Anaesthetists' Knowledge of South African Law Pertaining to Informed Consent

Anisah Ismail Mamoojee

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, Anisah Ismail Mamoojee, declare that this research report is my own work. It is submitted for the admission to the degree of Master of Medicine in Anaesthesiology by the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

AMamoojee (Signature of candidate)

26th day of March 2018

ABSTRACT

Lack of knowledge of the law places a medical practitioner at risk of litigation. Research has shown that medical personnel's knowledge of law and their consent taking practices are inadequate.

This prospective, contextual, descriptive study aimed to determine the University of the Witwatersrand (WITS) anaesthetists' knowledge of South African Law pertaining to informed consent.

167 willing anaesthetists answered 10 multiple choice questions (n=167) and the mean score achieved was 60.09% (SD 12.61%).

The question testing The Mental Health Care Act No. 17 of 2002 achieved the highest mean score of 88.92% (SD=22.22%) while the questions testing The Children's Act No. 38 of 2005 achieved the lowest mean score of 51.82% (SD=17.84%).

Knowledge of The Choice of Termination of Pregnancy Act No. 92 of 1996 worsened with increasing years after graduation from medical school (p=0.0013) while knowledge of The Children's Act No. 38 of 2005 correlated positively with professional designation (p=0.0004), increased years of anaesthetic experience (p=0.0180) and attendance at formal postgraduate teaching on informed consent (p=0.0080).

Improved knowledge of The National Health Act No. 61 of 2003 correlated with higher professional designation (p=0.0120). Knowledge of The Mental Health Care Act No. 17 of 2002 (p=0.0276) and of The Sterilisation Act No. 44 of 1998 (p=0108) worsened with increasing years after graduation from medical school.

Professional designation correlated with overall mean questionnaire score (p=0.0163), with those of higher professional designation performing better.

This study revealed that formal postgraduate teaching on informed consent correlated with a higher mean questionnaire score and, by implication, improved knowledge. The mean score in the group of participants that had not attended formal postgraduate teaching on informed consent was lower than the group that had attended.

Educational interventions to improve knowledge should be instituted to provide an optimal service to the patient and to reduce the burden of medicolegal claims.

ACKNOWLEDGMENTS

I would like to thank the following people:

To my supervisor, Ahmad Alli, for the idea for my research topic, for his constant input, time, guidance and indispensable knowledge.

To professors Christina Lundgren, Eddie Oosthuizen, Eva Frohlich and Dr Thomas Kleyenstuber for their supportive roles in the data collection process at academic meetings and in helping drive research on the WITS academic circuit.

To Professor Christina Lundgren and to Professor Fathima Paruk for validating my questionnaire.

To Helen Perrie for her insight into research and always being supportive and willing to help.

To all my colleagues in the department who partook in the study, for their co-operation and honesty.

To my dear father and mother, Ismail and Razia, for their constant love, encouragement and unwavering support.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABBREVIATIONS

WITS: University of the Witwatersrand

MPS: Medical Protection Society

HPCSA: Health Professions Council of South Africa

CHBAH: Chris Hani Baragwanath Academic Hospital

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

HJH: Helen Joseph Hospital

RMMCH: Rahima Moosa Mother and Child Hospital

WDGMC: WITS Donald Gordon Medical Centre

WHO: World Health Organisation

HIV: Human Immunodeficiency Virus

SASA: South African Society of Anaesthesiologists

CHAPTER 1: OVERVIEW OF STUDY

1.1 Introduction

In this chapter, an overview of the study is given and will include the background to the study, the problem statement, aim and objectives, demarcation of the study field, ethical considerations, research methodology, significance of study, research report outline and a summary.

1.2 Background

Anecdotally there is a perception that regulations or laws pertaining to informed consent for surgical procedures can be applied differently, if at all, to patients receiving anaesthesia or anaesthesia related procedures. However, the law specifies consent for procedures as a whole, and does not regard anaesthesia as a separate entity. Therefore, anaesthetists are expected to be familiar with laws governing informed consent for any procedure, with the view that the act of administering an anaesthetic is considered as a procedure.

Informed consent must be taken before any medical or surgical procedure is carried out. The National Health Act of South Africa aims to “regulate and provide uniformity in respect of health services across the nation.” It states that a “health service may not be provided to a user without the user’s informed consent” (1). For this consent to be valid, there are three main pillars that must be fulfilled: capacity, information and voluntariness (2).

Ethics and law are complementary processes used to guide the consent-taking process by health professionals.

Although ethical principles must be adhered to, it is also essential that doctors have adequate knowledge of the laws regarding informed consent in the country in which they practice medicine. Being “familiar with law” and “formal procedural regulations” should ensure that the doctor is carrying out his/her job correctly and

providing a quality service to the patient, but also avoids unnecessary litigation which may result from inappropriate or incorrect consent-taking practices (3).

Unfortunately, knowledge of these laws is often taken for granted and particularly at an undergraduate level, teaching of these laws may be inadequate. A study by Zajdel et al (3) on knowledge of medical law amongst allergists and pulmonologists in Poland discussed that the vast majority of medical staff had not had formal legal teaching prior to completion of their medical degrees. The same study noted that doctors depend heavily on external standards and do not appreciate that only the law is binding.

In South Africa, clearly stipulated laws are laid out to guide the consent-taking process. Anecdotally, it is known that the process of acquiring informed consent, including understanding of the relevant laws, is taught in undergraduate medical programs in South Africa. However, the adequacy of knowledge that anaesthetists possess with regards to these processes and laws is not known. Naidu and Gopalan (4) found, in KwaZulu Natal, that "the current process of obtaining informed consent for anaesthesia has been deemed…to be substandard and legally indefensible." This study raises the question of whether anaesthetists have adequate knowledge regarding informed consent.

In the same study by Naidu and Gopalan (4), two thirds of doctors claimed that the risk of facing the law would alter their clinical practice. The Medical Protection Society (MPS) in South Africa has stated that "over the past two years alone, the value of reported claims has more than doubled: an increase of 132%" and that the bulk of cost to MPS is incurred via clinical negligence claims (5). Improper consent taking practices such as inefficient communication and poor disclosure of risks undoubtedly adds to a large proportion of these claims. Dr Graham Howarth, the MPS Head of Medical Services in Africa reports that "a developing country like South Africa was always likely to see patient awareness of their constitutional rights grow, making them more likely to make a medical negligence claim" (5).

Adequate knowledge of the processes and laws regarding informed consent could help alleviate the burden of medicolegal litigation.

1.3 Problem statement

Doctors specialising in anaesthesia are expected to have thorough knowledge of South African Law pertaining to informed consent and to apply this knowledge in their clinical practice. The knowledge of anaesthetists working in the WITS Department of Anaesthesiology regarding informed consent practices, related to surgical procedures, was not known.

1.4 Aim and objectives

1.4.1 Aim

The aim of this study was to determine and describe the knowledge of South African Law pertaining to informed consent of anaesthetists who work in the WITS Department of Anaesthesiology.

1.4.2 Objectives

The primary objective of this study was to:

- describe the knowledge anaesthetists had regarding South African Law pertaining to informed consent in ten different clinical scenarios

The secondary objectives of this study were to:

- determine if knowledge of South African Law pertaining to informed consent was associated with years of anaesthetic experience.
- determine if knowledge of South African Law pertaining to informed consent was associated with number of years after graduation from medical school.

- compare knowledge of South African Law pertaining to informed consent between anaesthetists who have had formal postgraduate teaching on informed consent and those who have not had such teaching.

1.5 Research assumptions

The following definitions were used in the study:

Anaesthetist: A doctor (medical officer, registrar, and consultant) who works in the Department of Anaesthesiology affiliated to WITS.

Medical Officer: A qualified doctor practicing anaesthesia under specialist supervision. A medical officer who has more than 10 years of experience in anaesthesia is a career medical officer and is equivalent to a consultant.

Registrar: A doctor who is registered with the Health Professions Council of South Africa (HPCSA) as a trainee in the field of Anaesthesia.

Consultant: A doctor who has completed all requirements and successfully passed the required anaesthetic college examinations. He/she is a specialist in the field.

Knowledge: The knowledge that a doctor possesses regarding South African Law pertaining to informed consent.

1.6 Demarcation of study field

This study was conducted in the WITS department of Anaesthesiology. The Department of Anaesthesiology is affiliated to the following teaching hospitals: Chris Hani Baragwanath Academic Hospital (CHBAH), Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Helen Joseph Hospital (HJH), Rahima Moosa Mother and Child Hospital (RMMCH) and The WITS Donald Gordon Medical Centre (WDGMC).

The department consists of approximately 218 anaesthetists (85 consultants, including 12 career medical officers, 112 registrars and 21 medical officers).

1.7 Ethical considerations

Permission to conduct this study was obtained from relevant authorities.

This study was knowledge–based using an anonymous self-administered questionnaire (Appendix 4). Participation was voluntary and consent was implied on completion of the questionnaire. Care was taken to maintain the anaesthetists' anonymity and confidentiality and no identifying information was obtained from the participants.

The study was conducted in accordance with the Declaration of Helsinki (6) and the South African Good Clinical Practice Guidelines (7) .

1.8 Research methodology

1.8.1 Research design

This study was prospective, contextual and descriptive in nature.

1.8.2 Study population

This study population consisted of anaesthetists working in the WITS Department of Anaesthesiology.

1.8.3 Study sample

The researcher targeted as many of the approximately 153 available anaesthetists as possible. It was estimated that responses would be gained from at least 60% of the available anaesthetists.

1.8.4 Sampling method

This study made use of the convenience sampling technique.

1.8.5 Inclusion and exclusion criteria

All anaesthetists who attended the department's academic meetings were included.

Blank and illegible questionnaires were excluded from statistical analysis, but were still used to calculate the response rate. Interns were also excluded. Any questionnaires that had missing demographic data were excluded.

1.8.5 Data collection

1.8.6.1 Development of questionnaire

As no published questionnaires regarding knowledge of South African Law pertaining to informed consent were identified, a questionnaire was developed by the researcher and supervisor, based on the available literature. Two independent experts in the field of bioethics and the laws were consulted to achieve face and content validity. Following consultation, corrections were made.

The self-administered questionnaire (Appendix 4) consisted of two sections.

Section 1 consisted of demographic data.

Section 2 consisted of questions regarding the knowledge that anaesthetists had of South African Law and informed consent in ten scenarios.

The questionnaire was composed of multiple choice questions each with a single correct answer. The questionnaire was scored out of a total of 23, with one point allocated for each correct answer. Negative marking was not applied. Any questions that were not answered were scored as zero.

1.8.6.2 Data collection

Data was collected between September and November 2016.

Data was collected at the departmental academic meetings.

All questionnaires were numbered pre- distribution, to keep track of those completed, to prevent reproduction of results and allowed for calculation of a response rate.

Following an introduction to the study aim and objectives, an information letter (Appendix 3) and a questionnaire (Appendix 4) was distributed to each anaesthetist that wished to participate. After completion of the questionnaire, participants placed it into a collection box. Anonymity and confidentiality of the participants in the study was ensured as no identifying data was collected.

1.8.7 Data analysis

Data was captured onto a spreadsheet using Microsoft Excel. SAS™(8) was used to analyse data, using descriptive and inferential statistics.

Categorical data was described using frequencies and percentages. The knowledge of South African Law pertaining to informed consent was described using means and standard deviations or medians and ranges depending on the data distribution.

To determine if there was an association between knowledge of the law and years of experience, or knowledge of the law and years since graduation from medical school, a Spearman Rank Correlation Test was performed.

Comparison of knowledge between anaesthetists with and without formal postgraduate teaching on informed consent was performed using a Wilcoxon Mann Whitney U test.

In this study, a 0.05 level of significance and 95% confidence interval was used.

1.9 Significance of the study

South African Law governs the ethical practice of medicine and provides rules which must be followed when acquiring informed consent from patients. The inappropriate use of, or disregard for the law may result in serious legal ramifications for the clinician.

It was important to determine the current knowledge of anaesthetists working in the department of Anaesthesiology at WITS, as the results would allow for the creation of teaching programs designed to improve or refresh the knowledge of anaesthetists within the department.

1.10 Validity and reliability of the study

Measures were in place to ensure the validity and reliability of this study.

1.11 Research report outline

The report will be discussed as follows:
Chapter 1: Overview of study
Chapter 2: Literature review
Chapter 3: Methodology
Chapter 4: Results and discussion
Chapter 5: Summary, limitations, recommendations and conclusion

1.12 Summary

This chapter gave an overview of the study background, the problem statement, aim and objectives, demarcation of field of study, research methodology, significance of the study, and a research report outline.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

In this chapter, the literature regarding knowledge of the law pertaining to informed consent will be discussed. The literature review will detail surgical informed consent, and set the context of ethical and legal considerations behind informed consent. The Bill of Rights and the National Health Bill are discussed, before detailed analysis of the legal acts important in the clinical setting are elaborated upon. These include the laws regarding children, HIV testing, mental health care users, Jehovah's witnesses, termination of pregnancy and sterilisation. The concept of the validity of consent is delved into, and following this, the literature review expands to discuss the international milieu before concluding with a discussion of consent in the South African context.

Informed consent is an integral part of the physician's duty to the patient. It is an issue of professional ethics that has its foundation set on legal, moral and cultural principles (9, 10). The process begins with the provision of information to the patient, and is concluded by the completion of paperwork as evidence of a "mutual understanding" (10). This chapter will present the ethical and legal framework that underlies the provision of consent in South Africa.

2.2 Surgical informed consent

Surgical informed consent consists of three basic elements as described by the Nuremberg code, the Declaration of Helsinki, the United States National Institute of Health and the World Health Organisation (WHO) (11). These three stages are: an assessment of preconditions which entails assessing the patient's competence to decide; the provision of information which includes educating the patient, recommending a care plan and making sure that the patient has comprehended the information; and the stage of consent which includes producing a formal record of the patient giving authorisation to having the procedure.

The whole process of taking consent for a procedure should be one based on the creation of a rapport between the doctor and the patient. It is a process that should culminate in a properly informed patient, who is fully knowledgeable of all the risks, benefits and alternative therapy, who then autonomously gives his/her agreement to have a procedure done. Not only does a properly executed informed consent process result in a satisfied and confident patient, but it should also reduce the burden of medicolegal problems that may arise from an incomplete or poorly run process (11).

2.3 Ethical principles

The MPS Guide to Ethics defines ethics as being "the voluntary framework of guiding principles which brings order and purpose into what would otherwise be a void between laws, on the one hand, and a free-for-all on the other" (12). Medical ethics then, is seen as the "disciplined study of morality" (9). It has a deeply rooted history, often seen as having its birthplace lie in the creation of the Hippocratic Oath between 400-300 BC (9). The domain of ethics as we know it today arose primarily after the Second World War during which time a need arose for guidance regarding specifically medical research and therapy (9). By 1993 the study of ethics had formed an integral part of undergraduate medical curricula (9).

Doctors take The Hippocratic oath at the graduation ceremony from their undergraduate medical degrees. A notable passage in the original oath, is "I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice. I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect…Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice" (13).

The four ethical principles central to medicine are beneficence, non- maleficence, autonomy and social justice.

Beneficence is defined as "compassion; taking positive action to help others; desire to do good; core principle of our patient advocacy" (14). The principle of beneficence is based on acting in the patient's best interest. It is often seen as the

“duty of care” (15), in other words having the welfare of the patient in mind at all times when carrying out one’s practice.

On the other end of the spectrum is the principle of non-maleficence, defined as the avoidance of harm (14). This is equally important as every intervention or procedure carries inherent risks and there should always be a balance of risk versus benefit. When this balance tips to the side where the risk outweighs the benefit then carrying out the intervention or procedure has the propensity to harm the patient. In this case, the procedure should not be done as it would not be beneficent (14).

Autonomy is the third important ethical principle, and is key to informed consent. Autonomy is the “agreement to respect another’s right to self-determine a course of action; support of independent decision making” (14). In a paradigm shift away from the paternalistic approach to medicine where the doctor dictated and the patient obliged, we are seeing a refocus on the patient’s independence and their right to decide what medical care they would like to have. The patient is considered to have freedom of choice and self -determination (16). Respect for the patient’s autonomy is integral to modern medical practice. Autonomy implies that the patient has adequate insight and purposefully allows something to be done, without being under the control of another (15).

Social justice refers to “an equal and fair distribution of resources” (17) where “all citizens have an equal right to the goods distributed, regardless of what they have contributed or who they are” (17). Social justice is the concept of doing the best for the most people, with aim of favouring social equity.

The WHO recommends that ethics should be a mandatory part of medical education, and integrated into postgraduate training of doctors as well (15).

2.4 Legal principles

The Law is defined as the body of binding customs and practices of a community, with prescribed codes of conduct. These rules are enforced by the authorities and a violation may result in action taken against the violator (18).

The purpose of the law is regulation of the society it applies to and the provision of constructs by which people must abide.

Per a Polish study by Zajdel et al (3), sound knowledge of the law is integral to the proper performance of medical work (3). It is critically important that doctors acquire sound legal knowledge so that they may use this knowledge as a base for their everyday practice. Not only is this vital so that the doctor may be beneficent, but more so that they do not cause any harm to their patient. A corollary of this is to ensure that the doctor does not face legal action should he not follow the law.

Zajdel et al (3) also noted that most medical staff lacked formal legal training prior to completing their medical studies and that familiarity with the law and formal procedures should enhance the quality of the service provided (3).

2.5 The South African Bill of Rights

Chapter Two of The South African Constitution is known as The Bill of Rights. This document encapsulates the rights of all people who live in South Africa. The Bill of Rights is applicable to all laws in this land and is binding. The importance of the Bill of Rights in the health sector is that it lays the foundation for the ethical and moral responsibility of health care workers to their patients. The moral responsibilities and ethical principles form the basis of the laws that were formulated to guide doctors in conducting their duties (19).

Table 2.1 contains tenets taken directly from The Bill of Rights that are applicable to the health care sector.

Table 2.1: Aspects of The Bill of Rights Affecting Health Care.

Direct extract from the Bill of Rights (19)

POINT	EXTRACT QUOTED DIRECTLY FROM THE BILL OF RIGHTS
Point 10	Everyone has the right to dignity and to have their dignity respected and protected
Point 11	Everyone has the right to life
Point 12.2	Everyone has the right to bodily and psychological integrity which includes the right – (a) to make decisions concerning reproduction; (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent.
Point 27.1	Everyone has the right to have access to health care services, including reproductive health care
Point 28.1	Every child has the right to basic health care services
Point 28.2	A child's best interests are of paramount importance in every matter concerning the child.

2.6 The National Health Bill

The National Health Bill is the framework for the South African healthcare system, within the confines of the Constitution and laws of the country (20).

Chapter Two of this bill is titled "Rights and Duties of Users and Health Care Providers" (20). The National Health Bill is vitally important specifically to the acquisition of informed consent as it provides very specific guidelines for complex situations such as where the health user themselves cannot provide consent.

According to The Bill, informed consent is "the provision of a specified health service given by a person with legal capacity to do so and who has been informed as per section 6" (20).

Table 2.2 below contains sections taken directly from The National Health Bill that are applicable to informed consent.

Table 2.2 : Sections of The National Health Bill Pertinent to Informed Consent (20)

SECTION	CONTENT QUOTED DIRECTLY FROM THE NATIONAL HEALTH BILL
6: User to have full knowledge	Every health care provider must inform a user of- (a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user; (b) the range of diagnostic procedures and treatment options generally available to the user; (c) the benefits, risks, costs and consequences generally associated with each option; and (d) the user's right to refuse health services.
7. Consent of user	Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless - (a) the user is unable to give informed consent and such consent is given by a person-

	(i) mandated by the user in writing to grant consent on his or her behalf; or (ii) authorized to give such consent in terms of any law or court order; (b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, an adult child or a brother or a sister of the user, in the specific order as listed; (c) the provision of a health service without informed consent is authorised in terms of any law or a court order; (d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or (e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.
8. Participation in decisions	(1) A user has the right to participate in any decision affecting his or her personal health and treatment.

	(2) (a) If the informed consent required by section 7 is given by a person other than the user, such a person must, if possible, consult the user before giving the required consent. (b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7. (3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless disclosure of such information would be contrary to the user's best interest.

2.7 The laws regarding children

Despite very clear laws regarding the provision of consent to treatment of minors, complex scenarios often arise because of the emotional element attached to treating children. There may also be discord between the child's choice and the decision of the guardian/parent or between guardians regarding consent. The consent taker must consider the child's age, their maturity, developmental level, the wishes of the guardians and the clinical circumstances. It is not surprising that some conflict may arise as a result. The principle of beneficence is the overriding

principle here – it is vital that whatever is done to the child is in their best interest (2). This is also delineated in The Children's Act No. 38 of 2005, which states that "in all matters concerning the care, protection and well-being of a child, the standard that the child's best interest is of paramount importance, must be applied" (21). The Child Care Act No. 74 of 1983 stated that the age for a child to consent to medical treatment was 14 years of age and that parental consent was required for surgical treatment of a minor. This act was repealed when The Children's Act No. 38 of 2005 came into effect.

2.7.1 Medical and surgical treatment

The age at which the patient (the child) may consent depends on what the consent is being taken for. According to Section 129 of The Children's Act of No. 38 of 2005 (21), in order for a child to consent to their own medical treatment, they must be over 12 years of age, with the capacity and maturity to fully comprehend the "benefits, risks, social and other implications" (21) of the treatment. When consent is being taken for a surgical procedure, the child should be assisted by parental or guardian- given assent (21).

If a child is under 12 years of age or lacks the maturity or capacity to fully understand the "benefits, risks, social and other implications" (21) of the proposed medical or surgical treatment, then the parent or guardian of the child may consent on their behalf. In addition, a caregiver may consent to medical treatment of the child who meets the criteria delineated here.

As per the act, there are five specific scenarios in which the Minister of Health is authorised to provide medical and surgical consent on behalf of the child (21).

These are as follows:

1. If the child refuses consent and this refusal is deemed unreasonable
2. If the parent/guardian of the child has passed away
3. If the parent/guardian of the child is untraceable
4. If the parent/guardian of the child lacks the capacity to give consent or assent
5. If the parent/guardian of the child refuses to give consent or assent

The hospital superintendent or the person in-charge when the superintendent is absent may consent to medical or surgical treatment of a child if it is needed to save the child's life or prevent permanent or substantial disability or injury that would result from not having the proposed medical or surgical treatment (21).

If any instance arises where the child with capacity or the legally authorised person to give consent on behalf of a child either refuses or cannot give consent then the High Court or Children's Court must be approached to request consent (21).

A parent, guardian or caregiver may not refuse to provide consent or assent based on religious or other beliefs unless they can demonstrate a medically or surgically acceptable alternative (21).

In an emergency, if a parent/legal guardian is unavailable to provide consent to the treatment of a child who is less than 12 years of age or older than 12 years but of insufficient capacity to consent, the doctors may treat with the consent of the hospital superintendent or the person in-charge (clinical manager) if the child is in a state-run facility. If neither of these people are available, then the child should be treated, as long as this treatment is in the child's best interest, and is limited to what is emergency management (21).

In the elective scenario, an application for consent should be made to the Minister of Health, who may provide consent (22).

If the child's parents are refusing consent unjustly and this puts the child at risk, the hospital legal department must make an application for a court order or apply to the Minister of Health for his consent in this regard (22).

If a child with capacity to give consent refuses life- saving treatment, the court is required to overrule the patient's decision, apart from life-or limb threatening situations, where deliberate action needs to be instituted to preserve the child's life or prevent the child from suffering significant adverse effects.

2.7.2 Human Immunodeficiency Virus (HIV) testing

Regarding testing for HIV in children, Section 130 of The Children's Act No. 38 of 2005 (21) states that consent may be given by a child of 12 years or older or if under 12 years of age then the child must demonstrate maturity to comprehend the "benefits, risks, and social implications" of the test, and only after sufficient pre-test counselling has been provided. This counselling must detail the medical and social implications to the patient. According to the act, if the child is younger than 12 years of age and cannot adequately demonstrate adequate understanding and maturity, then the following people may provide consent (21):

a. The parent/caregiver
b. The designated child protection organisation that has organised placement for the child
c. The superintendent or in- charge of the hospital in the absence of the above
d. The provincial head of social development
e. The children's court if the consent is withheld for no reason or if either the child or the parent/caregiver are not capable of providing this consent.

It is only permissible to test a child for HIV if that is the beneficent thing to do, and once consent has been acquired. However, if testing the child is required because a health care worker may have been exposed to HIV due to contact with the child's body fluid during a medical procedure, or if anyone else may have contracted HIV from exposure to the child's body fluid, then testing may be carried out if it is authorised by a court of law (21).

2.7.3 Termination of Pregnancy

Section 5 of The Choice of Termination of Pregnancy Act No. 92 of 1996 deals with consent for termination of pregnancy. A pregnancy may only be terminated with the informed consent of the pregnant female, and further, only the pregnant patient's consent is required for this (23).

When the pregnant female is a minor, then the patient should be advised to consult with her parents, guardians, family members or even friends prior to the termination of pregnancy. However, she may still have the procedure if she chooses not to involve any of the above people (23).

2.7.4 Circumcision

For circumcisions, Section 12 of The Children's Act No. 38 of 2005 (21) delineates that male circumcision is only permissible in a patient less than 16 years of age if prescribed by religious practices and must be carried out in accordance with such, or for a medical indication as determined by a medical doctor (21).

In all other cases, a male may only consent to his own circumcision from age 16 onward, and must be done in a prescribed manner after sufficient counselling. All males possess the right to refuse being circumcised. The child's level of maturity, development and age must always be taken into account (21).

Female circumcision is prohibited.

2.7.5 A minor with parental responsibility

In the South African context, child headed households are a reality, as are minors who themselves are parents. This is seen due to the large burden of Human Immunodeficiency Virus (HIV) (24).

According to Section 129 of The Children's Act No. 38 of 2005 (21), a minor who has parental responsibility may consent to the medical treatment of his or her own child provided they are over 12 years old, mature enough and with the capacity to understand the "benefits, risks, social and other implications" (21) of the treatment. However, if the consent is for surgery, one should obtain assent of the parent or guardian of the child-parent themselves (21).

2.7.6 Sterilisation

A sterilisation may be consented to from 18 years of age as per The Sterilisation Act No. 44 of 1998 (25) and The Sterilisation Amendment Act No. 3 of 2005 (26).

A person who is under 18 years old may not be sterilised unless their health or life would be significantly impaired without it.

2.7.7 Jehovah's Witnesses

Jehovah's Witnesses are a sect of Christianity whose followers have special religious requirements that are clinically relevant to the attending physician and certainly the anaesthetist. They are known in the medical community as the group of patients who are unable to receive blood transfusions, even if it is their own blood.

The Watch Tower Society of Pennsylvania describes that, per Jehovah's Witnesses belief system, the Bible dictates that followers must abstain from blood, as noted in Genesis, Leviticus and Deuteronomy. They believe that "God views blood as representing life" (27). They "avoid taking blood not only in obedience to God, but also out of respect for him as the Giver of life" (27).

If they do accept a transfusion, they may face difficulties in their religious communities and it is often the fear of social implications that result in some of these patients refusing transfusions.

It is vitally important that the patient is informed that any decision made by them will be kept strictly confidential. The doctor should also inform the patient or in the case of a child, their guardian/parent, that their religious views will be respected as best as possible, if it does not conflict with what is in their child's best interest. Accepted alternatives to blood should always be discussed as well. If it is not an emergency, patients should be provided with sufficient time to obtain second opinions, legal and religious advice as they see fit.

According to The Children's Act No. 38 of 2005 (21), if a child is younger than 12 years old or older than 12 years but of inadequate maturity to provide consent, the parent/guardian must provide consent for a blood transfusion on the child's behalf. If a parent refuses consent to an emergency lifesaving blood transfusion for the child, based purely on religious reasons, the doctor may ignore their refusal and administer the transfusion, unless the parent can suggest the use a medically acceptable alternative. If the parent refuses to consent to a blood transfusion for

the child in an elective case, an application should be made to the courts for a ruling. The best interest of the child should always prevail.

It is uncertain whether a blood transfusion is deemed to be a medical treatment or a surgical procedure. This distinction is important as it determines whether the child over 12 years old with sufficient capacity to provide consent may do so unassisted, or should be assisted by the assent of his/her guardian as per the Children's Act (21).

If considered a surgical treatment, the scenario may arise where a child over 12 years of age who is mature enough to consent, refuses to consent to a blood transfusion, but the parents/guardians have provided their assent to go ahead with the transfusion. In this situation the doctor must contact the department of Social Development, and the minister will provide consent if he or she decides that the child's refusal is unreasonable (28).

If considered medical treatment, then the wishes of the child in the above scenario must be respected, as parental assent is not required. If the refusal is seen to be unreasonable, the Minister of Social Development may consent on behalf of the child (28).

Because of the complex interactions between the moral duty to do what is best for their child and the fear of being ostracised by the church, the child and the parents must be informed that all decisions will be kept confidential. It can happen that the parents wish for the child to have a transfusion, but cannot consent for religious reasons. In these cases, it may be welcomed to get the minister's consent to absolve the parents of being torn between a religious obligation and what is best for their child (28). It is important to note that the refusal of a minor is not binding and may be overruled by a high court or the minister of health (28).

Adult Jehovah's witnesses are discussed in section 2.10.

2.7.8 Determination of parental responsibility

According to Section 19 of The Children's Act No. 38 of 2005 (21), the biological mother has full parental responsibility. If however, the child's biological mother is herself an unmarried child and the child's biological father does not possess guardianship of the child, the child's guardianship falls under the person who is the child's biological mother's guardian (21).

Section 20 and 21 of the act states that the biological father has full parental responsibility if:

- he is married to the child's mother or he was when the child was conceived or born or at any time in between;
- he was living with the mother as her permanent life partner when the child was born;
- he identifies himself as the child's father or has applied to be identified as such or he has paid damages as per a customary law;
- he contributes to the maintenance of the child for an acceptable period;
- he contributes to the child's upbringing for a decent amount of time;
- or a court has conferred full parental responsibility to him (21).

Caregivers who care for the child voluntarily, temporarily, partially or indefinitely, without formal parental responsibility may consent to only medical treatment for the child as per Section 32 of The Children's Act No. 38 of 2005 (21), only if consent cannot be obtained from the parent or guardian. A parental rights and responsibilities agreement may formally be drafted and registered with a family lawyer between a person with full responsibility for the child and another who has taken an interest in caring for the child.

Even though it is sufficient for one person with parental responsibility to provide consent for a minor undergoing a procedure, it is preferable that both do, especially if the decision may have long lasting or severe consequences (2).

2.8 The laws regarding HIV testing

Guidelines regarding HIV testing are published by the HPCSA (29).

In the author's opinion, the situation may arise where the anaesthetist is required to attain consent for, and carry out an HIV test on, a patient to whom he/she has provided an anaesthetic service. Informed consent is vitally important when it comes to HIV testing, due to the far-reaching emotional, psychological and medical implications for the patient. Proper informed consent requires extensive pre-and post- test counselling sessions.

It is never acceptable to test for a patient's HIV status without their informed consent (29). However, HIV testing may be performed without the user's informed consent if, per The National Policy on Testing for HIV, "testing [is] for epidemiological purposes undertaken by the national, or a provincial or local health authority…in accordance with national, legal and ethical provisions" (29).

Where a health care provider has been potentially exposed to HIV such as by sustaining a needle stick injury or an eye splash with the patient's blood, and immediate post exposure prophylaxis is required, consent must still be acquired from the patient to test for their HIV status (29).

In the situation where the patient does not consent, and there is an existing blood sample from the patient, this sample may be tested if the patient is first informed that the test will be done and that their information will be kept private (29).

In the situation where the patient does not consent to an HIV test and there is no existing blood sample, then the patient must be assumed to be HIV positive and the health care provider should initiate post exposure prophylaxis (29).

If the patient is unable to provide consent and may not be able to for the foreseeable future, then attempt must be made to gain consent as delineated by Section 7 of Chapter 2 of The National Health Act No. 61 of 2003 (1). This would be from a proxy mandated in writing or a person authorised to give consent in terms of the law or a court order, or if not available, from a spouse/partner; a parent; grandparent; adult child; or a sibling in that order.

2.9 The laws pertaining to mental health care users

According to The Mental Health Care Act No. 17 of 2002 (30), involuntary and assisted mental health care users may still provide consent and only lose this right if the health care provider ascertains that the user does not have the capacity to consent medical treatment or a surgical procedure due to mental illness or an intellectual disability and is unwilling to receive such treatment.

In this case, a curator appointed by the court or a family member may consent on the user's behalf. Family members may consent in the order as prescribed by The National Health Act No. 61 of 2003 - the patient's spouse/partner; the parent; grandparent; adult child; or sibling, in that order (1). If not feasible, the head of the health establishment may be contacted for consent, as long as the mental illness is likely to result in the patient inflicting harm on himself or others and/or treatment is needed to safeguard the finances and/or reputation of the patient (30).

In accordance with The Mental Health Care Act No. 17 of 2002 (30), treatment for mental illnesses without informed consent may only be carried out if authorised by a court or review board. Treatment can also be carried out without the patient's consent if in an emergency situation, failing to treat the patient would result in irreversible harm to the patient, result in their death, or that the patient could cause significant harm to themselves, to others, or to property, and then too, this may not continue beyond 24 hours unless application is made to the review board to allow for continuation of treatment. Psychosurgery may never be carried out without informed consent.

The above law is important to the anaesthetist who could be required to provide an anaesthetic service to the psychiatry department, either for a psychiatric patient requiring surgery for an unrelated surgical problem or for psychosurgery.

2.10 Adult Jehovah's Witnesses

In terms of its implications to the anaesthetist in theatre who may be required to administer a blood transfusion, the competent adult Jehovah's witness is entitled to refuse an emergency blood transfusion, that could save his/her life (28).

If, however, the surgery is an elective procedure and a blood transfusion may be required intraoperatively, a surgeon/anaesthetist may refuse to conduct the procedure if the competent adult Jehovah's Witness patient refuses consent to a transfusion, providing the surgeon/anaesthetist is not involved in continuous treatment of the patient. It is important, however, that the risks and consequences of not accepting a transfusion are carefully explained to the patient, and other treatment options should be offered. The patient may also be referred to another doctor who may carry out the surgery/anaesthetic without the possibility of a transfusion and the relevant consequences thereof (28).

In the case of an adult Jehovah's witness patient who is either unable to consent to/refuse treatment, consent must be obtained in the order mandated by The National Health Act No. 61 of 2003 (1). This is, as described previously, by a proxy mandated in writing; a partner/spouse; a parent; a grandparent; an adult child; or a sibling. The situation may arise where the proxy may refuse consent to a transfusion, and in this case, if the doctor believes the patient should receive a transfusion, then the doctor may apply for a court order to overrule the proxy's decision (28).

If the patient has provided an advance directive when he/she was competent to do so, stating that they refuse a blood transfusion, then if there is no reason to believe they would have changed their mind, and the clinical situation is applicable to their advance directive, then their wishes must be respected. However, attempts should still be made to obtain proxy consent. In event the advance directive and proxy consent are conflicting such that the patient's advance directive was to refuse a transfusion, but the proxy consents to it, an application should be made to the court for a ruling (28).

In event of an emergency, and a court order cannot be obtained in time, then the patient's wishes must be respected and the family should be involved to confirm that the patient's wishes are still valid. Legal advice should be obtained if one is unsure about whether a blood transfusion should be administered (28).

2.11 Termination of Pregnancy

Section Two of The Choice of Termination of Pregnancy Act No. 92 of 1996 delineates when a pregnancy may be terminated (23).

Any pregnant woman in the first trimester (12 weeks) of her pregnancy may request a termination of pregnancy, and this may be carried out by a medical doctor or registered midwife (23).

Between the 13th to the 20th week, if a medical doctor, who has consulted with the pregnant lady, believes that her continuing to carry the pregnancy could affect her physical or mental wellbeing; result in the foetus having a serious physical or mental anomaly; affect her socioeconomic standing ; or if the pregnancy was a result of incest or rape; a termination may be carried out by a medical doctor providing consent from the patient has been obtained (23).

Beyond the 20th week, a medical doctor who after having consulted with another medical doctor, or a registered midwife, believes that if the woman continues to carry the pregnancy it could endanger her life; injure the foetus; or result in it being seriously malformed, the pregnancy may be terminated by a medical doctor, with the consent of the patient (23).

Section 5 of the act discusses consent regarding termination of pregnancy. A termination of pregnancy may only be carried out with the informed consent of the pregnant female (23).

If a pregnant woman has a serious mental disability and she neither has any understanding of the termination procedure nor any insight into the consequences of it, or if she is in a state of "continuous unconsciousness" (23) and is not expected to recover in good time to request or consent to a termination of pregnancy, then her pregnancy can be terminated during the first trimester

(12 weeks) or in the second trimester (13-20 weeks) upon request and consent of her natural or legal guardian or spouse. If these people cannot be contacted, then the person in control of the patient's welfare, or "curator personae", may request or consent on her behalf, but only if two medical doctors or a medical doctor and a registered midwife with completed training consent to it (23).

If two medical doctors, or a medical doctor and a registered midwife, with completed appropriate training, believe that the female mentioned in the previous paragraph, who is less than 20 weeks pregnant would risk her physical or mental wellbeing; or if there is a risk that the foetus would suffer a mental or physical anomaly should the pregnancy continue; they may consent to a termination of pregnancy on her behalf. If the same woman is more than 20 weeks pregnant, and they believe continuing the pregnancy would either risk injury or a severe anomaly to the foetus, or would endanger her life, then they (the medical personnel) may consent to the termination of pregnancy once they have discussed the matter with her natural or legal guardian, spouse or "curator personae". If any of these people who have been consulted, refuse consent to the procedure, the procedure may still be carried out anyway if it is in the patient's best interest to do so (23).

2.12 Sterilisation

Any person may consent to undergoing a sterilisation procedure if they are at least 18 years old and with the capacity to consent. This is in accordance with The Sterilisation Act No. 44 of 1998 (25). As a corollary to this, nobody capable of consenting may be sterilised without their consent.

As per The Sterilisation Amendment Act No. 3 of 2005 (26), if a person has a mental illness that makes them either incompetent or unable to consent, then a sterilisation request can be sent to the head of the hospital, with the consent of the parent/spouse/guardian/curator of the person in question, after an independent medical doctor has seen the patient and concludes in writing that a sterilisation is the most beneficent action for the patient. The head of the hospital will then arrange a panel that has a nurse, a psychologist or social worker and a psychiatrist or medical doctor. If the person is in the custody of another, the custodian or custodial organisation may not be a part of this panel. Similarly, if the

person is in a private facility, then nobody affiliated to the facility is allowed on the panel (26).

The panel must then consider the patient's age, their physical and mental state, and what effect a sterilisation could have, if other methods of contraception can be alternatives to sterilisation, what kind of sterilisation is to be performed, the chances that the patient may gain the capacity to consent later, if the procedure will be beneficent, and what the patient stands to benefit from having the procedure. If they are in agreement that the procedure should be carried out then it should be done in a manner that poses as little risk as possible to the person (26).

It is vitally important that when consent is being taken, for any procedure, but specifically for sterilisation, particularly due to the likely irreversible nature of it, that it is free of any coercion, that the patient is aware that they may withdraw their consent at any point before the procedure is carried out and that they have signed the appropriate paperwork, after being properly informed and understood the information supplied.

2.13 Consent and its validity

Informed consent is a vital part of all medical practice. The term as we know it was born in the United States of America in 1957. (10) The Declaration of Helsinki of 1964 expanded the concept of a standard ethical framework for research on humans (6). The declaration notes that after the person has fully comprehended the provided information, then the doctor should seek the subject's consent without placing any pressure on them, and this should be given in writing, and if this is not possible, then non written consent can be given and formally witnessed and documented (6).

In the process of acquiring consent, clear, applicable and understandable information is given to the patient so that they may make a rational choice from the options provided to them, per what they feel would be in their best interest, as guided by a discussion with their doctor. "It is universally recognized as an essential safeguard to ensure the preservation of individual's rights" (9).

Anecdotally, the task of obtaining informed consent is delegated to the most junior of doctors – certainly it is very seldom seen that the surgeon acquires the consent personally from the patient. This is problematic as the insight of junior doctors into the actual procedure and of the risks involved may be far more limited than that of the more experienced surgeon (15).

Consent must be obtained prior to any medical intervention. There are three central tenets to obtaining valid informed consent. These are: capacity; information and voluntariness (2).

2.13.1 Capacity

Assessing the patient's capacity to consent is a vital part of the acquisition of informed consent, and underlies many of the laws laid out. Capacity is determined firstly by the patient's age, and secondly by their decision- making capability (2). The patient must be considered competent enough to decide.

In South Africa, the legal age of providing informed consent is 18 years – i.e. someone who is 18 years should have the capacity to provide consent, unless they have a mental disability that impairs their ability to decide. The Children's Act No. 38 of 2005 (21) delineates the rules of age applicable to children, as discussed earlier.

Decision- making capability of patients is a continuum of understanding, determined mainly by their ability to comprehend the information, the consequences of the situation and the rationale behind the proposed treatment.

This decision- making capability may fluctuate, due to illness for example, and in this situation, the consent must either have been provided when they were in a mentally capable state or one should wait until the patient regains the mental capacity to do so. In an emergency, proxy consent in the order specified by The National Health Act No. 61 of 2003 (1) must be obtained. If none of these persons is contactable then the intervention which is limited to what is life-saving, may be carried out, provided the patient had not previously refused the treatment.

Decision-making capacity, therefore, is assumed to be intact in an adult – and one should be convinced that they lack this capacity before interfering in the process. On the contrary, children are assumed to lack this capacity and they must demonstrate sufficient capacity before one can accept it.

When one is in doubt about the patient's decision-making capability, one should carry out an assessment. This is usually accomplished by equipping the patient with information and discussing it with them to assess their understanding. Visual and other aids may prove useful, as well as discussing the consent in the patient's own language, making use of a translator, or a speech therapist (2).

It is important to note that if a patient does not possess decision-making capability, they must still retain involvement in the process.

When a patient lacks the ability to provide consent, and they do not have a valid advance directive, then The National Health Act No. 61 of 2003 details stipulates who may provide such consent and the order of preference in which they should be approached (1). These are as mentioned earlier: a proxy mandated in writing; a person authorised by the law or a court order; a spouse/partner; a parent; a grandparent; an adult child followed by a sibling.

If none of the above persons are contactable, then the healthcare professional responsible for the patient may proceed to do what is most beneficent– or what a reasonable person would do. If treatment is an emergency, then it may be carried out to prevent death or irreversible damage, unless the patient had previously refused treatment.

The situation may arise where the clinician and the proxy disagree about what is beneficent – and in this case, legal advice and a court order should be sought. However, if an emergency situation is present, then intervention to prevent death or irreversible damage may be carried out (1).

Perhaps the best method of describing the importance of assessing capacity is as described in a British study entitled "How much do doctors know about consent and capacity?" (31) where the author describes how doctors judge their patients' ability to provide consent on a daily basis given the litigious climate they practice

in, where claims of negligence are a reality if the capacity to provide consent was inadequately assessed, and more so if the patient sustained harm due to the treatment or withholding of such. Doctors “face the possibility that, from time to time, these decisions will be examined critically in a court of law” (31).

The same study mentions that “capacity fluctuates with both time and the complexity of the decision being made; thus, sound decisions require careful assessment of individual patients” (31). The study concludes that doctors’ knowledge of assessing capacity is not fool- proof, with a startling fifteen percent of doctors believing that they could force a competent adult patient into being treated despite the patient’s refusal. This shows that the issue of capacity deserves far more attention in medical curricula (31).

2.13.2 Information

In terms of the second tenet of informed consent, information, this must be provided as fully and completely as possible. The National Health Act No. 61 of 2003 (1) describes how the information provided must include the benefits and risks of the procedure, the costs that may be incurred, and other options available. This is a highly individualised process and one must be sensitive to the patient and their emotional state. Offering too much information may be as detrimental as providing too little, and a fine balance must be maintained so that the procedure is explained in full without causing unnecessary apprehension (15). The General Medical Council in the United Kingdom advocates that doctors tailor the information they provide to each patient’s needs (32). The concept of the “Nocebo effect of informed consent” is an interesting one described by Ashraf et al (33). They describe a “nocebo” as being the negative counterpart of a placebo – suggesting that doctors must have the insight to tailor the information given to the patient to prevent the patient from undue extra stress, as superfluous and poorly given information specifically about the potential for negative outcomes had the potential to harm the patient emotionally (33).

Information should also be provided on the patient’s intellectual level and in a language that they understand (32). It is vital that the doctor establishes a relationship with his or her patient so the patient feels at ease with them. In the

elective surgical scenario, there must be a forum for the patient to research the proposed procedure for themselves. They should be afforded the opportunity to ask questions, and voice any of their concerns or uncertainties, and these should be allayed and clarified respectively. The patient must also be informed that they reserve the right to refuse treatment, and be fully informed of the consequences of doing so (1).

In terms of consent and the legal basis to it, “the act of signing a consent form appears to protect a doctor from a charge of assault but might not be a defense should a patient claim that he or she was not properly informed” (15).

The information that must be provided includes the diagnosis, the prognosis of the condition; both treated and untreated; what the treatment options are; if more investigations are required, details of the procedure including who will perform it; what the patient will experience before; during and after the procedure, known side effects and complications; including the likelihood thereof. The patient must be informed of their right to refuse treatments, and the implications thereof, their right to a second opinion, the costs of the treatments, the duration of stay in hospital and/or high dependency unit, the expected recovery process, and the specifics about what the success of the procedures are and if any of it is experimental, or will be carried out by trainees (22).

2.13.3 Voluntariness

The third, and probably most vital, tenet of the informed consent process is that the consent gained must be obtained without placing the patient under any duress. They should not be made to feel guilty for the decisions they make, and they should do so freely and under no coercion. This is underwritten in the ethical principle of autonomy. “Lingering paternalism is not part of good practice, and cannot be excused by being disguised as mere beneficent intent or ‘doctor knows best” (32). Respecting a patient’s autonomy is essentially respecting their freedom to make their own choices (16).

2.14 Knowledge of the law – international literature

Few studies were found in the literature that specifically investigates doctors' knowledge of the law that is relevant to medical practice.

A study done in Poland in 2013, entitled "Knowledge of Medical Law Amongst Doctors of Internal Diseases" by Zajdel et al (3), described the knowledge of the law that allergists and pulmonologists in Poland possessed.

The value of a medical doctor possessing sound legal knowledge cannot be emphasised enough. It is integral to the practice of medicine, ensures that the doctor is competent and, importantly, diminishes the risk of facing legal action. Familiarity with the law and sound knowledge is linked to better service quality. The majority of doctors in Poland do not receive any training on the law in their studies, nor are there any formal standardised programs that provide for such training (3).

This study found that doctors were unaware that every legal rule is binding, and that inadequate knowledge of the law resulted in a health service of diminished quality that was provided to patients, and that this could result in doctors facing liability risks. Half of the respondents followed expert opinion instead of the law, and thought that this would exempt them from liability. The authors of the study described doctors' legal awareness as substandard. They suggest that other medical specialties may have better awareness of the law, and that specialised training programs on medical law are necessary to raise legal awareness. Doctors appreciate having legal know-how, despite their poor awareness. Well- informed patients who are up to date on current practice and their rights, and a litigious society dictate that sound legal knowledge is essential to avoid legal ramifications (3).

This conclusion concurs with a Canadian study in 1997 by Saltstone et al (34) entitled "Knowledge of medical-legal issues. Survey of Ontario family medicine residents", that stated that Canadian doctors felt it was necessary to be legally competent to provide good care and avoid legal action, but that they were not sufficiently trained. The doctors surveyed had excellent knowledge of some areas

of the law but lacked knowledge in other areas. More senior residents did not fare better than their junior colleagues. The authors suggest training programs to bridge this gap in knowledge (34).

Hariharan et al (35) , in their study entitled “Knowledge, attitudes and practice of healthcare ethics and law among doctors and nurses in Barbados” in 2006, described results that concur with the Polish and Canadian studies (35). Questionnaire respondents found themselves facing legal problems from a daily to yearly basis, with half of senior medical staff knowing little about the law that pertained to their scope of practice (35).

Jukic et al (10) performed a study in 2009 on 470 Croatian doctors, of which 93 were anaesthetists, entitled “Knowledge and practices of obtaining consent for medical procedures among specialist physicians: questionnaire study in six Croatian hospitals”. The study found that just over half of the doctors were aware that the process of informed consent is a legally regulated one. Interestingly, they found that internal medicine and surgical specialists fared better than the anaesthetists did. Thirty-eight percent were found to have sufficient knowledge regarding consent for medical services. There was no discernible difference between those doctors who worked in an academic environment compared to those working in community settings (10).

The same study describes how, in The United Kingdom, Canada and The United States of America, the doctors are well trained on consent matters due to the litigious societies they work in, and the laws there clearly define consent practices, which contrasts with Croatian norms. In Croatia, the procedures that require consent are not clearly defined and there is no standard consent form either. They suggest that gaining consent is just a formality and does not imply that any substantial interaction between the doctor and patient took place. They concluded that the process followed by doctors in Croatia to obtain consent did not adequately fulfil legal requirements. This may be because they do not have formal training on informed consent and more training is required to improve the process (10).

The study further found that anaesthetists had better knowledge about procedures and consent but provided less information to their patients compared to internal medicine specialists who tend to spend more time with their patients and thus provided more information to them (10).

Peters, in his 2009 New Zealand based study, called “Consenting to medical treatment: legal requirements vs. medical practice. Are healthcare providers exposing themselves to potential legal action?” showed that the level of knowledge of consent law was poor, with only half of the doctors having had sufficient training on consent to medical treatment (36).

Haberko et al (37) published an article in 2008 in Polish entitled “Awareness of basic medical law standards among doctors and patients in Poland” suggesting that awareness of medical law in Poland is poor at best. They conclude that although the doctors scored much better than the students and the patients did, educating doctors on medical law should not be limited to teaching medical students, but should also be part of postgraduate training, especially due to the real risk of legal consequences of not being adept in the laws (37).

The same study found a statistically significant difference that younger doctors possessed superior knowledge compared to their older counterparts, and doctors who worked in an urban setting fared better than those in more rural workplaces (37).

A cross sectional study done by Gupta et al (9) in 2015 on the “Knowledge and Attitude Toward Informed Consent Among Private Dental Practitioners in Bathinda City, Punjab, India” concluded that knowledge was associated with years of experience and the person’s qualification. Those who had more experience had more knowledge of consent compare to those with less experience. Those who had post graduate training had better knowledge than those with undergraduate training only. They concluded that there was a definite need to bridge knowledge gaps, by having undergraduate and postgraduate training on medical law (9).

Fisher-Jeffes et al (32) published their study on “Clinicians’ knowledge of informed consent” in the United Kingdom in 2007. They found that paediatricians fared

better knowledge- wise, but on the whole, doctors need to better their knowledge of consent to allow for better legal practice (32).

In a study by Houghton et al (15) on “Informed consent: patients’ and junior doctors’ perceptions of the consent procedure” in the United Kingdom in 1997, thirty-seven percent of junior doctors stated that their insight into the procedures they were obtaining consent for was not adequate. Most of the junior doctors and the patients questioned thought that the person performing the operation should be the one to obtain the consent. Almost half of the patients questioned believed that the person who took the consent from them was the one who was going to perform the operation. That a junior member of staff is tasked with this very important legal requirement – the taking of the consent – for a procedure that, not only are they not performing, but that they are not fully equipped with a thorough understanding of, opens up to the risk of litigation (15).

The same study found that junior doctors were meticulous in explaining risks of surgery to their patients, which was in keeping with the American practice of doing so, as it is a medicolegal necessity in the United States. It is interesting to note that only half of the consent notes documented the risks of the operation, and this omission is legally indefensible (15). The study concludes that due to the “ominous rise in confrontation between the medical profession and the public”, the patient and his expectations must be fully accounted for. Taking consent should be a meaningful experience, and it would be far better if the one performing the operation takes the consent, if only to prove that a discussion occurred between the surgeon and the patient and would result in less likelihood of medicolegal problems (15).

A study entitled “An audit of the knowledge and attitudes of doctors towards Surgical Informed Consent (SIC)” by Ashraf et al (33) in Pakistan in 2014, found that junior doctors performed worse knowledge-wise, compared to their senior counterparts, resulting in a surgical informed consent that had questionable legal validity, as they were unaware of the preconditions of the consent, provided less than complete information and didn’t ensure the patient was properly involved in the process (33).

They concluded that the process showed major deficiencies, a need exists to create awareness about consent, that a surgical informed consent guideline should be created and rolled out that essentially obliges doctors to abide by it and that there is a need for formal training to improve knowledge (33).

A study entitled “A survey of the current practice of the informed consent process in general surgery in the Netherlands” in 2013 found that knowledge on informed consent was limited and just over half of the participants were familiar with the three clearly defined stages of surgical informed consent. They also found that the surgical registrars fared poorer than the surgeons. A striking one out of six (17%) surgeons had faced an official consent related complaint in the last five years of practice. The study concluded that the quality of the consent and the knowledge and skills in this regard was suboptimal and more training was required (11). It is very interesting, perhaps startling to note, that when questioned, ninety-four percent of respondents thought that attaining proper surgical informed consent was vital – if they themselves were the patient. However, only seventy-three percent thought that their patients would consider a proper surgical informed consent as being equally important (11).

Lack of adequate training was cited as one of the key factors behind the poor performance. The surgical training program in the Netherlands only delineates surgical informed consent briefly. The authors suggested that surgeons learn the importance of informed consent “the hard way”- that is through litigation and complaints (11).

2.15 The South African setting

Anecdotally, South Africa is a country with a hybrid socioeconomic status with developed and developing world elements.

Medical staff in the public sector face many obstacles. Poor staffing, large patient burdens, language barriers, vastly differing cultural beliefs, poverty and lack of knowledge about their rights result in an often paternalistic approach to medicine, which translates into barriers to obtaining legally sound informed consent (16). This often manifests as coercion into consenting to treatment and/or procedures

without necessary insight into the risks involved, as per the doctor's advice that it is in their best interest.

Health care is unaffordable or simply out of reach for many, who tend to make use of traditional health care as opposed the formal western medicine (16).

A study done by Sylvester Chima in public urban hospitals in KwaZulu Natal over three months in 2013 entitled "Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study" (16) found that of 946 participating doctors, nurses and patients, the main difficulties encountered in the consent process was language barriers, the absence of appropriately trained people to interpret the different languages, the large burden of patients and lack of sufficient time. On average the doctors spent five to ten minutes per patient on consent matters, but their knowledge of the law was inadequate. Junior doctors scored less than their senior counterparts. Interestingly, anaesthetists scored the lowest of the specialties; while internal medicine specialists, general practitioners and obstetricians/gynaecologists fared the best. Nurses also scored lower than doctors overall (16).

In the introduction to his study, Chima describes several court cases that have occurred locally that delineate the importance of informed consent. One of note is that of the Minister of Safety and Security v. Xaba, where the court ruled that the police could not compel the accused to have surgery to remove a bullet to be used as evidence. The basis for this was that it was a contravention of the constitutional right to body integrity of the defendant (16).

Another case of note is that of Stoffberg v. Elliot where a patient with penile cancer successfully sued his doctor for wrongful amputation of his penis, without his informed consent.

In yet another case, Esterhuizen v. Administrator Transvaal, a child with Kaposi's sarcoma sustained severe burns due to radiation therapy that resulted in her having her limbs amputated. The court rejected the doctor's claim that because consent was given for the first cycle of superficial radiation, consent was implied,

and therefore acceptable, for the second cycle of more intense radiation when the tumour recurred (16).

He states that a more recent court case, of Castell v. De Greef, has put informed consent on the map and certain principles have been adopted as a result. These include a focus on patient autonomy, an emphasis on the “prudent patient”, and the level of disclosure of information required that would allow a reasonable man to make an informed decision (16).

The study suggested that adherence of the ethical and legal aspects of consent was poor. Doctors possessed a general knowledge base of informed consent, but the practical aspect was poor, with deficient knowledge of the law and regulations. Interpreters are required to assist the process, and to carry education of the law and ethics through medical training is vital to improve the quality of care (16). Doctors did not adhere closely enough to the specifications as described by The National Health Act, and cited language barriers as a major stumbling block, along with great workloads, time constraints and lack of interpreters (16).

The knowledge of laws such, for example, the age at which one can consent for medical treatment and termination of pregnancy was poor. The study also suggests that implied and presumed consent are heavily relied upon. He suggests the use of interpreters, and a standardised consent form that shows translations in different languages, including certain compulsory information in terms of law, with the option of including specific information on procedures. He further suggests the use of patient information leaflets in different languages and further education of doctors on ethics and medical law (16).

The study by Chima determined the quality of informed consent, in terms of whether it complies with the standards set by international ethical models and local South African regulations. The specific aim was to see whether adequate information was provided to the patients, if the patients understood the information provided and to determine if the consent was voluntary. Specifically, the study looked at responses from not only doctors (including interns) from a range of specialties, but also at nurses and patients’ perspectives. Demographic data including gender was collected (16).

Another local study from 2013 entitled “The perspectives of eThekwini public service anaesthetic doctors on the informed consent process for anaesthesia” by Naidu and Gopalan (4) found that the majority of doctors felt it was important to have consent documented on a designated form, and that informal verbal consent for anaesthesia is unacceptable. The study found that approximately ninety-three percent of doctors were familiar with the legal ramifications of not having documented informed consent, but about sixty-one percent of them stated that they did not document vital anaesthetic information. The overall conclusion was that informed consent for anaesthesia was not up to standard and was “legally indefensible” (4) and that further education was necessary.

The main limitations of the study done by Naidu and Gopalan were that, because the study was based on the doctors’ personal perspectives, the honesty of the responses could be questionable as they may have feared being critiqued. Open-ended questions opened the study to bias. Some questions were modified from previous studies and others were developed by the authors (4).

There is no international consensus on obtaining informed consent for anaesthesia (4). According to the guidelines published by the South African Society of Anaesthesiologists (SASA) revised in 2012, an information pamphlet should be given to the patient and the anaesthetic technique and associated risks must be explained clearly to the patient (4).

Anecdotally, consent for anaesthesia is limited to brief verbal bedside interaction with the patient, either on the red line at the entrance to theatre or at the preoperative visit. Most patients are more concerned with information regarding their surgery, and are unaware of the very real risks of undergoing any form of anaesthesia. Consent for anaesthesia is very rarely obtained on paper, and is usually part of the surgical consent form, where the patient signs for the surgery and the anaesthetic as one unit. While making a distinction between consent for anaesthesia and for surgery is important not only practically, but also legally and ethically, no distinction is made in any law in this land between the two – they are both part and parcel of the informed consent for a procedure.

The stumbling blocks encountered by the doctors in the study by Naidu and Gopalan also include language barriers and lack of time. They found that approximately seventy-nine percent of doctors in the study were aware that verbal consent may not be adequate defense in a court of law should a dispute arise between the doctor and the patient, however, it is seen that doctors are lax in this regard as the levels of litigation are seemingly low, and create a false safety net (4).

Approximately sixty-eight percent of doctors stated that the “threat of litigation would change the way they conducted their pre-anaesthetic practice” (4).

2.16 Summary

Chapter two has summarised the importance of having sound knowledge and understanding the law pertaining to informed consent. As there is no distinction between surgical informed consent and informed consent for anaesthesia, they go hand in hand and surgical informed consent is, as succinctly described by Ashraf et al (33) , a “comprehensive process that involves a competent patient, a clearly communicating doctor, and transfer of focused information” (33). Informed consent can be seen as a “legal and ethical doctrine derived from the principle of respect for autonomy” (16). Healthcare professionals who treat their patients without first obtaining valid informed consent can be seen to have compromised their patients’ rights to bodily integrity and well- being (16).

Anaesthetists are often faced with a poorly informed patient who requires more information not only about their anaesthetic but also about their surgery. It is vitally important that anaesthetists adequately provide an anaesthetic service to their patient and check the consent form for legality and accuracy. It is essential that anaesthetists know the specific South African laws pertaining to informed consent so that they may make accurate judgements in this regard. The threat of legal action is very real, and should a dispute arise, the anaesthetist would be as equally as liable as the surgeon if the consent process was not done in accordance with legal principles.

No previous study has been done in South Africa that has looked specifically at anaesthetists' knowledge of South African Law that pertains to informed consent.

Chapter three will follow with an explanation of the methodology behind the study design.

CHAPTER 3: RESEARCH METHODOLOGY

3.1. Introduction

In this chapter the problem statement, aim and objectives, ethical considerations, research methodology and the validity and reliability of the study are discussed.

3.2. Problem statement

Doctors specialising in anaesthesia must have a thorough knowledge of South African Law pertaining to informed consent, so they may apply this knowledge in their clinical practice. This study looked at the knowledge of trainees and specialists in the WITS Department of Anaesthesiology about informed consent practices related to surgical procedures. The knowledge and requirements for extra training with regards to this topic was unknown.

3.3. Aim and objectives

3.3.1 Aim

The aim of this study was to determine and describe the knowledge of anaesthetists, who work in the WITS Department of Anaesthesiology, of South African Law pertaining to informed consent.

3.3.2 Objectives

The primary objective of this study was to:

- describe the knowledge anaesthetists possessed regarding South African Law pertaining to informed consent in ten different clinical scenarios.

There were three secondary objectives of this study. They were

1. To determine if an association could be made between knowledge of South African law and years of anaesthetic experience.
2. To determine if there was an association between knowledge of South African law and number of years after graduation from medical school.
3. To compare knowledge of South African Law between anaesthetists who had formal postgraduate teaching (course/symposium/CPD accredited lectures) on informed consent and those who did not.

3.4. Ethical considerations

This study received ethics clearance from the WITS Human Research Ethics Committee (Medical), clearance certificate number M160685 (Appendix 1). It also received approval from the WITS Graduate Studies Committee (Appendix 2).

This study was knowledge–based, using an anonymous self-administered questionnaire. Participation was voluntary and consent was implied on completion of the questionnaire. Care was taken to maintain the anaesthetists' anonymity and confidentiality and no identifying information was obtained from the participants. Only the researcher and her supervisor have access to the raw data, and data will be stored securely for six years.

The study was conducted in accordance with the Declaration of Helsinki (6) and the South African Good Clinical Practice Guidelines (7).

3.5. Research methodology

3.5.1. Research design

This was a prospective, contextual and descriptive study.

A prospective study is one where a specific population is followed over time to observe an outcome (38). The data is collected at the time the study takes place.

A contextual study is one that targets a specific population group, which in this study was the anaesthetists working in the Department of Anaesthesiology at WITS.

According to Brink et al (38), a descriptive study describes a phenomenon by obtaining information from a representative sample of a population, without the intention of discovering a causal link, and in doing so, problems with current practice are identifiable. This cross- sectional study was observational. The variables were not manipulated by the researcher.

3.5.2. Study population

This study population consisted of anaesthetists working in the WITS Department of Anaesthesiology.

3.5.3. Study sample

3.5.3.1 Sample Size

As 30% of the department at any one time was on leave, pre-call, post call or rotating at a distant site, approximately 153 anaesthetists should have been available. Of these, the researcher targeted as many of the available anaesthetists as possible. It was estimated that responses would be gained from at least 60% of the available anaesthetists. The final sample size was determined by the response rate.

3.5.3.2 Sampling method

This study used convenience sampling. This is a non-probability sampling method, which is considered appropriate for a descriptive study (39).

Convenience sampling involves selecting the most easily available persons as participants (40). A sample of anaesthetists attending departmental academic meetings was used.

3.5.3.3 Inclusion and exclusion criteria

All anaesthetists attending the department's academic meetings were included.

Blank and illegible questionnaires were excluded, but were still used to calculate the response rate. Interns were excluded as their presence in the department is transient (a 2-month period) and the sample of interns at any one time may not be representative of the overall knowledge of interns in Anaethesia or of the Anaesthesia department as a whole.

3.5.4. Data collection

3.5.4.1 Development of questionnaire

A self-reporting technique is used when the aim is to discover the level of knowledge of the study population (38). The questions are directed to the study participants (39). This technique allows the researcher to collect "factual information about the participants…knowledge levels," as they must answer questions about the study variable (38).

As no published questionnaires regarding knowledge of South African Law pertaining to informed consent were identified, a questionnaire was developed by the researcher and supervisor, based on the available literature. To achieve face and content validity two independent experts in the field of bioethics and the laws regarding clinical informed consent were consulted. Following consultation, corrections were made, and a final questionnaire was created.

A vignette is a short written representation of a person or situation that is created to be a simulation of the salient features of a real life scenario (41). This assessment format can investigate "judgments and decision-making processes, including clinical judgments made by health professionals" (41).

The self-administered questionnaire (Appendix 4) consisted of two sections.

Section 1 acquired the following demographic data:

- professional designation
- years of experience in anaesthesiology
- years after graduating from medical school
- attendance at formal postgraduate teaching on informed consent.

Section 2 consisted of questions regarding the knowledge that anaesthetists possessed on South African Law and informed consent in ten scenarios, each testing a specific law. These laws are summarised in Table 3.1 below.

Table 3.1: List of laws tested

QUESTION	LAW TESTED
1	The Choice of Termination of Pregnancy Act No. 92 of 1996
2	The Children's Act No. 38 of 2005
3	The National Health Act No. 61 of 2003
4	The Mental Health Care Act No. 17 of 2002
5	The National Health Act No. 61 of 2003
6	The Children's Act No. 38 of 2005
7	The Children's Act No. 38 of 2005
8	The Children's Act No. 38 of 2005
9	The Sterilisation Act No. 44 of 1998 (Amended 2005)
10	The Children's Act No. 38 of 2005

The questionnaire was composed of multiple choice questions each with a single correct answer. The questionnaire was scored out of a total of 23, with one point allocated for each correct answer. Negative marking was not applied.

According to an article published in the Current Opinion in Anaesthesiology Journal entitled "Multiple choice questions: their value as an assessment tool", the use of this type of assessment is well-established and reliable. Different multiple-choice question formats exist, all with emphasis on correctly and clearly worded questions with non- ambiguous assessment objectives. It is important that the

candidates are aware of the marking system chosen by the assessor, however there does not seem to be any advantage or drawback of using negative marking compared to not making use of it. Multiple choice questions can be utilized to test continuing professional development and determine doctors clinical competence (42).

According to the University of Texas publication on the use of multiple choice questions for knowledge assessment, multiple choice questions possess strong diagnostic power if the distractors (incorrect response options) are designed to address common errors students would make (43). A broad knowledge spectrum can be assessed, responses can be marked objectively and analysed easily. Large numbers of assessments can be marked quickly and timeous feedback can be given. The test as a whole is only valid if each question and answer set is valid (43). The main limitations of multiple choice questions are that they are often difficult and time-consuming to create and phrase to allow for consistent interpretation by the candidates. It may happen that the questions test simple recognition instead of factual recall, reducing the effectiveness of the testing method. Guessing is a confounder as there is a twenty-five percent chance of correctly choosing the correct answer in a multiple choice item with 4 options (43).

Single best or correct answer questions are ideal, with options parallel in format so the correct answer doesn't stand out style or length-wise. Options should be plausible, logically arranged, mutually exclusive and options such as "all of the above" or "none of the above", should be avoided (43).

3.5.4.2 Data collection process

Data was collected at the departmental academic meetings. The chair was approached for permission to address the attendees. The researcher was present to assist with queries and to prevent data contamination.

Before the questionnaires were distributed, all questionnaires were numbered to keep track of those completed and prevent reproduction of results. It also allowed for calculation of a response rate.

Following an introduction to the study aim and objectives, the questionnaires were distributed to the anaesthetists that wished to participate. Those who agreed to participate received an information letter (Appendix 3) and the questionnaire (Appendix 4). After completion of the questionnaire, which took 15-20 minutes, participants placed it into a collection box. Anonymity and confidentiality of the participants in the study was ensured as no identifying data was collected.

3.6. Data analysis

Data was captured onto a spreadsheet using Microsoft Excel. SAS™(8) was used to analyse data, using descriptive and inferential statistics.

Categorical data was described using frequencies and percentages. The knowledge of South African Law pertaining to informed consent was described using means and standard deviations or medians and ranges depending on the data distribution.

The association of knowledge of the law with years of experience, and years since graduation from medical school was done using a Spearman Rank Correlation Test.

Knowledge comparisons between anaesthetists with and without formal postgraduate teaching on informed consent was done using a Wilcoxon Mann Whitney U test.

In this study, a 0.05 level of significance and 95% confidence interval was used

Spearman correlations form part of regression analysis – which provides a ‘best fit’ line to the study variables on a scatterplot, which is used to determine the way in which “the response variable changes with changes as the predictor variable changes” (44). The correlation coefficient “measures the extent to which two variables tend to change together. The coefficient describes the strength and direction of the relationship” (44).

The Spearman Rank Correlation Test determines the “monotonic relationship between two continuous or ordinal variables” (44). A monotonic relationship is one

in which the “variables tend to change together, but not necessarily at a constant rate” (44).

The Spearman correlation coefficient ranges from −1 to +1, with the former describing a perfect line for a decreasing relationship and the latter implying that a rise in one variable is associated with a consistent rise in the other” (44).

When there is no relationship, or a random relationship between variables, the correlation coefficient approximates naught (44).

If “one variable decreases when the other increases, but the amount is not consistent, then the Spearman coefficient is negative but greater than −1” (44). Similarly, if both variables increase but not by a consistent amount, the Spearman coefficient is positive but less than +1.

Knowledge comparisons between anaesthetists with and without formal postgraduate teaching on informed consent was done using a Wilcoxon Mann Whitney U test.

A Wilcoxon Mann Whitney U test is the equivalent test to the independent t test, but the key difference is that the data is non-parametric. It tests if two sample means from the same population are equal. It is commonly done on ordinal data or when the assumptions of the t-test are not met and it therefore does not assume any assumptions related to score distribution (45).

There are three key assumptions for the Mann Whitney U test:

1. A randomly drawn sample from the population.

2. “Mutual independence”, meaning that an observation is found in either one group or the other and not in both.

3. The data is ordinal in nature (45).

3.7. Validity and reliability of the study

Validity “indicates whether the conclusions of the study are justified based on the design and interpretation…[and] the degree to which a measurement represents a true value” (46).

Reliability “represents the consistency of the measure achieved” (46).

The validity and reliability of this study were ensured by:

- a standard questionnaire with face and content validity that was completed under the same, non-threatening circumstances.
- the researcher being present to clarify queries and prevent data contamination.
- having all completed questionnaires placed anonymously into a collection box.
- having checked every tenth data entry point on the spreadsheet for accuracy.

3.8. Summary

In this chapter the problem statement, aim and objectives, ethical considerations, research methodology, data analysis and validity and reliability were discussed. In the next chapter the results of the study are reported and discussed.

CHAPTER 4: RESULTS AND DISCUSSION

4.1 Introduction

The sample realisation, results of the study according to the objectives and the discussion are presented in this chapter. The objectives of this study are therefore repeated.

The primary objective of this study was to:

- describe the knowledge anaesthetists had regarding South African Law pertaining to informed consent in ten different clinical scenarios

The secondary objectives were to:

- determine if there is an association between knowledge of South African Law pertaining to informed consent and years of anaesthetic experience.
- determine if there is an association between knowledge of South African Law pertaining to informed consent with number of years after graduation from medical school.
- compare knowledge of South African Law pertaining to informed consent between anaesthetists who have had formal postgraduate teaching (course/symposium/CPD accredited lectures) on informed consent and those who have not had such teaching.

4.2 Results

The findings here are described and analysed using descriptive and inferential statistics. *p*-values of <0.05 are considered statistically significant. Each objective is discussed separately.

4.2.1 Demographic data

4.2.1.1 Sample realisation

A total of 191 questionnaires were distributed between the four hospitals during September and November 2016. Seven questionnaires were not returned. Seventeen questionnaires were excluded as demographic information was not completed, and these could therefore not be used to describe the results of the study. Therefore, a total of 167 questionnaires were included in the statistical analysis (n=167). There was a 96% response rate as 184 questionnaires were returned, but as 17 questionnaires were excluded, 87% of the total were included for data analysis. This sample size is well above the pre-defined estimated sample size. It was determined that as 30% of the department at any one time are on leave, pre-call, post-call or rotating at a distant site, approximately 153 anaesthetists should have been available to complete the questionnaires. It was estimated that responses would be gained from at least 60% of the available anaesthetists, which is approximately 92 anaesthetists.

Figure 4.1 describes the distribution of professional designation. The sample of anaesthetists consisted of 27 medical officers (16%), 17 first year registrars (10%), 9 second year registrars (5%), 27 third year registrars (16%) and 21 fourth year registrars (13%). There were 66 consultants, comprising 40% of the sample size of 167 anaesthetists.

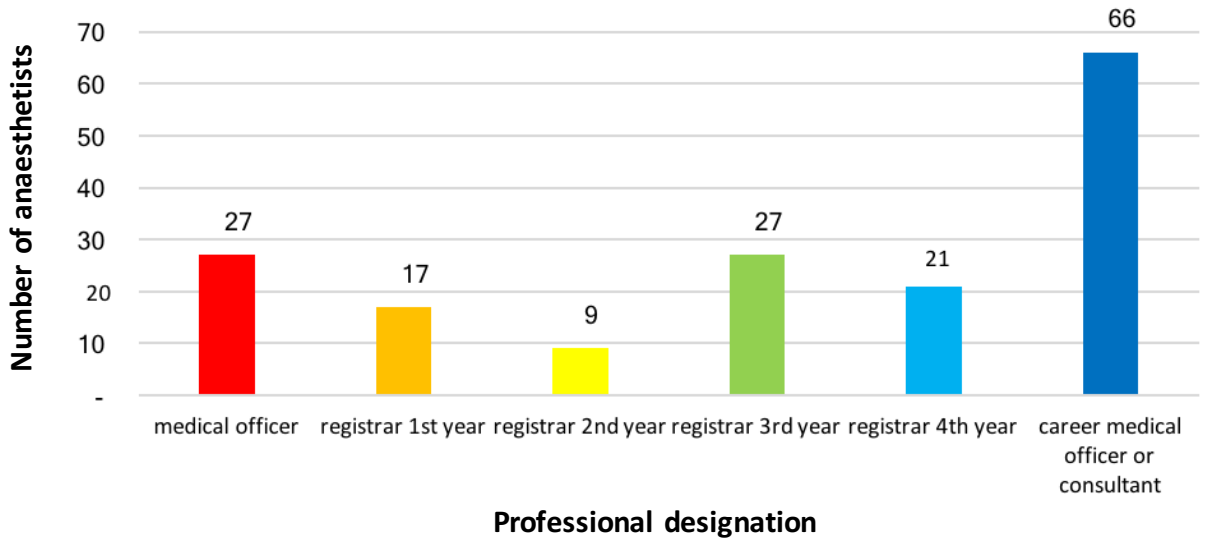

Figure 4.1 Distribution of professional designation

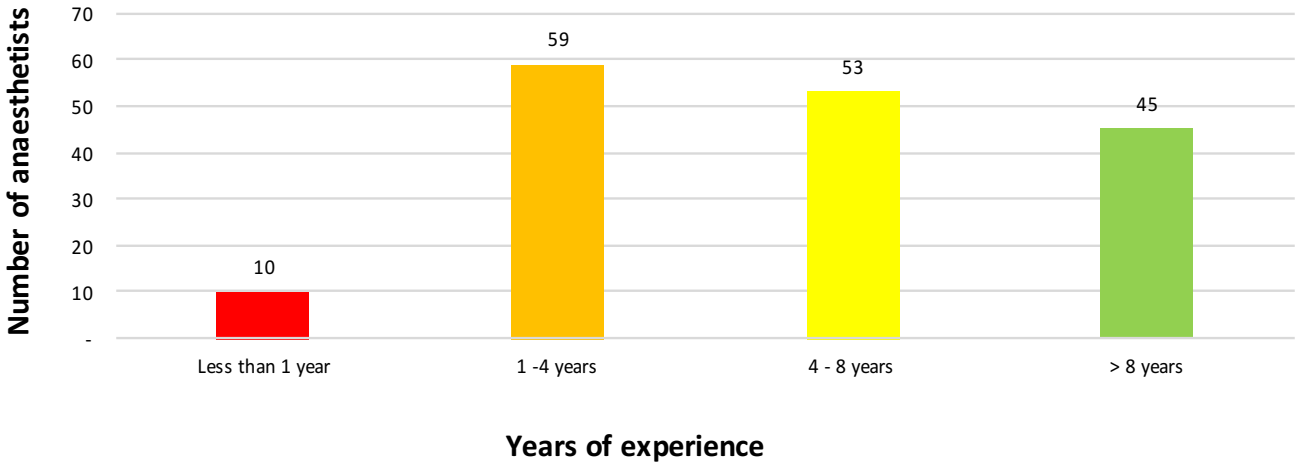

Figure 4.2 Distribution of years of experience in anaesthesia

Figure 4.2 describes the distribution of years of experience in Anaesthesia. Of the 167 anaesthetists, 10 (6%) had less than 1 year of experience in anaesthesia, 59 (35%) had 1-4 years of experience, 53 (32%) had 4-8 years of experience and 45 (27%) had more than 8 years of experience in anaesthesia.

Figure 4.3 shows the distribution of years after graduation from medical school. Seven anaesthetists (4%) were less than 4 years after graduation since medical school, 60 (36%) were 4-8 years after graduation from medical school, 57 (34%) were 8-12 years after graduation from medical school and 43 (26%) were more than 12 years after graduation.

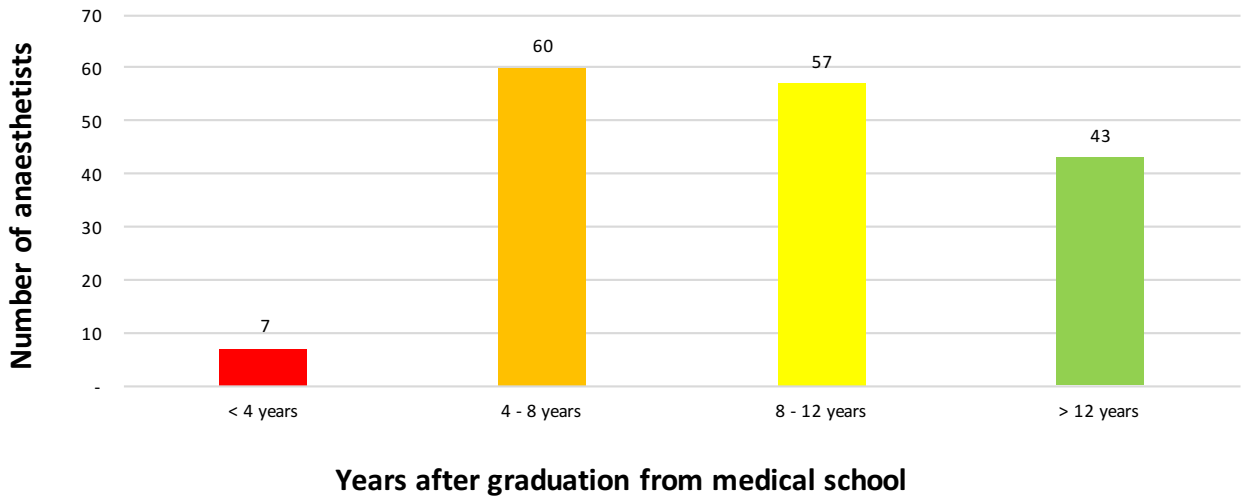

Figure 4.3 Distribution of years after graduation from medical school

The distribution of attendance at formal postgraduate teaching on informed consent showed that seventy- six anaesthetists (46%) had attended teaching on informed consent, while 91 (54%) had not.

4.2.2 To describe the knowledge anaesthetists had regarding South African Law pertaining to informed consent in ten different clinical scenarios

The questionnaire comprised of ten single correct answer multiple choice questions, split into parts, resulting in a questionnaire that was marked out of a total of 23 points. No negative marking was applied. One mark was allotted for each correct answer.

Of the 167 anaesthetists, nobody answered all ten questions correctly. The lowest score overall was 7 out of 23, or 30.43%, while the highest score was 20 out of 23, or 86.95%. The average score was 60.09%.

In terms of maximum total score by professional designation, career medical officers/consultants scored the best with their highest score 86.96%. Fourth year registrars fell slightly behind with a maximum score of 82.61% and this was followed by medical officers, first and third year registrars who scored a maximum of 78.26%. Second year registrars faired the poorest with their maximum score only 73.91%.

On the other end of the spectrum, in terms of minimum score by professional designation, medical officers and fourth year registrars fared the poorest with their lowest score 30.43%. First and third year registrars as well as career medical officers/consultants shared a lowest score of 34.78% and second year registrars scored a lowest mark of 39.13%.

In terms of averages, career medical officers/consultants had the highest average score of 62.78%, followed by fourth year registrars and third year registrars at 60.06%, medical officers at 57.97%, first year registrars at 55.24% and second year registrars at 54.59%.

The highest score was for question 7.1, with 152 (91%) of anaesthetists correctly answering the question. This question tested the Children's Act No. 38 of 2005 specifically dealing with consent for medical and surgical treatment of a child.

The lowest score in the questionnaire was for question 6.1 with 32 (19%) of anaesthetists answering the question correctly. This question tested the Children's Act No. 38 of 2005, specifically dealing with gaining consent for blood transfusion for a child in the setting of Jehovah's witnesses.

Appendix 5 consists of the correct answer memorandum to the questionnaire.

For data analysis purposes, the questions were grouped according to the acts they tested. Correlation was assessed using Spearman's rank correlation.

Question 1 tested **The Choice of Termination of Pregnancy Act No. 92 of 1996**.

The mean score for this question was 71.26% (SD= 35.74%).

There was a statistically significant correlation of years since graduation and the score achieved (p = 0.0013) and a correlation coefficient = -0.2468

This means that the greater the number of years since medical school, the lower the score the participants achieved on this question.

Questions 2, 6, 7, 8 and 10 all tested **The Children's Act No. 38 of 2005**.

The mean score for these questions was 51.82% (SD= 17.84%).

There was a statistically significant correlation of professional designation and the score achieved (p = 0.0004) and a correlation coefficient = 0.2711.

This means that the higher the professional designation, the greater the score achieved on this question.

There was also a statistically significant correlation of years of anaesthetic experience and the score achieved (p= 0.0180) and a correlation coefficient = 0.1829.

This means that the greater the years of anaesthetic experience, the greater the score achieved on this question.

Further, there was a statistically significant correlation of anaesthetists that attended formal postgraduate teaching on informed consent and the score achieved (p = 0.0080) and a correlation coefficient = -0.2045. This means that those who had attended formal teaching scored better.

In this question, the number "1" was categorised as having attended formal postgraduate teaching on informed consent, and "2" was the category that had not attended such formal teaching.

Questions 3 and 5 tested **The National Health Act No. 61 of 2003.**

The mean score for these questions was 59.52% (SD= 21.84%).

There was a statistically significant correlation between professional designation and the score achieved (p = 0.0120) with a correlation coefficient = 0.1939. This

means that the higher the anaesthetist's professional designation the greater the score achieved.

Question 4 tested **The Mental Health Care Act No. 17 of 2002.**

The mean score for this question was 88.92% (SD= 22.23%).

There was a statistically significant correlation of years since graduation from medical school and the score achieved (p = 0.0276) and a correlation coefficient of -0.1705.

This means that the greater the number of years since graduation from medical school, the lower the score on this question.

Question 9 tested **The Sterilisation Act No. 44 of 1998 (amended 2005).**

The mean score for this question was 64.67% (SD = 26.31%).

There was a statistically significant correlation of years since graduation from medical school and the score achieved on this question (p = 0.0108) and a correlation coefficient = -0.1969.

This means that the greater the years since graduation from medical school, the poorer the performance on this question.

Overall, the mean score was 13.8204 out of a total of 23, (SD= 2.9006). This equates to a percentage mean score of 60.08% (SD= 12.61%).

In order to categorise the data for statistical purposes, a coding system was formulated, which is provided as Appendix 6. Using this system, the median professional designation category was 5, with a range of 1-6. This corresponds to the median category being fourth year registrars, with a range that extended from medical officers to career medical officers/consultants.

A statistically significant relationship exists between the mean score achieved and professional designation (p = 0.0163), with a correlation coefficient = 0.1857. This

means that the higher the anaesthetist's professional designation, the greater the mean score achieved.

Figure 4.4 below graphically depicts this relationship, showing that the highest mean score was achieved by career medical officers/consultants.

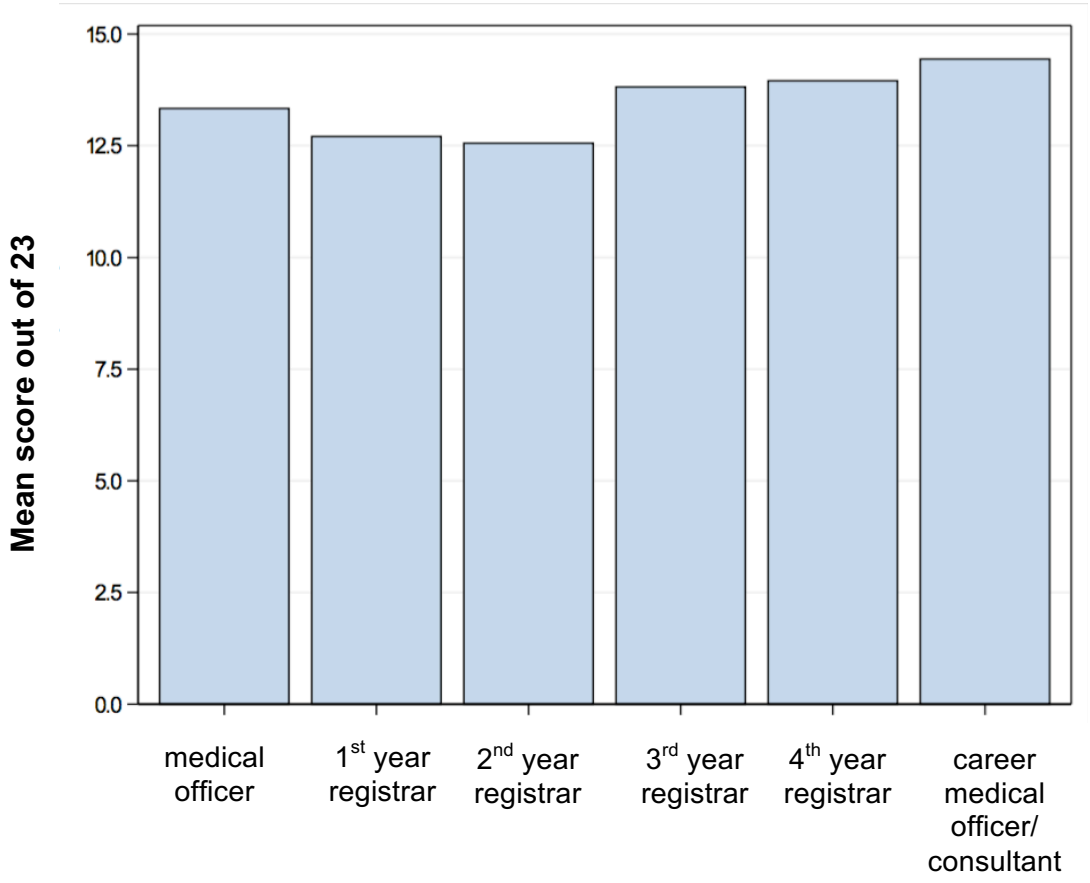

Figure 4.4 Mean score achieved as a function of professional designation

Using the same scoring system, the median category for years of anaesthetic experience was 3 with a range of 1-4. This means that the median category with regard to years of anaesthetic experience, was 4-8 years of anaesthetic experience, with a range from less than one year to more than 8 years.

The median category of years since graduation from medical school was 3 with a range of 1-4. This means that the median category regarding years since

graduation from medical school was 8-12 years, with a range that extended from less than 4 years to more than 12 years.

4.2.3 To determine if there is an association between knowledge of South African Law pertaining to informed consent with years of anaesthetic experience.

Of the 167 anaesthetists, the median category was 3 with a range of 1-4. The only statistically significant finding in terms of looking for an association between years of anaesthetic experience and knowledge of South African Law pertaining to informed consent, related to the questions that tested The Children's Act No. 38 of 2005. This revealed a correlation coefficient = 0.1829 (p = 0.0180) meaning that the greater the anaesthetist's number of years of anaesthetic experience, the better they scored on the questions that tested this act.

There was no statistically significant correlation between years of anaesthetic experience and mean score (p = 0.2897).

Figure 4.5 graphically depicts that the highest mean score was achieved by the anaesthetists who had 4-8 years of anaesthetic experience , followed by those who had less than one year of anaesthetic experience , those who had more than 8 years of anaesthetic experience and finally those who had 1-4 years of anaesthetic experience .

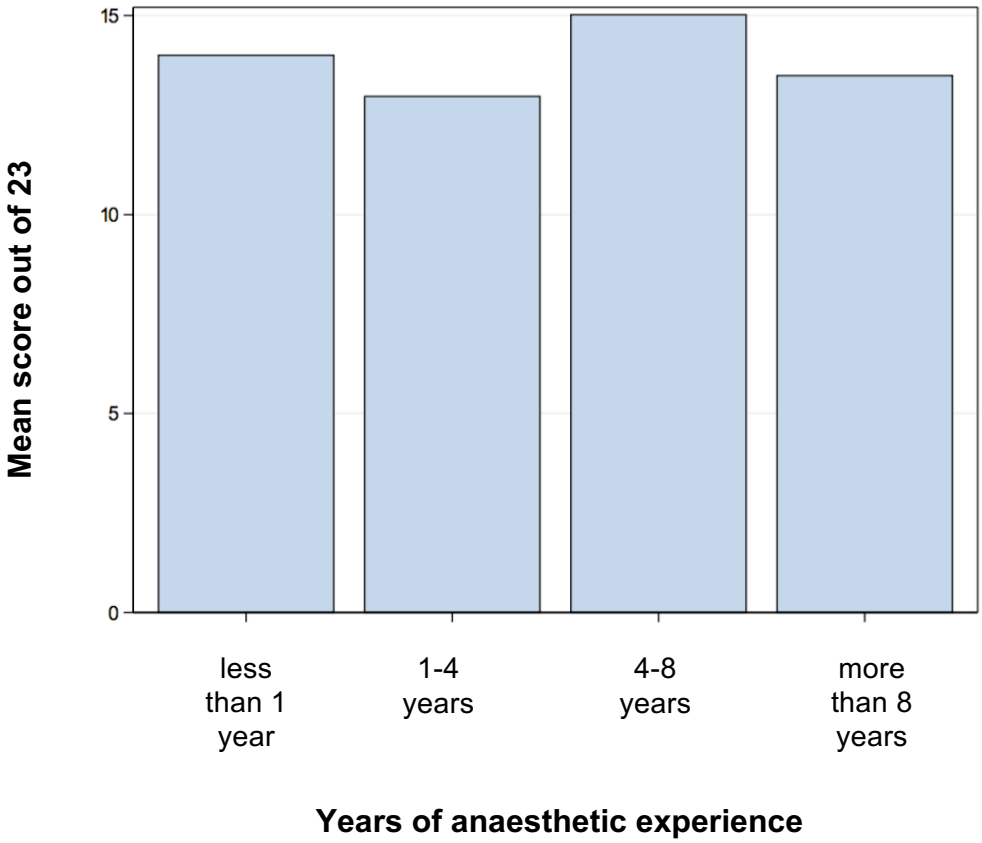

Figure 4.5 Mean score achieved as a function of years of anaesthetic experience

4.2.4 To determine if there is an association between knowledge of South African Law pertaining to informed consent with years after graduation from medical school

The median category in the sample of anaesthetists was 3 with a range of 1-4. This means that the median category regarding years after graduation from medical school was 8-12 years since graduating from medical school, with a range that extended from less than 4 years to greater than 12 years.

In the question that tested The Choice of Termination of Pregnancy Act No. 92 of 1996, the correlation coefficient = -0.2468 (p = 0.0013). This means that the greater the number of years after graduating from medical school, the poorer the score on this question.

Regarding the question that tested The Mental Health Care Act No. 17 of 2002, the correlation coefficient = -0.1705 (p = 0.0276).

This means that the greater the number of years after graduating from medical school, the poorer the anaesthetist fared on this this question.

Lastly, a negative correlation was also seen on the question that tested The Sterilisation Act No. 44 of 1998 (amended 2005), with a correlation coefficient = 0.1969 (p = 0.0108). This means that the greater the number of years after graduation from medical school, the worse the anaesthetist scored on this question.

Overall there was no statistically significant relationship that existed between years after graduating from medical school and mean score (p = 0.8815).

Figure 4.6 graphically depicts mean score as a function of years after graduating from medical school. The highest mean score was achieved by anaesthetists who were less than 4 years after graduating from medical school, followed by those 8-12 years after graduating, then those 4-8 years after graduating, and lastly by those more than 12 years after graduating.

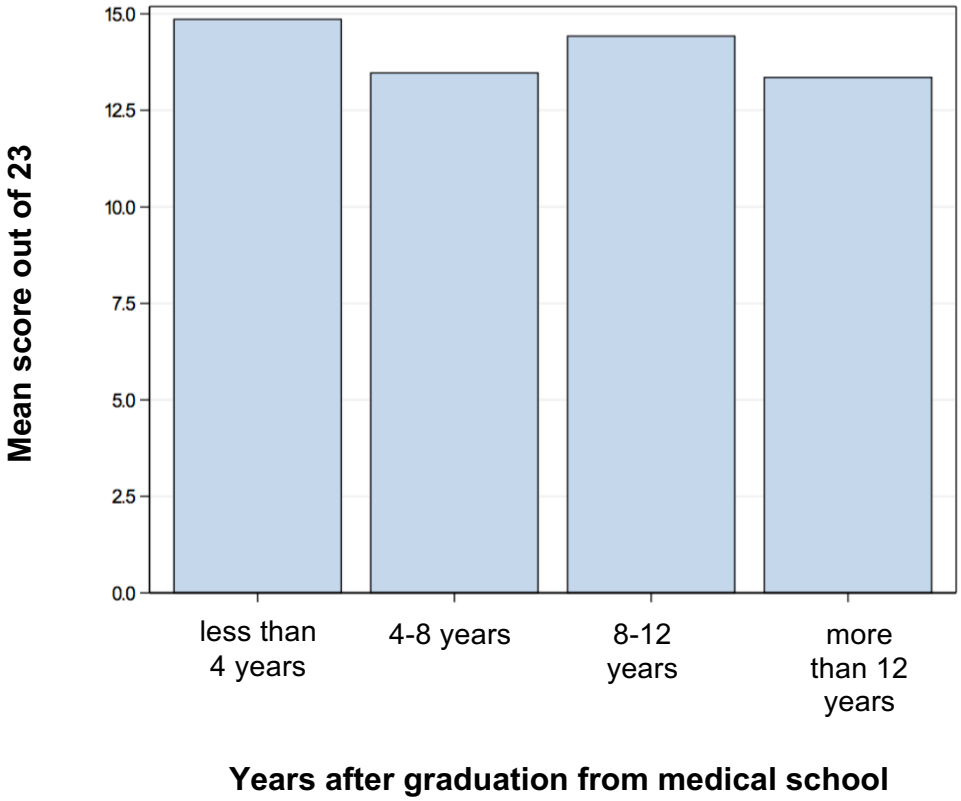

Figure 4.6 Mean score achieved as a function of years after graduation from medical school

4.2.5 To compare knowledge of South African Law pertaining to informed consent between anaesthetists who have had formal postgraduate teaching (course/symposium/CPD accredited lectures) on informed consent and those who have not had such teaching.

Two statistically significant comparisons were found:

1. The first is between the score achieved on the questions that tested The Children's Act No. 38 of 2005. The correlation coefficient = -0.2045 (p = 0.0080). This means that those who had not had formal postgraduate teaching fared worse than their counterparts who had attended formal teaching.
2. The second is between the overall mean score and attendance at formal postgraduate teaching on consent. Here, the correlation coefficient = 0.1861 (p = 0.0161). This means that those who had not had formal

postgraduate teaching fared worse and had a lower mean score than those who had attended formal postgraduate teaching.

Seventy- six anaesthetists had attended formal postgraduate training on informed consent and scored a mean of 14.41 points (SD= 2.95). Out of 167 anaesthetists, 91 had not attended formal postgraduate training on informed consent and the mean score in this group was 13.33 (SD= 2.78). The difference in the mean scores between the two groups was 1.08 (SD= 2.86), showing that those who had attended formal training fared better. This difference was shown to be statistically significant using the Wilcoxon Mann Whitney U Test (p= 0.0166).

The data relating the number of correct scores versus whether the anaesthetist undertook postgraduate teaching followed a normal distribution. This was confirmed by conducting a Shapiro Wilk Test.

4.3 Discussion

WITS anaesthetists' knowledge on South African Law pertaining to informed consent is not adequate.

No pass mark was assigned to this questionnaire, as it is, in the author's opinion, not sufficient for one's knowledge of the law to be anything less than 100%. Despite this, an overall average score of 60.09% implies that there are gaps in knowledge regarding approximately 40% of the law. Any room for error leaves room for litigation. While no studies could be found that specifically dealt with anaesthetists' knowledge of law for informed consent, either locally or internationally, similar knowledge based studies to assess the consent process have also found that doctors' knowledge in this regard is not adequate. In particular, a South African study by Naidu and Gopalan (4) found that the consent process was not only "substandard" but also "legally indefensible".

A study by Ashraf et al (33) revealed considerable shortcomings in doctors' knowledge of surgical informed consent. The same study revealed that junior doctors' knowledge was poorer than that of their more senior counterparts and this is particularly problematic as they are often the ones tasked with obtaining consent. The authors suggest that inadequate experience and/or teaching are the cause of this deficiency. In addition, they strongly recommend further education in this regard.

Leclercq et al (11) found that the knowledge of the surgical informed consent process in the Netherlands was suboptimal, and this was put down to inadequate training.

A discussion around the shortcomings of the anaesthetists' knowledge may elucidate reasons why the overall questionnaire scores are so poor. Therefore, a discussion around the questions, grouped by act tested follows below.

4.3.1 The Choice of Termination of Pregnancy Act No. 92 of 1996

Knowledge of this act was tested by a single question, number 1. The statistically significant negative correlation between years after graduation from medical school and the score on this question, is likely, in the author's opinion, due to anaesthetists having little involvement overall in the termination of pregnancy process, as an anaesthetic is seldom required for these procedures, and consequently, anaesthetic doctors are less familiar with the act that governs this process. Further, in the author's opinion, the reason the knowledge of this act is poorer with increasing number of years since graduation is likely because more junior doctors may still possess knowledge from medical school, internship and community service and from their interaction with obstetrics and gynaecology patients in the outpatient departments and wards, and with increasing time away from this discipline, these doctors may lose their knowledge of this law as they focus on more anaesthetic-applicable laws.

4.3.2 The Children's Act No. 38 of 2005

As this act is very broad in terms of content, it lends itself to many scenarios that anaesthetists are commonly presented with in theatre. Five questions in the questionnaire tested this act.

The most interesting finding was there being very little consistency in the knowledge of this act, as evidenced by widely varying scores. Knowledge of this same act produced the highest score in the questionnaire as a whole (question 7.1) and also the lowest score in the questionnaire as a whole (question 6.1).

Of particular mention is question 7.1 which tested whether anaesthetists knew that, according to The Children's Act No. 38 of 2005, a 12-year-old mother is allowed to provide consent for medical and surgical treatment of her own child, but that she should acquire the assent of the person who has parental responsibility over her. This was exceptionally well answered, with 152 of 167 anaesthetists answering correctly, suggesting sound knowledge in this regard.

Those who answered this question correctly were mostly career medical officers/consultants, those who had at least 1-4 years of anaesthetic experience,

anaesthetists who were 8-12 years after graduation from medical school and had not had postgraduate teaching on informed consent.

Question 6.1 tested whether anaesthetists knew that, according to The Children's Act No. 38 of 2005, a doctor must act in the best interest of Jehovah's witness child who is less than 12 years old. This means providing an emergency life-saving blood transfusion to the child, despite the parents' refusal to provide consent for this.

Only 32 anaesthetists out of 167 answered this question correctly, suggesting that anaesthetists are not well versed in law stipulated by this act. Anecdotally, it suggests that perhaps common clinical practice is to apply for and obtain a court order to allow the blood transfusion, as 100 candidates chose this option as their correct answer.

With regard to this question in particular, those who answered correctly were career medical officers/consultants, with 4-8 years of anaesthetic experience, were 4-8 years since graduation from medical school, and had not had formal postgraduate training on informed consent.

Additionally, the higher the anaesthetist's professional designation and the greater the years of anaesthetic experience, the better they fared in the questions that tested this act. Those who had not had formal post graduate teaching fared poorer than those who had teaching, which was the expected trend.

This suggests that those doctors who were more senior, who had more anaesthetic experience, and who had attended formal teaching at a postgraduate level on informed consent, had a better command of the laws stipulated by this act. This makes sense considering that anaesthetists work with paediatric surgical patients on a daily basis and become more familiar with the contents of this act as a result of continuing experience and training.

4.3.3 The National Health Act No. 61 of 2003

The two questions that tested this act found that the higher the anaesthetist's professional designation, the better the score.

The questions were consistently answered, except for part 5.1, where the score was significantly lower than for the rest of the questions that tested this act. This tested the specific sequence of gaining consent from someone other than the patient, when the patient is incapable of doing so, as delineated by the act. It is interesting to note that most anaesthetists (98 out of 167) chose the incorrect option (d), suggesting that most thought that the spouse/partner should be contacted first, followed by an adult child, a parent, grandparent, a person authorised by law or a court order and lastly a proxy mandated in writing. This suggests that anaesthetists are not familiar with this part of the act at all, and, in the author's opinion have just applied what to them seems to be "common sense", as opposed to the strictly ordered sequence stipulated by the law.

Most anaesthetists who answered correctly were those who were career medical officers/consultants, with 4-8 years of anaesthetic experience, 8-12 years after graduation from medical school and who had not had formal teaching on informed consent at a postgraduate level, suggesting that time working with patients had sufficed for them to have an adequate grasp of the law.

Fisher-Jeffes et al (32) note in their study conducted in the United Kingdom, specifically focusing on British Laws that govern the consent- taking practices in children, that doctors need to increase their knowledge on who is legally allowed to provide consent. This conclusion is reflected in the South African context, based on the data from our study.

4.3.4 The Mental Health Care Act No. 17 of 2002

Question 4 tested knowledge of this act.

The negative correlation between years after graduation from medical school and knowledge of this act means that with anaesthetists' increasing years after graduation from medical school, knowledge of this act decreased.

This is an expected finding, as anaesthetists do not interact with mental health care patients that require surgery on a regular basis. The further they are in terms of time after graduating from medical school, the more likely the chances of their knowledge fading as a result. Anaesthetists who do come across surgical mental health care patients are generally there to provide an anaesthetic service for electroconvulsive therapy. Given this fact it is quite interesting to note that even though knowledge of this act declined with years after graduation, as would be expected, this knowledge is still sound, as evidenced by the number of correct answers for this question.

4.3.5 The Sterilisation Act No. 44 of 1998 (amended 2005)

Knowledge of this act was tested by one question.

While most anaesthetists correctly answered that an 18- year old female may consent to a sterilisation, only half of the anaesthetists knew the name of the act being tested. Most did know that an 18- year old mentally impaired patient may have a sterilisation if her parent/guardian/curator/spouse provides consent after a healthcare professional panel has been convened by the head of hospital to consider the case.

The only statistically significant finding was that there was a negative correlation between years after graduation from medical school and score on this act. This may be because, as anaesthetists gain more experience, they are less likely to be involved in obstetrics and gynaecology cases, or perhaps are more likely to rather provide an anaesthesia service for more complex obstetrics and gynaecology cases. Reduced exposure to simple sterilisation procedures would result in a diminished experience and knowledge level with regard to the intricacies of informed consent in this arena.

4.3.6 Summary and comparison to existing literature

With regard to this study's questionnaire results, anaesthetists' knowledge of South African Law pertaining to informed consent, is lacking. For comparative purposes, a similar type of study on Croatian doctors, knowledge of the legal requirements for informed consent was also deemed inadequate in a study by Jukic et al (10).

This finding was echoed by Gupta et al (9) who found that the knowledge of informed consent amongst dentists in India was inadequate and further training would be needed.

In our study, there were only two statistically significant correlations with mean questionnaire score: that those with a higher professional designation and those who have attended formal postgraduate teaching on informed consent achieved greater test scores, implying that these two factors positively influenced level of knowledge.

Less than half of the anaesthetists had attended formal postgraduate teaching on informed consent.

The average total score achieved was higher in the group that had attended formal postgraduate teaching on informed consent, compared to those who had not attended any postgraduate teaching on consent. In terms of overall score achieved, both groups achieved the same minimum score, but the maximum score achieved was higher in the group who had attended formal postgraduate teaching.

These findings as a whole suggest that greater seniority may improve clinical experience and knowledge. Anecdotally, this may be from seeing increasing numbers of patients, and more time to gain competence and familiarity, not only with patients and the command of anaesthesia, but also with the laws that govern the consent processes.

It is self-explanatory that attending formal postgraduate teaching on informed consent not only provides new, up to date knowledge, but also refreshes old knowledge, reflected as a higher score on the questionnaire.

Overall the mean number of correct answers was 13.8204 (SD = 2.9006). The question that achieved the highest mean score was that which tested The Mental Health Care Act, while those that achieved the overall lowest mean score were those that tested The Children's Act No. 38 of 2005.

In terms of the results, in rank order, from highest mean score to lowest mean score, was The Mental Health Care Act No. 17 of 2002; The Choice of Termination of Pregnancy Act; The Sterilisation Act No. 44 of 1998 (amended 2005); The National Health Act No. 61 of 2003 and The Children's Act No. 38 of 2005.

Overall, the knowledge that WITS anaesthetists have regarding South African Law pertaining to informed consent may be suboptimal, given that, in the author's opinion, knowledge of the law should be at 100% to be considered optimal. No questions achieved full marks.

The reasons for this could be too little training at an undergraduate level, lack of a formal examination on ethics and the law, no standardised requirement for sound knowledge of the law, as evidenced by certification, and lack of continuing education on the law during postgraduate time. There is, anecdotally, a lack of interest in such subject matter, and many do not deem it important enough to focus on.

While these reasons may exist, it does not detract from the fact that lack of sound knowledge not only does a disservice to the patient, but undermines the doctor's professional integrity and also sets up a very real risk of plunging into litigation.

Anecdotally, the fact that for the most part, in daily clinical practice, the doctors who are tasked with taking consent from patients are often the junior members of the team, there is an assumption that they have sufficient knowledge from an undergraduate level to accurately do so. However, one should not assume that this "rite of passage" so to speak ensures one having acquired the knowledge of the applicable laws contained in the acts indefinitely. Knowledge is often only reliable if made use of or refreshed frequently.

Chima found similar results in his South African study, which showed that there was a gap in knowledge of law and regulation. They note that, specifically, the

points noted in The National Health Act are not strictly adhered to, and that knowledge of age of consent for medical treatment and termination of pregnancy was not generally known by doctors. Further, they state that doctors do not adequately adhere to the legal requirements of informed consent (16) .

This study determined the responses of only anaesthetic doctors (excluding rotating interns) and determined if their knowledge of the law was up to standard. No identifying information such as gender was collected, while the study by Chima collected data from doctors from a range of specialties, included interns, and surveyed responses from nurses and patients as well. Furthermore, more demographic data including gender for example, was also collected (22).

The main differences between the study by Naidu and Gopalan (4) and this study was that Naidu and Gopalan looked at the opinions, attitudes and skills of anaesthetic doctors about their daily clinical practice and how they obtain informed consent for adult patients that undergo anaesthesia, as opposed to their knowledge of South African Laws that underlie informed consent for all patients, including adult and paediatric patients. Their study was done on anaesthetic doctors who were employed in the public sector in the eThekwini municipality in KwaZulu Natal, while our study determined the knowledge of anaesthetic doctors that work at the WITS academic hospital circuit in Johannesburg.

Furthermore, the study by Naidu and Gopalan (4) made use of electronic questionnaires, and doctors were given two months to return the questionnaire, in contrast to this study in which questionnaires were manually distributed and had to be returned after the meetings, so that the knowledge was not shared and this maintained the authenticity of the answers given. There was no room for opinion in this study, as the questions simply aimed to establish whether doctors knew the law, so there was no concern over the honesty of answers, as the questionnaires were also anonymous.

Zajdel et al (3) found in their Polish study of a similar nature that younger doctors were found to have better knowledge of medical law than their older counterparts; doctors who had more than 20 years of experience fared poorer than those with less than 10 years of experience. Overall, however, knowledge was not deemed to

be adequate, and there was a general sense that doctors were not aware of the gravity of the situation, and that legal regulations were binding. This study did not find a statistically significant association between years of experience and overall knowledge, however increasing years of experience meant a greater propensity to answering more questions correctly.

4.4 Conclusion

The knowledge of WITS anaesthetists regarding South African Law pertaining to informed consent is not adequate overall. The general trend seen is that knowledge improves with higher professional designation, years of experience and with attendance at formal postgraduate teaching on informed consent. However, large knowledge deficits are still evident.

4.5 Summary

The results of this study have been presented in this chapter and discussed as per the research objectives. The data presented include demographic data of the study population and responses to a questionnaire regarding professional designation, years of experience in anaesthesia, years after graduation from medical school, and attendance at formal postgraduate teaching on informed consent. The findings have been described and analysed using descriptive and inferential statistics.

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

CHAPTER 5: STUDY SUMMARY, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 Introduction

In this chapter, a summary of the aim and objectives, research methods and results of the study will be presented. The limitations of the study will also be discussed and recommendations made regarding future research on knowledge of South African Law applicable to informed consent. A conclusion will also be presented.

5.2 Study Summary

5.2.1. Aim

The aim of this study was to determine the knowledge of South African Law pertaining to informed consent, of anaesthetists working in the WITS Department of Anaesthesiology.

5.2.2. Objectives

The primary objective of this study was to:

- describe the knowledge anaesthetists have regarding South African Law pertaining to informed consent in ten different clinical scenarios

The secondary objectives were to:

- determine if there is an association between knowledge of South African Law pertaining to informed consent with years of anaesthetic experience.
- determine if there is an association between knowledge of South African Law pertaining to informed consent with number of years after graduation from medical school.
- compare knowledge of South African Law pertaining to informed consent between anaesthetists who have had formal postgraduate teaching

(course/symposium/CPD accredited lectures) on informed consent and those who have not had such teaching.

5.2.3. Summary of methodology

This study was a prospective, contextual, descriptive study on a sample that comprised of anaesthetists working in the WITS Department of Anaesthesiology.
As 30% of the department at any one time was on leave, pre-call, post call or rotating at a distant site, it was approximated that 153 of a total department of 218 anaesthetists would be available. Of these, the researcher targeted as many of the available anaesthetists as possible. It is estimated that responses would be gained from at least 60% of the available anaesthetists, which was approximately 92 anaesthetists.

This study used a convenience sampling method, as is appropriate for a descriptive study (39). Of note, a sample of anaesthetists who were in the same place at the same time was used in order to eliminate pre-empting and sharing of answers. As a result, anaesthetists attending the weekly academic meetings who were willing to participate in the study were included. Any returned questionnaires that contained incomplete or blank demographic data were excluded. A score of zero was allocated to unanswered questions. No negative marking was used.

No questionnaires pertaining to the knowledge of South African Law pertaining to informed consent were identified in the literature. To ensure face and content validity of the questionnaire, consultation was made with two independent experts in the field of bioethics and the laws regarding clinical informed consent. The final questionnaire comprised of ten clinically relevant scenario- based vignettes that each tested knowledge of a particular South African Law in the setting of informed consent.

Before distribution of the questionnaires, all sheets were numbered to keep track of completed questionnaires and to prevent reproduction of results. A response rate was calculated.

Data was collected at departmental academic meetings during September and November 2016. The researcher was present during completion of the questionnaires to assist with queries and prevent data contamination.

After gaining permission from the meeting chair, the researcher addressed the attendees with a brief introduction to the study and invited them to participate. Information letters and questionnaires were then distributed and 15-20 minutes was allocated to complete the questionnaire.

To ensure anonymity and confidentiality of the anaesthetists partaking in the study, all the questionnaires, complete and incomplete, were placed in a collection box by the participants. No identifying data was collected.

Based on the results of the study, an update on South African Law pertaining to informed consent will be presented at a departmental academic meeting.

Using Microsoft Excel 2016, data was captured onto a spreadsheet. The statistical program, SAS™(8) was used to analyse data. A *p*-value of less than 0.05 was considered significant in this study.

5.2.4. Summary of results

A total of 191 questionnaires were distributed. Of these, 7 questionnaires were not returned and 17 were excluded for being incomplete. Therefore, 167 questionnaires were included in the statistical analysis. It was found that knowledge gaps exist, based on the clinical scenarios that tested the South African laws pertaining to informed consent. This was evidenced by a mean score of 60.09%. The study showed that anaesthetists with a higher professional designation and those who had attended formal postgraduate teaching on informed consent possessed more knowledge of South African Law pertaining to informed consent, as evidenced by a statistically significant higher mean score. This highlighted the importance of attending postgraduate teaching on ethics and the law.

Interestingly, the five questions that tested knowledge of The Children's Act No. 38 of 2005 had the highest and lowest scores overall in the questionnaire, suggesting that knowledge of this specific Act is not consistent.

For ease of interpreting the results of the study, questions were grouped according to the acts they tested. Certain statistically significant correlations were found between the mean score and certain demographic data that was collected to fulfil the objectives of the study, as listed in Table 5.1.

Table 5.1 Act tested and statistically significant results

ACT TESTED	RESULT
The Choice of Termination of Pregnancy Act No. 92 of 1996	Knowledge decreased with increased years after graduation from medical school
The Children's Act No. 38 of 2005	Knowledge increased with increased professional designation, years of anaesthetic experience and attendance at formal postgraduate teaching on informed consent
The National Health Act No. 61 of 2003	Knowledge increased with increased professional designation
The Mental Health Care Act No. 17 of 2002	Knowledge decreased with increased years after graduation from medical school
The Sterilisation Act No. 44 of 1998 (amended 2005)	Knowledge decreased with increased years after graduation from medical school

5.3 Limitations

Knowledge of South African Law pertaining to informed consent is integral to the practice of clinical medicine. As the study was contextual, the findings were limited to the anaesthetic doctors in the WITS Department of Anaesthesiology.

The sample size of the study, while adequately large, and certainly larger than expected, was not equally represented by anaesthetists from different professional designations. The greatest representation was from career medical officers/consultants who comprised 40% of the sample. First and third year registrars each comprised 16% of the sample, fourth year registrars comprised 13%, first year registrars 10% and second year registrars comprised the smallest proportion at 5%.

Questionnaires could have been distributed on the same day at the same time to reduce data contamination. However, the ability for the researcher to do this single handedly and to reach the required numbers of participants would have limited the size of the sample achieved.

As the study sample was a random convenience sample obtained from the anaesthetic department meetings, there was no control over who participated. Similarly, interns were excluded due to their temporary placement in the department, and as such including them would have not necessarily reflected the knowledge of the interns as a whole and may have skewed the overall results. However, it would have been interesting to assess their knowledge separately as we have seen, in the author's opinion, that interns are often the ones tasked with obtaining consent.

The grouping of categories of data corresponding to years of anaesthetic experience and years after graduation from medical school have ranges that overlap. For example, if one had exactly four years of experience, one could pick 1-4 or 4-8 years. Similarly, if one was eight years after graduating from medical school, one could have picked 4-8 or 8-12 years. The choice of group by the respondents, specifically for these two instances, and the way the data was

subsequently captured could have impacted the weighting of the results for that particular group.

While the questionnaire was reviewed by two experts in the field before being distributed to the anaesthetist sample group, it is not a standard questionnaire and may be open to misinterpretation of the questions. If this was the case, then it is possible that the question set would achieve a better, or worse, overall average score than what was represented by the questionnaire results. Furthermore, the questionnaire was not validated by someone with a legal degree.

It is plausible that a participant could be familiar with the contents of a particular act but not with the name of the act itself. In essence, it is the content of the act that is more important than the name, per se, and lack of knowledge of the name of the act would not be hindrance to the application and working of the act and as such obtaining valid informed consent. Perhaps the questions regarding the content of the act and the name could have been weighted differently. As a result, data analysis pertaining to knowledge of the names versus the content of the acts could have been different, and the picture painted by the combined data for each act could be skewed as being better or worse than it is in reality. However, it is the author's opinion that the name of the act and its content goes hand in hand, and that one cannot be familiar with the legal aspects of the act without knowing which act one was referring to, and as such they were grouped and marked as unit with equal weighting.

It could be argued that ten clinical scenarios were not sufficient to test full knowledge of this complex topic however the ten vignettes were comprehensive and tested the knowledge of the acts extensively.

Some knowledge-based studies have post-test teaching on the subject being investigated and a follow up questionnaire is then redistributed at a later to determine if there has been knowledge retention. As anonymity was ensured, this would be difficult to conduct. It would not have been feasible to compare the pre- and post- test questionnaire data to determine whether there was knowledge retention.

5.4 Recommendations

5.4.1 Clinical practice

Anaesthetists at WITS should be reminded of the South African Laws pertaining to informed consent by means of informative lectures or workshops. WITS anaesthetists should ensure that they are all up to date on the current South African Laws that apply to their consent taking practices for cases taken to theatre.

All anaesthetists should ensure that they attend formal postgraduate teaching on informed consent and attain appropriate certification of such.

The MPS in South Africa have published clear and clinically relevant documents with all the pertinent and relevant South African Laws that are applicable to clinical practice and for the correct and legally defensible acquisition of informed consent (2). WITS anaesthetists should all familiarise themselves with the information provided on the MPS website and in their casebooks.

Posters delineating key aspects of the law pertaining to informed consent could be put up in the anaesthetic department and inside operating theatres, for quick reference.

5.4.2 Further research

Should the abovementioned recommendations be put into practice in the WITS Department of Anaesthesiology, further research can be undertaken to determine the effectiveness of the interventions on knowledge.

This is an excellent opportunity for interdepartmental, national and international collaboration, and further research on this topic should be initiated. Investigating the knowledge of the law in the anaesthetics, surgical, medical and paediatric departments in South Africa and abroad should be undertaken, and the results of a comparison of knowledge between departments would be very interesting.

5.5 Conclusion

The knowledge of WITS anaesthetists, regarding South African Law pertaining to informed consent is inadequate.

The attainment of informed consent from the patient is a constitutionally protected right in our country (16). The consent of the patient is required for any lawful medical intervention, and this is a sanctioned part of South African law (16).

While it is not the task of the anaesthetist to acquire surgical informed consent on a regular basis, consent for anaesthesia is implicit in this practice and it is the duty of the anaesthesia provider to ensure that consent is legally valid. Inappropriately or incorrectly taken consent, is legally indefensible.

By making anaesthetists aware of their knowledge deficits, it is possible to educate the doctors and to encourage them to maintain up to date knowledge and to adhere to published, binding legal guidelines, to provide the best possible service to the patient and to prevent being confronted by the law.

REFERENCES

1. National Health Act No. 61 of 2003 Cape Town: Government Gazette; 2003 23 July 2004. 94]. Available from: http://www.gov.za/sites/www.gov.za/files/a61-03.pdf. [Accessed on: 25 May 2016]

2. Anthony S. Consent To Medical Treatment in South Africa: an MPS guide: 2010. 2010; 44]. Available from: http://www.medicalprotection.org/southafrica/advice-booklets/consent-to-medical-treatment-in-south-africa-an-mps-guide. [Accessed on: 20 May 2016]

3. Zajdel J, Zajdel R, Kuna P. Knowledge of medical law amongst doctors of internal diseases. International Journal of Occupational Medicine and Environmental Health. 2013;26(2):242-56.

4. Naidu S, Gopalan P. The Perspectives of eThekwini public service anaesthetic doctors on the informed consent process for anaesthesia. South African Journal of Anaesthesia and Analgesia. 2013;19(2):96-101.

5. Bown S. Counting the cost of litigation South Africa: MPS; 2012. Available from: http://www.medicalprotection.org/. [Accessed on: 29 May 2016]

6. World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects Brazil: World Medical Association 64th General Assembly; 2013 October 2013. 1964. Available from: http://www.wma.net/en/30publications/10policies/b3/17c.pdf. [Accessed on: 28 May 2016]

7. Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa Pretoria, South Africa: Department of Health; 2006. Available from: http://www.witshealth.co.za/Documents/South African Good Clinical Guidelines.pdf. [Accessed on: 28 May 2016]

8. Statistical Analysis System (SAS)™ University Edition Copyright © 2012-2016. Version 9.04 ed. Cary, NC, USA: SAS Institute Inc.; 2016.

9. Gupta VV, Bhat N, Asawa K, Tak M, Bapat S, Chaturvedi P. Knowledge and attitude toward informed consent among private dental practitioners in Bathinda City, Punjab, India. Korea Centers for Disease Control and Prevention. 2015;6(2):73-8.

10. Jukic M, Kvolik S, Kardum G, Kozina S, Juraga AT. Knowledge and Practices of Obtaining Informed Consent for Medical Procedures among Specialist Physicians: Questionnaire Study in 6 Croatian Hospitals. Croatian Medical Journal. 2009;50:567-74.

11. Leclercq WK, Keulers BJ, Houterman S, Veerman M, Legemaate J, Scheltinga MR. A survey of the current practice of the informed consent process in general surgery in the Netherlands. Patient Safety in Surgery Journal. 2013;7(4):1-7.

12. MPS. MPS Guide to Ethics A Map for the Moral Maze South Africa South Africa: Medical Protection Society; 2013. Available from: http://www.medicalprotection.org/. [Accessed on: 28 May 2016]

13. Tyson P. The Hippocratic Oath Today: 2003. Available from: http://www.pbs.org/. [Accessed on: 20 May 2016]

14. Beauchamp TL, Childress JF. Principles of Biomedical Ethics New York: Oxford University Press; 2009. Available from: http://www.nursingworld.org/. [Accessed on: 21 December 2016]

15. Houghton DJ, Williams S, Bennett JD, Back G, Jones AS. Informed consent: patients' and junior doctors' perceptions of the consent procedure. Clinical Otolaryngology and Allied Sciences. 1997;22(6):515-8.

16. Chima SC. Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: an empirical study. BioMed Central Medical Ethics. 2013;14(1):1-17.

17. Butts JB, Rich KL. Nursing ethics across the curriculum and into practice Sunbury, Massachusetts: Jones and Bartlett; 2008. Available from: http://www.nursingworld.org/. [Accessed on: 21 December 2016]

18. Merriam Webster Dictionary. Available from: http://www.merriam-webster.com/. [Accessed on: 22 December 2016]

19. The National Bill of Rights: Government of the Republic of South Africa; 1996. Available from: http://www.gov.za/. [Accessed on: 24 August 2016]

20. National Health Bill Cape Town: Government of South Africa; 2002. Available from: http://www.gov.za/. [Accessed on: 24 August 2016]

21. Children's Act 38 of 2005 Cape Town: The Presidency of the Republic of South Africa; 2006. Available from: http://www.gov.za/. [Accessed on: 24 August 2016]

22. Seeking Patients' Informed Consent: The Ethical Considerations HPCSA Booklet 9 Pretoria: HPCSA; 2009. Available from: http://www.hpcsa.ac.za/. [Accessed on: 24 August 2016]

23. Choice of Termination of Pregnancy Act No. 92 of 1996 Cape Town: Government of South Africa; 1996. Available from: http://www.gov.za/. [Accessed on: 17 October 2016]

24. J Mturi A. Child-headed households in South Africa: What we know and what we don't. Development Southern Africa. 2012;29(3):506-16.

25. Sterilisation Act No. 44 of 1998 Cape Town: Government of South Africa; 1998. Available from: http://www.gov.za/. [Accessed on: 16 September 2016]

26. Sterilisation Amendment Act No. 3 of 2005 Cape Town: Government of South Africa; 2005. Available from: http://www.gov.za/. [Accessed on: 16 September 2016]

27. Watch Tower Bible and Tract Society of Pennsylvania: 2016. Available from: http://www.jw.org/. [Accessed on: 22 December 2016]

28. Caine N, Zybrands K. The Challenges of Treating Jehovah's Witnesses: Medical Protection Society; 2014. Available from: http://www.medicalprotection.org/. [Accessed on: 23 July 2016]

29. HPCSA. Guidelines for Good Practice in Health Care Professions Ethical Guidelines for Good Practice in The Health Care Professions Ethical Guidelines for Good Practice With Regard To HIV Pretoria: HPCA; 2008. Available from: http://www.hpcsa.co.za/. [Accessed on: 16 September 2016]

30. Mental Health Care Act 17 of 2002 Cape Town: Government of South Africa. Available from. [Accessed on: 16 September 2016]

31. Jackson E, Warner J. How much do doctors know about consent and capacity? Journal of the Royal Society of Medicine. 2002;95(12):601-3.

32. Fisher-Jeffes L, Barton C, Finlay F. Clinicians' knowledge of informed consent. Journal of Medical Ethics. 2007;33(3):181-4.

33. Ashraf B, Tasnim N, Saaiq M, Uz-Zaman K. An audit of the knowledge and attitudes of doctors towards Surgical Informed Consent (SIC). International Journal of Health Policy Management. 2014;3(6):315-21.

34. Saltstone SP, Saltstone R, Rowe BH. Knowledge of medical-legal issues Survey of Ontario Family Medicine Residents. Canadian Family Physician. 1997;43:669-73.

35. Hariharan S, Jonnalagadda R, Walrond E, Moseley H. Knowledge, attitudes and practice of healthcare ethics and law among doctors and nurses in Barbados. BioMed Central Medical Ethics. 2006;7(7):1-9.

36. Peters C. Consenting to medical treatment: legal requirements vs medical practice. Are healthcare providers exposing themselves to potential legal action? [abstract]. New Zealand Journal of Medicine. 2009:50-9.

37. Haberko J, Kopaczynska Z, Talikowska E, Pawelczyk L, Jedrejczak P. [Awareness of basic medical law standards among doctors and patients in Poland] [abstract]. Przeglad lekarksi. 2008:237-40.

38. Brink H, van der Walt C, van Rensburg G. Fundamentals of Research Methodology for Healthcare Professionals. Ristić D, editor. Cape town: Juta & Company Ltd; 2012.

39. Burns N, Grove SK. The Practice of Nursing Research. Henderson L, Robertson R, editors. Missouri: Saunders Elsevier; 2009.

40. Polit DF, Beck CT. Sampling in Quantitative Research. In: Surrena H, editor. Nursing Research Generating and Assessing Evidence for Nursing Practice. International Edition (Ninth) ed. China: Lippincott Williams & WIlkins; 2012.

41. Evans SC, Roberts MC, Keeleyb JW, Blossoma JB, Amaroa CM, Garciaa AM, et al. Vignette methodologies for studying clinicians' decision-making: Validity, utility, and application in ICD-11 field studies. International Journal of Clinical and Health Psychology. 2015(15):1-11.

42. Moss E. Multiple choice questions: their value as an assessment tool. [abstract]. Current Opinion in Anaesthesiology. 2001:661-6.

43. The University of Texas at Austin Faculty Innovation Centre: Multiple Choice Questions Austin, Texas: University of Texas at Austin; 2016-2017. Available from: https://facultyinnovate.utexas.edu/teaching/check-learning/question-types/multiple-choice. [Accessed on: 27 February 2017]

44. The MiniTab Blog: 2016. Available from: http://www.minitab.com/. [Accessed on: 23 February 2017]

45. Statistics Solutions: 2016. Available from: http://www.statisticssolutions.com/. [Accessed on: 27 February 2017]

46. Botma Y, Greeff M, Mulaudzi F, Wright S. Quantitative Research. In: Merrington D, editor. Research in Health Sciences. Cape Town: Pearson Education South Africa 2010.

APPENDIX 1: Ethics approval

R14/49 Dr Anisah Ismail Mamoojee

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160685

NAME: (Principal Investigator)	Dr Anisah Ismail Mamoojee
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital Charlotte Maxeke Johannesburg Academic Hospital Rahima Moosa Mother and Child Hospital, Helen Joseph Hospital Wits Donald Gordon Medical Centre
PROJECT TITLE:	Anaesthestits' Knowledge of South African Law Pertaining to Informed Consent
DATE CONSIDERED:	24/06/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Ahmad Alli
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	20/07/2016

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 June and will therefore be due in the month June each year.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 2: Graduate Studies Committee approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

24 August 2016
Person No: 0600046G
PAG

Dr Al Mamoojee
P O Box 250
Crown Mines
2025
South Africa

Dear Dr Mamoojee

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Anaesthetists' knowledge of South African law pertaining to informed consent* 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 3: Participant information letter

Dear Colleague,

Hello, my name is Anisah, and I am a registrar in the WITS Department of Anaesthesiology. I would like to invite you to participate in my research study titled, “Anaesthetists’ Knowledge of South African Law Pertaining to Informed Consent”

My study aims to determine the knowledge that anaesthetists at WITS have regarding South African Law that pertains to informed consent. Doctors specialising in anaesthesia are expected to know the appropriate laws that underlie the correct acquisition of informed consent. It is unclear if anaesthetists working in the WITS Department of Anaesthesiology have a sound working knowledge of these laws. I would like to evaluate this knowledge by means of a self-administered questionnaire.

Your participation is voluntary. After you have read this information sheet you may decide if you would like to participate. If you would like to participate, please fill in the questionnaire. Your consent will be implied on completion of the questionnaire. All information will be confidential and anonymity will be maintained as no personal information will be acquired from you. There will be no penalty for not participating in my study. Withdrawal from my study will be allowed at any time without repercussions.

All questionnaires whether complete or not, should be deposited into the box supplied during the meeting. The questionnaires are numbered for practical purposes to prevent reproduction of information during the data capture process. No participant will be identifiable by the numbering system.

The questionnaire is composed of 10 multiple choice questions each with a single correct answer. Some questions are in two or three parts. The questionnaire will be scored out of a total of 23. Negative marking will not be applied. It should not take longer than 15-20 minutes to complete and participants are encouraged not

to share the information, as this will lead to an inaccurate representation of the study aims.
No incentives will be provided for the completion of the questionnaire. Identifying the current knowledge of South African Law within the department will assist in our continued professional development and reduce variation in practice regarding situations where it is important for the anaesthetist to acquire, or assess validity of informed consent.

Confidentiality will be ensured as only my supervisor and I will have access to the completed questionnaires. Once data collection is complete, you are welcome to contact me if you would like to know the correct answers to the questions. The results of my study will also be made available once it is complete.

The results of this study will be written up as a research report to be handed in to the Faculty of Health Sciences at the University of the Witwatersrand in order to fulfil my Master of Medicine (MMed) in Anaesthesiology degree. This study may also be published as conference proceedings and as a journal article.

Before completion of this questionnaire, please ensure that you understand the above information. I greatly appreciate your time. If you have any questions regarding this study, please direct them to:

- Anisah Mamoojee (researcher): 082 767 6747
- Professor Cleaton-Jones (chairperson of the HREC): (011) 717-1234

Thank you
Yours Sincerely,
Anisah Mamoojee

APPENDIX 4: Questionnaire: Anaesthetists' knowledge of South African Law pertaining to informed consent

SECTION 1:

Please provide the following information by placing an 'x' in the appropriate box:

Professional designation:

- Medical officer ☐
- Registrar 1st year ☐
- Registrar 2nd year ☐
- Registrar 3rd year ☐
- Registrar 4 years or more ☐
- Career medical officer or consultant ☐

	< 1 year	1-4 years	4-8 years	>8 years
Years of experience in anaesthesia				

	< 4 years	4-8 years	8-12 years	>12 years
Years since graduation from medical school				

Have you attended formal postgraduate teaching (course/symposium/CPD accredited lectures) on informed consent?

Yes ☐

No ☐

SECTION 2:

Question 1

Indicate the correct answer with an 'x' in the appropriate box provided. There is one correct answer per question.

An 11-year-old girl presents to the clinic requesting a termination of pregnancy.

1.1 Which one of the following is correct?

a) She may not consent to the procedure.

b) She may consent to the procedure. Her parent/guardian is required to provide assent to the procedure.

c) She may consent to the procedure. Her parent/guardian is not required to provide assent to the procedure.

d) She may consent to the procedure but her parent/guardian is required to give consent to the procedure as well.

a	**b**	**c**	**d**

1.2 Knowledge of which act is being tested in the above scenario?

a) Children's Act

b) Child Care Act

c) Choice of Termination of Pregnancy Act

d) National Health Act

a	**b**	**c**	**d**

Question 2

A 13-year-old girl presents to the clinic requesting an HIV test

2.1 Which of the following is correct?

a) She may consent with proper pre-and post-test counselling.

b) She may consent with proper pre-and post-test counselling. Her parents are required to provide consent as well.

c) She may consent to the procedure with proper pre-and post-test counselling. Her parents are required to provide assent as well.

d) She cannot consent to the procedure.

a	**b**	**c**	**d**

2.2 Which law is the above scenario testing?

a) Children's Act

b) Child Care Act

c) Health Professions Amendment Act

d) National Health Act

a	**b**	**c**	**d**

Question 3

You have provided a general anaesthetic to a 49-year-old male patient who presented to theatre for an emergency fracture reduction. After inserting a second intravenous line intraoperatively, you accidentally prick yourself with the contaminated needle. You check his file and his HIV status is not documented. He is wasted and has oral thrush. When he awakens from anaesthesia and is fully alert, he tells you he does not know his HIV status. You fully explain the situation to him and counsel him well. He refuses to provide his consent to an HIV test despite this.

3.1 Which of the following is correct?

a) You may draw a blood sample on the pretence of testing for another parameter and run the HIV test at the lab without the patient's knowledge or consent.

b) You may test the patient without his informed consent if an existing blood sample is available.

c) You ask for the patient to be restrained and proceed to draw the blood for the HIV test.

d) You assume the patient to be HIV positive and start taking post exposure prophylaxis.

a	**b**	**c**	**d**

The same patient in the above scenario is transferred intubated and ventilated to ICU postoperatively.

3.2 How would you attempt to get consent for the HIV test in this situation?

a) You take the blood sample anyway as he is intubated and he won't know about it when he wakes up in ICU.

b) You attempt to get proxy consent by a person legally able to give consent.

c) You attempt to get consent from the head of the orthopaedic unit the patient belongs to.

d) You attempt to get consent from the CEO of the hospital.

a	**b**	**c**	**d**

Question 4

A depressed and suicidal 57-year-old female is admitted by the psychiatry department. The registrar calls you to book the patient for an electroconvulsive therapy session the following day. She says that the patient is refusing to give consent. She says in this circumstance consent is not required as she is not of sound mind to understand the benefits of the procedure.

4.1 Which of the following is correct?

a) You agree to proceed without the patient's informed consent.

b) Consent should be obtained from a proxy, the court or a mental review board.

c) Consent should be obtained from the head of the psychiatry unit.

d) Consent should be obtained from the CEO of the hospital.

a	**b**	**c**	**d**

4.2 Which law is this in accordance with?

a) Health Professions Amendment Act

b) Mental Health Care Act

c) National Health Act

d) Primary Health Care Act

a	**b**	**c**	**d**

Question 5

An 80-year-old woman who was previously well slipped at her old age home and fractured her neck of femur. Upon examination, she is noted to be confused. She cannot give consent to an open reduction and internal fixation of her femur as she is delirious. When the orthopaedic surgeon books the case with you, he notes that he is unsure of who he should contact first to get consent.

5.1 He should attempt to contact these people, in the following order:

a) A proxy mandated in writing, a person authorised by law or a court order, the spouse/partner, the parent, the grandparent, the adult child, the brother/sister.

b) A person authorised by law or a court order, the spouse/partner, the parent, the adult child, the grandparent, the brother/sister, a proxy mandated in writing.

c) The adult child, the spouse/partner, the brother/sister/the parent, the grandparent, a proxy mandated in writing, a person authorised by law or a court order.

d) The spouse/partner, the adult child, the brother/sister, the parent, the grandparent, a person authorised by law or a court order, a proxy mandated in writing.

a	**b**	**c**	**d**

5.2 Which act is being tested in the above scenario?

a) Health Professions Amendment Act

b) Mental Health Care Act

c) National Health Act

d) Primary Health Care Act

a	b	c	d

The 50-year-old daughter of this patient is contacted and she refuses to give consent for surgery, despite being counselled about the risks and benefit of such, saying that she prefers her mum to be in bed in skin traction and does not want her to undergo any form of surgery. It is noted after a multidisciplinary team meeting that her surgery can be delayed.

5.3 Which of the following options is most appropriate?

a) The doctor may seek legal advice and apply for a court order.

b) The doctor may go ahead despite the patient's daughter's refusal on the basis that she doesn't have sufficient medical knowledge to make the correct decision.

c) The doctor may apply for consent from the CEO.

d) The patient should be approached for consent once the delirium has resolved.

a	b	c	d

Question 6

A 9-year-old child presents to theatre with a fractured tibia/fibula after being run over by a taxi while playing in the street. The child requires a blood transfusion. The child's parents inform you that they are Jehovah's witnesses. You counsel them extensively but they are adamant that they will not allow their child to be transfused or consider alternative therapy.

6.1 What is your recourse?

a) Ask the child if he is willing to have a blood transfusion and proceed with the transfusion if he agrees.

b) Accept the parents' choice and proceed as best as possible without transfusing the child.

c) You may act in the child's best interests which is to ignore the parents' wishes and proceed with the blood transfusion as this is an emergency.

d) Obtain a court order to allow a transfusion as long as it is in the best interest of the child.

a	**b**	**c**	**d**

Another 9-year-old Jehovah's Witness is booked for elective surgery which potentially will require a blood transfusion. The blood transfusion is not an emergency and the parents refuse the transfusion or alternatives.

6.2 What is your plan of action?

a) Ask the child if he is willing to have a blood transfusion and proceed with the transfusion intraoperatively as needed.

b) Accept the parents' choice and proceed as best as possible without transfusing the child intraoperatively.

c) You may act in the child's best interests which is to ignore the parents' wishes and proceed with the blood transfusion during the operation as the need arises.

d) Obtain a court order to allow for a transfusion as long as it is in the best interest of the child.

a	**b**	**c**	**d**

6.3 Which law is the above scenario testing?

a) Children's Act

b) Child Care Act

c) Health Professions Amendment Act

d) National Health Act

a	**b**	**c**	**d**

Question 7:

A 12-year-old girl brings her 4-week-old infant to paediatric OPD with symptoms of projectile vomiting. Pyloric stenosis is confirmed. The paediatric surgeon wonders if it is acceptable to get consent from the mother as she is just 12 years old, although she seems mature enough to understand the required surgical treatment.

7.1 Which of the following is correct?

a) She may consent to the medical and surgical treatment of her infant, but she should be assisted by someone who has parental responsibility over her.

b) She may not consent to the medical and surgical treatment of her infant, and her mother i.e. the infant's grandmother must provide consent.

c) She may not consent to the treatment of her infant and a court order must be obtained for consent.

d) She may not consent to the treatment of her infant and the head of the paediatric unit or the CEO of the hospital must provide consent.

a	**b**	**c**	**d**

7.2 Which law is the above scenario testing?

a) Children's Act

b) Child Care Act

c) Health Professions Amendment Act

d) National Health Act

a	**b**	**c**	**d**

Question 8

A 12-year-old child presents to hospital with her parents complaining of right iliac fossa pain and vomiting for the last 2 days. She is diagnosed with acute appendicitis requiring an appendectomy.

8.1 Which of the following is correct?

a) The child may consent to the operation if she is of sufficient maturity to do so. The parents' consent should also be obtained.

b) The child's parents must give consent to the surgery and the child may provide assent.

c) Only the child's parents are required to provide consent.

d) The child may consent to the operation if she is of sufficient maturity to do so. The parent's assent should also be obtained.

a	**b**	**c**	**d**

8.2 Which law is the above scenario testing?

a) Children's Act

b) Child Care Act

c) Health Professions Amendment Act

d) National Health Act

a	**b**	**c**	**d**

Question 9

An 18-year-old female presents to your obstetric theatre for an elective caesarean section for a twin pregnancy. She has requested a sterilisation to be performed at the same time as her caesarean section. She says she is married and her and her husband do not want more children, neither do they wish to make use of other contraceptive methods. The obstetrician has told her she is too young and she may not have a sterilisation.

9.1 What is the patient's recourse?

a) She may consent to the sterilisation.

b) She may not consent to the sterilisation due to her age.

c) She may consent to the sterilisation provided her partner gives his consent as well.

d) She may consent to the sterilisation provided her partner gives assent.

a	**b**	**c**	**d**

9.2 Which act is being tested in the scenario above?

a) Health Professions Amendment Act

b) National Health Act

c) Primary Health Care Act

d) Sterilisation Act and Amendment Act

a	**b**	**c**	**d**

An 18-year-old female with severe mental retardation and cerebral palsy is booked for a sterilisation as no other appropriate contraception can be provided. The patient will not be able to fulfil parental responsibility; nor will she develop further to make an informed decision about contraception or sterilisation.

9.3 What provisos are there for consent to be valid in terms of law?

a) The parent/guardian/spouse/curator of the patient may provide consent to the procedure after application to the head of the hospital who will convene a panel of 3 healthcare professionals to consider the case.

b) The parent/guardian/spouse/curator of the patient may provide consent to the procedure without application to the head of the hospital or the convening of a panel to consider the case.

c) Application should be made to the head of the hospital who may provide consent to the procedure after convening a panel of 3 healthcare professionals to consider the case.

d) The treating doctor can provide consent on behalf of the patient as the procedure is in the patient's best interest.

a	**b**	**c**	**d**

Question 10

A 11-year-old girl with Down's Syndrome (Trisomy 21) is booked on your Ear Nose and Throat list for tonsillectomy and adenoidectomy. She attends a learning centre every day is and seems to be of reasonable intelligence to understand the procedure.

The girl's parents are contacted. Her biological father refuses to give consent for the tonsillectomy and adenoidectomy after he is informed of the risks. He was never married to nor lived with the girl's mother. He also does not contribute to the child's upkeep. The child is fully informed of the procedure. The biological mother, however, gives her consent for the procedure.

10.1 Who can provide consent for the procedure?

a) The biological mother can give consent alone as she has full parental responsibility.

b) The biological mother and father must both consent to the procedure for it to go ahead.

c) The father's refusal negates the mother's consent.

d) Another proxy or a court order should be sought due to the parental conflict.

a	**b**	**c**	**d**

10.2 Which act is being tested in the above scenario?

a) Children's Act

b) Child Care Act

c) Mental Health Care Act

d) National Health Act

a	**b**	**c**	**d**

APPENDIX 5: Memorandum

QUESTION	CORRECT ANSWER
1.1	c
1.2	c
2.1	a
2.2	a
3.1	d
3.2	b
4.1	b
4.2	b
5.1	a
5.2	c
5.3	d
6.1	c
6.2	d
6.3	a
7.1	a
7.2	a
8.1	d
8.2	a
9.1	a
9.2	d
9.3	a
10.1	a
10.2	a

APPENDIX 6: Coding key of reference ranges for statistical analysis

Professional designation:	medical Officer	**1**
	registrar 1st year	**2**
	registrar 2nd year	**3**
	registrar 3rd year	**4**
	registrar 4th year	**5**
	career Medical Officer or consultant	**6**

Years of experience in anaesthesia	< 1 year	1-4 years	4-8 years	>8 years
	1	**2**	**3**	**4**

Years since graduation from medical school	< 4 years	4-8 years	8-12 years	>12 years
	1	**2**	**3**	**4**

Have you attended formal postgraduate teaching (course/symposium/CPD accredited lectures) on informed consent?

1 Yes

2 No

APPENDIX 7: Heads of department letters of approval

WITS UNIVERSITY

DEPARTMENT OF ANAESTHESIOLOGY
UNIVERSITY OF THE WITWATERSRAND,
JOHANNESBURG
Tel.(011)933-9334/5 / Fax (011)933-1843

FACULTY OF HEALTH SCIENCES

14 JULY 2016

Ms Zanele Ndlovu
Administrative Officer
Human Research Ethics (Medical) Committee

RE : DR ANISAH MAMOOJEE STUDENT NUMBER 0600046G

I herewith grant permission to Dr Anisa Mamoojee to conduct the study titled "Anaesthetists' Knowledge of South African law pertaining to informed consent" in the University of the Witwatersrand Department of Anaesthesiology. The proposed study entails distributing a questionnaire to doctors working in anaesthesia in Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital, Helen Joseph Hospital and Rahima Moosa Mother and Child Hospital.

With Kind Regards

Yours sincerely

PROF. A.C. LUNDGREN
CHIEF SPECIALIST AND HEAD
DEPARTMENT OF ANAESTHESIA
UNIVERSITY OF THE WITWATERSRAND

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL (CMJAH)

DEPARTMENT OF ANAESTHESIA
Area 361, CMJAH
Tel: 011 488 4344 Fax: 086 765 3477
Cell: 082 052 0765
e-mail: eeoosth@telkomsa.net

13 July 2016

Dr M Mofokeng
Clinical Director
CMJAH

Dear Dr Mofokeng

RE: DR ANISAH I MAMOOJEE – SUPPORT FOR PROPOSED RESEARCH STUDY

The proposed MMed study by Dr Anisah Mamoojee vtitled: "Anaesthetists' Knowledge of South African Law Pertaining to Informed Consent" is fully supported by the Department of Anaesthesia at Charlotte Maxeke Johannesburg Academic Hospital. The findings of this study will definitely contribute towards improving our informed consent practices in the department.

The mentioned study has been approved by the Human Research Ethics Committee of the University of the Witwatersrand subject to hospital approval.

I am looking forward to the findings of this study.

Regards,

Prof EE Oosthuizen
Clinical Head: Department of Anaesthesia
Charlotte Maxeke Johannesburg Academic Hospital

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

GAUTENG DEPARTMENT OF HEALTH
Helen Joseph Hospital
Prof E. Frohlich
HOD Anesthesiology
Tel: (011) 489-0884/0108
Fax: (011) 489-0084/0108
E mail: eva.frohlich@wits.ac.za

TO: WITS RESEARCH OFFICE **13 July 2016**

I Hereby give permission to Dr Mamoojee to collect data at the anaesthetic department as part of her MMed dissertation.

PROTOCOL NO: M160685

Project Title: Anaesthetists' Knowledge of South African Law Pertaining to Informed Consent

Kind regards

Prof. Frohlich
Principal Specialist
Clinical head of anaesthesia department
And pain management unit
HJH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

13 July 2016

Attention: Dr Anisah Ismail Mamoojee

Dear Dr Mamoojee

MMED study: Anaesthetists' Knowledge of South African Law Pertaining to Informed Consent

I hereby grant permission for the department of anaesthesia at Rahima Moosa Mother & Child Hospital to be included in your MMED study.

Kind Regards

Dr T Kleyenstuber

Acting Head: Clinical Unit - Anaesthesiology
Rahima Moosa Mother and Child Hospital