reviewed.

Limitations of the study must be noted. The sample size target of 80% of the study population was not reached. This may be due to poor attendance at academic meetings, eligible participants on leave at the time of data collection and individual choice not to partake in the study. However, by achieving 69%, the results of the study are valid. Secondly, it is known that the study design (prospective, contextual and descriptive) is of low power. Lastly, participants may have had recall bias when detailing errors and near miss events. Near miss events may not have been as obvious to participants as actual errors. Events that occurred a long time ago may not have been remembered. It is known that this is likely to result in under reporting and that errors resulting in negative consequences are more likely to be remembered.[15,25]

Conclusion

Medication errors and near miss events continue to occur in operating theatres at WITS. Ninety-three percent of participants reported medication errors and near misses. Despite previous research the types of errors, medications involved in errors and contributing factors remain similar. Two cases of major morbidity were reported, but no deaths. Fatigue has been shown to be an important risk factor associated with medication errors at WITS. The findings of this study are consistent with previous research. Efforts need to be made to alter behaviour and decrease errors in order to prevent adverse patient outcomes and potential increased cost to the health care system. Although there has been an increase in error reporting, rates still remain low.

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Section 4: Appendices

4.1 Ethics Clearance Certificate

R14/49 Dr Janine Claire Vally et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M170127

NAME: (Principal Investigator)	Dr Janine Claire Vally et al
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Medication Errors in Operating Theatres in the Department of Anaesthesiology at the University of the Witwatersrand
DATE CONSIDERED:	27/01/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Estie Mostert and Dr Des Lines
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	31/03/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review in January and will therefore be due in the month of January each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

4.2 Postgraduate Committee Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
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Reference: Mrs Sandra Benn
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20 March 2017
Person No: 1318117
PAG

Dr JC Vally
P.O Box 783519
Sandton
Johannesburg
2146
South Africa

Dear Dr Vally

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Medication errors in operating theatres in the department of Anaesthesiology at the University of the Witwatersrand* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Section 5: Proposal

MEDICATION ERRORS IN OPERATING THEATRES IN THE DEPARTMENT OF ANAESTHESIOLOGY AT THE UNIVERSITY OF THE WITWATERSRAND

Name: Janine Claire Vally

Student Number: 1318117

Degree: Master of Medicine in Anaesthesiology

Supervisors: Dr Estie Mostert MBChB (UP), DA (SA), FCA (SA), MMed (Anaes)

Dr Des Lines MBBCh (Wits), DA (SA), FFA

5.1 Introduction

The literature indicates that there is a high rate of medical error in developing countries such as South Africa. (16) The term 'medical error' encompasses all types of error that occur in medicine. In 2005, Grober et al. (8) defined medical error as "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result". Examples of medical errors include incorrect diagnoses, wrong site of surgery, misidentification of patients and medication errors. Medication errors occur commonly and account for up to 34.2% (range of 4-49%) of all medical errors. (16)

Literature has shown that medication errors in anaesthesia have a lower incidence compared to other hospital environments, such as in general wards and the intensive care unit (ICU). (2, 5, 9, 10, 29, 34, 39) However, in 2016 a study by Nanji et al. (5) has suggested medication errors in anaesthesia may occur as commonly as in the ward, with an error rate of approximately 1 in 20 medication administrations.

Anaesthetists have a unique role as they are involved in prescription, preparation, administration and monitoring the effects of medication once given. Due to the high number of potent medications given in a short space of time, it is understandable that errors can occur with potentially serious consequences. (4) Standard safety checks used in the ward environment are often bypassed in the theatre environment (5).

Medication errors in anaesthesia have the potential for grave consequences. (9, 10, 32, 34, 35) Although errors occur only in a minority of cases, severe morbidity with permanent damage and mortality can occur. (2, 3, 30, 35) Two examples are erroneous administration of adrenaline that resulted in the development of myocardial infarction and pulmonary oedema in one patient and ventricular fibrillation requiring defibrillation and resuscitation in another. (35)

Despite research into error rates, causes of errors and suggested solutions to the problem, little improvement in error rates has occurred (27). Prospective self-reporting studies have shown the incidence of medication errors in theatre by anaesthetists to range from 1 in 133 to 1 in 1285 cases. A review by Dhawan et al. (9) suggested the average to be approximately 1 error per 211 anaesthetics when three studies were combined. In 2016, Nanji et al. (5) published an observational study in the USA, which suggested that the error rate was much higher amongst anaesthetists. The error rate observed was 1 medication error per 20 medication administrations.

Survey studies have identified how many anaesthetists have experienced medication errors, possible causes, contributing factors and reporting behaviours. Orser et al. (4) conducted a survey of anaesthetists belonging to the Canadian Anaesthesiologist's Society. Eighty-five percent of respondents have experienced at least one medication error or near miss event with an average number of 1.5 errors per respondent. Although the majority of errors resulted in no clinical consequence (57.5%) or minor consequence (35.4%), major morbidity was noted in 1.4% of cases. This included cardiac arrest, stroke and permanent damage. Four respondents reported their errors resulted in the death of the patient affected (0.4%). (4)

In South Africa, there is limited data identified on this topic. A prospective study was conducted by Llewellyn et al. (34) in three South African academic hospitals in 2005-6. It showed the incidence of medication errors (including near miss events) was 1 in 274 anaesthetics administered. A near miss is defined as "an event that did not involve actual administration of a drug, medication or fluid". The most common type of error was substitution and incorrect dosage with muscle relaxants, opiates and vasoactive drugs. In this study, no mortality or long term sequelae occurred due to errors. (34) Survey studies have also been conducted in South Africa. In 2004 and 2006, Gordon et al. (35, 36) found that 93.5% and 94% of their respondents admitted to a medication error in a survey conducted at the University of Cape Town and in the South African Society of Anaesthesiologist's respectively.

Forty one percent reported errors on at least three occasions. As in Llewellyn et al. (34), substitution was the most common error made. In 17.5% of cases, errors were noted to have potential to cause serious harm to the patient.

It is evident that medication errors occur commonly in the peri-operative period. The potential for serious harm to patients exists and is clearly documented. The occurrence of medication errors in operating theatres amongst anaesthetists at the University of the Witwatersrand (WITS) is not currently known.

5.2 Problem Statement

International studies have shown the incidence of medication error in anaesthesia to range from 1 in 133 to 1 in 1285 anaesthetics. (9) Llewellyn et al. (34) in 2009 in a study in three academic hospitals in South Africa, showed the incidence of error and near miss to be 1 in 274 anaesthetics.

At WITS, there are four hospitals where anaesthesia is provided by the Department of Anaesthesiology namely Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital, Helen Joseph Hospital and Rahima Moosa Mother and Child Hospital. Annually, the WITS Department of Anaesthesiology does approximately 103 000 cases. The occurrence of medication errors in operating theatres, causes thereof, effects and reporting behaviours amongst anaesthetists working in the Department of Anaesthesiology at WITS is currently unknown.

5.3 Aim and Objectives

5.3.1 Aim

The aim of this study is to describe the occurrence of medication errors in operating theatres as reported by anaesthetists in the Department of Anaesthesiology at WITS.

5.3.2 Objectives

The objectives of this study are to:

- describe the type of medication errors and their outcomes
- describe the factors contributing to medication errors
- describe reporting behaviour of anaesthetists who have experienced a medication error.

Secondary Objective:

- compare medication errors between senior and junior anaesthetists.

5.4 Research Assumptions

The following definitions are used in this study:

Medication error: “any error in the medication process (prescription, dispensing and administration) whether there are any adverse consequences or not” *(9)*.

Near miss: “an event that did not involve the actual administration of a drug” *(4)*.

Professional Designation: in this study, the anaesthetist’s rank in the department e.g. registrar, is defined as the professional designation.

Anaesthetist: in this study, this refers to all doctors (community service officers, medical officers, registrars and consultants), working in the Department of Anaesthesiology at WITS.
Senior Anaesthetist: this includes consultants and career medical officers (with more than 10 years of experience) in anaesthesia.

Junior Anaesthetist: this includes community service officers, medical officers and registrars in anaesthesia.

Community Service Officer: a qualified doctor who has registered with the Health Professionals Council of South Africa (HPCSA) as a community service officer and is practicing anaesthesia under specialist supervision.

Medical Officer: a qualified doctor who has registered with the HPCSA as an independent practitioner and is practicing anaesthesia under specialist supervision.

Registrar: a qualified medical doctor who has registered with the HPCSA as a registrar in the speciality of anaesthesiology.

Consultant: any anaesthetist who has completed the required South African College of Medicine examinations and who is registered with the HPCSA. Career medical officers with more than 10 years of experience are included in this category.

5.5 Demarcation of Study Field

This study will be conducted in the Department of Anaesthesiology at WITS. WITS Medical School is associated with four hospitals: Chris Hani Baragwanath Academic Hospital, Charlotte Maxeke Johannesburg Academic Hospital, Helen Joseph Hospital and Rahima Moosa Mother and Child Hospital.

The current complement of staff in the Department of Anaesthesiology at WITS is: 27 medical officers (including community service officers), 112 registrars and 75 consultants.

5.6 Ethical Considerations

Permission to conduct the study will be requested from the Human Research Ethics Committee (Medical) and the Postgraduate Committee of WITS. The study will be conducted using an anonymous self-administered questionnaire (Appendix A). Permission to use and adapt two questionnaires was granted from the relevant authors (Appendix B and C).

Participants will be approached at various academic meetings (Wednesday afternoons and morning meetings) at each hospital. The study will be explained and anaesthetists will be invited to participate. The questionnaires will be completed on a voluntary basis and consent will be implied on completion of the questionnaire. Care will be taken to maintain anonymity (no identifying data requested) and confidentiality of the participants will be ensured as only the researcher and supervisor will have access to raw data. Questionnaires will be completed during academic meetings and placed in a sealed box. Data will be stored securely for six years after completion of the study.

The study will be conducted in accordance with the Declaration of Helsinki (40) and the South African Good Clinical Practice Guidelines. (41)

5.7 Research Methodology

5.7.1 Study (research) design

A research design is the framework that guides assumptions about variables established from the literature review, the approach to the appropriate investigation and decisions about the data collection methods (42).

The study will be a prospective, contextual and descriptive study.

According to Brink et al. (43) a prospective study is defined as '"data about a presumed cause are first collected and then the effect or outcome is measured". The study is thus prospective, as data will initially be collected and then the outcome will be measured.

The study is contextual as it is conducted in the Department of Anaesthesiology at WITS. It will concern the immediate circumstances, environment and context with which the study problem is associated. (44)
A descriptive study gives an account of the occurrence of an event in a study sample. Events or variables are investigated as they naturally exist in order to give a complete description of the study sample, so as not to be altered by the researcher. This account is specific to that sample and may not necessarily apply to the greater population. Data for descriptive studies are classically collected by 'structured observation, questionnaires and interviews or survey studies'. A questionnaire is the method being used to collect data in this study. (43)

5.7.2 Study population

The study population will consist of anaesthetists working in the Department of Anaesthesiology at WITS.

5.7.3 Study sample

Sample size

The 214 members of the Department of Anaesthesiology at WITS will be the study population. An 80% response rate will be targeted and form the study sample.

Sampling method

Consecutive, convenience sampling will be used. Anaesthetists will be invited to partake in the survey at various departmental academic meetings.

Inclusion and exclusion criteria

All anaesthetists working in the Department of Anaesthesiology at WITS meet the inclusion criteria of the study.

Exclusion criteria include:

- anaesthetists who decline to take part in the study
- anaesthetists who are on annual leave, special leave or sick leave
- blank questionnaires
- partially completed questionnaires.

5.7.4 Data Collection

Research Questionnaire

The questionnaire used in this study is based on a validated questionnaire previously used by Orser et al. (4) It has been adapted and some additions included from a second validated questionnaire used by Gordon et al. (35) to ensure it is valid in the South African context. The adapted questionnaire has been reviewed by three senior consultants in the Department of Anaesthesiology at WITS (see Appendix A).

The questionnaire consists of four sections. Section A consists of demographics of the participants, Section B gives details of participant's experience of medication errors and possible contributing factors and any adverse effects on patients, Section C addresses labelling and packaging of medications and Section D reporting behaviour.

Data Collection

Data will be collected at various departmental academic and morning meetings. Information letters (Appendix D) and questionnaires (Appendix A) will be distributed and the aim and objectives of the study will be explained. The questionnaires will be numbered to keep track of the response rate. The researcher will distribute questionnaires and be there to assist with any questions. It is estimated that it will take approximately 10 minutes to complete the questionnaire. This will be done during the academic or morning meeting. Completion will imply consent. Completed questionnaires will be collected and placed in a sealed box.

Data Collection Period

After approval from the relevant authorities is granted, data will then be collected until a target of 80% of the study population has been reached.

Data Analysis

Data will be captured on a Microsoft Excel ® 2010 spreadsheet and analysed in consultation with a biostatistician. Data will be analysed with Stata version 13.1 (StataCorp) statistical program. Descriptive statistics will be used to describe the data. Categorical variables will be described using frequencies and percentages. Medication errors amongst senior and junior anaesthetists will be compared using T-tests. A p-value of less than 0.05 will be considered statistically significant.

5.8 Significance of the study

The most recently identified data on medication errors in anaesthesia, is the study performed by Nanji et al. (5) They determined the rate of error by direct observation and retrospective chart review. They found the error rate to be 1 in 20 medication administrations. (5) An anaesthetist is estimated to administer approximately 250 000 medications during their career (6). At the currently suggested error rate by Nanji et al. (5) this would result in 12 500

errors in an anaesthetists career. It is well documented that errors have the potential to cause serious harm and death to patients. (4, 5, 30, 35)

It is imperative to conduct this study in order to identify current experiences of medication errors amongst anaesthetists at WITS. The study will increase awareness on the topic, which is one step towards decreasing the medication error rate. It will also identify contributing factors causing errors and strategies may be suggested to address these. Reporting behaviour and obstacles to reporting will also be described. An adequate incident reporting procedure is also one of the ways to identify and decrease error. The ultimate goal is to improve patient safety.

5.9 Validity and reliability of the study

Validity is defined as “the degree measurement reflects a true value”. Reliability describes a dependability, regularity and consistency of results. (45)

Validity and reliability will be ensured in this study by:

- having conducted an extensive review of currently available literature
- using an appropriate study design
- using previously published and validated questionnaire
- using local experts to ensure validity for the South African context
- having a single researcher who will ensure uniform instructions and data collection
- analysis of data with the assistance of a biostatistician.

5.10 Potential Limitations

There are a number of potential limitations in this study. Limitations are potential weaknesses of the study (42).

Firstly, sampling bias may occur due to the consecutive convenience sampling method used. The population may be over or under represented.

The number of questionnaires completed will depend on the response rate. If this is low, this may influence how representative the sample is of the study population.
The contextual design may restrict the extent to which results can be generalised and applied to other contexts.

Recall bias is likely to be a factor. It is well documented that underreporting occurs in recalling past events. (22) Clinicians are more likely to remember errors that resulted in serious consequences and highly unlikely to recall near miss event.

5.11 Project Outline

5.11.1 Time frame

Activity	Sep 2016	Oct 2016	Nov 2016	Dec 2016	Jan 2017	Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017
Proposal										
Literature review										
Proposal submission										
Ethics and postgrad approval										
Data collection										
Data analysis										
Writing article										
Submission										

5.11.2 Financial Plan

Statement	**Cost for 1**	**Number required**	**Total**
Binding	R50	2	R100
Paper and printing	R1	1000	R1000
Total			R1100

Questionnaires and the research report will need to be printed. The estimated costs are shown above. The cost of printing will be incurred by the WITS Department of Anaesthesiology.

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Appendix A: Research Questionnaire

Medication errors in operating theatres questionnaire

Where appropriate, please indicate your response with an "X".

Section A: Practice profile

1. How many years have you practiced anaesthesia (including community service)?

0-5 years	
5-10 years	
10-15 years	
15-20 years	
>20 years	

2. Approximately what percentage of your professional time is spent administering anaesthesia?

0-25%	
26-50%	
51-75%	
76-100%	

3. What is your level of training?

Consultant (includes career MO)	
Registrar	
Medical Officer	
Community Service Officer	

Section B: Medication errors in your anaesthetic practice

1. In the course of administering anaesthesia, have you ever given the wrong medication* to a patient (may answer more than one if applicable)?

Yes	
Near miss**	
No	

***medication**: includes medication, inhalational agents and fluids
****near miss**: an event that did not involve actual administration of a drug/medication/fluid

2. On how many occasions while providing anaesthesia in theatre have you had

   a) Medication errors: _____ occasions

   b) Near miss: _____ occasions

3. Please provide details of incidents (both errors and near misses) in the table below.

	Event 1	**Event 2**	**Event 3**	**Event 4**	**Event 5**
Name of drug/s involved					
Error or near miss					
Please give brief description of events and what type***** of error occurred (see page 3)					
Type of anaesthetic e.g. GA or regional					
Phase of anaesthesia e.g. induction or maintenance					
Emergency or elective					
Time of day					
Age and ASA status of patient					
Outcome of error: A) no clinical effect B) minor morbidity** C) major morbidity*** D) death					
Did the error occur in the last A) year B) 1-3 years C) 3-5 years D) >5 years					

	Event 1	Event 2	Event 3	Event 4	Event 5
Contributing factors(more than one may apply) A) misidentification of ampoule B) mislabelled syringe C) syringe swop D) did not read label E) incorrect drug given stocked in wrong location on trolley F) distraction G) fatigue H) pressure to proceed I) other (elaborate)					
Was the duration of the anaesthetic prolonged?					

***Examples of types of error:**
Omission: medication not administered
Repetition: extra dose of intended medication given
Substitution: incorrect medication administered instead of that intended
Insertion: medication administered which was not intended
Incorrect dose: incorrect concentration, amount or rate of infusion
Incorrect route: for example drug given intravenous instead of intramuscular

****Minor morbidity:** required immediate intervention to prevent permanent injury
*****Major morbidity**: e.g. cardiac arrest, stroke or permanent injury

Section C: Features of drug labelling and packaging

1. In your estimation, how often do you actually **READ** the medication name on the label or syringe if you are working in your usual workplace?

Never	
Sometimes	
Most of the time	
Always	

2. What is the single most important feature of the label that helps you identify a drug used in theatre on a daily basis?

A: There is NOT a single feature of the label container or cap that helps me identify a drug	
B: The single most important feature is	

3. Rate the importance of the following packaging features in assisting identification of anaesthetic drugs. Please select one answer from each option.

1 = not important
2 = somewhat important
3 = moderately important
4 = extremely important

AMPOULES AND VIALS	**1**	**2**	**3**	**4**
Colour of ampoule/vial				
Label colours				
Text size				
Text font				
Colour banding on snap-off portion				
Size of ampoule/vial				

SELF-PREPARED SYRINGES	**1**	**2**	**3**	**4**
Size of syringe used for specific drug				
Colour of needle on syringe				
Drug label				
Leaving needle of syringe in opened drug ampoule/vial				

4. Are you aware of the availability of colour coded standardised labels for anaesthetic drug syringes?

Yes	
No	

5. Please indicate your agreement or disagreement with the following statements.

1 = strongly disagree
2 = somewhat disagree
3 = somewhat agree
4 = strongly agree

	1	**2**	**3**	**4**
Colour coded self-adhesive labels decrease medication errors in anaesthesia				
A standardized system of labelling drug ampoules/vials would decrease the incidence of drug errors				
Pre-filled syringes for anaesthetic drugs would decrease drug errors				
Having ALL anaesthetic drugs look the same would decrease the incidence of drug errors (same ampoule, colour, size, neutral label)				

Do you have suggestions that would help reduce medication errors:

_____
_____
_____
_____

Section D: Reporting of medication errors in anaesthesia

1. Did you report any of the medication errors identified in Section B to a medical authority, hospital or anaesthetic department?

Yes	
No	

If yes, to whom or where did you report the error(s)?

_____

2. Did you report the error to the patient?

Yes	
No	

3. If you did not report the error, why not? (Check one or more)

Error was inconsequential	
Concern regarding opinion of colleagues	
Not certain to whom/where to report	
Concern regarding medico-legal risks	
Other implications of reporting errors	

Other implications:

_____
_____
_____

4. Have you made any changes to prevent errors from occurring again?

Yes	
No	

5. If yes, please list changes made.

_____
_____
_____
_____
_____

Thank you for your time and cooperation!

Appendix B: Permission from Dr B Orser to used validated questionnaire (email correspondence)

Mmed Project on Drug Errors

Janine Vally <1318117@students.wits.ac.za> 05/09/2016

to beverley.orser

Dear Dr Orser

My name is Janine Vally and I am currently a registrar in the Department Anaesthesia at the University of Witswatersrand in Johannesburg, South Africa.

As part of our training we are required to do an Mmed research project. I am interested in doing a survey amongst the anaesthetists in our department with regards to drug errors.

I have read your publication in the Canadian Journal of Anaesthesia 'Medication errors in Anaesthetic practice: a survey of 687 practitioners' and would like to request permission to use your validated questionnaire. We have not had a study of this kind in our department and feel it would help to explore this topic and ultimately improve patient safety and outcomes. I would like to use your questionnaire as it will give relevant information pertaining to my study and is already validated.

I would greatly appreciate your assistance.

Kind regards

Beverley Orser <Beverley.Orser@utoronto.ca> 05/09/2016

to me

Dr. Vally,

You are most welcome to use the questionnaire. Did you receive my previous response? And do you have a copy of the questionnaire? Good luck with your study.

Sincerely,
Bev Orser

Sent from my iPhone

Appendix C: Permission from Dr P Gordon to use validated questionnaire (email correspondence)

Janine Vally <1318117@students.wits.ac.za> 05/09/2016

Dear Dr Gordon

My name is Janine Vally and I am currently a registrar in the Department Anaesthesia at the University of Witswatersrand in Johannesburg, South Africa.

I am currently busy with my Mmed research project and have decided to do a survey amongst the anaesthetists in our department regarding drug errors. We have not had a study regarding drug errors for sometime in the department and I would like to review current issues around the topic.

I have read your publication in the SAJAA in 2004 'Wrong drug administration errors amongst anaesthetists in a South African teaching hospital' and would like to request permission to use your questionnaire. We have not had a study of this kind in our department and feel it would help to explore this topic and ultimately improve patient safety and outcomes. I would like to use your questionnaire as it will give relevant information pertaining to my study and is already validated.

I would greatly appreciate your assistance.

Kind regards

Peter Gordon <peter.gordon@uct.ac.za> 08/09/2016

Dear Janine

I would be very happy for you to use our questionnaire for your study and wish you well. I suggest you look at the latest edition of *Anesthesiology* that has a paper by Nanji on the paper that is worth reading. (See attachment) Even more important however is to read the criticism of their paper in *Anesthesiology* as it may change your thoughts on the methodology of such a study. Prof Lundgren and Des Lines were co-authors in our study and could provide support.

Kind regards

Peter

Peter Gordon BSc, MBChB, FFA(SA)?
Emeritus Associate Professor
Hon. Curator: Nagin Parbhoo History of Anaesthesia Museum
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Email: peter.gordon@uct.ac.za

Appendix D: Information Letter

October 2016

Information Letter

Dear Colleague

Hello, my name is Janine Vally. I am a registrar in the Department of Anaesthesiology at WITS. This letter is an invitation to partake in my MMed research study titled: "**Medication errors in operating theatres in the Department of Anaesthesiology at the University of the Witwatersrand**". This study will be handed in to the Faculty of Health Sciences at the University of Witwatersrand, in fulfilment of my MMed degree.

It has been well documented that medication errors in anaesthesia are common. Recent evidence suggests up to 1 error per 20 medication administrations. Errors have both a high financial and human cost with the potential to cause severe morbidity with permanent damage and even mortality. Error rates are also a reflection of our general level of patient safety. The aim of this study is to describe the occurrence of medication errors as reported by anaesthetists in the Department of Anaesthesiology at WITS. This will be determined by means of a self-administered questionnaire.

Completing the questionnaire will imply consent to participate in the study. Participation is voluntary and anyone is free to withdraw from the study at any time without penalty. Questionnaires are anonymous as no identifying data will be asked of you. It will take about 10 minutes to complete the questionnaire. Once the questionnaires have been completed, they will be placed in a sealed collection box (including those not completed). The process is confidential as only the study supervisors and researcher will have access to the raw data. Questionnaires have been numbered for data capturing purposes only.

The Human Research Ethics Committee (Medical) (protocol number x) and the Post-graduate Committee of the University of the Witwatersrand have approved the study proposal.

If you have any questions with regards to the study, please contact me on 082 663 9294 or janinevally@gmail.com. The chairperson of the Human Research Ethics Committee is Professor Cleaton-Jones. He can be contacted on 011 717 1234.

Thank you for taking the time to read this letter.

Yours sincerely

Janine Vally