

UFS: Department Anaesthesiology

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

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Declaration of own work

I, Doctor Tarina Lourens, hereby declare that this work is of my own creation and effort. This research work will form part of the requirements for the MMed (Anaesthesiology) degree at the University of the Free State. Student number: 2003017932.

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Professor G Joubert (Department of Biostatistics, UFS)

The Ethics Committee at the UFS

Participants at the Department Anaesthesiology of the UFS

Abstract:

Doctors follow an ethical code imprinted on them from the time of Hippocrates. Practicing medicine within these ethical codes, doctors also have to practice their craft within the legal boundaries of the country and institution they inhabit.

The primary aim of the study was to investigate the current knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the University of the Free State, UFS, in June 2015. The secondary aim of the study was to determine if doctors working at the Department Anaesthesiology of the UFS complete their section of the standard surgical consent form available in the hospitals they practice in.

The study was designed as a cross sectional observational study, using self-administered questionnaires after approval by the Ethics Committee of the Faculty of Health Sciences, UFS. Data analysis was performed by the Department of Biostatistics at the UFS. The results were summarised using frequencies and percentages.

Results of the primary aim of the study indicated a poor level of understanding pertaining to the medical laws in which doctors' practice with various levels of confusion to details especially regarding the Children's Act of 2005 and the Choice on Termination of Pregnancy Act of 1996.

This study demonstrated the poor understanding of biomedical ethical concepts and how they are incorporated in the various South African laws.

This study indicated that the doctors that worked at the Department Anaesthesiology of the University of the Free State during June 2015 expose themselves to possible medical malpractice and future litigation due to lack of documentation on the informed consent form.

Abbreviations:

FS	Free State
HPCSA	Health Professions Counsel of South Africa
M.B, Ch.B.	Medicinae Baccalaureus, Baccalaureus Chirurgiae
M+M	Mortality and Morbidity
MPS	Medical Protection Society
No.	Number
SA	South Africa
TOP	Termination of Pregnancy
UFS	University of the Free State
WHO	World Health Organisation

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Chapter 1

Introduction

When doctors in South Africa treat competent patients without their consent, they violate the patients' constitutional rights and the fundamental principles of medical law. This exposes the doctor to litigation and complaints to the Health Professions Counsel of South Africa (HPCSA).^{1, 2}

Treating competent patients without their consent may be seen as a breach of contract; civil or criminal assault (a violation of bodily integrity); civil or criminal injuria (a violation of dignity or privacy) or negligence.^{1, 2, 3}

Informed consent is a well-established practice in South Africa^{1,2,4,5} and it is not only important for legal and ethical reasons but also for quality of patient care.^{2,4,6} The HPCSA has published ethical guidelines for seeking informed consent where it emphasises that the doctor-patient relationship is built on mutual trust, achieved by acknowledging the patient's autonomy to decide whether to undergo treatment or not. Informed consent may be considered to be the core of the doctor-patient relationship, particularly with the paradigm shift that has occurred from medical paternalism to a patient-centred approach.^{1, 2, 3, 4-8}

When a legal dispute arises that questions informed consent the focus shifts to the quality of the evidence and the informed consent form. The informed consent form forms the basis of this evidence.^{1, 2, 4, 6, 9-12}

The aim of this study was to determine if doctors who administer anaesthesia know the laws they work with on a daily basis and do they comply with the laws and make use of the informed consent form used by Department of Health of the Free State at the University of the Free State Complex (Universitas Hospital/ Universitas Annex/ Pelonomi Hospital) for each patient they come in contact with.

PRIMARY AIM

To test the current knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the University of the Free State (UFS) in June 2015.

SECONDARY AIMS

Determining if doctors working at the Department Anaesthesiology of the UFS complete their section of the standard surgical consent form provided in the hospitals they practice in.

In an attempt to obtain the aims as set out above this study was planned to be conducted at the Department Anaesthesiology of the University of the Free State, including all doctors that work in the Department Anaesthesiology in June 2015. The study was planned as a cross sectional observational study, making use of a self-administered questionnaire that was handed out during a Friday morning Mortality and Morbidity meeting (M+M) and included all the doctors in attendance.

Doctors working at the Department Anaesthesiology during June 2015 included the following: specialist anaesthesiologist (9), anaesthetic registrars (29), anaesthetic medical officers (2), anaesthetic Interns (8).

Ethical approval was obtained from the Ethics Committee of the Faculty of Health Sciences, UFS.

Permission to conduct the study was obtained from the Head of the Department Anaesthesiology, as well as the Head of the School of Medicine at the University of the Free State. Permission was obtained from Universitas Hospital CEO.

The study was conducted on the 5th of June 2015 at the conference room in the Department Anaesthesiology of the University of the Free State and included all doctors in attendance of the Morbidity and Mortality meeting.

The information sheet informed participants of the aim of the study as well as assuring them that all information will be handled with confidentiality and anonymously. After completion of the questionnaire the participant placed the completed questionnaires in a container that was provided to ensure it remaining anonymous.

The questionnaires were evaluated by the researcher, Dr T Lourens and data analysis was performed by the Department of Biostatistics at the University of the Free State under guidance of Professor G Joubert. The results were summarised using frequencies and presentences.

Chapter 2

Literature review

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

Introduction:

When doctors treat competent patients without their consent, they violate the patients' constitutional rights and the fundamental principles of medical law. This exposes the doctor to litigation and complaints to the HPCSA.^{1,2}

Treating competent patients without their consent may be seen as a breach of contract; civil or criminal assault (a violation of bodily integrity); civil or criminal injuria (a violation of dignity or privacy) or negligence.^{1,2,3}

Informed consent is a well-established practice in South Africa^{1,2,4,5} and it is not only important for legal and ethical reasons but also for quality of patient care.^{2,4,6} The HPCSA has published ethical guidelines for seeking informed consent where it emphasises that the doctor-patient relationship is built on mutual trust, achieved by acknowledging the patient's autonomy to decide whether to undergo treatment or not. Informed consent may be considered to be the core of the doctor-patient relationship, particularly with the paradigm shift that has occurred from medical paternalism to a patient-centred approach.^{1,2,3,4-8}

During a legal dispute the question of informed consent shifts to the quality of the evidence that is documented within the informed consent form.^{1,2,4,6,9-12}

This study was planned to investigate the legal knowledge and use of the informed consent forms for each patient by the anaesthetic providers, in accordance with the law, working at the Department of Health of the Free State, the University of the Free State Complex (Universitas Hospital/ Universitas Annex/ Pelonomi Hospital) during June 2015.

Literature review:

To treat competent patients undergoing procedures, it is important to obtain informed consent.^{1,2,6} Informed consent often fails to meet its purpose even though it is a well-established practice in South Africa.^{1,2}

The **Constitution of the Republic of South Africa No. 108 of 1996** states that The Bill of Rights in the Constitution enshrines the rights of citizens to human dignity and to freedom and security of the person.^{1,2,4,13-16} In the case of children, their interests must be of paramount importance in any matter pertaining to them.

Treating competent patients without their consent, doctors may undermine patients' trust as well as violate their rights to physical integrity, and in this manner violate their constitutional rights.^{1,2,5}

Consent is not a once-off event, but the result of on-going communication.^{2, 4, 11} Consent may take on various forms: expressed consent is normally given by patients undergoing invasive procedures, by stating that they agree to go ahead with treatment (verbal consent) or by signing a consent form (written consent). Consent is also implied by the patient's compliance eg. A patient extends his arm for the drawing of blood (implied consent).^{2, 5}

Informed consent has a dual purpose: firstly to ensure the patients right to self-determination and freedom of choice and secondly to encourage rational decision-making by enabling the patient to make an enlightened decision to accept or refuse the intervention, by looking at the benefits, risks, side-effects and alternatives to the procedure, intervention.^{1, 2, 4, 5, 12, 17}

Written consent should be taken where: the treatment or care is not the primary purpose of the investigation or examination; there may be significant consequences for the patient's employment, social or personal life; the treatment is part of a research programme." ^{1, 2, 4, 5, 12, 18}

The Medical Protection Society (MPS) guide of South Africa dictates that there are three components to valid consent: capacity, information and voluntariness.

According to Buttigieg ¹⁹ the contractual terms of reference in the consent form must state that "the service must be made clear along with its limitations, dangers, advantages and disadvantages... The consent form requires disclosure of risks and alternatives that a reasonable patient... would consider material."

Written consent should contain various forms of information to comply with the expectations of the patient and medical laws. The patient should be provided with procedure-specific information with its own significant risks and/or side effects. This procedure-specific information should include pre- and post-procedure expectations, pre- and post-procedure instructions and medical record notes.^{1, 4, 10}

Complex decisions such as surgery or other invasive procedure require a discussion of uncertainties.^{1, 2, 6} Decision-making may be shared, autonomous or paternalistic.^{1, 2, 6, 11} "Informed consent" is a legal instrument that allows individuals to define their own interests and to protect their bodily privacy. ^{1, 2, 5, 11} The presence of a signed consent form is not proof of valid consent to treatment,^{13, 16} but the evidence of the discussion of the uncertainties related to the procedure or treatment beforehand. The consent form is a vital part of record keeping in medical management and good record keeping is ensuring good practice and may enlighten circumstances if a medico-legal dispute arises in the future.

The South African court has determined how much information to relate to a patient ^{1, 2, 5, 6, 20} about risks and include all "material risks" related to the procedure or treatment, which should be told to the patient, (a material risk is defined as a risk a reasonable person in the patient's position would attach importance to, or that a patient would consider the risk to be significant, if the health care practitioner warned them about it)^{2, 7} The Informed consent form should demonstrate key points, risks and side-effects discussed.^{1, 2, 5, 6, 21, 22}

Informed consent involving minors are of specific concern, involving recent legislative changes that occurred within the Children's Act of 2005. ²³

When a lawsuit develops due to a lack of informed consent, it often occurs because the patient believes that the outcome was not a risk of the procedure that they had previously acknowledged, but due to the negligence of the doctor, or that they were not informed of the risks and side-effects of the procedure or treatment; or that they would not have had the procedure had they known about the possible outcome.^{1, 2, 24, 25}

Conclusion:

Consent normally needs to be obtained by the health care worker performing the procedure.^{1, 2, 26, 27.} The process of obtaining consent may be delegated to a health care provider, provided that they are suitably educated, trained and qualified, with sufficient knowledge to fulfil this role. (HPCSA guidelines)^{2, 26} In the case where the anaesthesiologist is unable to obtain consent personally or timeously, the health care practitioner seeks consent for the SCOPE of procedures to be performed.^{2, 12.} Informed consent is procedure-specific and are not suitable as general consent.^{1, 2, 12, 28.} The responsibility remains with the anaesthesiologist to obtain informed consent for anaesthetic related procedures.²⁸ Written consent give the proof that consent were given and what detail was discussed, this protects the doctor and the patient.^{1, 2, 9}

Informed consent is based on a multiple of South African laws, which take into account the patients competency, age and medical and social situations. Every health care provider needs to be familiar with these laws as they have direct effect on patient management and care.

LAWS:

Constitution of the Republic of South Africa No. 108 of 1996

The Bill of Rights in the Constitution enshrines the rights of citizens to human dignity and to freedom and security of the person. In the case of children, their interests must be of paramount importance in any matter pertaining to them.

National Health Act No. 61 of 2003

Section 7 protects the rights of competent health service users to consent to treatment and places a duty of health service providers to "take all reasonable steps to obtain the user's informed consent".

Section 8 stipulates that health care users have the right to participate in decisions affecting their health and treatment. Furthermore, it requires health service providers to share relevant information with users who lack the capacity to make decisions "unless the disclosure of such information would be contrary to the user's best interests".

Child Care Act No. 74 of 1983

This Act will be repealed when the Children's Act comes fully into force. It sets the age at which a minor may consent to medical treatment without parental consent at 14. The written consent of parents is required for surgical treatment of a minor.

Children's Act No. 38 of 2005

This Act sets the age of majority at 18 and the age at which a child may consent to medical and surgical treatment at 12 years. It confers on children of 12 years old or older the right to consent to HIV tests and to purchase condoms without their parents' consent.

The Act also introduced important rights protecting children from undergoing virginity tests and circumcision against their will. The *General Regulations Regarding Children* (Regulation 261) set out how the provisions of the legislation should be implemented

Section 129 (10): No parent, guardian or care-giver may refuse to assist a child with consent or withhold consent by reason only of religious or other beliefs unless the parent or guardian can show that there is a medically acceptable alternative choice to the medical or surgical procedure.

Choice on Termination of Pregnancy Act No. 92 of 1996

This legislation allows a woman of any age to have a termination of pregnancy. There is no age or maturity test.

Criminal Law (Sexual Offences and Related Matters) Amendment Act No 32 of 2007

Alleged sexual offenders may be subjected to mandatory HIV tests under this legislation.

Chapter 3

Methods:

Ethical approval was obtained from the Ethics Committee of the Faculty of Health Sciences, UFS.

Permission to conduct the study was obtained from the Head of the Department Anaesthesiology, as well as the Head of the School of Medicine at the University of the Free State.

In an attempt to obtain the aims as set out above, this study was planned to be conducted at the Department Anaesthesiology of the University of the Free State, including all doctors that work in the Department Anaesthesiology in June 2015. The study was planned as a cross sectional observational study. Making use of a self-administered questionnaire that was handed out during a Friday morning Mortality and Morbidity meeting (M+M); it included all the doctors in attendance. All documentation used in this study was handled in English.

Doctors working at the Department Anaesthesiology during June 2015 included the following: specialist anaesthesiologist (9), anaesthetic registrars (29), anaesthetic medical officers (2), anaesthetic Interns (8).

A pilot study was conducted using five General Surgery registrars to determine if the questionnaire was easy to understand and complete. After review of the results of this pilot study, it was decided that no comments or adjustment were needed and the study proceeded.

The study was conducted on the 5th of June 2015 at the conference room in the Department Anaesthesiology of the University of the Free State and included all doctors in attendance of the Morbidity and Mortality meeting.

The Information sheet informed participants of the aim of the study as well as assuring them that all information will be handled with confidentiality and anonymously. After completion of the questionnaire the participants placed the completed questionnaires in a container that was provided to ensure it remaining anonymous.

The questionnaires were evaluated by the researcher, Dr T Lourens and data analysis was performed by the Department of Biostatistics at the University of the Free State under guidance of Professor G Joubert. The results was summarised using frequencies and percentages.

Chapter 4

Results:

A total of 26 participants took part in the study with 1 participant withdrawing after question 6 related to circumcision. The questionnaire was completed by anaesthetic interns 6 (23.1%), anaesthetic registrars 15 (57.7%) and anaesthetic consultants 5 (19.2%), with no medical officers in attendance of the meeting. Table 1 demonstrates the overall response rate between the various levels of doctors working at the Department Anaesthesiology of the UFS in June 2015.

	Total Doctors	Participating Doctors	
Anaesthetic Specialist	9	5 (19.2%)	
Anaesthetic Registrars	29	15 (57.7%)	
Anaesthetic Medical Officers	2	0 (0%)	
Anaesthetic Interns	8	6 (23.1%)	

Table 1 Anaesthetic provider response rate according to level.

Demographic information distinguished between 0-5 years, 6-10 years, 11-20 years, more than 20 years post-graduation (M.B,Ch.B). The demographic information is represented in figure 1. There were 8 doctors who qualified 0-5 years previously and 11 doctors who qualified 6-10 years previously. There were 4 doctors who qualified between 11-20 years before and 3 doctors who qualified more than 21 years before.

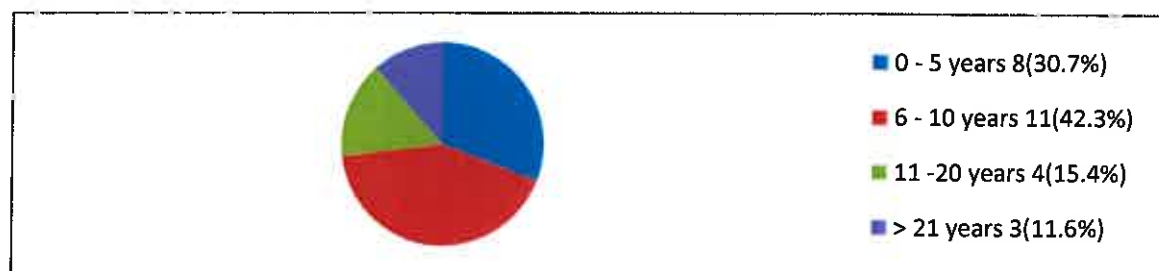


Figure 1 Demographic distinction between years post-graduation (M.B, Ch.B)

The anaesthetic consent form was “always” signed by 17 (65.4%) and “sometimes” by 9 (34.6%) doctors that administer anaesthesia at the Department of Anaesthetics of the UFS. The participants that signed the anaesthetic consent form were then asked if they added additional information to the consent form and 7 (26.9%) “always” added information, 11 (42.3%) added information “sometimes” and 8 (30.7%) admitted to “never” adding additional information. Participants were asked to indicate what information they added. There were 18 respondents to this question of which 14 (77.8%) named “anaesthetic choices”, 4 (22.2%) named the “anaesthetic risks” associated with the procedures and 7 (38.9%) named the “possible complications” associated with the anaesthetic choices and only 2 (11.1%) added additional information to the consent form.

Participants were asked to name laws in patient management. The response to this question showed a poor knowledge regarding these laws. Of the 26 participants in this study 20 (76.9%) could not name a law. Figure 2 demonstrates the various laws participants responded with that governed medical conduct. One participant named the Constitution of the Republic of South Africa No.108 of

1996 (Bill of Rights), 4 (15.4%) participants named the National Health Act No. 61 of 2003, 2 (7.7%) participants named the Child Care Act No. 74 of 1983, one participant named the Children's Act No. 38 of 2005 and one participant named the Mental Health Care Bill of 2003. There was no mention of the Choice on Termination of Pregnancy Act No. 92 of 1996, Criminal Law (Sexual Offences and Related Matters) Amendment Act No. 32 of 2007, Sterilisation Act No. 44 of 1998 or Sterilisation Amendment Act of 2005, Health Professions Act of 1974, Access to Information Act of 2000. These laws are all clearly stipulated in the MPS guide 2012 and HPCSA Booklet 2008.

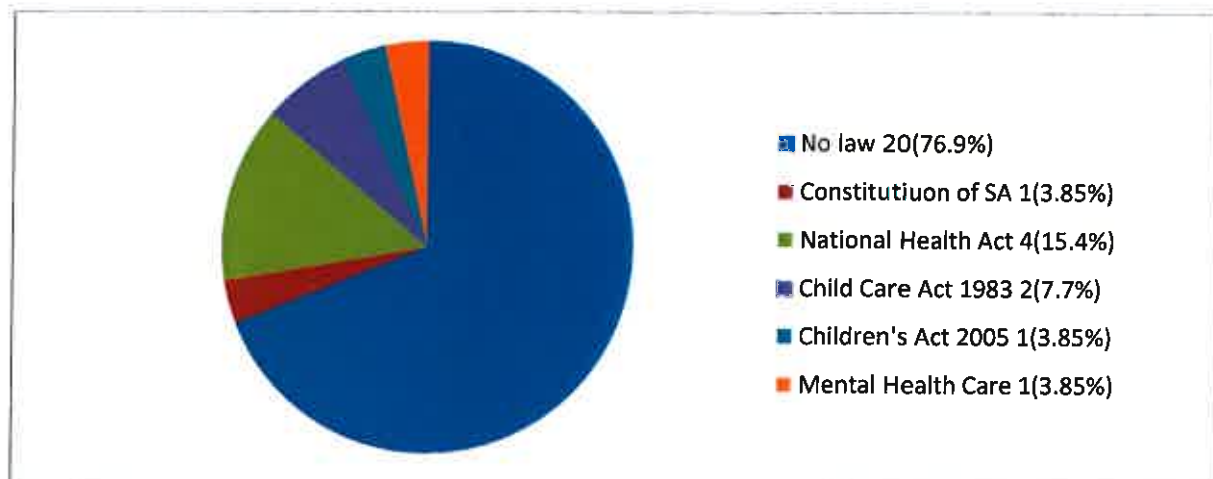


Figure 2 Medical laws named in patient management.

Participants were asked to stipulate in what order consent must be obtained in the case of a patient that is unable to give consent him-/her-self. There was no respondent that gave the correct order to obtain consent in the case that a patient was unable to give the consent.

Table 2 demonstrates that the most common order provided by 20% of the participants in descending order were as follows: consent should be obtained from the spouse firstly, followed by a parent then, brother or sister, adult child, the superintendent of the institution and lastly by a curator appointed in writing by the patient or the court.

Table 2 also demonstrates the correct order to obtain consent and the percentage of participants that mentioned them in the correct place. The correct order is as follows: firstly, the curator appointed in writing by the patient or the court, secondly if no curator was appointed consent may be obtained from a spouse, followed in descending order by a parent, adult child, brother or sister and lastly by the superintendent of the institution in the case of an emergency if all efforts were unsuccessful to obtain consent by the aforementioned.

CORRECT ORDER	Percentage in correct order (%)	Most Frequent order (20%)
Curator	0	Spouse
Spouse	4 (16%)	Parent
Parent	2 (8%)	Sibling
Adult Child	11 (44%)	Adult child
Sibling	3 (12%)	Superintendent of Institution
Superintendent of Institution	8 (32%)	Curator

Table 2 Descending order for obtaining informed consent. Illustrating the percentages in the correct order and the most frequent order provided by participants (20%).

In the case that a patient is unable to provide consent for a procedure the curator appointed in writing by the patient or the court should be approached first for consent. No participant named this option firstly but 3 (12%) named the curator as the second person to be approached for consent in such circumstances, 3 (12%) named the curator as a third choice, 2 (8%) as a fourth choice, 5 (20%) as the fifth choice and 12 (48%) named the curator as the last option for consent.

The second person to be approached in the case that a patient is unable to give consent is the patient's spouse. This option was most frequently provided as the first person to be approached by 18 (72%) of the participants, with only 4 (16%) naming the spouse as the second person to be approached in such circumstances.

The third person to be approached in the case that a patient is unable to provide consent is a parent or guardian of the patient. This option was most often chosen as the second person to be approached by 16 (64%) of participants, with only 2 (8%) correctly naming the parent or guardian as the third person to be approached.

The fourth person to be approached in the case that a patient is unable to provide consent is an adult child, with this option correctly chosen by most 11 (44%) of the participants and 2 (8%) participants that stated that an adult child should be approached second.

The fifth person to be approached in order to obtain consent for a person unable to give consent is a brother or sister of the patient. This option was given mostly 13 (52%) as the third person to be approached and only correctly named as the fifth by 3 (12%) of participants.

The superintendent of the institution should be the last person to be approached to give consent in the case where a patient is unable to give consent, after all measures were taken to obtain consent from aforementioned parties in an emergency situation. This option was mostly chosen as the second last choice by 11 (44%) of participants, 1 participant named it as the first option, 1 participant named it as the third option after a spouse and parent, with 8 (32%) correctly naming it as the last option for consent.

The following results were for questions that looked at the finer details of the various laws for obtaining consent from patients.

Participants were asked what the age of legal independence is in South Africa, i.e. the age when legal control of a parent or guardian terminates. The Children's Act No. 38 of 2005 sets the age of maturity and legal independence at 18 years old. Figure 3 demonstrates 5 (19.2%) of the participants

stated 12 years as the age of legal independence, one participant stated 14 years, 4 (15.4%) of the participants stated 16 years as the age of legal independence. Most of the participants (14 (53.9%)) stated correctly that the age of legal independence in South Africa is 18 years old. One respondent stated 21 years.

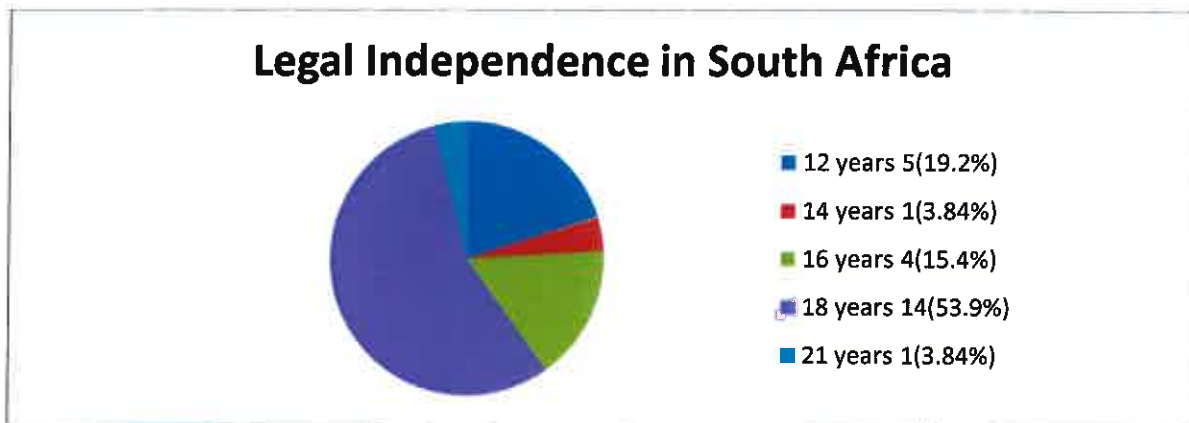


Figure 3 The age of legal independence in South Africa as indicated by participants.

The Children's Act No. 38 of 2005 has set specific guidelines regarding various forms of consent and protecting children against invasive tests and withholding treatment on religious grounds. In accordance to this Act participants were asked at what age a patient can consent to medical treatment. The Act sets the age at which a child may consent for medical treatment at 12 years if the following conditions are met: the child demonstrates sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the treatment; parental consent is not required for medical treatment if abovementioned is met.

The results from the participants are shown in Figure 4. Participants that stated patients of 12 years may consent to medical treatment were 15 (57%). Patients were said to consent to medical treatment at the age of 14 years by 5 (19%) participants and by the age of 16 years by 5 (19%) participants, One participant indicated that a patient of 18 years may consent to medical treatment. The conditions to be met was only mentioned by 7 (26.9%) of the participants as having sufficient maturity, with 16 (61.5%) participants mentioning mental capacity to understand the risks, benefits, social and other implications of the treatment. Parental consent is not required was stated correctly by 21 (80.7%) of respondents and is demonstrated in figure 5.

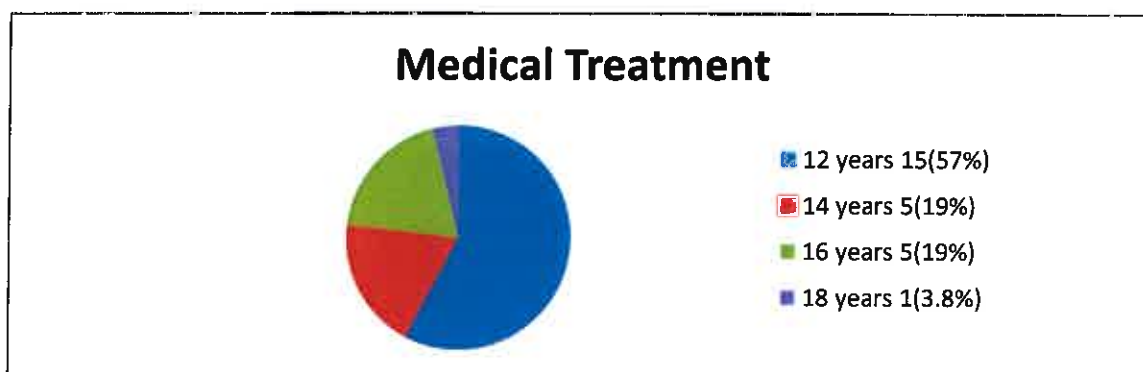


Figure 4 The various ages participants indicated that a minor may consent to medical treatment.

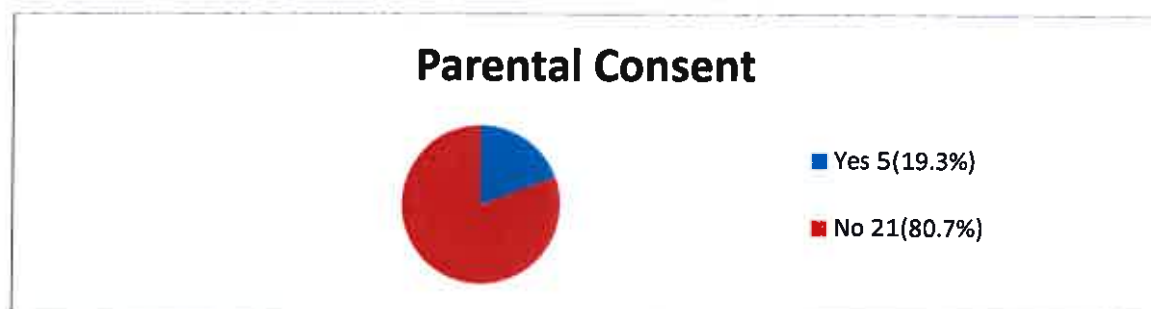


Figure 5 The percentages of participants that indicated additional parental consent were and were not needed for medical treatment of a minor.

The Children's Act No. 38 of 2005 also give guidelines on consent for surgical treatment and set the age of consent at 12 years with conditions to be met. The child must demonstrate sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the surgical treatment. Parental consent and parental consent must be in writing and signed using Form 34 as set out in the Children's Act No. 38 of 2005. (All forms in terms of draft regulations under The Children's Act and Bill 19 of 2006 is obtainable in PDF format on http://ci.org.za/depts/ci/plr/pdf/regulation/draft_forms.pdf alternatively from the HPCSA website under legislation)

Figure 6 shows that 8 (30.8%) of the participants responded that children may consent for surgical treatment at the age of 18 years. In descending order, the results were: 12 years – chosen by 7 (26.9%) participants, 14 years – 5 (19.3%) participants, 16 years – 5 (19.3%) participants and one participant indicating a patient must be 21 years old to consent to surgical treatment. The conditions that need to be met in accordance to Children's Act of 2015 were only mentioned by 13 (50%) of the participants but none of the participants mentioned that Form 34 must be completed that demonstrate parental consent. Participants were asked directly if parental consent was required and only 5 (19.3%) replied that you need parental consent correctly and 21 (80.7%) responded that parental consent was not required as demonstrated by figure7. Minors are defined according to the Children's Act as children younger than the age of legal independence.



Figure 6 The various ages participants indicated that a minor may consent to surgical treatment.

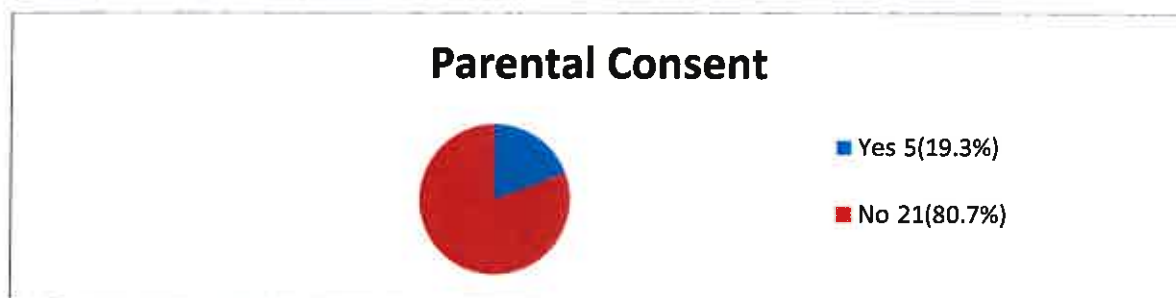


Figure 7 The percentages of participants that indicated additional parental consent were and were not needed for surgical treatment of a minor.

The Children's Act No. 38 of 2005 confers on children of 12 years or older the right to consent to HIV testing without parental consent and to purchase condoms without their parents' consent. Proper pre and post-test counselling must be done and the clinical and social implications must be explained to the child. Consent may also be given by younger children with sufficient maturity to understand the implications of the HIV test.

The results of the participants' response are given in Figure 8. The majority of participants, 16 (61.5%) indicated that a child of 12 years may consent to HIV testing. Three (11.5%) participants indicated that a child must be 14 years to consent to HIV testing, with 4 (15.4%) participants indicated that a child must be 18 years old to consent to HIV testing.

Pre and Post-test counselling was not mentioned as a condition to be met by 24 (92.3%) of participants. The explanation of clinical and social implications of the HIV testing was not mentioned by 20 (76.9%) of participants and 23 (88.5%) did not mention that younger children may also consent to HIV testing if sufficient maturity is displayed. The majority of participants 23 (88.5%) were correct in stating that parental consent was not needed if a child meets the conditions set out in the Children's Act No. 38 of 2005, these results are shown in figure 9.

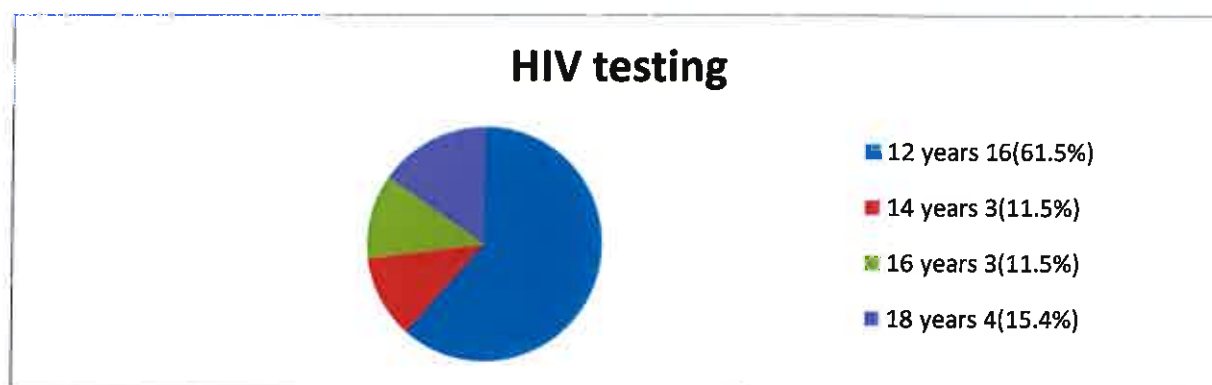


Figure 8 The various ages for consenting to HIV testing as indicated by the participants.

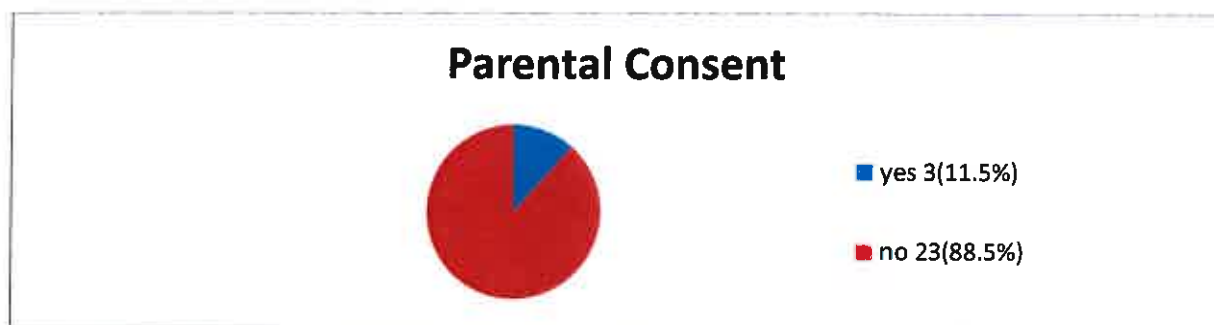


Figure 9 The percentages of participants that indicated that additional parental consent were and were not needed for consenting to HIV testing by a minor.

The Choice on Termination of Pregnancy Act No. 92 of 1996 allows a woman of any age to have a termination of pregnancy. There is no age or maturity test. This law governs abortion in South Africa and replaced the Abortion and Sterilisation Act of 1975. In this act “termination of pregnancy” is defined as the separation and expulsion, by medical or surgical means, of the content of the uterus of a pregnant woman. Under this Act a “woman” is defined as any female person of any age.

The Choice on Termination of Pregnancy Act of 1996 mentions the circumstances in which and conditions under which pregnancy may be terminated. The circumstances relate to various gestational periods and by whom the termination of pregnancy may be carried out.

A woman may request a TOP (termination of pregnancy) in the first 12 weeks of gestation and this may be performed by a medical practitioner or a registered midwife who has completed the prescribed training course.

During the 13th to 20th week of gestation a medical practitioner in consultation with the pregnant woman may induce a TOP if the pregnancy is a result of rape or incest, pose a risk to the woman’s mental or physical health, or will significantly affect the social or economic circumstances of the woman. A TOP may also be done during this period if the fetus would suffer from severe mental or physical abnormality.

After the 20th week of gestation a TOP may be performed by a medical practitioner, after consultation with another medical practitioner or registered midwife with the opinion that continuation of the pregnancy will endanger the life of the woman or the continuation of the pregnancy would result in a severe malformation of the fetus.

The Choice on Termination of Pregnancy Act of 1996 states that: the State shall promote and provide non-mandatory and non-directive counselling pre- and post-TOP.

The Act also states that no consent other than the pregnant woman shall be required for the TOP. If the woman is a minor, she will be advised to consult her parents, guardian, family member, but the TOP shall not be denied if the minor chooses not to consult them.

The results of the participants are demonstrated in figure 10. The majority of the participants, 15 (57.7%) indicated that a woman may consent to a TOP at 12 years of age. Six (23.1%) participants indicated a woman of 14 years may consent to a TOP, with 3 (11.5%) participants referring to 16 years for consent to TOP and 1 (3.8%) participant that said 18 years are required for consent to TOP and 1 (3.8%) participant that said that a woman of any age may consent to a TOP.

Participants that mentioned that this act indicates various stages of gestation were 4 (15.4%) and no participant mentioned that minors must consult with a parent, guardian or family member. Figure 11 illustrates that 22 (84.6%) participants indicated that parental consent is not needed in the case of a minor pregnant woman that request a TOP.

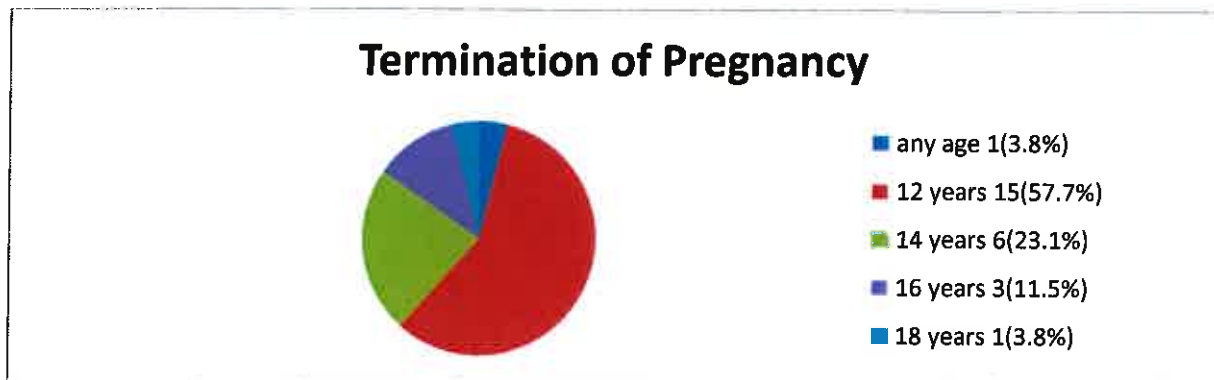


Figure 10 The various ages participants indicated that a woman may consent towards a TOP.

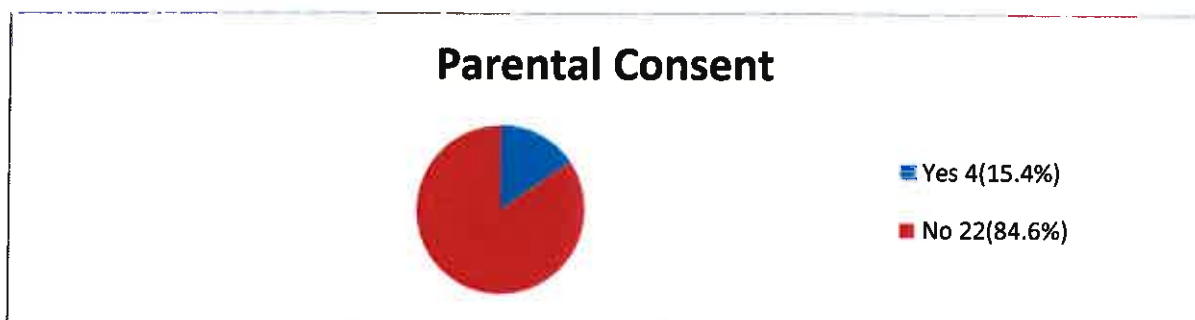


Figure 11 Percentages of participants that indicated that additional parental consent were and were not needed for a TOP.

The Constitution of South Africa gives each person the right to “participate in the cultural life of... choice”. In the Children’s Act No. 38 of 2005, circumcision of a male over the age of 16 years of age is allowed with consent from the child and carried out in the prescribed manner as set out in the Act. The Act hereby makes provision for cultural and social indications of circumcision, taking into account the child’s age, maturity and stage of development. Regarding, circumcision for a male under the age of 16 years the Children’s Act makes provision that a circumcision may be carried out in accordance with the child’s religion or when a medical practitioner recommended a circumcision for medical indications as therapeutic management. Every male child has the right to refuse a circumcision

Figure 12 demonstrates the response of participants when they were asked at what age a patient may consent to circumcision under the age of 18 years if the circumcision was for cultural or social indications. Seven (26.9%) participants indicated 12 years, 7 (26.9%) participants indicated 16 years, 6 (23.1%) participants indicated 14 years and 5 (19.2%) participants indicated 18 years.

Circumcision for social or cultural indications



Figure 12 The various ages indicated by participants that a minor may be circumcised for social and cultural indications.

The participants were asked which conditions needed to be met for circumcision of minors, no participant indicated that female circumcision is prohibited in South Africa or that the Children's Act mainly concern male children. Only 2 (8.0%) participants mentioned written consent after appropriate counselling. Figure 13 depicts that parental consent was required as indicated by 12 (48.0%) of the participants.

Parental Consent



Figure 13 Parental consent to circumcision for social or cultural indications.

Next, the participants were asked at what age a parent or guardian may request a circumcision for medical or religious indications. The results are shown in Figure 14. The majority 16 (64.0%) indicated that circumcision may be requested at any age for medical or religious indications. Once again only 2 (8.0%) of participants stated that written consent must be obtained and that the consent must state that the indication for the consent is of a religious nature or a medical therapeutic intervention. The majority of participants 19 (76.0%) stated that the child may still refuse the circumcision.

Circumcision for medical or religious indications



Figure 14 The various ages indicated by participants that a minor may be circumcised for medical or religious indications.

According to the Sterilisation Amendment Act No. 3 of 2005, that amended the Sterilisation Act No. 44 of 1998. Sterilisation is defined as “a surgical procedure performed for the purpose of making the person on whom it is performed incapable of procreation, but does not include the removal of any gonad, a procedure whereby a person could be permanently incapable of fertilisation or reproduction.” This Act dictates that a sterilisation may only be performed on a person over 18 years of age, unless the physical health of the person is threatened and informed consent in writing is given freely and voluntarily without any inducement by a person who is lawfully entitled to give consent.

Figure 15 demonstrates the results from the participants when asked what age a patient may consent to sterilisation. The majority of participants, 15 (60.0%) indicated that a person has to be 18 years old to consent to sterilisation. Two (8.0%) of the participants indicated that a person has to be 21 years old to consent to sterilisation. Four (16%) participants stated a patient of 16 years may consent to sterilisation. One (4%) participant stated a patient must be at least 14 years old to consent to sterilisation, two (8%) participants replied a patient of 12 years may consent to sterilisation and one (4%) participant indicated a patient of any age may consent to sterilisation.

On the conditions that need to be met, no participant mentioned that sterilisation may be performed on minors if their life would be jeopardised or their health seriously impaired by failure to do so and that in such cases, a sterilisation can be performed if the parent/guardian have consented and an independent medical practitioner, after counselling with the child concerned, makes a written statement that the sterilisation would be in the best interest of the minor.



Figure 15 Various ages participants indicated that patients may consent to sterilisation.

The Children’s Act No. 38 of 2005 also gives guidance on consent issues regarding minors with parental responsibilities (child-parents). The Act indicates that a minor that is a child-parent of 12 years old or older, with sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the proposed medical treatment may consent to the proposed medical treatment of his/her child without his/her parental assent.

The Act also indicates that a minor with parental responsibilities of 12 years or older, with sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the proposed surgical treatment of his/her child may consent to the proposed surgical treatment of his/her child with also the written consent of the parent/guardian of the aforementioned child-parent.

The results of the participants are shown in figure 16 with regards to medical consent for a minor by a child-parent. The majority 11 (44.0%) of participants stated that child-parents are only allowed to consent to medical treatment of his/her child once they become 18 years old. The remaining participants 6 (24%) stated that a child parent may consent to the medical treatment of his/her child when they are 12 years old or 3 (12%) participants replied 14 years old and 5 (20%) participants indicated they may consent at the age of 16 years. Only 4 (16%) participants maintained that the child parent must still fulfil the requirements of demonstrating sufficient maturity and mental capacity to understand the benefits, risks, social and other implications.

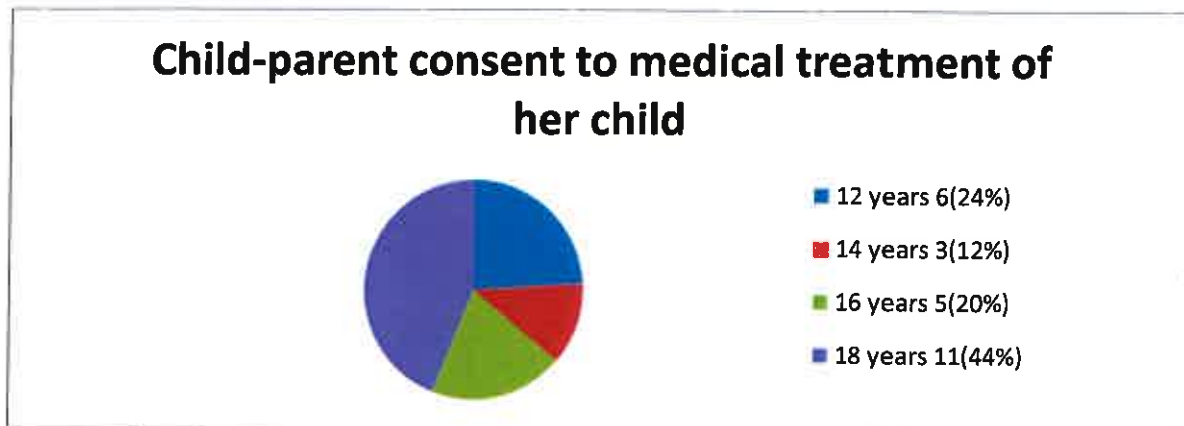


Figure 16 Percentages of the different age's participants indicated that a child-parent may consent to medical treatment of his/ her child.

Figure 17 shows the results for surgical consent for a minor by a child-parent. The majority 13 (52%) of participants answered that child parents are only allowed to consent to surgical treatment of his/her child when the child-parent turns 18 years old. Of the remaining participants, 3 (12%) indicated 12 years old, 5 (20%) participants indicated 14 years old and 4 (16%) participants indicated that the child-parent must be 16 years old to consent to surgical treatment of his/her child. In this case 3 (12%) of participants maintained that the child-parent must demonstrate sufficient maturity and mental capacity to understand the benefits, risks, social and other implications regarding the proposed surgical treatment of his/her child. No participant mentioned that the child-parent must still obtain consent from his parent/guardian for the surgical treatment of the child-parent's child.

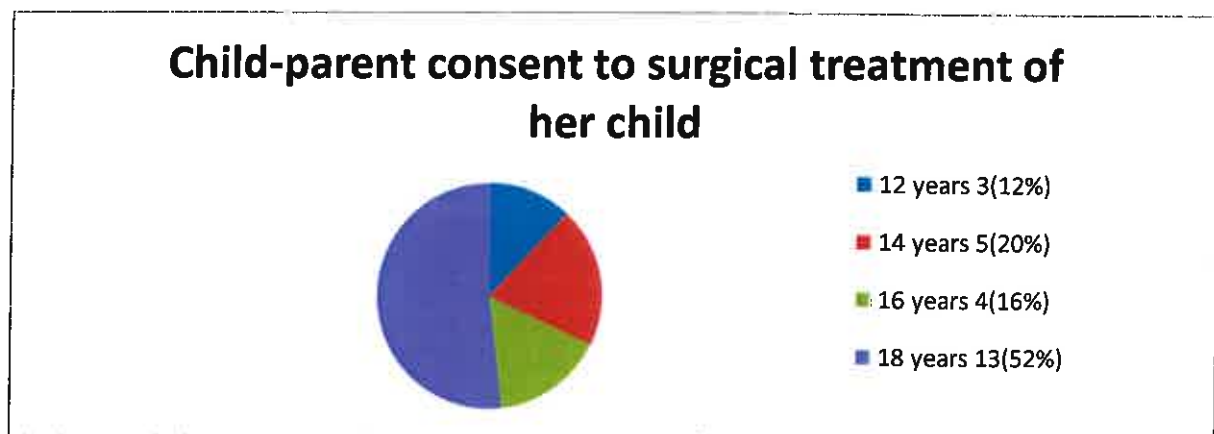


Figure17 Percentages of the different age's participants indicated that a child-parent may consent to surgical treatment of his/ her child.

Chapter 5

Discussion:

Doctors practice the art of medicine within biomedical ethical guidelines and these guidelines are grounded within the medical legislation of South Africa.

The biomedical ethical guidelines include:

Respect for autonomy (*Voluntas aegroti suprema lex*): the patient has the right to choose/refuse their treatment.

Beneficence (*Salus aegroti suprema lex*): the balancing of benefits against risks and costs in the patient's best interest.

Non-maleficence (*Primum non nocere*): firstly do no harm.

Justice (*Institia*): fairness and equality.

Other ethical guidelines of importance include: respect for persons, truthfulness and honesty.

Anaesthesiologists work contractually for a patient in the best interest of that patient and his/ her medical background, adhering to the Constitution of South Africa of 1996, which state that every citizen has the right to human dignity and to freedom and security of the person.^{14, 15, 16} (Non Maleficence and Justice)

Section 7 of the National Health Act No. 61 of 2003 protects the rights of competent health service users to consent to treatment and places a duty of health service providers to "take all reasonable steps to obtain the user's informed consent"^{1, 2, 7, 17, 22} (Respect for autonomy)

Section 8 of the National Health Act of 2003 indicates that health care users have the right to participate in decisions affecting their health and treatment. This section also requires the health service provider to share relevant information with health care users who lack the capacity to make decisions unless the disclosure of such information would be contrary to the user's best interests."¹⁴ (Respect for autonomy and beneficence)

It is widely known that doctors often have a poor knowledge of the law. A study done in Barbados in 2013 on legal knowledge, attitudes and practice at Queen Elizabeth Hospital demonstrated that 52% of senior medical staff and 20% senior nursing staff had a poor knowledge of the law pertinent to their work.¹⁹

According to recent surveys^{29, 30} by the age of 65 years, 75% of physicians in low-risk specialities experienced at least one malpractice law suit over the course of their career and 99% of those in high-risk specialities. Across specialities, 7.5% of physicians were sued annually. By the end their career, all anaesthesiologists in the Medscape survey of 2015, had been sued at least once and their main advice for other doctors was to make better clinical notes and to document everything.

In view of the risk of experiencing a law suit in the lifespan of an anaesthetic provider and the lack of knowledge regarding the laws that govern their management of patients, this study set out to test the current knowledge of relevant medical laws pertaining to informed consent by doctors working at the Department Anaesthesiology of the University of the Free State in June 2015.

The results obtained in this study should be interpreted with the following shortcomings and limitations in mind.

The response rate was poor with 26 (54%) of the total anaesthetic providers working at the Department Anaesthesiology of the UFS participating in this study.

The poor response rate was due to not all doctors in the Department Anaesthesiology being present at the meeting. Some were in theatre for emergency operations, other doctors were resting after being on call the night before and others were on leave.

The distinction between years post –graduation with medical degree,- showed the majority, 42.3%, of the respondents were between 6-10 years, followed by 30.8% participants between 0-5 years, then 15.4% after 11-20 years and participants with more than 21 years of postgraduate experience at 11.6%.

There was no further demographic distinction during the rest of the questionnaire, which raised the question if the years of experience provided more knowledge in this field or if the recently qualified had a better understanding of this subject. This might be a field of inquiry in a future study. This might have led to systemic errors in interpreting the results from the questionnaire.

The results of this study indicated a poor legal knowledge and compliance of doctors that provide anaesthesia in regard to obtaining a signed consent form. These results echoed the results found by similar studies.^{19, 31} With only 65.4% of the participants that “always” signed the anaesthetic consent form and from these only 26.9% added “additional information” regarding type of anaesthesia, possible risks and complications of the anaesthetic choices available to the patient and 30.7% admitted to “never” adding any additional information to the consent form. These practices indicate a habit of poor documentation.

The ethical implications of this is that the anaesthetic provider exposes themselves to non-compliance to the ethical code of non-maleficence as there is no proof that they explained the material risk and complications to the patient, as well as beneficence as they cannot prove that they weighed the risk to benefits towards the patient. We recommend that the anaesthetic providers form a habit of thinking in legal terms when embarking in a contract with the patient. Thinking of the consent form as a functional form, with functional reference to language the patient understands, the patients cognizance and practicality of environment and services offered. When an anaesthetic provider thus embarks on non-compliance as discussed above they then expose them towards possible litigation as the ethical codes are incorporated in the Constitution of South Africa and medical laws that govern the doctor’s medical conduct. (Secondary aim of this study)

In an open question the participants were asked to name laws in patient management or litigation governing their medical conduct. This question was left open by 76.9% of participants.

The reason the anaesthetic providers did not know these laws involve some speculation. One might speculate that there is no specific module within the various medical faculties in South Africa that teaches the specific laws that govern medical conduct to medical students at the same level of importance as eg. Anatomy and Physiology, but only touches on the primary ethical codes namely: autonomy, beneficence, non-maleficence and justice leaving the doctors exposed to ignorance towards the specific laws that govern their medical conduct. Another reason why the anaesthetic providers are not familiar with the specific laws that govern their conduct might be due to the fact that all the participants in the study are employed by the Department of Health of South Africa and that they might perceive to be protected to a degree against medical litigation, a form of institutional indemnity perhaps, as opposed to which the anaesthetic providers in private practice are possibly more exposed towards legal issues and would therefore be more familiar with practicing their craft within the legal boundaries of the law.

Anaesthetic providers were asked more in-depth questions to test their grasp on the concepts within the various laws that govern their conduct. These results also indicated poor insights to the various laws.

The results of this study demonstrated that anaesthetic providers have poor insight regarding the autonomy of a patient. The participants of this study demonstrated confusion in the order of precedence of medical responsibility in the event that a patient lost the capacity to provide informed consent.

Informed consent is closely related to the values of autonomy and truth telling and thus includes informed refusal as well. Participants demonstrated poor insight to the level of legal rights regarding the patient and his autonomy by appointment of a curator or the legal sequence of the medical responsibility in the absence of such a curator. According to South African law, the medical responsibility passes from the patient to the curator (appointed by the patient or the court) then the spouse, parent, adult child, sibling and lastly the superintendent of the hospital or institution only in an emergency if all efforts were unsuccessful to obtain consent by aforementioned.

The MPS guidelines state that any treatment that is authorised by law or a court order, or is necessary to protect the public health, might lawfully be carried out under the terms of the National Health Act. The National Health Act also allows for emergency treatment to prevent either death or irreversible damage to the patient's health, provided the patient had not previously "expressly, impliedly or by conduct" refused such treatment (MPS)

The confusion in the order of precedence and unfamiliarity with the legal rights of patients was shared by 20% of study participants when they indicated the order as: patient, spouse, parent, sibling, adult child, superintendent of institution and lastly the curator appointed in writing by the patient or court. This confusion may arise from an institutional point of view or a cultural contributor in the decision making process.

The HPCSA and MPS have set out clear guidelines based upon the legal rights of patients within the law regarding the treatment of patients and the obtaining of consent to medical and surgical treatment.

The age of legal independence in South Africa is set as 18 years old by the Constitution of the Republic of South Africa 1996 (Bill of Rights) and the Children's Act of 2005. The age of legal independence demonstrates the age when legal control of a parent or guardian is terminated. Participants demonstrated some confusion on this aspect as well with the majority 14(53.9%) indicating 18 years, the other ages indicated was 12 years 5(19.2%), 14 years 1(3.8%), 16 years 4(15.4%) and 21 years 1(3.8%).

The possible reason for the confusion regarding age of legal independence in South Africa might be that the Children's Act of 2005 has replaced the previous Child Care Act of 1983 that placed the age of legal independence at 21 years old. The implementation of the Children's Act of 2005 had a pronounced implication regarding consent related to children. The Children's Act has clear guidelines dividing medical and surgical consent and whether written parental consent is also required if consent is obtained from the competent child.

For a child to consent he/she must demonstrate certain requirements that must be met for either medical consent or surgical consent. These requirements have various age restrictions, with certain age restrictions related to various specific surgical procedures. Medical management requires a child of 12 years old with sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the medical treatment and written parental consent is not required for this; most participants understood these principles.

Surgical management requires a child of 12 years old with sufficient maturity and mental capacity to understand the benefits, risks, social and other implications, but for surgical consent the child as well as a parent need to provide written consent to the surgical treatment. The child that is able to consent to surgical treatment after all the requirements are met, still need the written parental assent for the surgical treatment. In these circumstances the parent gives written assent/ agreement/ consent to the decision of the child to proceed with the surgical treatment using the parental assent form, Form 34, as stipulated in the Children's Act of 2005. (The autonomy to decide on surgical treatment lies with the competent child and not the parent, but the parent still needs to agree with the decision of the child to proceed with the surgical treatment. All forms in terms of draft regulations under The Children's Act and Bill 19 of 2006 is obtainable in PDF format on http://ci.org.za/depts/ci/plr/pdf/regulation/draft_forms.pdf alternatively from the HPCSA website under legislation)

It is regarding the surgical consent of a minor, a child younger than legal independence in SA, where the results started indicating levels of confusion regarding the details of this law. The results showed only 26.9% of the participants indicated that the child must be 12 years of age and only 50% of participants referred to conditions that needed to be met for a child of this age to consent to surgical management. In the case of medical treatment participants knew that a parent does not need to consent additionally for the medical treatment of the child if the aforementioned conditions were met, but they also indicated (76.9%) that parental consent was not needed for surgical management if the conditions were met, but parental written consent is still required even if the child met all the requirements regarding surgical management.

The results of this study indicate a poor understanding and confusion towards the principles set out in the Children's Act of 2005. It is near impossible for an anaesthetic provider to exclude minors from

their clinical practice. This poor understanding of the Children's Act exposes them to areas of ethical misconduct and possible medical malpractice litigation.

The results of this study also demonstrated confusion regarding the principles of The Choice on Termination of Pregnancy Act No. 92 of 1996. This act allows a woman of any age to have a termination of pregnancy (TOP). There is no age or maturity test. This law governs abortion in South Africa and replaced the Abortion and Sterilisation Act of 1975.

A possible cause to the confusion may be found within the various definitions used within these two acts. The definition in the Choice of Termination of Pregnancy Act do not clearly define abortion in terms of viability or gestational age of the fetus as the Abortion and Sterilisation Act of 1975 did and thus has led to a possible interpretation that a caesarean section is also a form of termination of pregnancy by surgical means after 20 weeks of gestation if indicated by two medical practitioners.

If we have a closer look at the definitions used within the Choice on Termination of Pregnancy Act of 1996 we find the following.

TOP: separation and expulsion, by medical or surgical means, of the content of the uterus of a pregnant woman. *(No reference to duration of pregnancy or viability of fetus)*

Woman: any female person of any age

The definitions found in the Medical dictionary.com as well as the Abortion and Sterilisation Act of 1975.

Abortion: termination of pregnancy before the fetus has developed to a stage of viability (20 weeks of gestation or fetal weight less than 500 grams)

Induced abortion: abortion brought on intentionally by medication or instrumentation.

Therapeutic abortion: abortion induced legally by a qualified physician to safeguard the health of the mother

Premature birth: infants born after stage of viability (20 weeks of gestation or fetal weight less than 500 grams) but before 37 weeks of gestation.

The Choice on Termination of Pregnancy Act of 1996 is more extensive and differs from the previous Abortion and Sterilisation Act of 1975 by giving various circumstances in which/ conditions under which a pregnancy may be terminated and these differences may be contributing to the confusion in the interpretation of the current Act as it stands.

The differences include circumstances during various gestational periods of a pregnancy and by whom the TOP may be carried out. The Act states that an elective abortion may be performed within the first 12 weeks of gestation by a medical practitioner or registered midwife that completed the required training. Alternatively the Act states that a therapeutic abortion may be performed during weeks 13-20 of gestation by a medical practitioner in consultation with the pregnant woman.

The Act however states that a therapeutic termination of pregnancy after 20 weeks of gestation may be performed by a medical practitioner in consultation with another medical practitioner or registered midwife that completed the required training and it is this last statement that does not fit in with the definition of abortion and some medical practitioners use this last statement to motivate for performing a caesarean section under this law.

Another point of confusion is the differences between the Children's Act of 2005 and the Choice on Termination of Pregnancy Act of 1996 when considering the age required by a patient to provide consent to a TOP. A TOP may be performed on a woman of any age under the Choice on Termination of Pregnancy Act of 1996 but the results of this study showed that participants still applied the age and requirements of surgical and medical consent required by the Children's Act of 2005 when obtaining consent for the TOP.

The results in this study also highlighted confusion regarding requirements set out in the Children's Act of 2005 for circumcision for social and cultural indications. The Children's Act of 2005 makes provision for circumcision of a male child if carried out in the prescribed manner as set out in the Act. The Act hereby makes provision for cultural and social indications of circumcision, taking into account the child's age, maturity and stage of development. Circumcision may be performed on a male child under the age of 16 years for religious or medical indications as therapeutic management. Circumcision for social or cultural indications may only be performed on a male child over 16 years of age with his consent. Only 23.1% of participants stated that a male child of 16 years old may consent to circumcision for social and cultural indications. When regarding circumcision for medical or religious indications, participants were more consistent in their replies and 64% indicated that circumcision for medical or religious indications may be performed at any age and 76% of participants replied that the child may still refuse the circumcision at any age.

Chapter 6

Conclusion:

The ethical codes doctors follow and the medical legislation that govern their clinical practice are closely intertwined. This study has fulfilled the primary and secondary aims as set out to be investigated.

The primary aim indicated a poor level of understanding pertaining to the medical laws in which doctors' practice with various levels of confusion to details within these laws, especially regarding the Children's Act of 2005 and the Choice on Termination of Pregnancy Act of 1996.

This study demonstrated the poor understanding of biomedical ethical concepts and how they are incorporated in the different South African laws. The concept of informed consent is incorporated within the boundaries of the Constitution of South Africa and other medical laws that govern medical practice within South Africa, as they refer to patient autonomy, beneficence, non-maleficence and justice.

This study indicated that the doctors that worked at the Department Anaesthesiology of the University of the Free State during June 2015 were unfamiliar with the legal aspects of informed consent and were exposing themselves to possible medical malpractice and future litigation due to lack of documentation on the informed consent form.

The findings will be presented to the Department Anaesthesiology with a lecture to explain the current standing of legislation that the doctors need to be aware of as well as a brief summary regarding these laws after the completion of this paper in 2016.

The results of this study may also be presented to other surgical departments eg. Department of Surgery, Department of Orthopaedics, Department of Obstetrics and Gynaecology at a later stage, with a similar lecture to explain the laws regarding consent.

(This work will form part of the requirements towards obtaining the MMed (Anaesthesiology) degree.)

Chapter 7

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Appendices

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Appendix A

ETHICS APPROVAL

Appendix B

COVER LETTER

Purpose of the study (lay terms) Ethics Committee

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

Doctors treat patients on a daily basis and this study is to determine if the doctors that provide anaesthesia and working at the Department Anaesthesiology of the University of the Free State during June 2015 know the laws in which they practice every day, with specific focus on informed consent for procedures and surgery.

The study is an anonymous questionnaire that will be handed out to the doctors in the Anaesthetic department during a Friday morning mortality and morbidity meeting after a pilot study was done under five doctors in the surgical department. They will take approximately 10 min to complete it and they will place it in a container that will be provided at the end of completion.

Dr. T Lourens will evaluate the completed questionnaires. The data will be analysed by the Department of Biostatistics at the University of the Free State, under guidance of Prof G Joubert.

Time till expected completion of the study is September 2015. The results will be announced to the Department Anaesthesiology and will be used for a MMed study.

Appendix C

Permission from Universitas Hospital CEO

Dean of the Faculty of Health, UFS

Prof GJ van Zyl

School of Medicine

Prof A St Clair Gibson

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

We are conducting a study to test the knowledge of the relevant medical laws involved in the medical management of patients. As doctors we work with patients in the scope of medical legislation that govern our actions. We want to determine if doctors giving anaesthesia to patients working at the Department Anaesthesiology, at the Faculty of Health Sciences of the University of the Free State, working at Universitas Academic Complex, are aware of the laws that govern their scope of practice.

We ask your permission to conduct this research study under the doctors working in the Department Anaesthesiology during June 2015.

This study is conducted using a questionnaire and participants are asked to complete the questionnaire during a Friday morning meeting in June 2015, it will take approximately 5 minutes to complete and participation is voluntarily and the questionnaire is anonymous.

On completion of the study, the results will be made available to the Department Anaesthesiology, at the Faculty of Health Sciences of the University of the Free State with a lecture explaining the current medical legislation that govern actions of doctors treating patients.

For further information regarding this study you may contact Dr. T. Lourens. Tel nr. (084) 5040500 or e-mail: Tarina_lourens@hotmail.com

For any complaints or problems you may contact the secretariat and chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State. Tel nr. (051) 4052812

Dean of the Faculty of Health/ School of Medicine

Date: _____

Dr. T Lourens

Date: _____

Appendix D

Permission from departments involved

Prof BSJ Diederiks

Department of Anaesthesia, UFS

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

We are conducting a study to test the knowledge of the relevant medical laws involved in the medical management of patients. As doctors we work with patients in the scope of medical legislation that govern our actions. We want to determine if doctors giving anaesthesia to patients working at the Department Anaesthesiology, at the Faculty of Health Sciences of the University of the Free State, working at Universitas Academic Complex, are aware of the laws that govern their scope of practice.

We ask your permission to conduct this research study under the doctors working in your department during June 2015.

This study is conducted using a questionnaire and participants are asked to complete the questionnaire during a Friday morning meeting in June 2015, it will take approximately 5 minutes to complete and participation is voluntarily and the questionnaire is anonymous.

On completion of the study, the results will be made available to the Department Anaesthesiology, at the Faculty of Health Sciences of the University of the Free State with a lecture explaining the current medical legislation that govern actions of doctors treating patients.

For further information regarding this study you may contact Dr. T. Lourens. Tel nr. (084) 5040500 or e-mail: Tarina_lourens@hotmail.com

For any complaints or problems you may contact the secretariat and chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State. Tel nr. (051) 4052812

Prof. BSJ Diedericks

Date: _____

Dr. T Lourens

Date: _____

Prof HR Hay

Vice-Rector: Academics

Faculty of Health, UFS

Department of Anaesthesia, UFS

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

We are conducting a study to test the knowledge of the relevant medical laws involved in the medical management of patients. As doctors we work with patients in the scope of medical legislation that govern our actions. We want to determine if doctors giving anaesthesia to patients working at the Department Anaesthesiology, at the Faculty of Health Sciences of the University of the Free State, working at Universitas Academic Complex, are aware of the laws that govern their scope of practice.

We ask your permission to conduct this research study under the doctors working in your department during June 2015.

This study is conducted using a questionnaire and participants are asked to complete the questionnaire during a Friday morning meeting in June 2015, it will take approximately 5 minutes to complete and participation is voluntarily and the questionnaire is anonymous.

On completion of the study, the results will be made available to the Department Anaesthesiology, at the Faculty of Health Sciences of the University of the Free State with a lecture explaining the current medical legislation that govern actions of doctors treating patients.

For further information regarding this study you may contact Dr. T. Lourens. Tel nr. (084) 5040500 or e-mail: Tarina_lourens@hotmail.com

For any complaints or problems you may contact the secretariat and chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State. Tel nr. (051) 4052812

Prof. HR Hay

Date: _____

Dr. T Lourens

Date: _____

Appendix E

Participant information and consent form

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

Greetings:

We are conducting a study to test the knowledge of the relevant medical laws involved in the medical management of patients. As doctors we work with patients in the scope of medical legislation that govern our actions. We want to determine if doctors giving anaesthesia to patients working at the Department Anaesthesiology, at the Faculty of Health Sciences of the University of the Free State, working at Universitas Academic Complex, are aware of the laws that govern their scope of practice. We invite you to participate in this research study.

This study is conducted using a questionnaire and we ask that you complete the questionnaire, it will take approximately 5 minutes to complete and participation is voluntarily and the questionnaire is anonymous. Participation may be discontinued at any time.

For further information regarding this study you may contact Dr. T. Lourens. Tel nr. (084) 5040500 or e-mail: Tarina_lourens@hotmail.com

For any complaints or problems you may contact the secretariat and chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State. Tel nr. (051) 4052812

Appendix F

Data collection sheets

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

You have been asked to participate in a research study. Please note that by completing this questionnaire you are voluntarily agreeing to participate in this research study. You will remain anonymous and your data will be treated confidentially at all times. You may withdraw from this study at any given moment during the completion of the questionnaire. The results of the study may be published.

Consent Questionnaire:

☐ ☐

(Please mark the appropriate box with an X)

Demographic Data

Level of training: ☐ Intern ☐ MO ☐ Registra ☐ Consultant ☐

Years post-graduation (M.B, Ch.B) ☐ 0-5 ☐ 6-10 ☐ 11-20 ☐ >21 ☐

Do you sign the anaesthetic part on the surgical consent form?

☐ Always ☐ Sometimes ☐ Never ☐

If always or sometimes:

Do you add information to the consent form? ☐ Always ☐ Sometimes ☐ Never ☐

☐

What information do you add?

☐ Anaesthetic choices

☐ Anaesthetic Risks

☐ Possible Complications ☐

Other: ☐ YES ☐ NO

☐ ☐

Name laws in patient management (Legislation governing medical conduct)

1. _____ ☐

2. _____ ☐

3. _____ ☐

4. _____ ☐

5. _____ ☐

When a patient is unable to give consent, in which order should consent be obtained?

(Please number from 1 to 6)

	Brother/ Sister
	Superintendent
	Parent
	Curator (written/court)
	Spouse
	Adult child

--	--

Please complete the questions below

(Mark with an X where appropriate)

1. What is the age of legal independence in South Africa?

(The age when legal control of a parent/ guardian is terminated)

12 14 16 18 21

--

2. MEDICAL TREATMENT:

2.1 At what age can a patient consent to medical treatment?

12 14 16 18 21

2.2 Which conditions need to be met?

2.3 Is parental consent required ?

yes no

3. SURGICAL TREATMENT:

3.1 At what age can a patient consent to surgical treatment?

12 14 16 18 21

3.2 Which conditions need to be met?

3.3 Is parental consent required ?

yes no

4. HIV TESTING:

4.1 At what age can a patient consent to HIV testing?

12 14 16 18 21

4.2 Which conditions need to be met?

4.3 Is parental consent required ?

yes no

5. TERMINATION OF PREGNANCY:

5.1 At what age can a patient consent to termination of pregnancy?

12 14 16 18 21

5.2 Which conditions need to be met?

5.3 Is parental consent required ?

yes no

6. CIRCUMCISION:

6.1 At what age can a patient under 18 years consent to circumcision for cultural or social reasons?

12 14 16 18 any age

6.2 Which conditions need to be met?

6.3 Is parental consent required ?

yes no

7.1 At what age of a patient can his parent or guardian request a circumcision for medical or religious reasons?

12 14 16 18 any age

7.2 Which conditions need to be met?

7.3 Can the child then refuse the circumcision? yes no

8. STERILISATION:

8.1 At what age can a patient request a sterilisation?

12 14 16 18 21

8.2 Which conditions need to be met? _____

8.3 Is parental consent required? yes no

9. CHILD-PARENT (Minor with parental responsibilities)

9.1 At what age can a child-parent consent to medical treatment of her child?

12 14 16 18 21

9.2 Which conditions need to be met? _____

9.3 At what age can a child-parent consent to surgical treatment of her child?

12 14 16 18 21

9.4 Which conditions need to be met? _____

Appendix G

Data collection sheets memorandum

Knowledge of relevant medical laws pertaining to informed consent, by doctors working at the Department Anaesthesiology of the UFS in June 2015.

You have been asked to participate in a research study. Please note that by completing this questionnaire you are voluntarily agreeing to participate in this research study. You will remain anonymous and your data will be treated confidentially at all times. You may withdraw from this study at any given moment during the completion of the questionnaire. The results of the study may be published.

Consent Questionnaire:

☐ ☐

(Please mark the appropriate box with an X)

Demographic Data

Level of training: ☐ Intern ☐ MO ☐ Registra ☐ Consultant ☐

Years post-graduation (M.B, Ch.B) ☐ 0-5 ☐ 6-10 ☐ 11-20 ☐ >21 ☐

Do you sign the anaesthetic part on the surgical consent form?

☐ Always ☐ Sometimes ☐ Never ☐

If always or sometimes:

Do you add information to the consent form? ☐ Always ☐ Sometimes ☐ Never ☐

☐

What information do you add?

☐ Anaesthetic choices

☐ Anaesthetic Risks

☐ Possible Complications ☐

Other: ☐ YES ☐ NO

☐ ☐

Name laws in patient management (Legislation governing medical conduct)

1. Constitution of the Republic of South Africa no. 108 of 1996 (Bill of Rights)
2. National Health Act no. 61 of 2003
3. Child Care Act no. 74 of 1983
4. Children's Act no.38 of 2005
5. Choice on Termination of Pregnancy Act no. 92 of 1996
6. Criminal Law (Sexual Offences and Related Matters) Amendment Act no. 32 of 2007
7. Mental Health Care Bill of 2003
8. Sterilisation Act 44 of 1998 and Sterilisation Amendment Act of 2005
9. Health Professions Act of 1974
10. Access to Information Act of 2000

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When a patient is unable to give consent, in which order should consent be obtained?

(Please number from 1 to 6)

☐☐

5	Brother/ Sister
6	Superintendent
3	Parent
1	Curator (written/court)
2	Spouse
4	Adult child

☐
☐
☐
☐
☐
☐

Please complete the questions below *(Mark with an X where appropriate)*

1. What is the age of legal independence in South Africa?

(The age when legal control of a parent/ guardian is terminated)

☐

12 14 16 **18** 21

2. MEDICAL TREATMENT:

2.1 At what age can a patient consent to medical treatment?

12 14 16 18 21

2.2 Which conditions need to be met? ☐ AND sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the treatment.

2.3 Is parental consent required? yes **no**

3. SURGICAL TREATMENT:

3.1 At what age can a patient consent to surgical treatment?

12 14 16 18 21

3.2 Which conditions need to be met? ☐ AND sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the treatment. Patient consent and parental assent must be in writing and signed using Form 34.

3.3 Is parental consent required? **yes** no

4. HIV TESTING:

4.1 At what age can a patient consent to HIV testing?

12 14 16 18 21

4.2 Which conditions need to be met? ☐ Proper pre-and post-test counselling. The clinical and social implications must be explained. (Consent may also be given by younger child with sufficient maturity to understand the implications of the test)

4.3 Is parental consent required? yes **no**

5. TERMINATION OF PREGNANCY:

5.1 At what age can a patient consent to termination of pregnancy?

--

12 14 16 18 21 ~~Any age~~

5.2 Which conditions need to be met? ___ various stages <12, 13-20, >20, advised to consult with her parents/guardian, though she is not denied a TOP if she fails to do so.

5.3 Is parental consent required? yes ~~no~~

6. CIRCUMCISION:

6.1 At what age can a patient under 18 years consent to circumcision for cultural or social reasons?

12 14 **16** 18 any age

6.2 Which conditions need to be met? MALE (Female circumcision is illegal at any age). Using Form 3 written consent and parental assent, after appropriate counselling.

6.3 Is parental consent required? **yes** no

7.1 At what age of a patient can his parent or guardian request a circumcision for medical or religious reasons?

12 14 16 18 **any age**

7.2 Which conditions need to be met? ___ MALE (Female circumcision is illegal at any age). Form 2 written consent, if patient is under 16 yo and indication is for a religious or medical reason.

7.3 Can the child then refuse the circumcision? **yes** no

8. STERILISATION:

8.1 At what age can a patient request a sterilisation?

12 14 16 **18** 21

8.2 Which conditions need to be met? ___ Minors may only be sterilised if their life would be jeopardised or their health seriously impaired by failure to do so. In such cases, a sterilisation can be carried out if the parents/guardian have consented and an independent medical practitioner, after counselling with the child concerned, makes a written statement that the sterilisation would be in the best interests of the child.

8.3 Is parental consent required? yes ~~no~~

9. CHILD-PARENT (Minor with parental responsibilities)

9.1 At what age can a child-parent consent to medical treatment of her child?

12 14 16 18 21

9.2 Which conditions need to be met? ___ AND sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of the treatment.

9.3 At what age can a child-parent consent to surgical treatment of her child?

12 14 16 18 21

9.4 Which conditions need to be met? ___ Consent must be completed on Form 35, Child-parent consent as well as parent/guardian of the child-parent assent must be in writing.

Appendix H

Children's Act Forms

FORM 34**CONSENT TO SURGICAL OPERATION BY A CHILD****(Regulation 54(1), (2))****[SECTION 129(3) OF THE CHILDREN'S ACT 38 OF 2005]**

NB Child to be 12 years of age or older and of sufficient maturity and having the mental capacity to understand the benefits, risks and social implications of the surgical operation

Part A: Details concerning the child, the particulars of the person performing the surgical operation or institution where it is to be performed and the parent/guardian assisting the child

Full name of child	
Date of Birth/ID number/passport no	
Address of child	
Contact details	
Age of child (12 or older)	

Particulars of person/hospital/clinic/surgery/other institution* performing surgical operation

Name	
Practice no/hospital/clinic/surgery/ staff position	
Address	
Contact details	
Nature of surgical operation	
Details of other institution performing surgical operation*	

*Please furnish details concerning the name and type of institution in the space provided

Particular of parent(s) or guardian(s) assenting to surgical operation

Parent/Guardian 1

Full name of parent/guardian	
Date of Birth/ID number/passport no	
Address of parent	
Contact details	
Relationship to child	

Parent/guardian 2 (where necessary or desirable)

Full name of parent/guardian	
Date of Birth/ID number/passport no	
Address of parent	
Contact details	
Relationship to child	

Part B: Explanation of nature, consequences, risks and benefits of surgical operation

I(name of person seeking child's consent to perform a surgical operation) confirm that I have explained to(name of child consenting to surgical operation) the following in a manner that is understandable to the child: -

- ☐ The nature of the problem requiring a surgical operation
- ☐ The most suitable surgical operation in my opinion
- ☐ Any risks associated with the surgical operation

- ☐ The benefits associated with surgical operation
- ☐ Any alternative forms of treatment
- ☐ The social implications of the treatment or surgical operation (if any)
- ☐ Any other implications or possible consequences of the surgical operation (specify in space provided below)

.....

I have given the child an opportunity to ask questions relating to the above.

I have satisfied myself that the child is 12 years or older and sufficient maturity and has the mental capacity to understand the risks, benefits, social and other implications of the surgical operation.

I have satisfied myself that..... (insert name of parent(s)/guardian(s)) has duly assisted the child to give consent to the surgical operation.

.....
 Signature of person seeking consent to perform the surgical operation

.....
 Name of person seeking consent to perform the surgical operation (write in full)

.....
 Designation of person seeking consent to perform the surgical operation

Date:

Part C Consent of the child.

I,(insert child's name) understand that the following surgical operation is going to be performed on me:

.....
 I.....(insert child's name) understand the risks and benefits and possible consequences of this surgical operation that have been explained to me, and I confirm that I have been given an opportunity to ask questions about my condition, alternative forms of treatment, and the risks of non-treatment, and possible consequences of the surgical operation.

I believe that I have sufficient information to give my informed consent, and do so freely.

.....
 Signature of child

.....
 Name of Child (write in full)

Date.....

I.....(insert name of parent(s) or guardian (s) assisting the child to consent to a surgical operation) confirm that the child is 12 years or older and is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the following surgical operation.....(insert type of surgical operation), and that(insert name of child) has been duly assisted by me to furnish consent.

.....
 Signature parent(s)/guardian(s)

.....
 Full name of parent or guardian

.....
 Date

FORM 35**CONSENT TO SURGICAL OPERATION OF A CHILD BY A PARENT WHO IS AGED BELOW 18 YEARS****(Regulation 55(2))****[SECTION 129(3) OF THE CHILDREN'S ACT 38 OF 2005]**

Part A: Details concerning the child, the parent aged under 18 years of the child upon whom the surgical operation is to be performed, the parent(s) or guardian of the child parent aged below 18 years, and the particulars of the person performing the surgical operation or institution where it is to be performed

Child upon whom surgical operation is to be performed

Full name of child	
Date of Birth/ID number/passport no	
Address of child	
Contact details	
Age of child (12 or older)	

Parent aged below 18 years giving consent ("child parent")

Full name of child parent	
Date of Birth/ID number/passport no	
Address of child	
Contact details	
Age of child parent	

Parent/Guardian assisting the child parent to give consent

Full name of parent/guardian	
Date of Birth/ID number/passport no	
Address of parent	
Contact details	
Relationship to child parent	

Particulars of person/hospital/clinic/surgery/other institution* performing surgical operation

Name	
Practice no/hospital/clinic/surgery/ staff position	
Address	
Contact details	
Nature of surgical operation	
Details of other institution performing surgical operation*	

*Please furnish details concerning the name and type of institution in the space provided

Part B: Explanation of nature, consequences, risks and benefits of surgical operation

I(name of person seeking consent to perform a surgical operation) confirm that I have explained to(name of child parent consenting to surgical operation) the following in a manner that is understandable to him /her: -

- ☐ The nature of the problem requiring a surgical operation
- ☐ The most suitable surgical operation in my opinion
- ☐ Any risks associated with the surgical operation
- ☐ The benefits associated with surgical operation
- ☐ Any alternative forms of treatment
- ☐ The social implications of the treatment or surgical operation (if any)

- ☐ Any other implications or possible consequences of the surgical operation (specify in space provided below)

.....

I have given the child parent an opportunity to ask questions relating to the above.

I have satisfied myself that the child parent is 12 years or older and of sufficient maturity and has the mental capacity to understand the risks, benefits, social and other implications of the surgical operation upon(insert name of child upon whom surgical operation is to be performed).

I have satisfied myself that..... (insert name of parent(s)/guardian(s)) has duly assisted the child giving consent to the surgical operation.

.....
 Signature of person seeking consent to perform the surgical operation

.....
 Name of person seeking consent to perform the surgical operation (write in full)

.....
 Designation of person seeking consent to perform the surgical operation

Date:

Part C Consent of the child parent.

I,(insert name of child parent)
 understand that the following surgical operation is going to be performed (insert type of surgical operation):

.....
 on.....(insert name of child upon whom surgical operation to be performed).

I understand the risks and benefits and possible consequences of this surgical operation that have been explained to me, and I confirm that I have been given an opportunity to ask questions about the health condition of my child, alternative forms of treatment, and the risks of non-treatment, and possible consequences of the surgical operation.

I believe that I have sufficient information to give my informed consent, and do so freely.

.....
 Signature of child parent

.....
 Name of child parent (write in full)

Date.....

I,.....(insert name of parent(s) or guardian (s))
 assisting the child parent to consent to a surgical operation) confirm that he / she is 12 years or older and is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the following surgical operation.....(insert type of surgical operation), and that(insert name of child) has been duly assisted by me to furnish consent.

.....
Signature parent(s)/guardian(s)

.....
Full name of parent or guardian

.....
Date