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An Audit of Syringe Labelling Practices of Anaesthetists at Four Academic Hospitals

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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 the branch of Anaesthesiology

Johannesburg, 2016

Declaration

I, Mologadi Pride Tshabalala, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

.....
Mologadi Pride Tshabalala
Signed on this 24 October 2016

Abstract

Background

Drug administration errors have seen a marked rise in the medical fraternity. In anaesthesia these are expected to be higher as for any anaesthetic given, multiple drugs are administered. Although many risk factors have been identified as causes of medication errors, in anaesthesia in particular, syringe labelling has been identified as an easily preventable source of medication error.

Methodology

The aim of this study was to audit the syringe labelling practices of anaesthetists in four academic hospitals affiliated to the University of the Witwatersrand. The research design used to conduct the study was a prospective, contextual and descriptive one. The study population was all syringes prepared for anaesthesia during the course of the data collection days at the four academic hospitals. A consecutive convenience sampling method was used to collect the data

Results

A total of 279 syringes were included in the study. Of the 279 syringes, 242 (87%) were labelled. Six (2%) of the 242 labels were colour coded. A total of 37 (13%) syringes had no labelling at all.

All labelled syringes had the name of the medication present, either in full or abbreviated. Two hundred and nine (86%) of the labelled syringes had the dose and/or concentration of the medication. Fifteen (6%) of syringes had date, 6(2%) had time. A total of six (2%) syringes had a signature of the person who prepared the drug and one (0.4%) had a signature of the person that checked the drug. The majority 193 (69%) of syringes had only two out of the six required labelling items.

Conclusion

This study revealed that syringe labelling practices of anaesthetists in the four academic hospitals associated with Wits did not meet the recommended standards. It is recommended that a standard operating procedure for syringe labelling be introduced as studies have shown that syringe labelling is an easy way of preventing and/or reducing medication error.

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List of abbreviations

ASA	American Society of Anesthesiologists
CHBAH	Chris Hani Baragwaneth Academic Hospital
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
HJH	Helen Joseph Hospital
ISO	International Organization for Standardization
ISMP	Institute for Safe Medication Practices
RMMCH	Rahima Moosa Mother and Child Hospital
SABS	South African Bureau of Standards
SASA	South African Society of Anaesthesiologists
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation
Wits	University of the Witwatersrand

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Chapter 1: Overview of the study

1.1 Introduction

This study is of an audit of syringe labelling practices of anaesthetists in four academic hospitals affiliated to the University of the Witwatersrand (Wits). In this chapter the study is introduced under the headings: background, problem statement, aim, objective, research assumptions, demarcation of the study field, ethical considerations, research methodology, significance of study and study outline.

1.2 Background

An increase in errors in the medical profession has been seen recently so much so that the term “error pandemic” is being used in some medical publications. Kohn et al (1) stated that “it is human to err”, however, in the medical profession these errors may lead to severe disabilities and fatalities. In various studies the incidence of these errors have been very high and the resultant fatalities have been extrapolated to surpass those resulting from vehicle accidents, breast cancer and AIDS in the USA(1, 2).

Medication errors are a hindrance to patient safety initiatives. They, however, are often preventable, especially if medical practitioners adhere to prescribed protocols(3). Patient safety is defined by the World Health Organisation (WHO) as ensuring that patients are protected against preventable harm (4). Llewellyn et al (5) have suggested that patient safety be included in the curriculum of medical students and in continued training of doctors as it is invaluable in the health care profession.

Orser et al (6)refers to anaesthesiology as the “ODAM” profession as unlike other practitioners, anaesthetists **o**rder, **d**ispense, **a**dminister and **m**onitor high risk drugs, all this while performing other duties in the operating theatre. This is why anaesthetic practice is susceptible to medication errors, the true incidence of which is likely to be higher than the literature suggests, as the statistics are dependent on self reporting.(6)

Another reason for the underestimation of the impact of errors is that mortality is rarely reported as a result of medication errors. This is because often the outcome of anaesthesia and surgery can be attributed to multiple factors and there may be

under reporting of drug errors, especially when the anaesthetist remains ignorant of the error. (3)

Syringe labelling has been identified as a significant and easily preventable source of medication errors. It is alarming, however, that although simple studies revealed that although simple, the compliance to consistent syringe labelling was very poor, ranging from 37 to 70% .(7, 8).The Helsinki Declaration on Patient Safety in Anaesthesia (7) states that all institutions administering anaesthesia should include syringe labelling in their list of protocols. A South African study conducted in an academic hospital in the Free State concluded that only 62% of the anaesthetists were aware of the existence of standardised colour coded syringe labels and of these anaesthetists, only 19% reported using them.(8)

The poor compliance with syringe labelling protocols and ignorance of their existence is disquieting as there are a number of guidelines and standards that have been published regarding syringe labels (3, 9-12). These include the International Standard Organisation (ISO)(13), from which the majority of the standards have been adopted.

The outcome of medication errors in anaesthesia can vary from no adverse event to fatalities, depending on the drugs administered. Medication errors in anaesthesia can lead to adverse events. The most frequently reported were awareness during anaesthesia and prolonged action of muscle relaxants, leading to unplanned post-operative ventilation and prolonged unconsciousness (14). In other instances disability and death may result and these lead to legal action being taken against the practitioner or the health care facility. The American Society of Anesthesiologists (ASA) Closed Claims Project found that as many as 4% of the malpractice cases in anaesthesia were due to errors of drug administration. These were largely related to administration of incorrect doses or incorrect drugs. (15)

The consequences of these errors may extend to judgments being passed in the courts of law. Merry et al (16) state that there is a move towards a just culture system, where there is a tendency to blame the system as opposed to the individual. This is a reasonable approach where a practitioner consistently adheres to safety and prescribed guidelines. “On the other hand, if a practitioner chooses to ignore widely accepted safety practices (such as labelling syringes), then blame may be

appropriate. In a just culture, the question becomes one of differentiating blameworthy behaviour from blameless behaviour.” (16) This may lead to a judgement such as manslaughter being imposed in a case where such an error has resulted in a loss of life. In the case where the error has resulted in severe disability, fines may be awarded. Twenty four million pounds were awarded to an 11 year old girl who was left with a severe disability after the contents of an unlabelled syringe (containing tissue glue), mistaken for contrast, was injected intra-arteriallypost an aneurysm repair(17).

1.3 Problem statement

Studies done internationally and nationally have revealed that erroneous drug administration was a frequent occurrence in anaesthetic practice (8, 11, 14, 18-22). This is not unexpected as the average anaesthetist administers at least a quarter of a million drugs in the course of their professional career (22). An important cause of medication error that has been highlighted in the literature is that of incorrect syringe labelling (3, 11, 16, 18, 20, 22, 23).

In South Africa, the South African National Standards (SANS 26825:2009) (24) based on the ISO standard of 2008(13), recommends the use of standard colour coded labels to mark syringes used forthe administration of anaesthetic drugs. This standard also includes general properties, such as size, adhesive properties etc, which a syringe label should meet. However, it is important to note that additional information such as the date, the time and the signature of the healthcare worker who prepared the syringe should also appear on the label.

Currently, in the operating theatres of the hospitals affiliated to the Department of Anaesthesiology at Wits, various medications such as emergency, induction and analgesic agents and antibiotics, are prepared in advance by a healthcare worker. The researcher's perception is that syringes are not marked in the recommended manner. A concern is that the person administering the prepared medication is often not the person who prepared it. Jansen (25) stated in her thesis that “No medical practitioner (or any other health worker) may administer medication without checking it properly” (translation from Afrikaans).

The syringe labelling practices of anaesthetists working in four academic hospitals affiliated to Wits was unknown.

1.4 Aim

The aim of this study was to audit the syringe labelling practices of anaesthetists in four academic hospitals affiliated to Wits.

1.5 Objectives

The objectives of this study were to:

- describe the current method of labelling syringes
- describe the information recorded on the syringes
- document the number of items written on each syringe label.

1.6 Research assumptions

The following definitions were used in the study.

Syringe: refers to a syringe on an anaesthetic work surface, filled with medication, for use by the anaesthetist and does not include those that were empty or labelled “flush”.

Predetermined standard: refers to the standard against which the current syringe labelling practices was compared. This was drawn up following an extensive literature review and included the following: name of medication, dose/concentration of medication, date and time medication was prepared, signature of person preparing medication and signature of person checking medication.

1.7 Demarcation of study field

The research was done in the operating theatres of Chris Hani Baragwaneth Academic Hospital (CHBAH), Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Helen Joseph Hospital (HJH) and RahimaMoosa Mother and Child Hospital (RMMCH). All four of the above hospitals are affiliated to Wits.

- CHBAH is a central hospital with 2888 beds and 25 theatres
- CMJAH is a central hospital with 1200 beds and 23theatres
- HJH is a regional hospital with 500 beds and 7 theatres
- RMMCH is a regional 338 beds and 5 theatres

1.8 Ethical considerations

Approval to conduct the study was obtained from the Postgraduate Committee of Wits (Appendix 1). The Human Research Ethics Committee (Medical) of Wits was approached for an ethical waiver (Appendix 2) as this was a study not involving human subjects. Approvals were received from the Medical Advisory Committee of CHBAH (Appendix 3) and the CEOs of CMAH, HJH and RMMCH (Appendix 4).

1.9 Research methodology

The research design was prospective, contextual and descriptive. The study population was all syringes prepared for anaesthesia during the data collection period at each of the four academic hospitals. A consecutive convenience sampling method was used to collect data. Data was collected on two consecutive days to ensure that the routine syringe labelling by anaesthetists was not influenced by the study. All the syringes on all the anaesthetic surfaces in all the functioning theatres in the four hospitals were evaluated on two consecutive days. Each theatre was only included once to ensure that syringes prepared by any one anaesthetist were not included more than once. All syringes on anaesthetic work surfaces containing solutions were included in the study and those that were empty and unlabelled or labelled “flush” were excluded.

1.10 Significance of the study

Studies done internationally and nationally have revealed that erroneous drug administration is a frequent occurrence in anaesthetic practice (11, 14, 16, 22, 26, 27). This is not unexpected as the average anaesthetist administers at least a quarter of a million drugs in the course of their professional career (22). An important cause of medication error that has been highlighted in the literature is that of incorrect syringe labelling (9, 11, 18, 19, 26, 28). The anaesthetist is legally accountable for drug errors that occur (25).

Should this audit reveal inadequate syringe labelling practices amongst anaesthetists in the study hospitals, this may lead to the standardisation of drug labelling and therefore safer patient care in the Department of Anaesthesiology at Wits.

1.11 Study outline

The study contains the following chapters:

Chapter 1 Overview of the study

Chapter 2 Literature review

Chapter 3 Research methodology

Chapter 4 Results and discussion

Chapter 5 Summary, limitations, recommendations and conclusion.

1.12 Summary

In this chapter a brief overview of the study was given. The following chapter contains the literature review.

Chapter 2: Literature review

2.1 Introduction

In this chapter, the literature related to this study is reviewed under the following headings: patient safety and medical errors, medication administration errors in anaesthesiology, drug error coding system, syringe labelling practices both international and local, guidelines for syringe labels, legal requirements, legal consequences and management of drug errors.

2.2 Patient safety and medical errors

WHO defines patient safety as, “the absence of preventable harm to a patient during the process of health care.” The discipline of patient safety is the coordinated effort to prevent harm, caused by the process of health care itself, from occurring in patients (4).

The 2000 American Institute of Medicine’s now famous report “To err is human, building a safer health system” (1) has given rise to the so called “patient safety movement” that has resulted in an increased awareness of patient safety and research to address the safety of health systems (29).

Human beings, irrespective of their profession, unfortunately are prone to making errors. The medical profession as a whole, including the anaesthetic speciality provide no exception. This is especially true in recent decades, so much so that some medical publications have coined the term “error pandemic”. These errors, however, are preventable with the establishment of guidelines which, when consistently adhered to, will minimise both the number and amplitude of these errors. (1)

High risk industries such as aviation and nuclear plants have a comparably better safety record than health care. There is a 1 in 100 000 chance of a traveller being harmed while in an aircraft. However there is a 1 in 300 chance of a patient being harmed when receiving health care. (4)

Studies conducted in various institutions throughout the world have all reported an alarmingly high incidence of medical errors, a significant number of which have led to fatalities. In a study conducted in Colorado and Utah hospitals in the United States of

America (USA), the fatalities from preventable medical errors were so high that, once extrapolated, revealed this to be one of the leading causes of death in the USA, surpassing vehicle accidents, breast cancer and AIDS. (1)

In monetary value, the total cost of medical errors in the USA was estimated to be between 17 to 29 billion US dollars. Half of these costs were medical costs as a result of prolonged hospitalisation. The rest of the cost was attributed to loss of income. It is however the patient's loss of trust and even fear of the healthcare facilities and the healthcare professional's loss of confidence in themselves that constitute the greatest loss. This human cost is often not emphasised as it is not easy to measure, yet its value undeniably high. (1, 2)

In Seattle, during a procedure for a coil placement in a cerebral angiography to repair a brain aneurysm of a 69 year-old woman, clear chlorhexidine solution was injected into her arteries instead of contrast. This error occurred as both basins containing the two solutions were not labelled and the solutions looked the same. At the end of the procedure, contrast medium had to be injected into her artery for radiographic visualisation of the repair site. At this point chlorhexidine was drawn into the syringe; the patient received the antiseptic into her artery. This toxic substance resulted in multi-organ failure and both her legs being amputated before she eventually succumbed to the toxin. This tragic demise of a 69 year-old woman is a stark reminder of the horrors that can be prevented with a step as simple as the application of a label. Just as tragic is the emotional impact of such errors on the affected families: once the family found out that the error that resulted in their mother's death could have been avoided with a label, they pledged to get involved in promoting greater awareness of patient safety.(30, 31)Medical errors such as this case are preventable, especially if prescribed protocols, which are aimed at ensuring patient safety, are enforced (1).

Patient safety in anaesthesiology is emphasised in the Helsinki Declaration on Patient Safety in Anaesthesiology(7), which is expressed as a set of principal requirements that state that any institution administering anaesthesia should have protocols on:

- "checking equipment and drugs
- preoperative assessment and preparation
- syringe labelling
- difficult/failed intubation
- malignant hyperpyrexia
- anaphylaxis
- local anaesthetic toxicity
- massive haemorrhage
- infection control and
- post-operative care including pain relief."

Espin et al (29) suggest that the operating theatre is one area where there is a pressing need for improved safety. This presents a significant challenge and a vital first step is to understand the factors that promote unsafe practice in this area.

2.3 Medication administration errors in anaesthesiology

The anaesthetic profession requires that multiple, and at times complex preparations of drugs be administered at any one time (14). Medication errors in anaesthetics can be expected, especially when one keeps in mind the observation made by Fraind et al (32) that drug preparation prior to administration may at times require that up to 40 separate manoeuvres be carried out. This means that there are up to 40 points at which an error can occur.

Morgan refers to ASA Closed Claims Project which found that as many as 4% of the malpractice cases in anaesthesia were due to errors of drug administration. This is largely related to administration of incorrect doses or what is known as “syringe swap”, where an incorrect drug is administered (15).

Brown-Brumfiels et al (33) noted that in the perioperative period, medication errors posed a potentially serious threat to patients’ well being. They concluded that the

practice of safe medication dispensing and labelling needed to be constant across the perioperative spectrum.

Llewellyn et al (5) suggested that patient safety should be part of the undergraduate curriculum at medical school. They also noted that the possibility and prevention of medication errors should be constantly emphasised throughout doctors' training, at internship and registrar level, so that some level of patient safety is constantly ensured.

2.4 Drug error coding system

In 2005 Abeyskekera et al (11) developed a comprehensive medication administration error coding system when reviewing reports from the Australian Incident Monitoring Study Database with regard to drug errors in anaesthetic practice. The coding system that provides a common language to describe drug errors is as follows:

- **"Drug error**: a failure to give the drug or dose of drug that was intended.
- **Pre-error**: an incident that may have led to drug error, but in which no drug was given.
- **Syringe swap**: this occurred when a drug was given from a correctly labelled syringe but the drug was not the intended one.
- **Equipment error**: occurred when equipment malfunction or misuse caused an error in drug delivery.
- **Communication error**: occurred when the narrative suggested a miscommunication between the anaesthetic and or recovery staff or surgeon to be the primary cause of a failure to give the drug that was intended.
- **Wrong drug ampoule labelling error**: occurred when the contents of the syringe were different from that indicated on the label or from what was expected to be in the drug ampoule used. This occurred when the drug was being prepared either due to the drug being drawn up from an incorrect ampoule or mislabelling of the syringe once it was drawn up.
- **Pharmaceutical preparation error:** this is defined as a dilution error or when the concentration of the intended drug was incorrect, also included were errors where there was no drug in the syringe due to failure to draw up or mix a drug with diluents. " **(11)**

One other coding system quoted in the literature classifies errors into; omission, incorrect dose, substitution, repletion, insertion, incorrect route and other (which includes, too rapid administration, wrong interval and sequence errors). However this coding was not defined comprehensively.(14, 34)

2.5 Syringe labelling practice

Paparella(23) quotes two incidents where unlabelled syringes resulted in erroneous drug administration. The first case was where an 11 year old patient was given large doses (15 mg) of midazolam, mixed with acetaminophen liquid, intended for oral administration into the intravenous line. This occurred after the nurse was called away momentarily and upon her return she arrived at the bedside with two unlabelled syringes and injected the medication. The patient lost consciousness for an extended period of time but he subsequently recovered fully. Another case was where an infant was injected with massive doses of an antibiotic which was meant for the oral route. The child had a respiratory arrest and fortunately resuscitation was successful. These incidents highlight the need for good and consistent labelling practices.

There has been a number of studies done internationally and in South Africa highlighting the occurrence of drug errors in anaesthetic practice. A few international and South African studies are discussed below.

2.5.1 International studies

A study was conducted in 2001 at two hospitals in New Zealand, where anaesthetists were requested to anonymously complete a survey. This revealed that drug errors and pre-errors were mostly reported by more senior anaesthetists with an average experience of greater than 10 years. The most common errors were the administration of incorrect doses and incorrect drug, one of the causes being incorrect labelling of syringes by the anaesthetist. In the majority of the cases the most reported adverse events were, awareness, prolonged action of muscle relaxants leading to unplanned post operative ventilation and prolonged unconsciousness. (14)

In the above mentioned study it was extrapolated that an average of approximately one error per 133 anaesthetics given occurred and this led to a conclusion that one

anaesthetist is likely to make approximately seven errors per year. Meticulous syringe labelling could significantly contribute to reducing this number. (14)

Medication errors affect all healthcare workers that prescribe, prepare or administer medication. An online survey on challenges of labelling syringes conducted by the American Nurses Association in 2007 reported that 97% of nurses worry about medication errors and that 68% were of the opinion that these errors can be reduced with consistent syringe labelling. Only 37% of the nurses reported always labelling their syringes. (35)

A review of 896 reports from the Australian Incident Monitoring Study Database (11) conducted in 2009, revealed that the incident of drug errors and pre-errors associated with syringe or drug preparation error was as high as 50%. Syringe swap accounted for 37% of these errors and 25% of the syringe swaps, were due to drug labelling errors. The list of drugs in syringe swaps often includes opioids, neuromuscular blocking agents, reversal agents, benzodiazepines, vasopressors and local anaesthetics. The therapeutic indexes of these drugs vary greatly and potential consequence from errors resulting in their substitution could range from minor to fatal. In the study minor morbidity was reported in 11.7% of cases, major morbidity in 4.4% and death in 0.3%. Mortality is rarely reported as a result of a medication error. This is because often the outcome of anaesthesia and surgery can be attributed to multiple factors and there may be under reporting of drug errors, especially when the anaesthetist remains oblivious of this error. (11)

In 2010, Brown-Brumfield et al (33) conducted a study aimed at quality improvement in the operating theatre at the Cleveland Clinic in Ohio. The aim of this study was to assess the staff adherence to a revised medication and solution labelling protocol. This protocol was implemented with recommendations from the Joint Commission and Association of Peri-Operative Registered Nurses. There were 45 recommendations including that; all medication be labelled to accommodate the needs of the anaesthetic care provider and that all medication should be labelled in accordance with generally accepted safety standards. Once the new protocol was announced, staff members at the Cleveland Clinic received educational training in its implementation. This was followed by a study to assess adherence asking the following questions.

- " Would staff members dispense and label medication and solutions according to the protocol?
- Would adherence to the protocol differ amongst the various surgical specialties?
- Would adherence to the protocol differ by years of staff member experience? " (33)

It was reported that medical personnel labelled medication 70% of the time and checked medication in 60% of the observed cases. The study revealed that non-adherence to standard labelling protocols was still a problem. Staff members with more than 20 years' experience had a 40% non-compliance rate with the labelling of medication as opposed to 27% in their less experienced colleagues. It was also noted that the rate of adherence to prescribed protocols differed amongst different medical specialities. Although this was not quantified, it highlighted the need for standardisation of medication labelling practice. (33)

In 2011, a study was conducted at the Carolina Medical Centre Mercy in the USA with the aim to ascertain whether the provision of pre-printed medication labels would improve compliance with the labelling protocols introduced. The study reported that the availability of pre-printed labels improved compliance up to 96% as opposed to the control group which only had 26% compliance. The control group was supplied with blank labels. (26)

Much of the reviewed literature has supported the introduction of one internationalised method of colour coding and labelling of syringes.(6, 21, 28, 34, 36, 37) Haslam et al (21) raised concerns of a possible period of increased errors during the transition to the international colour coding syringe labelling system. A small study was performed where two groups of anaesthetists were asked to use the new ISO colour coded labels. The first group had no prior experience with the use of the new labels and the second group had used the labels before. In the first group 15% pre-errors were reported and 0.9% errors were made. The second group reported only 3% pre-errors and no errors occurred.

2.5.2 South Africa

A survey on medication errors was conducted by Gordon et al (20) in 2004. It was electronically distributed to 720 anaesthetists registered with the South African

Society of Anaesthesiology (SASA). A total of 133 anaesthetists responded and of these, 125 (94%) admitted to having administered the wrong drug. Only 28 of 125 anaesthetists reported the errors. Out of the errors reviewed as many as 50% involved muscle relaxants and 14% involved vasoactive drugs. The main causes of errors were reported to be syringe swap in 40% of the cases, misidentification of the drugs in 27.1%, fatigue was responsible in 14.1% and 4.7% were mislabelled syringes. In this survey 62% of the anaesthetists were aware of the existence of the South African standard colour coding of syringe labels in theatre and only 19% of the participants reported using syringe labels as per the national standard. The result of the errors was five fatalities, three non-cardiac arrests and in 9.9% of the cases this resulted in prolonged anaesthetic time. (20)There was a small sample realisation, which may likely have led to an underreported sample.

A study(22) done in South African academic hospitals between April 2005 and January 2006, revealed results similar to the Australian studies mentioned above (11, 14). It was found that errors were more likely to be reported by more senior anaesthetists and that more than half the errors (54%) were those of drug substitution. It was reported that about 21.3% of the drug substitution errors were related to syringe identification and that an average of one medication error occurred per week. It was suggested in this study that hospitals need to adopt a uniform, international, colour coded syringe labelling system as clear labelling of all syringes was vital in the efforts to decrease the incident of medication errors. (22)

In another survey conducted in 2011 amongst 188 doctors in 22 public sector hospitals in the Free State it was revealed that only 23% of the respondents indicated that they were aware of a South African Standard for colour coded syringe labels and of these only 25% used them regularly. In this survey 80% of registrars reported having made administration errors and 93.8% of the consultants reported the same. Only 16.7% of the interns reported drug errors, although they administered anaesthetic drugs most often in these hospitals. (8)

2.6 Guidelines for syringe labels

The Helsinki Declaration on Patient Safety in Anaesthesiology requires that all institution administering anaesthesia have protocols on syringe labelling (7) . Various countries and institutions have drafted guidelines to be followed by anaesthetists.

2.6.1 First registered colour coded labels in the world

The first colour coded syringe labels in the world were registered in South Africa in 1985 (SABS 0207-1985), after Professor Pat Foster from Tygerberg hospital, with the support of SASA in partnership with SABS, pioneered the development of national standard colourcoded syringe labels for anaesthetic drugs. This colour coding system has been revised and adopted by various other countries such as Australia, Canada and the United Kingdom (UK). The ISO in partnership with SABS on the advice of SASA developed the international standards, ISO 26825:2008. (38) Details of the ISO 2685 and some of the adopted and revised guidelines will be discussed later in the document.

2.6.2 Australian and New Zealand College of Anaesthesia Guidelines (AS/NZS 4375:1996)

The Australian and New Zealand College of Anaesthesia adopted the colour coding guidelines and revised them to include more information about the drug. The Australia and New Zealand Guidelines for the Safe Administration of Injectable Drugs in Anaesthesia, were first published by the Australian and New Zealand College of Anaesthetists in 1996. (16) These labelling recommendations put a focus on enhancing patient safety. They stipulate which containers should be labelled, e.g. bags and bottles for infusion were injectable medicines were added and jugs and basins in theatre settings. They also outlined what is to be included on the label and where the label should be placed. The information on the syringe labels include:

- “ patient name (given and family name)
- patient identifier
- date of birth
- active ingredients
- amount of medicine/s added (including units)
- volumes of fluid in the syringe in ml
- concentration (units/ml)
- diluents
- date and time prepared
- prepared by (signature)
- checked by (signature) and

- route of administration (where not specified by wording and colour)” . (16)

The Australian and New Zealand Guidelines suggest colour coding labels by the route of administration e.g. intrathecal, intravenous, oral etc, as opposed to ISO standard which colour code labels according to medication class e.g. opioids, muscle relaxants etc.

2.6.3 USA Guideline

The USA Guidelines (ASTM D4774) were published by ASA in 2004 and are based on reports published by the American Society of Testing and Materials and the ISO standards. These guidelines are technical and focus mainly on the quality of the labels as opposed to the information written on them. They do, however, have a place for the dose, date, time and initials of the person that prepared the drugs (see Figure 4). The standard focuses on size, colour, pattern and font faceused on labels applied to unlabelled syringes filled by the users to identify the drug content. A disclaimer attached to the standard states that the standard does not address safety concerns in their entirety and if any concerns are associated with its use the responsibility lies with the user(39).

2.6.4 ISO 26825:2008 Standard

ISO is the world’s largest developer of voluntary international standards. It has approximately 160 member countries and 3368 technical bodies that develop standards. The international standards produced by ISO provide gold standard specifications for products, services and good practice to various industries, ensuring their efficacy. Once a standard is developed, it requires approval by at least 75% of the member bodies. (13)

The general properties of the label to meet the ISO 26825:2008 (24)standard are listed below.

- The label needs to be self-adhesive and not be easily peeled off even after 12 hours on polyethylene syringes, (material with poor adhesion properties), immersion in 50% solution of isopropanolol and water for five minutes.
- The labels must be easily separable from each other, whether in a tape or backing material.

- The material of the label should be suitable for the user to write additional information on it with a ball-point pen without smudging or blurring.
- The label packaging should be marked with the number and date of the standard, in this case ISO 26825:2008.

The standard also dictates background colours and designs, examples of which can be seen in Figure 2.1. The size of the label should be between 25 to40 mm in length and 10 to 15 mm in width. It is dictated as such so as to fit most syringes without covering the graduation marks. (24).

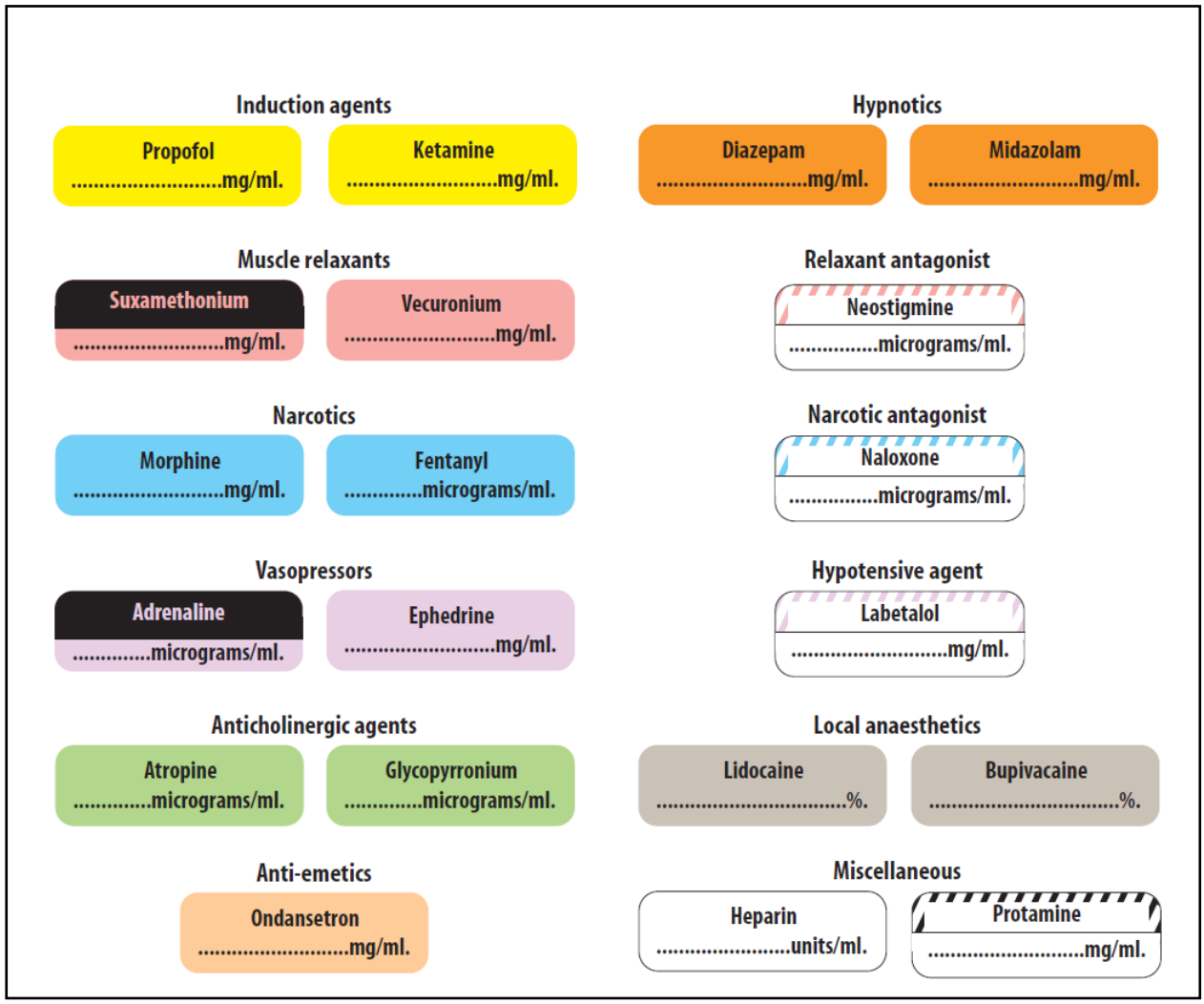


Figure 2.1 ISO colour coded pre printed labels (24)

South Africa has adopted the ISO 26825:2008 guidelines which were implemented by the SABS in 2009 (SANS 26825:2009), replacing the 1985 standards. The standard focuses on technical aspects of the labels. This covers only the colour,

size, design and general properties of the label and the typographical characteristics of the wording for the drug name. The standard does not require as much detail as that stipulated in the Australian and New Zealand guideline (AS/NZS 4375:1996)**.** (24)

2.6.5 Institute for Safe Medication Practice (ISMP)

The ISMP which was established with the sole purpose of ensuring patient safety, also recognised that labelling of syringes was poorly done and that a standard for syringe labelling was required in all hospital departments. Their 2004 survey revealed that out of 1600 hospitals in the USA only 41% always labelled medication containers and solutions in operating rooms. According to the survey, 18% of hospitals did not have labels on their containers and another 42% applied labels inconsistently. (30). In 2010, the ISMP offered their recommendations as one of the approaches to the prevention of medication errors related to label misinterpretation. Figure 2.2 shows an example of the information the ISMP recommends be included on the syringe labels.

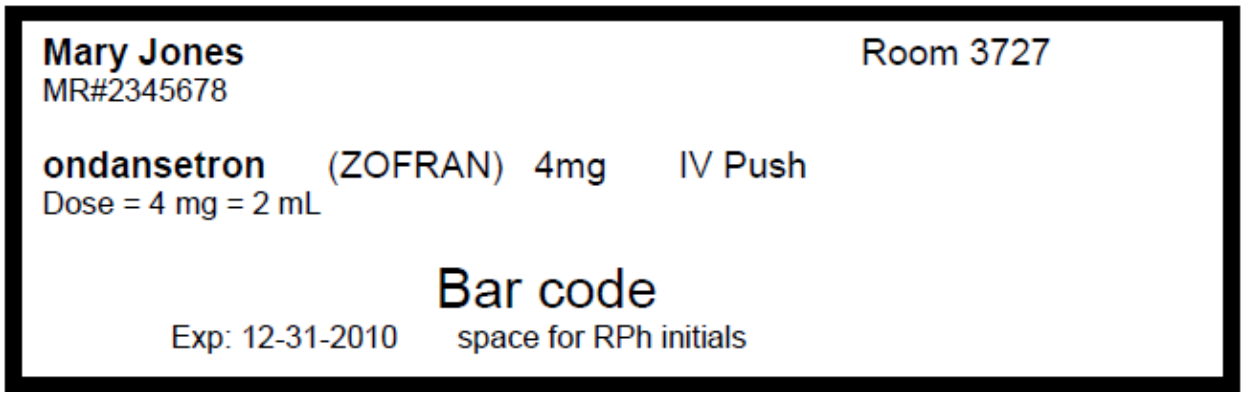


Figure 2.2 an Example of the label proposed by the ISMP for use in acute settings (40)

2.7 Legal requirements

In South African courts, negligence is decided on the “reasonable practitioner” basis (41). Strauss (41) states that:

“In order to determine whether or not a person was negligent, the criterion of the reasonable man is applied. The question is asked: how would a reasonable man have acted in the same circumstances in which the person before the

court (the defendant) found himself? The reasonable man is the person of average intelligence, knowledge and wisdom. The test is not that of the reckless man, but of the person who is aware of possible dangers and who takes the necessary precautions to guard against dangers. The (subjective) powers of judgement, knowledge and insight of the defendant himself is not the determining factor."(41)

Legal criteria for negligence is met when it is established that the adverse event experienced by the patient was as a result of the clinician's failure to provide acceptable standard of medical care (42). This may well be the case in erroneous drug administration; as a result, Jansen (25) stated in her thesis that "No medical practitioner (or any other health worker) may administer medication without checking it properly" (translation from Afrikaans).

2.8 Legal consequences

In an era of increasing litigation being brought against physicians, it is important that definitions and associated implications of terms often used are well understood. Errors, by definition have no blame. Violations on the other hand, are intentional deviations from known guidelines and/or protocols designed to maintain safety and reflect carelessness and would be judged as such in a court of law. Routinely labelling syringes is an internationally accepted important safety measure in all medical specialities. Choosing not to adhere to this action may be judged as a violation and reasonably considered blameworthy. (3, 16)

Malpractice complaints, if found in the favour of the patient, may have a variety of consequences for the doctor, depending on the complications of the medication error. In cases where the doctor is deemed negligent and the patient dies the charge of culpable homicide may be brought against the doctor. In some instances a law suit may be instituted and in other cases the doctor may be struck off the registration board and their practice licence revoked. (43)

An example of the tragic consequences and heavy penalties that can be incurred from drug administration errors, especially when labelling the syringe would have prevented the outcome, is the story of Meisha Najeeb. Mesiha Najeeb was a ten-year-old in London who received a multimillion pound pay out, after sustaining brain damage from having glue accidentally injected in her brain instead of contrast. This

error was a result of the two syringes, one with contrast, to make the arteries visible and another with the glue to embolise any bleeding vessels, not being labelled and hence no way of telling the syringes apart. The judgement in this case ruled that Meisha was to receive a £2.8 million lump sum and a £383000 pay out annually until she turns 19 and from then on £423000 annually for the rest of her life. According to experts she is expected to live well into her 60's making this a £24 million pay out, the largest ever awarded in the London high court. (17)

2.9 Management of drug errors

Drug administration errors are common in all the spheres of medicine that include drug administration as a scope of practice. Although there are many guidelines with regards to labelling syringes, these are not always adhered to or used. It has been shown that a good labelling policy can reduce medication errors in the theatres. (44) In Orser et al (6) the anaesthesiology speciality is referred to as the "ODAM" profession as unlike other practitioners, anaesthetists **o**rder, **d**ispense, **a**dminister and **m**onitor high risk drugs, all this while performing other tasks in the operating theatre. This highlights the complexity of administering anaesthesia and the multiple opportunities for drug errors to occur. Standardised colour coded syringe labelling is one way of reducing drugs errors.

Hintong et at (27) in their analysis of the problem of drug errors in anaesthesia in Thailand, suggested strategies for the prevention of drug errors. These were suggested as they had noted that the introduction of standardised colour coded syringe labelling was not necessarily implemented throughout the world and also that it was only one way of prevention. Their suggested strategies were as follows

- All anaesthetists should routinely be careful and attentive in their preparation and administration of all drugs.
- The practitioner should, carefully read every ampoule prior to drawing the drug into the syringe. The syringe should be clearly labelled with the drug name and concentration and the ampoule is to be checked again prior to being discarded.
- Care should be taken when reading the label on the syringe and the syringe content should always be checked with the person who prepared the drug prior to administration.

- Every change in the drug formula or packaging should be announced prior to being implemented.
- Use newly prepared drugs and in a case of multi-dosage drug preparations, extra care should be taken when reading the label of the drug and the concentration and date of preparation should also be noted. (27)

Prevention of medical errors is a multi-step process and although consistent, accurate syringe labelling will go along to prevent many of the errors, it will not completely rid the anaesthetic department of the problem. The table used at Royal Berkshire Hospital in the UK offers a comprehensive approach to the erroneous drug administration frequently seen in theatres. The table is headed “The ten commandments for drug usage in theatre”. These are listed below.

- “Drugs to be stored in generic alphabetical order in the cupboards.
- No drug to be drawn up in advance of the instruction by the anaesthetist.
- Extra vigilance to be observed with ‘emergency drugs’
- All drugs to be labelled at the time of drawing up.
- Never inject a drug from a non-labelled syringe
- Never inject a drug that you are not familiar with.
- Discard all unused, drawn up drugs at the end of the list.
- Unopened ampoules must not be returned to drug boxes.
- Keep all empty vials until the patient leaves theatre.
- Whoever injects a drug is responsible for the drug.” (45)

In 2005 a large teaching hospital in Ontario, Canada, adopted patient safety as a priority. The hospital’s board of trustees accepted the Accountability for Patient Safety Policy. This safety policy created awareness for all staff, volunteers and physicians, that ensuring safe health care systems was a shared responsibility. The safety policy was adopted after a safety project for operating rooms, under the leadership of the Departments of Anaesthesia and Nursing in collaboration with The ISMP (Canada), was conducted. The project’s aim was to recognise areas of risk and to make suggestions to improve medication safety in the hospital and also to inform development of a medication safety self-assessment specific to the theatre environment. A number of findings were made and recommendations tabled. One finding was that practitioner prepared solutions, basins and syringes were

inconsistently labelled. It was then recommended that all medications and solutions up to the point of use be labelled using standardised labelling procedures. (46)

In 2006 the National Patient Safety Goals, under the directive from The Joint Commission(33), USA, instructed health care providers to immediately label all medications and medication containers on and off the sterile field in the peri-operative and other procedural settings. In 2007, extra requirements were added to the directive with regards to the detail on the label. The label would include the medication's name, strength, amount and expiry date. It was also stated that all labels attached should be verified by at least two qualified individuals.

Drug administration errors are common in all medical specialities. Although there are many guidelines regarding syringe labelling practices, they are not always adhered to or used. It has been shown that a good labelling policy can reduce medication errors in theatres. It is also imperative to note that guidelines and protocols have no value if there are no means in place to ensure their enforcement. (44)

2.10 Summary

Medication errors in anaesthesia are a common occurrence. The number may be higher than that quoted in studies as the results are dependent on self-reporting surveys and in cases where no adverse event occurred, many practitioners may not consider this a notifiable error (24). Much of the reviewed literature has noted that syringe labelling is a significant cause of medication errors and an easily preventable one with consistent adherence to prescribed guidelines (10, 11, 14, 25, 40). These guidelines are numerous and many countries have adopted and revised the ISO colour coded syringe labels, which were first pioneered by SABS and SASA (25, 26, 28, 29).

Adherence to available guidelines is essential, as it could minimise adverse events from drug errors and the complications that may ensue, which may range from minor to death (5). The legal implications and consequences may range from fines to charges of man slaughter being imposed (30, 31). Although poor syringe labelling techniques are flagged as easily preventable, there are a number of causes of medication errors ranging from individual to system problems and it is thus important to have a multi-factorial approach to prevention strategies (37, 38).

This chapter reviewed the literature relevant to the study. The next chapter will discuss the methodology of the study.

Chapter 3: Research methodology

3.1 Introduction

The research methodology was discussed in this chapter under the following headings: aim, objectives, ethical considerations, research methodology, validity and reliability.

3.2 Problem statement

Studies done internationally and nationally have revealed that erroneous drug administration was a frequent occurrence in anaesthetic practice (8, 11, 14, 18-22). This is not unexpected as the average anaesthetist administers at least a quarter of a million drugs in the course of their professional career (22). An important cause of medication error that has been highlighted in the literature is that of incorrect syringe labelling (3, 11, 16, 18, 20, 22, 23).

In South Africa, the South African National Standards (SANS 26825:2009) (24) based on the ISO standard of 2008, recommends the use of standard colour coded labels to mark syringes used in the administration of anaesthetic drugs. This standard also includes general properties, such as size, adhesive properties etc, which a syringe label should meet. However, it is important to note that additional information such as the date, the time and the signature of the health care worker who prepared the syringe should also appear on the label.

Currently, in the operating theatres of the hospitals affiliated to the Department of Anaesthesiology at Wits, various medications such as emergency, induction and analgesic agents and antibiotics, are prepared in advance by a healthcare worker. The researcher's perception is that syringes are not marked in the recommended manner. A concern is that the person administering the prepared medication is often not the person who prepared it. Jansen (25) stated in her thesis that “No medical practitioner (or any other health worker) may administer medication without checking it properly” (translation from [Afrikaans]).

The syringe labelling practices of anaesthetists working in four academic hospitals affiliated to Wits are currently unknown.

3.3 Aim

The aim of this study was to audit the syringe labelling practices of anaesthetists in four academic hospitals affiliated to Wits.

3.4 Objectives

The objectives of this study were to:

- describe the current method of labelling syringes
- describe the information recorded on the syringes
- document the number of items written on each syringe label.

3.5 Ethical considerations

Approval to conduct the study was obtained from the Postgraduate Committee of Wits (Appendix 1). The Human Research Ethics Committee (medical) of Wits was approached for an ethical waiver (Appendix 2) as this was a non-human study. Approvals were received from the Medical Advisory Committee of CHBAH (Appendix 3) and the CEOs of CMAH, HJH and RMMCH (Appendix 4).

Anonymity of the anaesthetists working in the operating theatres at the time of the audit was ensured as their identities were not requested or noted and it is not known who drew up the drugs. Confidentiality was maintained as only the researcher and supervisors had access to the raw data. Raw data will be stored securely for six years following completion of the study.

The study did not involve the administration of any drug or therapeutic management and was conducted in adherence to South African Good Clinical Practice Guidelines (47) and the Declaration of Helsinki (48).

3.6 Research methodology

3.6.1 Study design

The research design was prospective, contextual and descriptive.

A prospective study is one where the researcher collects present time data over a course of time. (49) This data was collected from syringes being used in the theatres at the time the study was taking place.

This study was contextual as it only took place in four academic hospitals affiliated to Wits. Context refers the setting for an event(50).

A descriptive study is one where information is collected in the demarcated study field. It aims to describe the variables and, at times, to identify problems with the current practice. (49, 51) The researcher did not modify or intervene in the practice in the study field. The study described the current syringe labelling practices in the operating theatres of the four study hospitals.

3.6.2 Study population

The study population was all syringes prepared for anaesthesia during the course of a day at the four study hospitals.

3.6.3 Sample size

In consultation with a biostatistician and using Epi Info version 6, sample size was calculated. Assuming a 35% prevalence of noncompliance to guidelines based on an extensive literature review, with a precision of 10% and a 95% confidence interval, the minimum number of syringes required was 108. The actual number of syringes from each hospital was realised by the number of functional theatres in each hospital on the days that the study took place.

3.6.4 Sampling method

A consecutive, convenience sampling method was used to collect data. This method is inexpensive, accessible and often less time consuming. A convenience sampling method is the selection of all the readily available people or objects for the study(51). Consecutive sampling is the best choice of non-random sampling as every available individual or object within the accessible population is chosen consecutively(52).

3.6.5 Inclusion and exclusion criteria

The inclusion criterion was all syringes containing medication, labelled and unlabelled, found on the anaesthetic work station. The exclusion criteria were empty unlabelled syringes found on the anaesthetic work surfaces and any syringe labelled “flush”.

3.6.6 Data collection

The surgical list of patients is often booked the day before surgery and the anaesthetist assigned that list has the duty to assess the patients and review the results specific to these patients preoperatively. The anaesthetist then formulates an anaesthetic plan for the patients. On the morning of the surgery, the practice is for the anaesthetist to arrive early and to prepare for the surgical list. This preparation includes checking the anaesthetic machine and other equipment and ensuring that all drug cupboards are stocked.

The emergency drugs are often drawn up before the start of the first case as they may need to be diluted prior to use. This ensures that no time is wasted in the event of an emergency. The number of drugs drawn up pre-emptively varies depending on the anaesthetists' preferences and the patient profile for the day. The general practice is to dilute adrenaline, phenylephrine, atropine and ephedrine in their respective syringes and to then label the syringes. Often one drug is diluted in at least two syringes, with different concentrations of the same drug in each syringe, for e.g. 1 mg ampoule of adrenalin may be diluted into normal saline in a 10 ml syringe giving a 100 µg/ml dose, 1 ml of this is then diluted into a 20 ml syringe giving a concentration of 5 µg/ml.

The induction of anaesthesia requires that multiple drugs be administered at any one time. These drugs are prepared beforehand and include short acting opioids, induction agent and a muscle relaxant at minimum. Antibiotics, analgesics and other drugs are frequently necessary depending on the patient profile and type of surgery being performed.

These syringes are often prepared and labelled with a permanent marker by any one member of the anaesthetic team which includes a consultant, registrar, medical officer and /or intern. Therefore the medication may not be administered by the person who prepared it.

All the syringes on all the anaesthetic surfaces in all the functioning theatres in the four academic hospitals were evaluated. Data was collected from the four academic hospitals on two consecutive days. CHBAH was sampled on the first day in the morning; some of the theatres were sampled before the start of the list and others were sampled after the list had commenced. CMJAH was sampled on the morning of

the second day and again different theatres were sampled at various stages of the lists. HJH and RMMCH were sampled in the late morning to early afternoon of the second day, and at both hospitals sampling was done after the lists had started and at various stages of individual cases. All running theatres, including emergency theatres were sampled. This was to ensure that the routine syringe labelling of anaesthetists was not influenced by the study (the Hawthorne effect). Each theatre was only included once to ensure that no anaesthetists were included more than once.

The predetermined standard against which the syringe labelling was compared, was drawn up following an extensive literature review. The predetermined standard is reflected in the data collection sheet (Appendix 5).

The following data was collected on a data collection sheet:

- label present
- colour-coded label
- name of medication
- name of medication abbreviated
- dose/concentration of medication
- date medication prepared
- time medication prepared
- signature of person preparing medication
- signature of person checking medication.

3.6.7 Data Analysis

Data was entered on a Microsoft Excel® spread sheet and analysed. Frequencies and percentages were reported.

3.7 Validity and reliability of the study

Validity of a study is an indication of how accurately the measurement represents the true value. It is a representation of the appropriateness of the study design and the means used to interpret the results. Reliability of a study represents consistency of the measure achieved.(53)

Validity and reliability of this study were ensured by:

- using a suitable study design
- having a representative study sample
- collecting data on two consecutive days ensured that routine practice was not changed
- researcher being the sole data collector
- using a validated, predetermined standard against which to compare the current labelling practice.

3.8 Summary

This chapter discussed the research methodology used for this study. In the following chapter research results will be presented and discussed.

Chapter 4: Results and discussion

4.1 Introduction

In this chapter the results of the study according to the objectives as well as a discussion of the results are presented.

The objectives of this study were to:

- describe the current method of labelling syringes
- describe the information recorded on the syringes
- document the number of items written on each syringe label.

4.2 Sample realisation

The minimum number of syringes required for this audit was 108. A total of 279 syringes were included from theatres at CHBAH, CMJAH, HJH and RMMCH on 27and 28 January 2015. Of the 279 syringes 122 (44%) were from CHBAH, 84 (30%) from CMJAH, 56 (20%) from HJH and 17 (6%) from RMMCH. The actual number of syringes from each hospital was determined by the number of functional theatres in each hospital on the day of data collection. The number and percentage of syringes collected at each hospital are shown in Figure 4.1

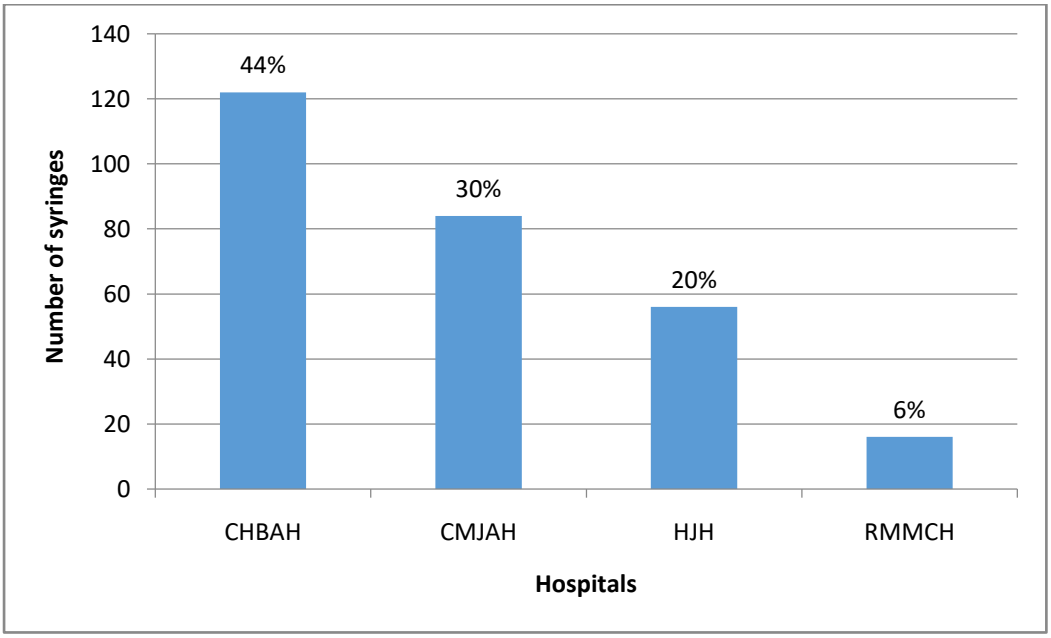


Figure 4.1 Number of syringes audited per hospital

4.3 Results

The findings are described using descriptive statistics. The percentage values are rounded off to whole numbers.

4.3.1 Objective: describe the current method of labelling syringes

Of the 279 syringes included in the audit, 242 (87%) had a label, either stuck on or written directly onto the syringe with a permanent marker pen. Of the labelled syringes six (2%) were colour coded; these were either in a form of different coloured permanent marker pens or coloured labels. Thirty seven (13%) syringes containing solutions had no label at all.

4.3.2 Objective: describe the information recorded on the syringes

The audit assessed whether the labels included any of the parameters from the predetermined standard as described under data collection in Chapter 3. Of the labelled syringes, 242 (100%) had the medicine name and of these 92 (38%) had the name of the medication abbreviated, 209 (86%) had the drug dose or concentration, 6(2%) had time, 15(6%) had date, 5(2%) had both time and date, 6(2%) had the signature of the person who prepared the drug and1 (0.4%) of the 242 syringes had the signature of the person that checked the solution. This information is shown in Figure 4.2

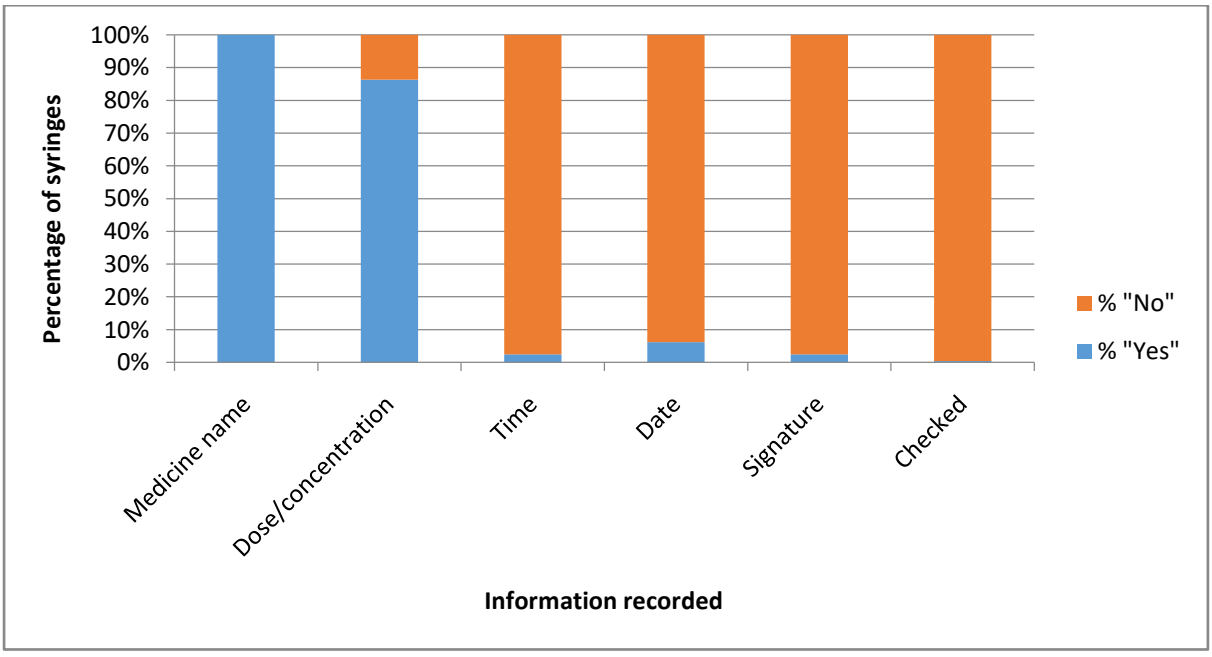
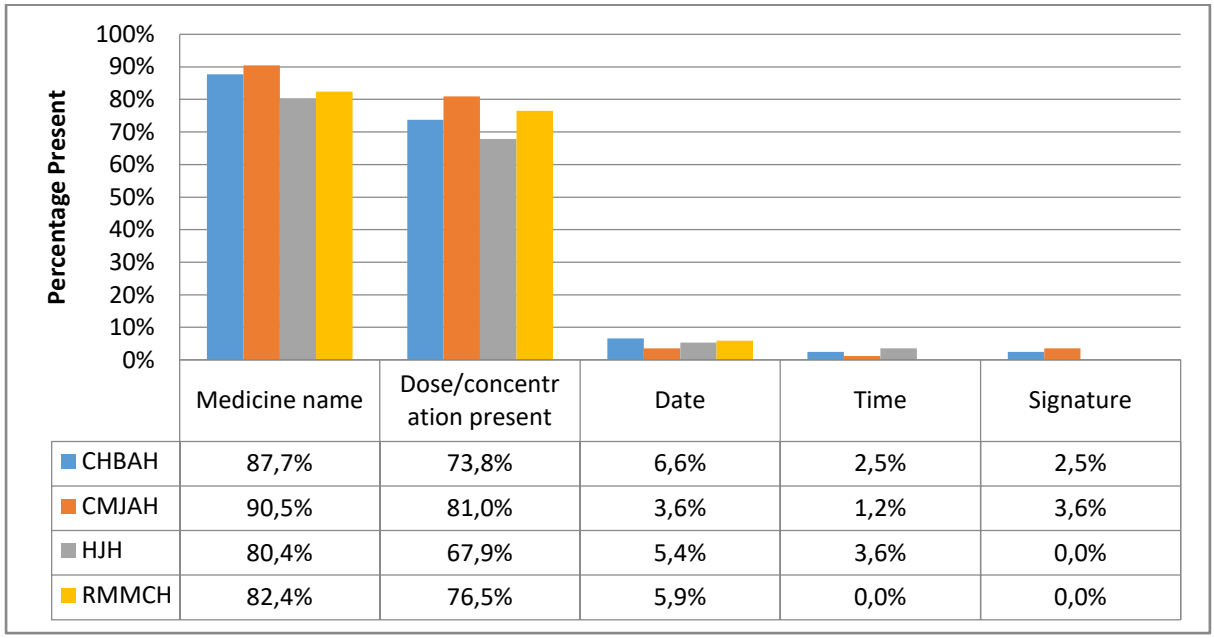


Figure 4.2 Labelling information recorded on syringes

The breakdown of labelling information per hospital is shown in Figure 4.3. Only one syringe had the signature of a person who checked it, therefore this variable is omitted from the graph.



	Medicine name	Dose/concentration present	Date	Time	Signature
CHBAH	87,7%	73,8%	6,6%	2,5%	2,5%
CMJAH	90,5%	81,0%	3,6%	1,2%	3,6%
HJH	80,4%	67,9%	5,4%	3,6%	0,0%
RMMCH	82,4%	76,5%	5,9%	0,0%	0,0%

Figure 4.3 Break down of labelling information per hospital

4.3.3 Objective: document the number of items written on each syringe label

Six items were identified from the literature as essential when labelling syringes. The number of items written on the syringes audited for this study is shown in Table 4.1. None of the syringes complied fully with the predetermined standard.

Table 4.1 Number of items on the syringe label

Number of Items on syringes	Number of syringes	Percentage
0	37	13%
1	33	12%
2	193	69%
3	6	2%
4	8	3%
5	2	1%
6	0	0%

4.4 Discussion

Syringe labelling, although not the only factor, has been identified as one of the correctable system factors that can reliably reduce drug errors in the operating theatre(3, 11, 16, 18, 20, 22, 23).

Out of 279 syringes audited from theatres at the four academic hospitals affiliated to Wits, 242 (87%) syringes were labelled. These finding were better than those reported by Brown-Brumfield et al (33) in 2010 when answering the objective " would staff members dispose and label medication according to protocol?". In their study only 70% of syringes had some form of label and a total of 30% were not labelled at all. (33) This is particularly disturbing as the literature suggests that routinely labelling syringes is an internationally accepted important safety measure in all medical specialities. Not adhering to routine syringe labelling will be deemed a violation that may result in litigation and consequently severe penalties where negligence is clearly proven. (3, 16)The findings in our study are also better than Jenning and Foster (54) reported as only 59% of the syringes in their study were labelled. although the numbers in our study are larger than those in similar studies, lack of labels on syringes and other medication containers is a very serious omission associated with significant morbidity and at times mortality(2, 13, 17, 40, 48). According to Merry et al (16), unlabelled syringes containing any solutions intended for a patient should be considered unsafe and should never be used. They referred to a case where the anaesthetist administered dopamine to a patient instead of magnesium sulphate. The authors reported this error as a result of similarity in the two ampoules. In this case, it is suggested that syringe labelling would have provided an additional safety step where the name and dose of the drug would have been double-checked against the ampoule.

The labels used on syringes varied in our study. Some syringes had labelling with a permanent marker pen, whereas others had a blank label which was written on with a pen and some had ampoule stickers pasted on the syringe. In our study only six (2%) of syringe labels had some sort of colour coding. The variation of labelling formats shows a lack of standardisation with syringe labelling methods by anaesthetists in the study hospitals. Brown-Brumfield et al (33) highlight the need for standardisation of labels attached to medication or fluid intended for injection into a

patient. They discussed a case where a patient died after glutaryldehyde was injected into the patient's spinal space after the container was mistaken for that containing spinal fluid. This mistake was made even although the anaesthetist had labelled the container with spinal fluid “SF” and no label was on the other container. (33) Colour coding has not been fully identified as an important tool in reducing the number of medication errors, however it has been suggested that it may change the nature of medication errors. It has been suggested that colour coding may help reduce drug errors between different classes of drugs and could reduce the severity of resulting morbidity from the errors. (14, 16, 22, 36, 55) Colour coding has also been identified to be especially helpful in cases where syringes are viewed from an angle or in stressful situations such as emergency surgery in unstable patients (56). In South Africa colour coded syringe labels are available. The study by Labuschage et al (8) revealed that only 23% of anaesthetists in the public hospitals in the Free State were aware of this fact.

Standardisation of syringe labelling is an initiative that can be implemented in theatres as international and local standards for syringe labels are already in place and these only need to be adopted to come into effect. Some examples of these labelling standards include the international standard, ISO 26825, (24) which the SABS has adopted into their standards and the Australian and New Zealand standard adopted from the ISO (AS/NZS 4375:1996). (13, 16) Christie et al (36) state that standardisation is an essential component in the design of a safe system and that standard colour coded syringe labels are an example of a system based approach to syringe labelling.

Information audited in our study included: presence of a label, whether the label was colour coded or not, name of medication, dose and/or concentration of the drug, date and time, signature of the person who prepared the drug and the signature of the person that checked the drug. These parameters were chosen after an extensive literature review and by reviewing different standards for labelling worldwide. The ISO 26825 (24) labelling standard highlights colour coding, name of drug and dosage as its main content. The Australian and New Zealand Colleges of Anaesthetists guidelines published in 2009 required that patient name, hospital identification, active ingredients, amounts of medication, volume of fluid, concentration, diluents, date and time prepared, signature of the person that

prepared the drug and the person that checked the drug be on the label. (16) The ASTM D4774-11el requires that the label be colour coded and information to be recorded include: name of drug, dose, date, time, and initials of the person that drew up the drug (39).

In our study 100% of the labelled syringes contained the name of the solution and 86% of these had the concentration or dose of drug on the label. Merry et al (16) state that these are the two most essential items on the syringe label. Out of the 242 labelled syringes only one (0.4%) had the signature of the person who checked the medication, but whether this can be extrapolated into concluding that only one syringe was checked by a second person is not certain. Jensen et al (12) emphasise the importance of having a second person double-check medication labels before drawing up the drug or before administering the drug to the patient. In their research they found that having a second person check the drug label would have prevented 58% of errors.

A graphical breakdown of results according to hospitals, although not statistically analysed, did not show much variation in results between the different hospitals. Hospitals sampled on second day did not have better labelling practices than those on the first day. It was also noted that the hospitals sampled later in the day did not necessarily perform worse than those sampled earlier in the day, suggesting that the labelling practices were not influenced by fatigue. The syringes are often prepared by registrars who rotate amongst the hospitals and their practice is not expected to change depending on their location.

Another objective of our study was to describe the number of items written on syringes compared to those on the predetermined standard. This standard was drawn up by the researcher after extensive literature review and from existing labelling standards. There were a total of six items audited namely: name of the drug, dose or concentration of the drug, date and time, signature of the person who prepared the drug and signature of person who checked the drug. None of the syringes had all six. The majority of the syringes, 193 (69%) had two items, but not necessarily the same two items were recorded on these syringes. Radharishna (55), reports on the lack of standardisation both between and within the 35 hospitals he surveyed on type of syringe labelling techniques and reports that the great variation

and lack of standard protocols was a serious threat to patient safety and called it “ an accident waiting to happen” . This variation, although not quantified in our study, was also observed, as syringe labelling techniques included labelling with a permanent marker pen, a blank label which was written on with a pen and ampoule stickers pasted on the syringe. Thirteen percent of syringes had no label at all.

The Helsinki Declaration on Patient Safety in Anaesthesiology (7) states that one of the protocols that should be drawn up in any anaesthetic department is one for syringe labelling. They emphasise that this fact is as important as factors such as difficult intubation and massive haemorrhage, and that it is a significant cause of morbidity and mortality.

Although medication error is regarded as mostly a system error, the “person” actually still prevails and the law has the tendency to hold the last person holding the “smoking gun” accountable. Although this was a small study, it is a significant one as it highlights one system error that will see the practitioner being held liable for the outcome.(25)

4.5 Summary

In this chapter, results of the study were presented and discussed. The next chapter contains a study summary, the limitations, recommendations and a conclusion of the study.

Chapter 5: Summary, limitations, recommendations and conclusion

5.1 Introduction

In this final chapter a summary of the study, the limitations of the study, recommendations and the conclusion of the study are presented.

5.2 Study summary

5.2.1 The aim of the study

The aim of this study was to audit the syringe labelling practices of anaesthetists in four academic hospitals affiliated to Wits.

5.2.2 The objectives of the study

The objectives of this study were to:

- describe the current method of labelling syringes
- describe the information recorded on the syringes
- document the number of items written on each syringe label.

5.2.3 Summary of the study methodology

The research design of this study was prospective, contextual and descriptive. It described the syringe labelling practices of anaesthetists in the four academic hospitals affiliated to Wits, namely CHBAH, CMJAH, HJH and RMMCH. A consecutive, convenience sampling method was used to collect data.

The study population was all the syringes prepared for anaesthesia during the course of the data collection day at the study hospitals. Included in the study were labelled and unlabelled syringes containing medication found on anaesthetic work surfaces. Empty unlabelled syringes found on anaesthetic work surfaces and any syringes labelled “flush” were excluded from the study.

Data was collected by the researcher on two consecutive days. The syringes in each theatre were only audited once to ensure that no anaesthetist was included more than once. The syringes were audited against predetermined standards.

5.2.4 Summary of results

A total of 279 syringes were included in the study. Of the 279 syringes 242 (87%) were labelled. Six (2%) of the 242 labels were colour coded. A total of 37 (13%) syringes had no labelling at all.

All labelled syringes had the name of the medication present, either in full or abbreviated. Two hundred and nine(86%) of the labelled syringes had the dose and/or concentration of the medication. Fifteen (6%) of syringes had date, 6(2%) had time and 5(2%) had both time and date written on them. A total of six(2%) syringes had the signature of the person who prepared the drug and only one (0.4%) of the 242 labelled syringed had the signature of the person that checked the drug. The majority 193 (69%) of syringes had only two out of the six required labelling items.

5.3 Limitations of the study

The limitations of the study included the following:

- The study is contextual and the results of the study may not be generalisable to other hospitals.
- It was also a “snapshot” of practice during weekday normal working hours and does not reflect practice over 24 hours and especially during calls.
- As data collection was done over two days, there was a possibility that anaesthetists in the hospitals sampled on the second day may have heard of the study and had an opportunity to change their practice. This is known as the Hawthorne effect. In our study there did not appear to be any change of practice on the second day.

5.4 Recommendations for the study

5.4.1 Recommendation for clinical practice

Recommendations for clinical practice.

- Feedback of the results of the study be communicated to the anaesthesiology department and educational lectures be conducted.
- Syringe labelling standing operating procedure should be developed.

- Motivate for the use of pre printed colour coded syringe labels in the study hospitals.

5.4.2 Recommendations for research

Recommendation for research.

- The study should be repeated after the feedback and educational lecture as well as the implementation of the standard operating procedure.
- A study to understand the possible systems problems that contribute to incorrect labelling practices.
- A study comparing labelling practices in emergency drugs vs. non-emergency drugs and also looking at labelling practices in emergency cases vs. elective cases.
- As the literature has shown a correlation between anaesthetist level of experience and labelling practice, a study could be done to address this issue.

5.5 Conclusion

This study revealed that syringe labelling practices of anaesthetists in the four academic hospitals associated with Wits did not meet the recommended standards. It is recommended that a standard operating procedure for syringe labelling be introduced as studies have shown that syringe labelling is an easy way of preventing and/or reducing medication error.

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Appendix 1: Approval from Postgraduate Committee

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

20 May 2014
Person No: 855972
PAG

Dr PM Tshabalala
P.O. Box 3077
Witkoppen
2068
South Africa

Dear Dr Tshabalala

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *An audit of syringe labelling practices of anaesthetists at four academic hospitals* 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

Appendix 2: Ethical waiver

Human Research Ethics Committee (Medical)

Research Office Secretariat: Senate House Room SH 10005, 10th floor. Tel +27 (0)11-717-1252
Medical School Secretariat: Medical School Room 10M07, 10th Floor. Tel +27 (0)11-717-2700
Private Bag 3, Wits 2050, www.wits.ac.za. Fax +27 (0)11-717-1265

Ref: W-CJ-140303-3 03/03/2014

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: Dr M P Tshabalala (student no. 855972).

Project title: An audit of syringe labelling practices of anaesthetists at four academic hospitals affiliated to the University of the reporters ran

Reason: This non-human study will inspect labels on syringes containing medication on the anaesthetic surfaces in operating theatres for comparison with predetermined standards. A list of the four hospitals and written permission to do the study from the hospitals' CEOs must be lodged with the HREC(Medical) Secretariat for the Committee's records.

UNIVERSITY OF THE WITWATERSRAND
PROF PE CLEATON-JONES
HREC (MEDICAL)
2014 -03- 03
JOHANNESBURG

Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee (Medical)

Copy - HREC(Medical) Secretariat: Anisa Keshav, Zanele Ndlovu.

Appendix 3: Approval from Medical Advisory Committee CHBAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 21 November 2014

TITLE OF PROJECT: An audit of syringe labelling practices of anaesthetists at four academic hospitals

UNIVERSITY: Witwatersrand

Principal Investigator: MP Tshabalala

Department: Anaesthesiology

Supervisor (If relevant): H Perry

Permission Head Department (where research conducted): Yes

Date of start of proposed study: November 2014
Date of completion of data collection: December 2015

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 21 November 2014

.....
Approved/Not Approved
Hospital Management
Date: 05/12/14

Appendix 4: Approval from CEOs

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

PERMISSION FOR RESEARCH

DATE: 24/11/2014

NAME OF RESEARCH WORKER: Dr Mologadi Tshabalala

CONTACT DETAILS OF RESEARCH (INCLUDE ALTERNATE RESEARCHER):

mologaditshabalala@yahoo.com

0721207584

TITLE OF RESEARCH PROJECT: Audit of Syringe labelling practi
of anaesthetists at four academic hospitals

OBJECTIVES OF STUDY (Briefly or include a protocol): To audit and
assess information on syringes and labels
by anaesthetists at four academic hospitals

METHODOLOGY (Briefly or include a protocol): Carried out as
an audit carried out prospectively

THE APPROVAL BY THE SUPERINTENDENT IS STRICTLY ON THE BASIS OF THE FOLLOWING:

(i) CONFIDENTIALITY OF PATIENTS MAINTAINED: Yes

(ii) NO COSTS TO THE HOSPITAL: Yes

(iii) APPROVAL OF HEAD OF DEPARTMENT: Yes

(iv) APPROVAL BY ETHICS COMMITTEE OF UNIVERSITY: Yes

SUPERINTENDENT PERMISSION

Signature: [signature] Date: 26/11/14

SUBJECT TO ANY RESTRICTIONS: NO

Helen Joseph Hospital
Perth Road
Tel: 011 489 1011

Private Bag X47
Auckland Park
2006

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries: Mrs. L. Mapaisa
Office of the Director: Clinical Services
Tel: (011)488-3365
Fax: (011)488-3753
24 November 2014

Dr. Mologadi Tshabalala
Department of Anaesthesiology
University of the Witwatersrand

Dear Dr. Tshabalala

RE: An audit of syringe labeling practices of anaesthetists at four academic hospitals

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / ~~not supported~~

Dr. M.I. Mofokeng
Director: Clinical Services
DATE: 27/11/2014

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 28/11/2014

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL
Enquiries: Mrs. S. Jordaan
Tel: (011) 470 9030/4
Fax: (011) 477 4117
Email: sjordaan@icon.co.za

University of Witwatersrand
Department of Anaesthesiology
Faculty of Health Science
JOHANNESBURG
2001

Re:"An Audit of Syringe –labelling Practices of Anaesthetists at four Academic Hospitals"

Dear Dr. Mologadi P. Tshabalala

Permission is granted for you to conduct the research as indicated in your request as per the title above.

The terms under which this permission is granted is contained in the Researcher Declaration form that you signed. Failure to comply with these conditions will result in the withdrawal of such permission.

Note that it is imperative that you notify the hospital of the actual start and end dates of your study by notifying the CEO's secretary preferably by email or fax.

Should the study commence more than 12 months from receipt of this letter then the Researcher Declaration form needs to be re-signed prior to commencement of the research. Your are strongly advised to keep a signed copy of the declaration form so as to ensure that the terms of this agreement are complied with at all times.

Yours sincerely,

Jordaan

CHIEF EXECUTIVE OFFICER
SJ/cj. 2015-01-31

ADDRESS: cnr. FUEL & OUDSTHOORN STREET CORONATIONVILLE 2093 / PRIVATE BAG X20 NEWCLARE 2112 JHB

Appendix 5: Data collection sheet

Study Number		
Present	**Yes**	**No**
Label present		
Colour-coded label		
Name of medication		
Name of medication abbreviated		
Dose/concentration of medication		
Date medication prepared		
Time medication prepared		
Signature of person preparing medication		
Signature of person checking medication.		