

**AN INVESTIGATION OF INFORMED CONSENT IN CLINICAL
PRACTICE IN SOUTH AFRICA**

By

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STATEMENT

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I, SYLVESTER CHIDI CHIMA, declare that:

“AN INVESTIGATION OF INFORMED CONSENT IN CLINICAL PRACTICE IN SOUTH
AFRICA”

Is my own work and that all sources that I have used or quoted have been indicated and
acknowledged by means of complete references.

28 February 2018

SYLVESTER CHIDI CHIMA

DATE

DEDICATION

This thesis is dedicated to the memory of my parents Paul Nwokocha Chima and Virginia Ukauwa Chima nee Ajagha; who both firmly believed in the power and opportunity that education provides to uplift the dignity of a person and therefore dedicated their lives to see that all their children obtained valuable education. Unfortunately, they both passed on during the period of my work on this research project, my father in 2010, and my mother joined him 4 years later in 2014, leaving me to finish this work with a heavy heart. Which brings to mind the closing lines of an ancient poem by Al-Hariri as quoted by Jay Katz¹

*What we cannot reach flying,
We must reach limping
And the books tell us that...
Limping is no sin²*

¹ A free translation of one of the Maqīmiit of Al-Hariri in *Die beiden Gulden* (Translated from the original German by Beyer C) (6 Friedrich Ruckert Werke 1897) 21.

² Katz J “Limping is no sin: Reflections on making health care decisions” 1984 *Cardozo Law Review* 243.

ABSTRACT

This study was designed to evaluate the quality of informed consent practiced by healthcare professionals in South Africa using an empirical quantitative methodology combined with medico-legal analysis to produce an interdisciplinary thesis on bioethics and medical law. Informed consent is an ethical and legal doctrine derived from the principle of respect for autonomy, whereas the rights to bodily integrity, privacy and human dignity are constitutionally protected in South Africa. The *National Health Act* 61 of 2003 codified requirements for informed consent by stipulating that healthcare providers must inform healthcare users about diagnosis, risks, benefits, treatment options, and the right of refusal, while taking into consideration users language and literacy levels. However, African communities are inherently challenged by problems of poverty, poor education, power asymmetry, and unfamiliarity with libertarian rights-based autonomy, which could affect informed consent practice. An empirical study was conducted at randomly selected public hospitals in EThekweni metropolitan municipality involving 927 participants; comprising 168 medical doctors, 355 professional nurses, and 404 patients. The study showed that healthcare professionals had limited knowledge regarding ethical and legal requirements for informed consent, and were partially compliant with current informed consent regulations. Barriers to informed consent identified were language, poor education, workload, and lack of interpreters. Most patients attending public hospitals were indigent, but preferred full information disclosure, and a shift from informed to shared-healthcare decision-making. The study recommends that a corps of trained interpreters should be introduced at public hospitals. This will improve provider-patient communications and minimize workloads, increase job satisfaction, and the overall quality of healthcare service delivery. Analysis of recent South African case law on informed consent revealed vacillations between the “reasonable doctor” and “prudent patient” standards of information disclosure which are inconsistent with the jurisprudence from comparative foreign common law jurisdictions. Therefore, South African court judgments on informed consent ought to be re-evaluated to establish a uniform standard of information disclosure consistent with international jurisprudence, current legislation, and constitutional protections relating to human dignity and security of the person.

Key terms: Empirical bioethics; Doctors, Health law, Informed consent, Medical Law, Legislation, Nurses, Patients, Public hospitals, Regulation, Jurisprudence, South Africa

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In morals, no one can claim he is an adult, that is to say, in full possession of an experienced moral conscience, deciding by himself and comfortably certain he is right. In morals, an adult is he who knows that he needs to be kept awake, shaken, disputed, and challenged so that genuine moral demands emerge within himself³

Paul Valadier s.j.³

Firstly, I would like to acknowledge my former teachers on Medical Law, Michelle Robson, Malcolm Khan and Kristina Swift, who introduced me to the fascinating, yet intricate but close relationship between Medicine and the Law.

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³ Valadier P, Society of Jesus, Jesuit Priest and Philosopher, Emeritus Professor Centre Sèvres, Facultés J suites de Paris.

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PART ONE

CHAPTER 1- ORIENTATION TO THE STUDY

1.1 Introduction

Informed consent (IC) in medical practice is derived from the ethical principle of respect for autonomy, which refers to self-determination, or freedom of choice.⁴ The idea that every person has a right to determine what can be done to his or her own body, has found expression in many national and international statutes and ethical codes through the doctrine of IC.⁵ It has been argued that autonomy itself has never been found to be a legally enforceable right; rather two rights derived from the principle of respect for autonomy have been universally accorded legal protection.⁶ These are the right to bodily integrity protected by legal rules against assault or battery, and the right to bodily well-being, protected by rules against professional negligence.⁷ Supporting these is the right to liberty or the condition of being free.⁸ Coggon and Miola have described autonomy in medical law as relating to free will, whereby an “autonomous agent” is one with the free will to act, while liberty refers to the freedom to act without interference from another.⁹ It has been submitted by South African scholars on medical jurisprudence that IC before medical treatment is a constitutionally protected right.¹⁰ This was demonstrated in the

⁴ Chima SC “Respect for autonomy as a prima facie right: Overriding patient autonomy in medical practice” 2009 *Transactions: Journal of the Colleges of Medicine of South Africa (CMSA)* 38-44.

⁵ National Health Act 61 of 2003 see also United Nations International Convention on Civil and Political Rights (ICCPR) 1966 Article 7 and UNESCO *Universal Declaration on Bioethics and Human Rights* 2005.

⁶ Schultz MM “From informed consent to patient choice: A new protected interest” 1985 *Yale L J* 219-299.

⁷ Jennings S “Medical law and individual autonomy- competing perspectives” 2003 <http://www.nuigalway.ie/law/GSLR/2003/MedicalNegligence.pdf> (Date of use: 20 July 2009).

⁸ Chima SC “Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study” 2013 *BMC Med Ethics* S3 [1-17].

⁹ Coggon J and Miola J “Autonomy liberty and medical decision-making” 2001 *Camb Law J* 523-547.

¹⁰ Van Oosten FFW “Castell v De Greef and the doctrine of informed consent: Medical paternalism ousted in favour of patient autonomy” 1995 *De Jure* 164-179 see also Carstens P and Pearmain D *Foundational principles of South African medical law* (LexisNexis Durban 2007) 29-32.

case of *Minister of Safety and Security v Xaba*,¹¹ where the police wanted a court order to compel an accused person to undergo a surgical procedure in order to obtain a bullet to be used as evidence in his prosecution. The court held that such an order would violate the defendant's constitutional rights to a fair trial, bodily integrity and privacy. The South African Constitution of 1996 (hereinafter the Constitution), recognized the rights of autonomy by codifying the rights to human dignity, and bodily integrity in sections 10 and 12(2).¹² Section 12 of the Constitution stipulates that everyone has a right to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experimentation without their informed consent.¹³ It has been argued that when sections 12(2) of the Constitution, "everyone has the right to bodily and psychological integrity", and 12(2)(b) which includes the right "to security in and control over their body" are read together, this makes it clear that decisions regarding one's body relate to both a physical and psychological dimension.¹⁴ Accordingly, IC as a requirement for lawful medical interventions is a well-established principle in South African law.¹⁵ Van Oosten has long suggested that patients consent, as a requirement for all lawful medical interventions, has been recognized as a well-established principle in South African common law.¹⁶ Leading cases on the legal doctrine of informed consent in South Africa include *Stoffberg v Elliot* 1923,¹⁷ and *Esterhuizen v Administrator Transvaal* 1957¹⁸ (hereinafter the *Esterhuizen* case). In the former case a patient whose penis was wrongfully amputated due to penile cancer without consent, sued his doctors for damages for assault. While instructing the jury Watermeyer J opined that:

In the eyes of the law, every person has certain absolute rights, which the law protects. They are not dependent upon a statute or upon a contract, but they are rights to be respected, and one of those rights is the right of absolute security of the person....Any

¹¹ *Minister of Safety and Security v Xaba* 2003 (2) SA 703 (D).

¹² Constitution of the Republic of South Africa 1996.

¹³ Carstens and Pearmain *Foundational Principles* 29.

¹⁴ Mswela M "Cultural practices and HIV in South Africa: A legal perspective" 2009 *PER* 197.

¹⁵ Van Oosten 1995 *De Jure* 164-179 see also Carsten and Pearmain *Foundational Principles* 29-32.

¹⁶ Van Oosten FFW *The doctrine of informed consent in medical law* (LLD Thesis University of South Africa 1989).

¹⁷ *Stoffberg v Elliot* 1923 CPD 148-150.

¹⁸ *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T).

bodily interference with or restraint of a man's person which is not justified in law or excused by law, or consented to, is a wrong, and for that wrong the person whose body has been interfered with has a right to claim such damages as he can prove he has suffered owing to that interference.¹⁹

In the *Esterhuizen* case, a 10-year-old child diagnosed with Kaposi's sarcoma, was initially treated with superficial radiation with parental consent. Later, due to tumour recurrence, the child was subjected to radical radiation therapy resulting in severe tissue damage necessitating amputation of the limbs. In an action for damages by the child's mother against the treating doctors, the court held that while the superficial radiation was duly performed with appropriate consent from the parents, the latter procedure was performed without full information disclosure and IC from the child's guardians, though there was adequate time to do so. The court rejected the defendant doctor's argument that IC was implied because the parents had brought the child to hospital previously and consented to initial treatment. The court also rejected arguments that treatment was in the child's best interests, holding instead that the child's guardians ought to have been adequately informed of the dangers inherent in more radical treatment for such consent to be considered valid.²⁰ A more recent South African case of *Castell v De Greef* 1994²¹ (hereinafter the *Castell case*) appears to have consolidated the doctrine of IC into South African medical jurisprudence, leading to the adoption of the following ethical and legal principles:

- A shift from medical paternalism to patient autonomy
- A shift from a 'reasonable doctor' standard to the 'prudent patient' standard
- A shift in information disclosure to the 'material risk' standard, where the level of disclosure required is what a reasonable patient would consider important before making a healthcare decision
- Places IC within the legal framework of *volenti non fit injuria* or voluntary assumption of risk rather than delict²²

¹⁹ *Stoffberg v Elliot* 1923 CPD 148.

²⁰ *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T) see also Carstens and Pearmain *Foundational Principles* 500-501.

²¹ *Castell v De Greef* 1993 (3) SA 501(C).

²² *Castell v De Greef* 1993 (3) SA 501[719].

1.2 Recent developments in South African case law since the Castell case and enactment of the National Health Act 2003.²³

Following the judgment of Ackerman J in the *Castell case*,²⁴ some legal scholars have argued that South African Courts have not endeavoured to develop the common law on informed consent as envisaged by the Constitution.²⁵ These commentators have suggested that in several cases brought to South African courts since the National Health Act (NHA)²⁶ was implemented the Courts have been reluctant to apply the regulations laid down in the NHA with regards to the legal application of the IC doctrine in medical practice.^{27,28} Some of the pertinent cases which have been tried by South African Courts following the Castell case include *Broude v McIntosh and Another 1998*.²⁹ In this case a claimant brought an action against a surgeon for negligence following facial paralysis occurring secondary to an operation which the claimant alleged had been wrongfully performed. The claimant also alleged that the defendant surgeon had failed to obtain appropriate informed consent, and had also failed to warn of the risk of facial paralysis prior to surgery. The provincial High Court dismissed the claim based on the fact that the claimant had failed to prove any negligent conduct on the part of the surgeon. The claimant then appealed to the Supreme Court of Appeal (SCA) based on two heads of argument: (a) That the respondent wrongfully failed to obtain the appellants real or informed consent for the surgical procedure and that the respondent therefore committed an assault on the claimant by performing the surgery (b) alternatively, that in carrying out the surgical procedure on the patient, the surgeon acted in a negligent and unskilful manner by failing to inform the claimant before performing the surgery regarding the risks and hazards involved in the procedure and the availability of alternative treatments.³⁰ In

²³ National Health Act 61 of 2003 (hereinafter National Health Act or NHA).

²⁴ *Castell v De Greef* 1993 (3) SA 501(C).

²⁵ The Constitution.

²⁶ National Health Act.

²⁷ Britz R and Roux-Kemp A "Voluntary informed consent and good clinical practice for clinical research in South Africa: Ethical and legal perspectives" 2012 *SAMJ* 746-748.

²⁸ Thomas R "Where to from Castell v De Greef? Lessons from recent developments and abroad regarding consent to treatment and the standard of disclosure" 2007 *SALJ* 188-215.

²⁹ *Broude v McIntosh and Another* 1998 (3) SA 60 (SCA).

³⁰ Carstens and Pearmain *Foundational Principles* 681.

arriving at a decision, the SCA opined that while the sole interest of the surgeon or doctor was to alleviate the suffering of the patient, it was somewhat strange that the doctors' actions in this case should be considered an assault due to failure to disclose some risks, which if disclosed may have caused the patient to abandon the surgery by withholding consent. The Court suggested that this was unusual and concluded in part that such an approach might be unsound. However, on the facts of the case the SCA rightfully held that failure to obtain real informed consent should in fact be considered an assault. The SCA also considered in detail the judgment of Ackerman J in the *Castell* case³¹ but did not overrule the judgment in that case. However Marais J expressed an obiter dictum regarding his reservations about the observation that failure to disclose material risks which were in the opinion of a doctor likely to lead to a patient withholding consent could constitute assault.^{32,33} In another South African case *Louwrens v Oldwage* 2006³⁴ (hereinafter the *Oldwage* case), Yekiso J sitting in the High Court found based on a preponderance of the evidence, that there was a failure to obtain informed consent by a vascular surgeon in performing a procedure on a patient, based on several grounds, including the fact that the said surgical procedure as noted on the informed consent document signed by the patient and submitted as evidence in court, was different from the procedure that was eventually performed on the patient. Secondly, that the surgeon could not recall when such consent was obtained from the patient, and thirdly that the doctors clinical notes regarding his consultations with the patient could not be found and could not be presented as evidence in court, and might have been shredded by the surgeon prior to expiry of the time legally required for the preservation of medical notes.³⁵ Despite noting the obiter dictum of Marais J in *Broude v McIntosh*,³⁶ the trial Judge Yekiso J concluded that he was legally bound by the opinion of the full bench of the High Court in the *Castell* case which held that failure to disclose material risks to a patient and obtain valid informed consent prior to surgery amounted to assault.³⁷ In the subsequent appeal

³¹ *Castell v De Greef* 1993 (3) SA 501.

³² *Broude v McIntosh and Another* 1998 (3) SA 60 (SCA).

³³ Carstens and Pearmain *Foundational Principles* 682.

³⁴ *Louwrens v Oldwage* 2006 (2) SA 161 (SCA).

³⁵ *Louwrens v Oldwage* 2004 CASE NO: 10253/01 (CPD) [76-85].

³⁶ *Broude v McIntosh & Others* 1998 (3) SA 60(SCA) at 671.

³⁷ *Louwrens v Oldwage* 2004 CASE NO: 10253/01 (CPD) [99].

heard by the SCA, the higher Court overruled the judgment of Yekiso J, arguing that on the issue of informed consent, the surgeon had duly informed the patient of the appropriate surgery based on the opinion of expert witnesses who stated that the difference between the surgical procedure stated on the informed consent document as ‘femoro-femoro bypass’ and the procedure subsequently performed by the surgeon an ‘illio-femoral bypass’ was merely semantic in that the two expert witnesses for the defence and prosecution concurred that both procedures were generally referred to as ‘femoro-femoro bypass’. Similarly on the issue of whether the illio-femoral bypass was the cause of the patients subsequent development of a ‘steal syndrome’, the SCA held that the patients expert witness’ argument based on 1976 clinical evidence that the incidence of such complications occurred in 4% of cases, was not acceptable in 2007. Rather the Court preferred the evidence of the appellants’ expert witness who contended that because of modern techniques now available, the incidence of such complications was in the region of 2%.³⁸ The claimant had argued that based on the judgment reached by the court in the *Castell* case, the patient ought to have been warned about material risks as outlined Ackerman J, where he said that for consent to be used as a defence, the following conditions must be satisfied:

- (a) The consenting party must have had knowledge and been aware of the nature and extent of the harm or risk;
- (b) The consenting party must have appreciated and understood the nature and extent of the harm or risk;
- (c) The consenting party must have consented to the harm or assumed the risk;
- (d) The consent must be comprehensive, that it extends to the entire transaction, inclusive of its consequences.³⁹

The *Castell* court further held, that a medical practitioner has a duty to warn a patient of a material risk associated with a procedure, whereby risk is regarded as material where:

- (a) A reasonable person in the position of the patient, if so warned of the risk, would be likely to attach significance to it; or

³⁸ Louwrens v Oldwage 2006 (2) SA 161 (SCA) [20-25].

³⁹ Castell v De Greef 1993 (3) SA 501[425].

- (b) The medical practitioner is or should reasonably be aware that the patient, if warned, would be likely to attach significance to it.⁴⁰

In arriving at its decision in the *Oldwage* case, the SCA referred to the “reasonable doctor standard” as elucidated in *Richter and Another v Estate Hamman*⁴¹ rather than the subjective “prudent patients’ standard” of information disclosure as arrived at in the *Castell* case.⁴² South African legal scholars have since argued that the SCA erred in its judgment in the *Oldwage* case, because it applied the discredited reasonable doctor standard of information disclosure rather than the more accepted prudent patients’ standard as established in the *Castell* case.⁴³ It can be further argued that in arriving at its decision in the *Oldwage* case, the SCA did not pay attention to the judgments from similar cases in other comparable common law jurisdictions like England, where the English Court of Appeals (CA), held in cases such as *Chester v Afshar*,⁴⁴ that failure of a doctor to disclose serious risks in the range of 1-2% amounted to negligence. Similarly in the Canadian case of *Reibl v Hughes*,⁴⁵ the Canadian Supreme Court held that failure to disclose material risks in the range of 1% could also amount to actionable negligence. Therefore the judgment of the SCA in the *Oldwage* case has been generally criticized by several commentators based on these grounds.^{46,47,48} Firstly, it has been argued that though the SCA first set out to answer the question of whether “the claimant gave informed consent to the surgical procedure performed by the defendant, in the absence of that, whether such a surgical intervention would have amounted to assault.”⁴⁹ The Court ended up not addressing this question, it rather concluded that the absence of informed consent was not proven and failure to obtain consent did not amount to assault. Secondly, in *Broude v McIntosh*,⁵⁰ the Court had alluded to the need for the SCA to review the issue of whether

⁴⁰ Castell v De Greef 1993 (3) SA 501[426].

⁴¹ Richter and another v Estate Hamman 1976 (3) SA 226 (C) [232G-H].

⁴² Castell v De Greef 1993 (3) SA 501[425 H-I].

⁴³ Carstens and Pearmain *Foundational Principles* 685-687 see also Britz and Roux-Kemp 2012 SAMJ [746] and Thomas 2007 SALJ [192].

⁴⁴ Chester v Afshar [2002] 3 All ER FR 552 (CA).

⁴⁵ Reibl v Hughes (1980) 114 DLR (3d) 1 (SCC).

⁴⁶ Carstens and Pearmain *Foundational Principles* 685-687.

⁴⁷ Britz and Roux-Kemp SAMJ 2012 [746].

⁴⁸ Thomas 2007 SALJ 188-215 [192].

⁴⁹ Carstens and Pearmain *Foundational Principles* 685-687.

⁵⁰ Broude v McIntosh and Another 1998 (3) SA 60 (SCA).

failure by a doctor to obtain informed consent amounted to assault. When confronted with this argument, the SCA did not refer to this particular case in its judgment, neither did it review the arguments from that case or answer the query from the lower court. Thirdly, while the SCA accepted and applied the principles elucidated by Ackerman J in the *Castell* case,⁵¹ it subsequently also accepted and eventually applied the discredited “reasonable doctor standard” arrived at in *Richter and Another v Estate Hamman*⁵² in its judgment thereby creating some confusion in the interpretation of cases regarding informed consent in South Africa. It has been argued that by doing so, the SCA did not provide needed clarity as to whether the principle of respect for autonomy should take precedence over medical paternalism.⁵³ Further, it has been suggested that this failure to clarify issues do not appear to be consistent with constitutional provisions for respect for security, privacy and bodily integrity as elucidated in section 12 of the Constitution.⁵⁴ Further, the SCA judgment in the Oldwage case was also inconsistent with the constitutional provisions to expand the common law by reference to judgments in foreign legal jurisdictions when interpreting the bill of rights or when interpreting any South African legislation.⁵⁵ It can also be argued that the SCA should have also taken into consideration the current regulations and legislation regarding informed consent as elucidated in the National Health Act.⁵⁶ In another recent judgment in the case of *McDonald v Wroe* 2006,⁵⁷ a Western Cape High Court found that failure of a dentist to warn a patient of the risks of permanent nerve damage subsequent to extraction of an infected wisdom tooth amounted to violation of the patients right to bodily integrity as enshrined in section 12 (2) of the Constitution.⁵⁸ Further, the Court held that the patient was subjected to surgery without real informed consent due to incomplete disclosure of the material risks.⁵⁹ In arriving at its decision the High Court applied the rule established by Ackerman J in the *Castell* case while

⁵¹ *Castell v De Greef* 1994 (4) SA 408 (C) [425H-I].

⁵² *Richter and Another v Estate Hamman* 1967 (3) SA 226 (C).

⁵³ Carstens and Pearmain *Foundational Principles* 686.

⁵⁴ The Constitution s12.

⁵⁵ The Constitution s39.

⁵⁶ National Health Act s7.

⁵⁷ *McDonald v Wroe* [2006] 3 All SA 565 (C).

⁵⁸ The Constitution s12 (2).

⁵⁹ *Nicola McDonald v Dr Graham Wroe* (2006) 3 All SA 565 (C) [37-39] see also Carstens and Pearmain *Foundational Principles* 687 and Esterhuysen S “Medical negligence” www.bowmanslaw.com/insights/tax/medical-negligence (Date of use: 25th October 2017).

emphasizing that in South African law there is a duty upon a medical practitioner to disclose the material risks of a planned procedure to the particular patient, whereas it has been determined that, in order for consent to be used as a defence, the patient must have knowledge of the risks, understood the risks, assumed the attendant risks and all its consequences.⁶⁰

The National Health Act (NHA)⁶¹ codified the requirements for informed into South African law. Section 7 of the NHA stipulates:

- (1) 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) Authorised 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, grandparent, 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.
- (2) A health care provider must take all reasonable steps to obtain the users informed consent

The NHA⁶² further requires that:

- (1) Every health care provider must inform a user of-

⁶⁰ Baron M "The medical duty of care revisited: *McDonald v Wroe* [2006] 3 All SA (C) Deneys Reitz General Case Law Update March 2007
http://www.deneysreitz.co.za/directors/Monique_baropn.html (Date of use: 15 July 2017).

⁶¹ National Health Act 61 of 2003.

⁶² National Health Act s6.

- (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, and consequences generally associated with each option; and
 - (d) The user's right to refuse health services and explain the implications, risks, obligations of such refusal.
- (2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

South African Courts has previously debated the issue of how much information should be disclosed to a patient prior to informed consent since the case of *Lymberg v Jeffries* 1925,⁶³ where the court was of the opinion that a "doctor is not obliged to disclose all the conceivable complications that may arise during a medical procedure." This opinion was probably based in part on the precedent case of *Van Wyk v Lewis* 1924,⁶⁴ where the court held that "in deciding what is reasonable, the Court will have regard to the general level of skill and diligence possessed and exercised at the time by members of the branch of the profession to which the practitioner belongs".⁶⁵ However, the *Castell* court concluded that a doctor is obliged to warn the patient of all "material risks" inherent in the treatment, where such "material risks" are based on a "prudent patient standard".⁶⁶ Therefore the requirement for information disclosure in South African law tends towards the practice in North American jurisdictions where libertarian rights-based autonomy is predominant. In the context of comparative international law, the "prudent patient standard" of information disclosure has become the accepted standard as opposed to the "reasonable doctor standard" of information disclosure. As explained by a recent judgment of the UK Supreme Court, Scotland, in the case of *Montgomery v Lanarkshire* [2015] UKSC 11⁶⁷ (hereinafter the *Montgomery* case) where the High Court argued that:

⁶³ *Lymberg v Jeffries* 1925 AD 236.

⁶⁴ *Van Wyk v Lewis* 1924 AD 438 [444].

⁶⁵ Carstens and Pearmain *Foundational Principles* 364.

⁶⁶ *Castell v De Greef* 1993 (3) SA 501[426].

⁶⁷ *Montgomery v Lanarkshire* [2015] UKSC 11[75].

Since *Sidaway*⁶⁸... it has become increasingly clear that the paradigm of the doctor-patient relationship implicit in the speeches in that case has ceased to reflect the reality and complexity of the way in which healthcare services are provided, or the way in which the providers and recipients of such services view their relationship. One development which is particularly significant in the present context is that patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint, which has underpinned some of the developments in the provision of healthcare services. In addition, a wider range of healthcare professionals now provide treatment and advice of one kind or another to members of the public, either as individuals, or as members of a team drawn from different professional backgrounds (with the consequence that, although this judgment is concerned particularly with doctors, it is also relevant, *mutatis mutandis*, to other healthcare providers).⁶⁹

The UK Supreme Court then concluded that:

The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in *Sidaway* by Lord Scarman,⁷⁰ and by Lord Woolf MR in *Pearce*,⁷¹ subject to the refinement made by the High Court of Australia in *Rogers v Whitaker*,⁷²...An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.⁷³

In light of the above judgments, it has become apparent that South African Courts ought to take into consideration the opinions expressed by foreign legal jurisdictions on informed consent, consistent with the injunction in section 39 of the Constitution.⁷⁴

⁶⁸ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643.

⁶⁹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

⁷⁰ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643.

⁷¹ *Pearce v United Bristol NHS Healthcare Trust* [1998] 48 BMLR 18.

⁷² *Rogers v Whitaker* [1992] HCA 58; 175 CLR 479.

⁷³ *Montgomery v Lanarkshire* [2015] UKSC 11 [87].

⁷⁴ The Constitution s39.

1.3 Informed consent, the socio-cultural milieu and patient rights' in South Africa

In complex multicultural societies and resource-poor countries like South Africa; where education standards and literacy levels are low, in addition to high levels of poverty and cultural influences.⁷⁵ In these situations, knowledge and power asymmetry usually exists between patients and healthcare professionals.^{76,77} It has been suggested that it is important to recognize the backdrop of marginalization and ongoing challenges of poverty during the IC process. In spite of such challenges however, doctors and other HCPs still have a duty to explain clinical procedures to patients or their surrogates without turning them into students of medicine.⁷⁸ Since it is uncertain how much information healthcare providers should actually disclose to patients before they feel empowered enough to make a healthcare decision, building trust between healthcare providers and patients may be critical to obtaining IC and enhancing the doctor-patient relationship.^{79,80,81} Further, the ability to use written information is important to comprehension and understanding.⁸² Barriers to communication arising from illiteracy and language differences may prevent a common understanding of medical procedures, thereby putting a patient at risk of providing consent without comprehension.^{83,84,85,86} But how does a HCP ensure that a

⁷⁵ Chima SC "Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa" 2015 *Niger J Clin Pract* 49.

⁷⁶ Tindana PO, Kass N and Akweongo P "The informed consent process in a rural African setting: A case study of the Kassena-Nankana district of Northern Ghana" 2006 *IRB* 5-6.

⁷⁷ Irabor DO and Omonzejele P "Local attitudes, moral obligation, customary obedience and other cultural practices: Their influence on the process of gaining informed consent for surgery in a tertiary institution in a developing country" 2009 *Dev World Bioethics* 37.

⁷⁸ Lore W "Medical ethics in the protection of patients' rights" 1993 *Medicus* 227-229 as cited in Chima 2013 *BMC Med Ethics* 13.

⁷⁹ Appelbaum PS "Assessment of patients' competence to consent to treatment" 2007 *N Engl J Med* 1834-1835.

⁸⁰ Appelbaum PS and Grisso T "Assessing patients' capacities to consent to treatment" 1988 *N Engl J Med* 1635.

⁸¹ Chima *Niger J Clin Pract* 54.

⁸² Green JB et al "Putting the 'informed' into 'consent': A matter of plain language" 2003 *J Paediatric Child Health* 700.

⁸³ Lindegger G and Richter LM "HIV vaccine trials: critical issues in informed consent" 2000 *S Afr J Sci* 313.

⁸⁴ Schlemmer A and Mash B "The effects of a language barrier in a South African district hospital" *SAMJ* 2006 1085-1086.

⁸⁵ Flores G "Language barriers to healthcare in the United States" 2006 *N Engl J Med* 230.

⁸⁶ Clark S et al "The informed consent: A study of the efficiency of informed consents and the associated role of language barriers" 2011 *J of Surg Educ* 145-146.

patient understands a proposed treatment or procedure prior to providing consent? Some authorities have suggested a verbal or written test to ascertain patient capacity, competence or understanding before considering IC to be valid.⁸⁷ In South Africa, about 25% of the population is unemployed, with a low labour force participation rate of 54% compared to a global average of 69%.^{88,89} There are also historical inequities within racial population groups.^{90,91,92} In this situation basic health care is unaffordable and out of reach for a majority of the population, as reported in a previous aspect of this study, where it was shown that a majority of the patients attending public hospitals in KwaZulu-Natal province South Africa are unemployed and indigent.⁹³ Therefore any offer of medical assistance is often seen as better than nothing, thereby encouraging undue influence and paternalism.⁹⁴ Further, there is a dichotomy in the organization of the South African healthcare system, which is dual in nature consisting of private hospitals or private healthcare services which are patronized by the fewer patients (20%), who have health insurance or financial means to pay, compared with the public health services which accounts for the majority (80%) of indigent patients and citizens.^{95,96} This dual healthcare system is further characterized by better infrastructure in private hospitals because of commercial competition and better funding, and arguably better educated and more knowledgeable patients and consumers of healthcare services.⁹⁷ Ideally, in order for a

⁸⁷ Appelbaum PS "Assessment of patients' competence to consent to treatment" 2007 *N Engl J Med* 1834-1840 see also Appelbaum and Grisso 1988 *NEJM* 1635-1638.

⁸⁸ Trading Economics "South Africa unemployment rate 2000-2017" <http://www.tradingeconomics.com/south-africa/unemployment-rate> (Date of use: 19 October 2017).

⁸⁹ Vollgraaff R "Little hope of hitting job-creation target" 2011-02-20 *Sunday Times Newspaper* South Africa.

⁹⁰ Mhlongo SW and Mdingi GV "Informed consent is light years away for black African patients" 1997 *BMJ* 252.

⁹¹ London L and Baldwin-Ragaven L "Human rights and health: Challenges for training nurses in South Africa" *Curationis* 2008 5-18 see also Maphai VT "Affirmative action in South Africa - genuine option?" 1989 *Social Dynamics: A Journal of African studies* 1-24.

⁹² Truth and Reconciliation Commission *Truth and Reconciliation Commission of South Africa Report* vol 4 *The Health Sector* (Truth and Reconciliation Commission 1998) 109-157.

⁹³ Chima 2015 *Niger J Clin Pract* 50-51.

⁹⁴ Annas GJ and Grodin MA "Human Rights and maternal-fetal HIV transmission prevention trials in Africa" *Health and Human Rights* Mann JM, Gruskin S and Grodin MA et al (eds) (Routledge New York 1999) 373-380.

⁹⁵ Department of Health *KwaZulu -Natal Strategic Plan 2010-2014* (DOH KZN 2010).

⁹⁶ Piertese M "The interdependence of rights to health and autonomy in South Africa" 2008 *SALJ* 553-572.

⁹⁷ Chima SC 2015 *Niger J Clin Pract* 50-51.

doctor or other HCP to obtain a patient's valid consent to medical treatment, the HCP must fully explain the proposed procedure, the short-term risks and long-term consequences, the available alternatives, their risks and benefit and the consequences of delaying or declining treatment. The patient should also be made aware of both short term costs such as pain, recovery time and length of confinement to the hospital. Long term costs such as loss of functioning and physical scarring or loss of function must also be divulged.⁹⁸ The HCP must also disclose all information that would be regarded as "material" by a reasonable person, with material defined as any information that would make a particular patient choose a different option.^{99,100,101} Legally securing consent without providing adequate information constitutes redressable negligence.^{102,103} Despite these established legal requirements, in developing countries such as South Africa, where the doctor-patient ratio is rather high, though it may be ethically desirable, and legally required for patients to be as fully informed as required by the NHA,¹⁰⁴ and HPCSA guidelines,¹⁰⁵ doctors may not have the time to spend on unduly lengthy explanations of all the ramifications of treatment.^{106,107} This presents a challenge in ensuring that patients are armed with sufficient, relevant and accurate information before they consent to any medical procedure or treatment. Comprehension is another key element of informed consent that focuses on ensuring that a patient is not only informed, but that the patient understands the information provided. According to the Belmont report,¹⁰⁸ information must be provided in a language that can be understood bearing in mind the level of intelligence, rationality,

⁹⁸ Schuck PH "Rethinking informed consent" 1994 *Yale LJ* 899-959.

⁹⁹ Lantos D "Informed consent- the whole truth for patients" 1993 *Cancer Suppl* 2811-2815.

¹⁰⁰ Pelias MK "Research in human genetics: The tension between doing no harm and personal autonomy" 2005 *Clinical Genet* 1-5.

¹⁰¹ *Castell v De Greef* 1993 (3) SA 501[426].

¹⁰² Svoboda JS, Van Howe RS and Dwyer JG "Informed consent for neonatal circumcision: An ethical and legal conundrum" 2000 *J Contemp Health Law Policy* 61-199.

¹⁰³ *McDonald v Wroe* [2006] 3 All SA (C).

¹⁰⁴ National Health Act 61 2003.

¹⁰⁵ Health Professions Council of South Africa (HPCSA) *Guidelines for good practice in the health care professions-seeking patients informed consent: The ethical considerations* 2nd ed (HPCSA Pretoria 2008).

¹⁰⁶ Mason JK and Laurie GT *Law and Medical Ethics* 6th ed (Oxford University Press Oxford 2006) 348-393.

¹⁰⁷ Schuck PH 1994 *Yale LJ* 899-959.

¹⁰⁸ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *The Belmont Report-Ethical principles and guidelines for the protection of human subjects of research* (Department of Health Education and Welfare US Government Washington DC 1979).

education and maturity of the patient. The ability to comprehend the information may be determined by the language of communication and the literacy levels of the patient concerned. Discussion of a clinical procedure therefore needs to be carried out in a non-technical language so that maximal exchange of information between a patient and the HCP can occur.¹⁰⁹ Even when dealing with educated people, it has been argued that explanations of the details of the medical procedure are mandatory.¹¹⁰ The requirement of comprehension imposes on a doctor the duty to assess whether a person is capable of making a rational decision based upon the information provided by evaluating whether the patient understands the information. While it may be easier to assess the adequacy of information disclosed and imparted, it is far more difficult to assess whether the information is understood by the patient or research subject.^{111,112} The causes of misunderstanding among such patients include differences in language, culture, level of education, and lack of a shared understanding between the HCP and the patient about health and disease.¹¹³ In another African study from Nigeria, it was reported that 18 patients (1.5%) out of 133 patients had difficulties understanding the information given to them. They complained that the doctors used technical terminology. Nevertheless, the patients gave consent to prevent their operations or surgical procedures being cancelled.¹¹⁴ These findings make it clear that even where consent is given, it may not always be fully informed or valid based on legal and ethical requirements for validity.

Another component of informed consent is voluntariness. Volition is concerned with the protection of the patient's right to make health care choices free of coercion or undue influence.¹¹⁵ In medical law generally, consent obtained through threat or intimidation for

¹⁰⁹ Bailey PB "Informed consent" In *Legal medicine annual* Wecht CH (ed) (Appleton-Century-Crofts New York 1978) 271-284.

¹¹⁰ Kyambi JM "Issues involved in pre-operative consent" 2004 *East Afr Med J* 329-330.

¹¹¹ Richter ML et al *Guidelines for the development of culturally sensitive approaches to obtaining informed consent for participation in HIV vaccine-related trials* (University of Natal, Scottsville, South Africa 1999).

¹¹² Appelbaum PS "Assessment of patients' competence to consent to treatment" 2007 *N Engl J Med* 1834-1840.

¹¹³ Ijsselmuiden C and Faden R "Research and informed consent in Africa-Another look" 1992 *N Eng J Med* 830-834.

¹¹⁴ Osime OC et al "Current practices and medico-legal aspects of informed consent" 2004 *East Afr Med J* 331-335.

¹¹⁵ Svoboda JS, Van Howe RS and Dwyer JG 2000 *J Contemp Health Law Policy* 61-199.

a clinical procedure may not be valid and the doctor may be held liable for assault or trespass to the person.^{116,117} The power imbalance between a patient and a doctor also creates a danger of undue influence,¹¹⁸ since a patient cannot obtain treatment without an agreeable healthcare professional.¹¹⁹ In such cases the patient can do little more than respond to treatment offered by the HCP lest they are labelled as rude and uncooperative.¹²⁰ Chima recently reported that patients in South Africa might consent without asking questions when they are afraid to forfeit free medical treatment benefits.¹²¹ Patients are also often anxious at the time consent is sought, thereby making them even more vulnerable and subject to undue influence and coercion¹²² and manipulation by HCPs during the informed consent process.¹²³

In Africa, unlike the more developed countries of the West, the appropriateness of first person informed consent has been questioned in the cultural context, where people are seen as part of a community and not as an isolated individual. Here, consent is usually first sought from community elders, and in case of married women permission is sought from their husbands. It is therefore questionable whether such consent is autonomous and free from coercion or undue influence.^{124,125} The real question on volition then is whether patients' consent is freely given, or whether their decision is influenced by patients' relationship to the HCP or surrogate/persuader as demonstrated in the case of *Re T*¹²⁶ where a mother's influence on her daughter was said to have overborne her

¹¹⁶ Carstens and Pearmain *Foundational Principles* 879.

¹¹⁷ Grubb A, Liang J and McHale J *Principles of Medical Law* 3rd ed (Oxford University Press Oxford 2010) 439.

¹¹⁸ Maclean AR *Consent to medical treatment and the competent adult* (PhD Thesis University of Glasgow 2006) 1-2.

¹¹⁹ Beauchamp TL and Childress JF *Principles of Biomedical Ethics* 5th ed (Oxford University Press New York 2001) 61-63 see also Maclean *Consent to medical treatment and the competent adult 2*.

¹²⁰ Molyneux CS et al "Even if they ask you to stand by a tree all day, you will have to do it (laughter)...!": Community voices on the notions and practice of informed consent for biomedical research in developing countries" 2005 *Soc Sci Med* 443-454.

¹²¹ Chima SC 2015 *Niger J Clin Pract* 53.

¹²² Jones B "Legal aspects of consent" 2006 (86) *BJU International* 275-279.

¹²³ Olufowote JO "A structural analysis of informed consent to treatment: (Re) productions of contradictory sociohistorical structures in practitioners' interpretive schemes" 2009 *Qualitative Health Research* 802-814.

¹²⁴ Tindana et al 2006 *IRB* 1-6.

¹²⁵ Ijsselmuiden and Faden 1992 *N Engl J Med* 830-834.

¹²⁶ *Re T* (An adult) (Consent to medical treatment) [1992] 2 FLR 458.

daughters volition to the extent that she refused life-saving blood transfusion since the mother was a Jehovah's witness. Some researchers and legal scholars hold the view that sometimes the influence of parents on their children or of one spouse on another, or master over a servant, may result in coercion, and undue influence due to the asymmetric power relationship.¹²⁷ From the foregoing, it is clear that there are challenges that exist in the process of obtaining informed consent.

In some instances, the information given is not sufficient and/or is inaccurate. In other instances the information maybe too technical that it cannot be understood by an ordinary patient based on language barriers, low education, poverty or other cultural barriers, or sickness which may all impact on the patients sense of vulnerability. In yet other instances, patients may feel intimidated by the power asymmetry due to differences in knowledge and influence between the patient and the HCP,¹²⁸¹²⁹ or the hospital environment, so that they do not consent freely or may feel intimidated.¹³⁰ Finally, it is debatable whether all individuals giving consent have the legal capacity to give consent. This study will seek to shed some light on these aspects of the informed consent process in public hospitals within an urban setting in South Africa.

1.4 Justifications for using empirical methods to study informed consent

In recent times applied ethicists have frequently combined established social scientific methods of inquiry with normative ethical reflection and analysis.^{131,132} This is based on the criticism that philosophical bioethics is too abstract and insensitive to social realities

¹²⁷ Jones MA *Textbook on Torts* 8th ed (Oxford University Press Oxford 2002) 531.

¹²⁸ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

¹²⁹ Tindana et al 2006 *IRB* 1-6.

¹³⁰ Molyneux et al 2005 *Soc Sci Med* 443-454.

¹³¹ Sulmasy DP and Sugarman J "The many methods of medical ethics (Or, thirteen ways of looking at a blackbird)" in *Methods of medical ethics* DP Sulmasy and J Sugarman (eds) (Georgetown University Press Washington DC 2001) 3-18.

¹³² De Vries R and Gordijn B "Empirical ethics and its alleged meta-ethical fallacies" 2009 *Bioethics* 193-201.

and context.^{133,134} According to a study by Braunack-Mayer,¹³⁵ critics of mainstream bioethics, particularly from the social sciences, argue that the forms, styles and language of bioethics bear little relationship to the ways in which ordinary people describe and explain their moral problems. According to Ezekiel Emmanuel,¹³⁶ the two most common criticisms of bioethics is that it is divorced from reality and the actual issues that arise in medical practice, research, and health policy debates; and secondly that bioethicists may be willing to layout arguments but are skittish about actually deciding anything. One symbol of this divorce from reality is the lack of engagement with empirical data or 'experience'.¹³⁷ On the other hand, moral philosophical ethicists have charged that one of the problems of empirical ethics or bioethics is the conflict with certain meta-ethical fallacies including the is-ought gap of Hume,¹³⁸ which argues that one cannot derive moral conclusions from factual premises, or otherwise one could violate the fact-value distinction amongst other alleged fallacies.¹³⁹ However, it has been observed that although there could be many ways of doing empirical ethics, they all have certain basic objectives in common which states that "the study of peoples actual moral beliefs, intuitions and reasoning yields information that is meaningful for ethics and should be the starting point of ethics".¹⁴⁰

Others have attempted to define empirical ethics as 'normatively oriented bioethical or medical ethical research that directly integrates empirical research'.¹⁴¹ In this formulation of empirical ethics, the key elements of its application are that it (a) encompasses

¹³³ Ives J "Encounters with experience: Empirical bioethics and the future" 2008 *Health Care Ana* 1-6.

¹³⁴ Mbugua K "Respect for cultural diversity and the empirical turn in bioethics: a plea for caution" 2012 *J Med Ethics Hist Med* 5:1.

¹³⁵ Braunack-Mayer AJ "What makes a problem an ethical problem? An empirical perspective on the nature of ethical problems in general practice" 2001 *J Med Ethics* 98-103.

¹³⁶ Emanuel EJ "The relevance of empirical research for bioethics" in *Interfaces between bioethics and the empirical social sciences* Fernando Lolas S and Lorenzo Agar C (eds) (PAHO Chile 2002) 99-110.

¹³⁷ Ives J 2008 *Health Care Ana* 1-6.

¹³⁸ Hume D *A Treatise of human nature* 2nd ed Selby-Bigge LA (ed) revised by Nidditch PH (Oxford University Press 1888) 1740/1978.

¹³⁹ De Vries R and Gordijn B 2009 *Bioethics* 196-200.

¹⁴⁰ De Vries R and Gordijn B 2009 *Bioethics* 195.

¹⁴¹ Mertz M et al "Research across the disciplines: a road map for quality criteria in empirical ethics research" 2014 *BMC Med Ethics* 17.

empirical research, as well as (b) normative arguments and analysis, and (c) tries to integrate both elements in such a way that new knowledge is produced, which might not have been possible without combining both methods.¹⁴² According to Emmanuel, the issue is not whether bioethics should focus on conceptual analysis or empiric research but that it must focus on both.¹⁴³ Borry and others¹⁴⁴ citing McHale et al,¹⁴⁵ assert that empirical ethics can assist with ethical reflection and decision-making in several different ways:¹⁴⁶

- i. It can challenge established authority and experience by showing how practice varies.
- ii. It can illuminate understanding of the reality of ethical decision-making
- iii. It can raise awareness of the underlying important questions and ethical implications of various practices
- iv. It can explore the limits of what is tolerable or acceptable
- v. It can give insight into what constitutes a good process
- vi. It can offer insight on what others think about a certain situation or moral dilemma
- vii. It can provide a comprehensive picture of the situation at hand.

De Vries and Gordijn further grouped some of these uses of empirical ethics into 5-fold typology of potential usage:¹⁴⁷

- A. Description and analysis of the actual conduct of a group with respect to a morally relevant issue
- B. Identification of moral issues that have escaped the attention of ethicists, but may be relevant in a specific context.

¹⁴² Mertz et al 2014 *BMC Med Ethics* 17.

¹⁴³ Emanuel "The relevance of empirical research for bioethics" 99.

¹⁴⁴ Borry P, Schotsmans P and Dierickx K "Empirical ethics: A challenge to bioethics" 2004 *Med Health Care Philos* 1–3.

¹⁴⁵ McHaffie HE et al "Deciding for imperilled new-borns: Medical authority or parental autonomy?" 2001 *J Med Ethics* 104–109.

¹⁴⁶ Borry P, Schotsmans P and Dierickx K "What is the role of empirical research in bioethical reflection and decision-making? An ethical analysis" 2004 *Med Health Care Philos* 41-53.

¹⁴⁷ De Vries and Gordijn 2009 *Bioethics* 194-195.

- C. Description and analysis of actual moral opinions and reasoning patterns of those involved in certain practices
- D. Making ethics more context sensitive or realistic
- E. Description of facts relevant to normative arguments.

Sulmasy and Sugarman¹⁴⁸ argue that two potential reasons may exist for studying the actual conduct of a group, with regards to compliance with moral and ethical dilemmas. One would be to describe compliance with existing moral norms, and secondly, to determine whether policies and procedures designed to operationalise certain moral norms have been successful. In terms of practical applications of empirical bioethics, Emmanuel has suggested that empirical bioethics serves three valuable functions in healthcare or contemporary medical practice and enriches the field of bioethics,¹⁴⁹ where bioethics are defined as “a discipline concerned with the ethical dimensions of health care and the biomedical sciences”.¹⁵⁰ In this context, empirical data or bioethics can assist with (a) debunking widely held but erroneous views, (b) assessing the importance of ethical concerns; and (c) facilitating the realization of certain ethical values.¹⁵¹ Emmanuel was able to substantiate his views by citing contemporary empirical studies that have been able to show that rather than the generally held belief that pain is the most difficult or predominant issue with regards to euthanasia and end-of-life care. He observed that contrary to such beliefs, empirical data demonstrate that depression, hopelessness, and general psychological distress are consistently associated with interest in physician-assisted-suicide and euthanasia. Other areas in which empirical bioethics and data analysis could play a role would include “assessing the importance of ethical concerns”.¹⁵² For example, by helping to resolve the conflict in informed consent regarding the comprehensiveness of information disclosure and understanding of information disclosed, as well as determining the methodological or the ethical concerns surrounding the storage and use of human biological specimens. Empirical bioethics can also assist with the

¹⁴⁸ Sulmasy and Sugarman “The many methods of medical ethics” 3–18.

¹⁴⁹ Emanuel “The relevance of empirical research for bioethics” 99.

¹⁵⁰ Kuhse H and Singer P “What is bioethics- a historical introduction” in *A companion to bioethics* 2nd ed Kuhse and Singer (eds) (Oxford University Press London 1998) 3.

¹⁵¹ Emanuel “The relevance of empirical research for bioethics” 99.

¹⁵² Emanuel “The relevance of empirical research for bioethics” 100.

realization of ethical values such as respect for autonomy, and in some cases distributive justice such as the just allocation of scarce healthcare resources.¹⁵³ Other empirical studies have shown that people generally have problems in understanding the risks and benefits of medical treatment and decision-making, and this could influence the actual application of existing laws.¹⁵⁴ For example, a study by means of a questionnaire on Dutch nurses charged with taking care of nursing home residents with due respect to the patients autonomy rights and liberty revealed that the nurses did not comply with the existing regulations on patient care in Dutch nursing homes.¹⁵⁵

Based on the various observations and illustrations above, it has been suggested by Birnbacher that to guide action; ethical guidelines, codes and rules must be based in reality and should be formulated in such a way that it is continuous with accepted moral norms.¹⁵⁶ Others have suggested that empirical ethics should be used to defend or criticize concrete moral principles or practices rather than make general claims about moral concepts.¹⁵⁷ Consequently, in recent times, applied ethicists have shifted towards combining empirical, especially social scientific research with normative ethical analysis. Proponents of this approach called empirical ethics or bioethics have argued that the study of people's actual moral beliefs, behaviour and reasoning should be the starting point of ethics. It has also been acknowledged that the methodologies of the social sciences, especially quantitative and qualitative research, using surveys, interviews and questionnaires is probably the best way to map the reality of peoples actual moral norms.¹⁵⁸ Finally, it has been suggested that the ultimate goal of empirical inquiry is to improve the quality of healthcare.¹⁵⁹ In this role, Alexander Kon¹⁶⁰ has described four

¹⁵³ Emanuel "The relevance of empirical research for bioethics" 104-106.

¹⁵⁴ Musschenga AW "Empirical science and ethical theory: The case of informed consent" in *Reasoning in ethics and law* Musschenga AW and Van der Steen WJ (eds) (Ashgate Aldershot 1999) 183-204.

¹⁵⁵ Van Thiel GJ and Van Delden JJ "Dealing with patient autonomy in Dutch nursing homes" 1997 *Health Care in Later Life* 177-186.

¹⁵⁶ Birnbacher D "Ethics and social science: Which kind of co-operation" 1999 *Ethical Theory Moral Pract* 319-336.

¹⁵⁷ De Vries and Gordijn 2009 *Bioethics* 193-201.

¹⁵⁸ Borry et al 2004 *Med Health Care Philos* 1-3.

¹⁵⁹ Emanuel "The relevance of empirical research for bioethics" 99-110.

¹⁶⁰ Kon AA "The role of empirical research in bioethics" 2009 *AJOB* 59-65.

hierarchical categories of empirical bioethics, which can build on one another to assist in ethical decision-making. These categories of empirical ethics enquiry are described as:

- I. “Lay of the land” studies which are usually overviews of current practices and the status quo
- II. “Ideal versus reality studies” which attempt to map out how well clinical practice matches normative ethical principles or ideas
- III. “Improving care studies” which focuses on how we can bring ethical ideals closer to match normative practice, and
- IV. “Changing ethical norms” studies which focus on how we can bring together data from various empirical studies to inform or change current ethical norms.¹⁶¹

Other ethicists such as Borry and others¹⁶² have described three possible roles for empirical research in bioethics. First, it can assist in describing morally relevant facts; secondly, it can assist in the analysis of moral questions since empirical research possesses “the normative power of the factual”.¹⁶³ Therefore in this study, I decided to evaluate the practice of informed consent as stipulated by the South African common law, and the NHA and its regulations,¹⁶⁴ by actually conducting a field study using quantitative empirical data, to determine whether HCPs, in this case doctors and professional nurses, are actually practicing in compliance with the current regulations, and also to evaluate from the point of view of patients, how compliant the HCPs are with regard to the legal requirements and ethical regulations. In view of this, the rationale or point of departure of this study, as well as the aims and objectives of this study, are as outlined below.

1.5 Rationale for the study

Reports in the scientific and medico-legal literature indicate that medical procedures are conducted globally in violation of the ethical principle of respect for autonomy and

¹⁶¹ Kon AA 2009 *AJOB* 59-62.

¹⁶² Borry et al 2004 *Med Health Care Philos* 41-53

¹⁶³ Borry et al 2004 *Med Health Care Philos* 43.

¹⁶⁴ National Health Act 61 of 2003.

sometimes without valid IC. This is most evident in developing countries such as South Africa, where the health system is poorly developed, and where the doctor to patient ratio is high, and long queues outside doctors' clinics and public hospitals are everyday features. Under these circumstances, it is difficult for doctors and other HCPS to spend enough time with patients in order to provide adequate information to enable valid IC.^{165,166} The poor educational standards, high illiteracy levels, language difficulties, cultural belief systems, and the power/information asymmetry that exists in the doctor-patient relationship in this setting also makes it difficult for a large proportion of vulnerable African population groups to comprehend the medical procedures as described by HCPs.^{167,168,169,170} Consent documents, including forms and information sheets for treatment procedures are often written in a language that cannot be clearly understood by the majority of patients.^{171,172,173} Translation, on the other hand, may also not provide an accurate picture of what is at stake. Worse still, voluntary consent is sometimes problematic and difficult to obtain since any offer of medical assistance or other assistance incidental thereto will be accepted as better than nothing, based on a therapeutic misconception,¹⁷⁴ which encourages undue influence. Further, the power imbalance that exists between a doctor and a patient may create an intimidating environment that inhibits patients from providing voluntary consent.^{175,176,177}

Since the end of the apartheid era in South Africa, new laws have been introduced to safeguard individual human rights including provisions within the final Constitution in

¹⁶⁵ Chima SC "Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study" 2013 *BMC Med Ethics* S3.

¹⁶⁶ Chima SC 2015 *Niger J Clin Pract* 48-51.

¹⁶⁷ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

¹⁶⁸ Ijsselmuiden and Faden 1992 *N Engl J Med* 830-834.

¹⁶⁹ Tindana et al 2006 *IRB* 1-6.

¹⁷⁰ Chima SC "Global medicine: Regulation of biomedical research in Africa" 2006 *BMJ* 848-851.

¹⁷¹ Flores G "Language barriers to healthcare in the United States" 2006 *N Engl J Med* 229-331

¹⁷² Green JB et al "Putting the 'informed' into 'consent': A matter of plain language" 2003 *J Paediatr and Child Health* 700-703.

¹⁷³ Schlemmer A and Mash B "The effects of a language barrier in a South African district hospital" 2006 *SAMJ* 1084-1087.

¹⁷⁴ Sugarman J et al "Evaluating the quality of informed consent" 2005 *Clinical Trials* 34-41.

¹⁷⁵ Chima SC 2015 *Niger J Clin Pract* 51-52.

¹⁷⁶ Ijsselmuiden and Faden 1992 *N Engl J Med* 830-834.

¹⁷⁷ Molyneux et al 2005 *Soc Sci Med* 443-454.

1996.^{178,179,180,181} Furthermore, the evident dichotomy in the provision of health services in South Africa¹⁸² may also influence the practice of informed consent in this setting, considering that indigent patients are predominant in using overstretched public health facilities, while the affluent and arguable better educated patients would generally patronize private healthcare services.¹⁸³ Moreover, most African societies, being culturally complex and paternalistic in nature may require that consent or approval be obtained from community elders/extended family members, or men as heads of households before the actual patients/human subjects can provide consent to medical treatment or research.^{184,185} Therefore the challenge in this type of situation is how to ensure that informed consent is truly voluntary and that community or surrogate consent is not substituted for individuals' consent, which ideally should be obtained voluntarily in the absence of coercion.¹⁸⁶ In view of the above factors, it is arguable whether the healthcare providers (HCPs) and healthcare users (patients) are fully aware of the current applicable laws and ethical regulations regarding IC in South Africa. This study, therefore, seeks to investigate how all these factors play themselves out in clinical practice in South Africa.

1.5.1 Aims and objectives of this study

In the light of the foregoing, this study is designed to establish whether the informed consent obtained from patients in clinical practice in South Africa is fully informed, comprehensible, voluntary, and is obtained within the context of applicable local laws and regulations; when compared to internationally acceptable standards. The general

¹⁷⁸ Truth and Reconciliation Commission *Truth and Reconciliation Commission of South Africa Report vol 4 The Health Sector* (Truth and Reconciliation Commission 1998)109-157.

¹⁷⁹ National Health Act 61 of 2003.

¹⁸⁰ Choice on termination of Pregnancy Act 92 of 1996.

¹⁸¹ Constitution of the Republic of South Africa 1996.

¹⁸² Department of Health *KwaZulu-Natal Strategic Plan 2010-2014* (DOH KZN 2010).

¹⁸³ Chima SC 2015 (18) *Niger J Clin Pract* 49.

¹⁸⁴ Jansen I "Decision making in childbirth: the influence of traditional structures in a Ghanaian village" 2006 *International Nursing Review* 44-45.

¹⁸⁵ Tindana et al 2006 *IRB* 3-5 see also Irabor and Omonzejele 2009 *Dev World Bioeth* 38 and Molyneux CS Peshu N and Marsh K "Trust and informed consent: insights from community members on the Kenyan coast" 2005 *Soc Sci Med* 1469.

¹⁸⁶ Frimpong-Mansoh A "Culture and voluntary informed consent in African health care systems" 2008 *Dev World Bioeth* 107-109.

objective of this study is to establish whether informed consent is obtained from patients prior to involvement in clinical procedures and medical treatment in South Africa.

1.5.2 The study addressed the following hypotheses:

- 1) That there is no relationship between sufficiency of information provided to patients and informed consent.
- 2) That there is no relationship between comprehension of information given to patients and informed consent.
- 3) That there is no association between mental capacity of patients and informed consent.
- 4) That there is no association between language and informed consent.
- 5) That there is no association between volition of patients and informed consent.
- 6) That there is no association between valid informed consent and clinical practice in South Africa.

1.5.3 Specific objectives

While the general objective of this study was to establish whether informed consent is obtained from patients prior to involvement in medical treatment or procedures in South Africa, the specific objectives of the study are:

- I. To find out whether sufficient information is provided to patients in clinical practice before consent is sought.
- II. To establish whether patients involved in clinical procedures understand the information provided.
- III. To establish whether consent is obtained from patients voluntarily and without coercion or undue influence.
- IV. To establish whether informed consent provided by patients in clinical practice in South Africa is truly valid.
- V. To evaluate by means of a review of the legal literature, whether South African courts are applying the requirements of recently enacted laws, specifically, the

National Health Act 61 of 2003,¹⁸⁷ when arriving at legal decisions pertaining to informed consent in medical practice.

1.5.4 Research questions

- 1) Is sufficient information provided to patients involved in clinical practice before consent is obtained in South Africa?
- 2) Do patients understand the medical procedure or treatment option before they provide consent?
- 3) Are patients undergoing medical procedures in South Africa generally competent to consent to such treatment?
- 4) Do patients involved in medical procedures in South Africa consent voluntarily?
- 5) Is the informed consent given by patients in medical practice in South Africa truly valid?

1.6 Significance of the study

The study will be significant by improving the quality of informed consent and care provided to patients in clinical practice in South Africa. It will also enhance the protection of human rights and respect for persons; reducing potential litigation arising due to failure to obtain valid IC from patients, thereby enhancing the ethical and human rights responsibilities of HCPs towards healthcare users. The results of the study will assist in improving patients' education and awareness; reinforcement of patients' human rights and protections; and be beneficial to lawmakers in drafting better regulations, and in enforcing current laws and regulations to assist in medical practice. The study may also assist in the design of improved and new consent documents and information sheets, aimed at obtaining valid informed consent from patients undergoing medical procedures in clinical practice. The study results will disseminated via published academic papers and a thesis designed to further knowledge and future investigations in the field of informed consent,

¹⁸⁷ National Health Act 61 of 2003.

healthcare law, and medical jurisprudence with particular relevance to South Africa, and other African countries, and common law jurisdictions.

1.7 Research design and methodology

The empirical design for this study is based on a quantitative descriptive cross sectional design in contemporary clinical practice settings. This approach was followed because the time between procuring informed consent and medical treatment is very short and patients are normally in hospital for a limited time. The descriptive approach allowed HCPs and patients to describe their experience with the informed consent process as it happened, thereby bringing out the required information. In addition I analysed the current relevant case law from South Africa and other common law jurisdictions, as well as the current academic literature pertaining to informed consent; to elucidate any similarities or differences between the practice of informed in South Africa and similar legal jurisdictions within the context of an interdisciplinary legal analysis.

1.7.1 Triangulation

Triangulation refers to a “combination of methodologies in the study of the same phenomenon,”¹⁸⁸ or the use of multiple data sources in an investigation to produce understanding.¹⁸⁹ The original purpose of triangulation was to seek confirmation of apparent findings, or in other words, consistency. More recently, it has also been used for completeness purposes. Triangulation also refers to the use of multiple references to draw conclusions about what constitutes the truth.^{190,191} Generally, four types of triangulation have been described,¹⁹² comprising:

¹⁸⁸ Denzin NK (ed) *Sociological methods: A sourcebook* (Routledge New York 2017) 31.

¹⁸⁹ Robert Wood Johnson Foundation “Triangulation” Qualitative Research Guidelines Project www.qualres.org/HomeTria-3692.html (Date of use: 7 November 2017).

¹⁹⁰ Begley C “Using triangulation in nursing research” 1996 *J Adv Nurs* 122-128.

¹⁹¹ Taylor BJ *Research in nursing and practice: Evidence for practice* (Cengage Australia 2006) 235.

¹⁹² Patton MQ “Enhancing the quality and credibility of qualitative analysis” 1999 *HSR: Health Services Research* 1189-1208 see also Robert Wood Johnson Foundation “Triangulation” www.qualres.org/HomeTria-3692.html.

- I. **Data triangulation** - this involves the use of multiple data sources in a study to get diverse points of view as an aid in validating the conclusions. Data triangulation may include either
 - a) Time triangulation-whereby the researcher collects data from the same sources at different points in time;
 - b) Space triangulation-whereby the researcher collects data from different locations during the same study; or
 - c) Person triangulation-whereby the researcher collects data from different individuals or groups to as part of the same study.
- II. **Investigator triangulation** - this refers to the use of two or more trained researchers to analyse and interpret the same set of data in arriving at a conclusion.
- III. **Theory triangulation** - this is the use of competing theories or hypotheses in the analysis and interpretation of a single set of data.
- IV. **Method triangulation** - this would involve the use of multiple methodologies in collecting data about the same phenomenon).^{193,194}

Therefore, triangulation may involve the use of:

- different data collection tools with the same sample of participants;
- different qualitative methodologies to answer the same research question;
- a combination of quantitative and qualitative research methodologies to answer the same research question;
- the same data collection tools with different samples.¹⁹⁵

Redfern and Norman (1994)¹⁹⁶ summarized the advantages of triangulation to include the following:

¹⁹³ Denzin N *The research act: A theoretical introduction to sociological methods to 3rd ed* (McGraw-Hill New York 1989) 297.

¹⁹⁴ Begley 1996 *J Adv Nurs* 122-128.

¹⁹⁵ Taylor *Research in nursing and practice* 235.

¹⁹⁶ Redfern SJ and Norman J "Validity through triangulation" 1994 *Nurse Researcher* 41-56.

- overcoming the bias of single-method, single-observer and single theory studies;
- increasing confidence in the results;
- providing an understanding of the domain;
- overcoming the elite bias of naturalistic research;
- allowing divergent results to enrich explanation.^{197,198}

In the present study, I applied the techniques of 'data triangulation' in the form of person-triangulation, whereby I collected data from doctors, nurses and patients. Further I have used a form of 'space triangulation' whereby I have collected data from different public hospitals and clinical sites to evaluate the practice of informed consent in different clinical settings and locations in order to check for consistency and completeness of data, and to validate the results of the study reported in this thesis.

1.8 Study populations and sources of data

1.8.1 Target population groups

Practicing healthcare professionals (medical doctors and professional nurses) and healthcare users (patients), attending selected provincial public hospitals within EThekweni metropolitan municipality (Durban), Kwazulu-Natal Province (KZN), were selected by random sampling to participate in this study. Randomization occurred at the level of health care facility, whereby provincial hospitals in EThekweni were stratified alphabetically and then randomly selected for inclusion in the study. Individual participants at the selected institutions, whether doctors, nurses or patients had an equal chance to participate voluntarily in the study.

¹⁹⁷ Begley *J Adv Nurs* 1996 122-128.

¹⁹⁸ Taylor *Research in nursing and practice* 235.

1.8.2 Categories of nurses in South Africa

There are three main categories of registered nurses in South Africa. These are professional nurses, staff nurses and nursing auxiliaries. There are also nursing assistants and student nurses.¹⁹⁹

- i. **Professional nurse** - A professional nurse (PN) or registered nurse or midwife (RN) (sometimes called a nursing sister), is an individual who has completed a four-year programme at university or a nursing college. This person is educated and competent to practice comprehensive nursing and midwifery.²⁰⁰
- ii. **Staff nurse** - A staff nurse also known as an enrolled nurse refers to a registered nurse with a minimum of two years tertiary nursing education.
- iii. **Auxiliary nurse** - These are nurses with one year of nursing education from a nursing school.²⁰¹
- iv. **Inclusion criteria:** As stated, there are three categories of registered nurses in South Africa, professional nurses, staff nurses and nursing auxiliaries as described above. In this study only nurses in the categories of “professional nurse” and “enrolled or staff nurse” were included. Nurses working in the surgical, internal medicine, paediatric, obstetrics and gynaecology, wards and clinics that were available and willing to participate during the site visit and study period were given an equal opportunity to participate in the study.
- v. **Exclusion criteria:** Apart from the two categories of registered nurses as specified above; all other categories of nurses, including student nurses studying for Bachelor degrees, were excluded from this study. The objective was to ascertain the level of knowledge of practising professional nurses in the field.

¹⁹⁹ South African Nursing Council (SANC) *Strategic plan for nurse education training and practice 2012/13 – 2016/17* (SANC Pretoria 2012) 21.

²⁰⁰ Health Personnel www.hst.org.za/healthstats/index (Date of use: 28 February 2011).

²⁰¹ SANC *Strategic plan for nurse education training and practice* 21.

1.8.3 Medical Practitioners

For medical doctors, all qualified medical doctors including specialists registered with the Health Professions Council of South Africa (HPCSA) and currently engaged in clinical practice and working in the selected hospitals, who voluntarily agreed to participate in the study, were included.

1.8.4 Patients

a) **Inclusion criteria:** All patients in the selected hospitals in the surgical, internal medicine, paediatric, obstetrics and gynaecology, wards and outpatient clinics had an equal chance of participating in the study, if they were available and willing to participate voluntarily during the site visit to the hospital.

b) **Exclusion criteria:** Patients with severe mental incapacity due to mental health or behavioural disorders such as unconsciousness, and those who are unable to provide informed consent either by themselves or by means of a guardian, were excluded from the study. Similarly, minors below the legal age of consent whose guardians or parents were absent during the study to provide informed consent, were excluded from the study.

1.9 Research Setting

1.9.1 Study location

This study was carried out at selected public hospitals within EThekweni metropolitan municipality (Durban city and environs) in KwaZulu-Natal Province of South Africa. EThekweni metropolitan municipality comprises a major urban city (Durban) and semi-urban areas (townships) with a population of around 3.2 million people (2010 estimate).²⁰² Based on statistics from KZN department of Health, there are 17 public hospitals in EThekweni municipality.²⁰³ According to Terre-Blanche and others, 30% of the population

²⁰² Statistics South Africa http://www.statssa.gov.za/?page_id=1021&id=ethekwini-municipality (Date of use: 26 April 2016).

²⁰³ KZN Department of Health <http://www.kznhealth.gov.za/district1.htm> (Date of use: 12 April 2016).

is adequate when conducting a descriptive study.²⁰⁴ Therefore, six (6) provincial/public hospitals were finally included in this study.²⁰⁵ Figure 1 below shows a map of eThekweni municipality showing the approximate locations of Level 1 healthcare facilities (district and regional hospitals) included in the study.

1.9.2 Selected hospitals and sampling procedures

As mentioned above, citing Terre-Blanche (2008),²⁰⁶ thirty percent of any population is generally adequate when conducting a cross-sectional descriptive study. Since this study was limited to public hospitals, out of the 17 public hospitals, six were randomly selected as study sites for this research study. Multi-stage stratified random sampling was used to select eligible hospital sites. The hospitals were first stratified by authority (provincial or private) and then selected using systematic random sampling. This was done by arranging the public hospitals by name alphabetically. Then every third hospital from the list was then selected. Further, purposive sampling was used to include the two central tertiary teaching hospitals within eThekweni municipality, because they were likely to yield the largest number of study participants, i.e. professional nurses, doctors at all levels including specialists and interns and a variety of patients and HCPs in various clinical departments to assist with a more robust sample population. The rest of the hospitals within the municipality were randomly sampled as described above. Random selection of the public health hospitals for the study ensured that patients from all socio-economic strata were covered and eligible for inclusion. Further, HCPs with different types of clinical practice experience regarding informed consent were thereby included in the study.

²⁰⁴ Terre-Blanche M, Durrheim K and Painter D *Research in practice* (University of Cape Town Press Cape Town 2008) 50.

²⁰⁵ Statistics South Africa <http://www.statssa.gov.za/census01/html/C2001munic.asp> (Date of use: 24 February 2011)

²⁰⁶ Terre-Blanche et al *Research in practice* 50.

1.10 Research instruments

Data was collected using separate questionnaires for HCPs and healthcare users (patients). Two different semi-structured questionnaires with open and close-ended questionnaires were applied to patients and HCPs. The questionnaires used are included in Appendices 1 and 2 of this thesis.²⁰⁷ Further, patient questionnaires were further translated from English into the dominant South African language spoken in KZN province-IsiZulu (Appendix 3). Translation of this questionnaire was done by a qualified translator from the Department of IsiZulu Studies, University of KwaZulu-Natal (UKZN). The patient interviews were conducted in the surgical, internal Medicine, paediatrics, obstetrics, gynaecology, departments of the hospitals under study, including inpatient, and outpatient departments. The questionnaires were distributed by hand to HCPs working in the selected hospitals under study. Further, patients had the option of completing the interviews in either English or IsiZulu, and had the option of filling the questionnaires out by themselves or having the questions read out by a trained bilingual research assistant/interviewer who recorded the answers verbatim. Three research assistants who were trained on the questionnaire and interview methods conducted the patient interviews. HCPs completed the questionnaires on their own after providing and signing informed consent documents. Therefore, in this study, I used two separate semi-structured questionnaires for HCPs and another for the patients. Samples of both questionnaires are shown in appendices 1 to 3 of this thesis.

1.10.1 Description of questionnaire for healthcare professionals (HCPS)

The questionnaire for HCPs (doctors and nurses) was designed in 4 sections as shown in Appendix 1, but a brief description is provided here. The first section was used to obtain information about respondent demographics or dependent variables, such as age, sex, job title, position, department in the hospital, years of professional experience, clinical speciality, etc. The second part of the questionnaires contained questions about informed consent practices such as; time spent on obtaining informed consent, patient workload,

²⁰⁷ See appendices 1 to 3.

information disclosed to patients, language and methods used to communicate with patients; understanding of information by patients and challenges faced by HCPs when obtaining informed consent from patients. The third section of the questionnaire asked general knowledge questions about local healthcare laws such as 'age of consent to medical treatment' and 'age of consent to termination of pregnancy', and standards of information disclosure. The fourth section solicited questions about HCPs knowledge and practices regarding implied or presumed consent in clinical practice. The questionnaire for HCPs was first circulated for comment by a small sample of doctors and nurses and was then modified based on comments from initial participants prior to distribution to all eligible and agreeable HCPs. The questionnaires were distributed by hand at all selected hospital sites by research assistants and retrieved by hand after completion by respondents at their own convenience. Participation in the study and completion of the questionnaire was entirely voluntary.

1.10.2 Description of questionnaire for patients

The main study instrument for patients was a semi-structured questionnaire in English language, which was also translated into IsiZulu, the dominant language spoken by about 81% of the population of KZN.²⁰⁹ Professional translation of this questionnaire was done by the Department of IsiZulu studies, UKZN. The questionnaire consists of three sections as shown appendices 2 and 3. The first section collected sociodemographic data; including age, sex, marital status, employment status, educational level, income and living situation of patient participants. These served as dependent variables. The second part of the patient questionnaire was used to gather information on independent variables such as details of patient experiences of IC when interacting or when receiving treatment from HCPS. The section contained questions about time spent on the clinical encounter, information disclosed by HCPs to patients before obtaining consent, methods and language used to communicate with patients, satisfaction level with information disclosure, and completeness of information disclosure, understanding and the absence of coercion or undue influence by HCPs during clinical encounters. The third part of the patient questionnaire asked questions about patient's general knowledge, understanding, and opinions on IC, such as 'the legal age of consent to treatment', who assisted patient in obtaining informed consent, or making decisions regarding medical treatment as well open ended questions regarding patients level of satisfaction with their clinical encounters and communications with local HCPs. Participants were interviewed by three trained bilingual research assistants. Those patients who were able to read and write and preferred were allowed to complete the questionnaire by themselves and return to research assistant at the same clinical site during the site visit. Patient respondents had the option of completing questionnaires either in English or IsiZulu or their preferred language. Patient participation was entirely voluntary and questionnaires were completed by parents or guardians in the case of children or individuals not capable of giving informed consent themselves.

²⁰⁹ EThekwini Municipality "EThekwini language policy"
<http://www.Durban.gov.za.eThekwiniLanguagepolicy.pdf> (Date of use: 19 August 2014).

1.11 Sampling procedures

Multi-stage stratified random sampling was used to select participating hospitals. Purposive sampling was used to include the two central/ regional tertiary hospitals within eThekweni municipality because they contain the largest number of medical doctors including specialists as well as professional nurses. The rest of the district hospitals within the municipality was randomly sampled. A total of five hospitals from Durban and one outlying hospital in nearby Pietermaritzburg with rotating surgical registrars from Durban were included in the study. Therefore, a total of six provincial/public hospitals were included in this study population.

1.11.1 Sample size calculations

Preliminary sample size for each group of study participants was calculated using a web based sample size calculator by Raosoft®.²¹⁰ Based on the formula for sample size with the margin of error set at 5%. Based on the above assumptions the estimated sample size for each category of participants was:

- A. **360** Medical Practitioners (doctors including specialists)
- B. **373** Professional nurses
- C. **385** Patients

The above numbers gave an estimated total sample size for this study cohort at **1118** participants. This served as a baseline for the number of participants to be recruited in each respondent/ participant category for the entire study. Participant recruitment and hospital site visits were conducted during a 3-month period extending from March to June 2012. Multiple visits to study sites were made to selected hospitals during this period after obtaining research ethics approval from the various regulatory authorities and gate-keepers at each institution. The actual distribution of the questionnaires was conducted

²¹⁰ Raosoft™ <http://www.raosoft.com/samplesize.html> (Date of use: 15 February 2012).

by three trained research assistants who also were at the minimum bilingual in (English/Zulu/Xhosa/Sotho). The research assistants distributed the questionnaires to willing participants and made arrangements to collect same at the respondents' convenience. Multiple visits were made to the various study sites to aid participant recruitment until the maximum number willing to participate was reached. In case of patients, the estimated sample size for patients was exceeded by 5% (20) patients to compensate for incomplete forms or ineligibility.

1.12 Data collection, storage and analysis

Primary data was collected using questionnaires and patient interviews as described above. Further, case law and statutes from data available in the public domain, as well as applicable regulations were obtained by review of literature. In addition, currently used standard consent documents or consent forms were collected from the various selected hospitals. The data from the questionnaires was filled out by hand and stored in a locked cabinet to maintain participant confidentiality and security. Then at the end of each collection date or site visit, the questionnaires were entered into a single laptop computer by one of the trained research assistants who also doubled as a data capturer. The raw data was evaluated for completeness and accuracy by the principal investigator (myself) and also cross-checked prior to analysis by a qualified biostatistician.

1.12.1 Statistical methods

The software used for data capturing storage and analysis was the Statistical Package for Social Sciences (SPSS versions 18- 22 IBM Corporation Armonk New York).²¹¹

Descriptive statistics such as proportions, median, mode and interquartile range were used to summarize the data. Bar charts, pie chart and graphs were used to present the results, using Microsoft Excel.²¹² The scores for comprehension of informed consent were worked out from the responses. The Mann-Whitney test was used to examine the

²¹¹ IBM *SPSS Statistics for Windows* (IBM Corp Armonk NY 2012).

²¹² Microsoft Corp *Microsoft Excel for Windows* (Microsoft Corp Seattle 2010).

difference in scores between doctors and nurses and other applicable variables. Kruskal-Wallis test was used to examine the relationship between (1) education level and the scores, (2) Clinical department and scores and (3) Profession and the scores, income level and scores etc., as will be described in the results and findings sections. Chi-squared tests or Fisher's exact test were used to test association between any categorical variables in the study, as well as analysing and comparing the informed consent aggregate scores (ICAS) scores between various cadres of HCPs as will be detailed further in chapters 5-7 of this thesis.

1.12.2 Validity and reliability of statistical methods

The study design and statistical methodology proposed for this study were reviewed and validated by a consultant biostatistician at College of Health Sciences, University of KwaZulu-Natal, South Africa. The statistical methodology of the study was further evaluated and approved by the knowledge management and strategic services division of the KZN Department of Health, before approval of the proposed research proposal (see annexure 5).

1.12.3 Work Units

The wards and clinics in each participating hospital were also be randomly sampled. The aim was to sample about 30% of the wards at each selected hospital.²¹³ Thereafter eligible HCPs and patients in the wards and outpatient clinics who were willing to participate in the study were all given a chance to participate in the study by completing the questionnaires. Generally, the OPDs were randomly selected on the day of visit by the researcher and research assistants. Patients and HCPs were then approached by the research assistants, those who were willing participants were given the informed consent documents to read and sign. Then the study instrument (questionnaire) was handed over to the participant to complete for HCPs, and for patients those who preferred were given

²¹³ Terre-Blanche et al *Research in practice* 50.

the questionnaires to complete by themselves, while those who wanted the questions to be read out, the research assistant would read out the questions and record the answers given by the patients verbatim onto the questionnaire.

1.13 Ethical considerations

Ethical approval was obtained from a subcommittee of UNISA Research Ethics Committee (annexure 4), and local permits were obtained from the KZN Department of Health knowledge and strategic management division as well as the eThekweni municipality department of health after review of the research proposal (annexure 5). Further approvals were contained from each selected local hospital administration after evaluation of research proposals and ethical approvals (annexure 6). Finally, informed consent was obtained from every participant in the research study, after full information disclosure and signing of the consent form prior to participation in the study (appendices 4 and 5). Participant confidentiality was maintained by safe storage of data and anonymization of data, research results were also be reported anonymously.

1.14 Scope and limitations of the study

Due to limited resources, the length of time allocated and data collection procedures for this study were limited to selected public hospitals within eThekweni metropolitan municipality, KZN, province, South Africa. The study among HCPs was also limited to medical practitioners and professional nurses in the clinical departments or units of Internal medicine, Surgery, Obstetrics and Gynaecology, Paediatrics at the selected hospitals. The study period was also limited to a 3-month period from April to June 2012 due to resource limitations.

1.15 Assumptions of the study

In carrying out this study, it is assumed that medical doctors, nurses and patients in the selected hospitals and departments will freely and willingly provide the requisite

information. It was further assumed that HCPs and patients will be willing to give accurate information. It was also assumed that necessary ethical approvals will be given by the regulatory authorities and participants.

1.16 Definition of key concepts and terms

- i. **Information disclosure** in this study will be defined as sufficient and adequate when it includes diagnosis, risks, benefits, alternatives to the procedure, and the right of refusal.
- ii. **Comprehension** in this study will be defined as the ability to understand, in a language or signs that can be communicated between the doctor and the patient.
- iii. **Volition** in this study will be defined as free from coercion, undue influence or deception.
- iv. **Valid informed consent** in this study will be defined as comprising five key elements, information disclosure, competence, comprehension, voluntariness and consent or agreement to the procedure.
- v. **Capacity** in this study will be defined as the legal capacity to consent to a medical intervention or procedure.
- vi. **Professional nurse** - a professional nurse (PN) or registered nurse or midwife (RN) (sometimes called a nursing sister), is an individual who has completed a four year programme at university or a nursing College. This person is educated and competent to practice comprehensive nursing and midwifery.²¹⁴
- vii. **Enrolled or staff nurse** - a staff nurse refers to a registered nurse with a minimum of 2-years tertiary nursing education.²¹⁵
- viii. **Medical Practitioner** - a qualified medical doctor including specialists registered with the Health Professions Council of South Africa (HPCSA) and currently engaged in clinical practice.
- ix. **Healthcare user or patient** – a person attending the hospital or healthcare facility to seek treatment.

²¹⁴ Health Personnel www.hst.org.za/healthstats/index Date of use: 15 February 2011)

²¹⁵ SANC *Strategic plan for nurse education, training and practice* 21.

- x. **Public hospital** - refers to a hospital owned and managed by a provincial government in South Africa. These hospitals are usually non-profit and free to the public. There are three main categories of public hospitals in South Arica, namely: tertiary (specialist, teaching hospitals), regional (specialized), or district hospitals (general medical services).

1.17 Summary of chapter 1 and conceptual outline of the study

This study may be described as a multidisciplinary legal research because it draws on an integration and application of the disciplines and methodologies of law, medicine, social sciences, biostatistics and epidemiology to evaluate the quality of informed consent as practiced in South African public hospitals. At the same time, this is an example of interdisciplinary legal research by definition because it was conducted by a researcher with advanced expertise in medicine and law.²¹⁶ Since this is an interdisciplinary/ multidisciplinary thesis, the empirical studies included in part two of this thesis have been written using a recognizable method for reporting scientific papers the-the IMRaD format.²¹⁷ IMRaD is an acronym for introduction- methods-results-and-discussion. The IMRaD format is a way of structuring a scientific article. It is often used in health care and the natural sciences, but unlike articles or theses in the social sciences, the IMRaD format does not include a separate theory chapter,²¹⁸ and therefore there may be noticeable theoretical repetitions in this thesis. However, a synthesis of both the theoretical and empirical research results are fully integrated and discussed in chapter 8 of this thesis.

²¹⁶ Kroeze IJ "Legal research methodology and the myth of interdisciplinarity" 2013 *Potchefstroom Electronic Law Journal* 35-65.

²¹⁷ Sollaci LB and Pereira MG "The introduction, methods, results, and discussion (IMRAD) structure: a fifty-year survey" 2004 *J Med Libr Assoc* 364–371.

²¹⁸ "IMRAD: What goes into each section"
http://www.jpgmonline.com/documents/author/24/2_Aggarwal_10.pdf see also
<http://sokogskriv.no/en/writing/structure/the-imrad-format/> (Date of use: January 24 2017)

In concluding this chapter, one may argue that this study is consistent with Kon's hierarchies of empirical ethics research²¹⁹ whereby Kon describes four categories of empirical ethics enquiry as:

- I. **“lay of the land”** studies which are usually overviews of current practices and the status quo,
- II. the second level of study involves **“ideal versus reality studies”**, which attempt to map out how well clinical practice matches normative ethical principles or ideas,
- III. the third level of this hierarchy involves **“improving care studies”** which focuses on how we can bring ethical ideals closer to match normative practice,
- IV. the fourth element of these hierarchy **“changing ethical norms”** studies focuses on how we can bring together data from various empirical studies to inform or change current ethical norms

This study is consistent with Kon's categories 1 and 2 which are described as *“lay of the land”* studies designed to evaluate current practice of informed consent by HCPs at public hospitals in South Africa. It also includes elements of “ideal versus reality” type study designed to map out how well current clinical practice matches normative principles of ethics and current legal regulations regarding informed consent as laid down by and contained in case law, current legislation, and ethical guidelines, especially in the context of the regulations regarding informed consent as codified in the National Health Act 61 of 2003.²²⁰

²¹⁹ Kon 2009 *AJOB* 59-65.

²²⁰ National Health Act 61 of 2003 s6-9.

CHAPTER 2 – BACKGROUND

2.1 Introduction

In chapter one, I provided a detailed overview and orientation to this thesis. In this chapter, I elaborate further on the background studies underlying this thesis starting with definitions of consent, consent to treatment, and what makes consent valid. This will be followed by a discussion of the key elements of informed consent, starting with competence or decision making capacity (DMC), including analysis of standards of DMC, fluctuating capacity, and DMC in incompetent patients as well as children including ‘mature minors’. I will also explore the unique context of consent to termination pregnancy in South Africa. Furthermore, I will discuss the other key elements of IC including voluntariness, and forms of undue influence affecting IC. This will be followed by analysis of information disclosure, including standards for information disclosure in the context South African law, as well as comparative analysis of the South African case law with other common law jurisdictions. As previously discussed in chapter one, there is a paucity of legal discourse and clarity regarding information disclosure in South African case law. Some South African legal scholars have suggested that South African courts have not endeavoured to develop the common law on informed consent as envisaged by the Constitution.²²¹ Such commentators have also suggested that in several cases brought to South African courts, since the National Health Act (NHA)²²² was enacted, the courts have been reluctant to apply the regulations laid down in the NHA with regards to the legal application of the IC doctrine in medical practice.^{223,224} In addition, some South African legal scholars have since argued that the SCA might have erred in its judgment in the *Oldwage* case,²²⁵ because it applied the discredited reasonable doctor standard of information disclosure rather than the more accepted prudent patients’ standard as established in the *Castell* case.²²⁶ Furthermore, it has been suggested that in arriving at

²²¹ The Constitution s39.

²²² National Health Act 61 of 2003.

²²³ Britz R and Roux 2012 *SAMJ* 746-748.

²²⁴ Thomas R 2007 *SALJ* 188-215.

²²⁵ *Louwrens v Oldwage* 2006 (2) SA 161 (SCA).

²²⁶ *Castell v De Greef* 1993 (3) SA 501.

its decision in the *Oldwage case*,²²⁷ the SCA did not pay attention to the judgments from similar cases in other comparable common law jurisdictions like England,²²⁸ Canada,²²⁹ and Australia.²³⁰ It has also been argued that this failure to clarify issues do not appear to be consistent with constitutional provisions for respect for security, privacy, and bodily integrity as elucidated in section 12 of the Constitution.²³¹ Further, it has been suggested that the judgment of the SCA in the *Oldwage case*,²³² and other judgments in *Richter and Another v Estate Hamman*,²³³ and the recent judgment by a full bench of the Cape High Court in the case of *McDonald v Wroe*,²³⁴ might be inconsistent with the constitutional provisions to expand the common law by reference to judgments from foreign legal jurisdictions when interpreting the Bill of Rights or when interpreting any South African legislation.²³⁵ It can also be argued that the SCA should have taken into consideration the current regulations regarding informed consent as elucidated in the National Health Act.²³⁶ Therefore, to correct or address this anomaly, it was important in this thesis to discuss and refer to case law from other common law jurisdictions in North America, England and Australia when discussing the standards of information disclosure and other key elements of IC in this thesis. The rest of chapter two then discusses briefly the differences between IC in biomedical research and treatment. I also discuss the exceptions to the IC doctrine including public policy, the doctrine necessity including the Roman-Dutch law doctrine of negotiorum gestio, Further, I elaborate on the doctrines of best interests, therapeutic privilege and waivers to informed consent. The rest of the chapter then focuses on factors affecting the comprehension of IC including the problem of language barriers and information overload. Moreover, I explore other factors that would make consent or agreement to medical treatment valid or what constitutes the elements of 'true' or valid consent. Finally I discuss the different types of IC including express consent, 'broad' or open

²²⁷ Louwrens v Oldwage 2006 (2) SA 161 (SCA).

²²⁸ Chester v Afshar [2002] 3 All ER FR 552 (CA).

²²⁹ Reibl v Hughes (1980) 114 DLR (3d) 1 (SCC).

²³⁰ Rogers v Whitaker [1992] HCA 58; 175 CLR 479.

²³¹ The Constitution s12.

²³² Louwrens v Oldwage 2006 (2) SA 161 (SCA).

²³³ Richter and Another v Estate Hamman 1967 (3) SA 226 (C).

²³⁴ McDonald v Wroe [2006] 3 All SA 565 (C).

²³⁵ The Constitution s39.

²³⁶ National Health Act s7.

consent, implied or presumed consent, the problems and implications of consent forms, and the limits, durations, and refusals of informed consent.

2.1 What is consent?

Consent may be defined as the voluntary and ongoing permission of an individual for a particular purpose. The Oxford English dictionary²³⁷ defines consent as a noun, 'agreement', or as verb 'permission'. From its etymological origin in Latin, 'consent' is derived from two words 'con'-'together' and 'sentire'- feel. Therefore, consent may be described roughly as 'feel together', which denotes shared decision-making. However, this practice of shared decision-making has never been fully recognized in medical practice, with doctors and other HCPs generally requiring patients to give permission or agree to medical interventions without a complete understanding by the patient, or full disclosure by the HCP, of what the patient is required to consent or agree to. It has thus been suggested that consent in healthcare can have several meanings. On the one hand, consent as an agreement can create a 'contract', which is generally binding on both parties. This was demonstrated in the American case of *Grimes v Kennedy Krieger Institute* (hereinafter *Grimes v KKI*),²³⁸ where the Maryland Court of Appeals, held that consent can create a contract enforceable by law if consent agreements contain provisions where "mutual assent, offer, acceptance, and consideration exist".²³⁹ The Court held that researcher/human subject consent in nontherapeutic research can create a contract, where a contract would mean "a written or spoken agreement intended to be enforceable by law",²⁴⁰ although the Court refused to make a determination as to whether IC in a therapeutic research context or medical treatment can create contractual obligations.²⁴¹ According to Gillon,²⁴² consent as a simple agreement is not applicable to medical treatment. He suggests that consent to treatment means "a voluntary, uncoerced

²³⁷ Anon *Oxford South African concise dictionary* 2nd ed (Oxford University Press Southern Africa Cape Town 2010) 248.

²³⁸ *Grimes v Kennedy Krieger Institute Inc.* 366 Md. 29, 782 A.2d 807 (Md. 2001) http://biotech.lawlsu.edu/cases/research/grimes_v_kki.htm (Date of use: 31 August 2017).

²³⁹ *Grimes v KKI* [13-14].

²⁴⁰ *Grimes v KKI* 2001 [62-63].

²⁴¹ *Grimes v KKI* 2001 [64].

²⁴² Gillon R *Philosophical medical ethics* (John Wiley & Sons Chichester 1987).

decision, made by a sufficiently competent or autonomous person on the basis of adequate information and deliberation, to accept rather than reject some proposed course of action that will affect him or her.”²⁴³

It has been suggested that consent, when viewed as a contractual agreement would not normally give the patient or consentor the unilateral and autonomous right to withdraw from a medical procedure which entails invasion of bodily integrity, privacy and self-determination.^{244, 245} As demonstrated in *Ciarlariello v Schactr*.²⁴⁶

An individual's right to determine what medical procedure will be accepted must include the right to stop the procedure...the patients right to bodily integrity provides the basis for the withdrawal of a consent to a medical procedure even while it is underway. Thus if it is found that the consent is effectively withdrawn during the course of the procedure, then it must be terminated.²⁴⁷

On the other hand, it has been suggested that in South Africa, where the law on consent to treatment is based on the Roman-Dutch law maxim of *volenti non fit injuria* or voluntary assumption of risk, the particulars of claim in cases of lack of consent before treatment would if based on legal principles include a “breach of contract, or alternatively breach of a legal duty [delict], or alternatively assault”.²⁴⁸ The authors conclude that in the absence of these elements in a particulars of claim when failure to obtain IC is alleged, this illustrates that consent to treatment in medical law may transcend the boundaries of law.²⁴⁹ This observation somehow corroborates Gillon's assertion that consent as a simple agreement or contract is not applicable in the context of medical treatment.²⁵⁰ These observations were further reinforced by the judgment of the Missouri Court of Appeals in the case of *Moore v Webb*,²⁵¹ where the court opined that the relationship between doctor

²⁴³ Gillon *Philosophical medical ethics* 113.

²⁴⁴ Maclean AR *Consent to medical treatment and the competent adult* (PhD Thesis University of Glasgow 2006) 83-120.

²⁴⁵ Gilbert M “Agreements, coercion, and obligation” 1993 *Ethics* 679-691.

²⁴⁶ *Ciarlariello v Schactr* 1993 100 DLR 94th 609 SCC.

²⁴⁷ *Ciarlariello v Schactr* 1993 [609] see also Grubb et al *Principles of Medical Law* 450.

²⁴⁸ Carstens and Pearmain *Foundational Principles* 878.

²⁴⁹ Carstens and Pearmain *Foundational Principles* 878.

²⁵⁰ Gillon *Philosophical medical ethics* 113.

²⁵¹ *Moore v Webb* (1961) 345 SW 2d 239 (MO App).

and patient is based on a fiduciary duty of trust and not merely contract as in other trade agreements, stating:

This question is not to be ruled by the law of trade and commerce governing transactions between parties who deal at arms-length in the market place. It is to be viewed in the light of the physician-patient relationship which existed between the parties...A physician occupies a position of trust and confidence as regards his patient - a fiduciary position. It is his duty to act with the utmost good faith. This duty of the physician flows from the relationship with his patient and is fixed by law - not by the contract of employment...The law's exaction of good faith extends to all dealings between the physician and the patient. A person in ill health is more subject to the domination and influence of another than is a person of sound body and mind. The physician has unusual opportunity to influence his patient. Hence, all transactions between physician and patient are closely scrutinized by the courts which must be assured of the fairness of those dealings. In regard to any contract between physician and patient, it is the rule that the physician has the burden of proving that the patient entered into it voluntarily and advisedly, and without undue influence.²⁵²

The above observations may have led Maclean to conclude that “consent to treatment is either not an agreement or it is a particular kind of agreement that does not impose a binding obligation on the consenter”.²⁵³ He suggests that one can therefore conceive of consent to treatment and healthcare decision-making as comprising of two aspects which include consent as an ‘agreement’ and consent as ‘permission’. Whereas the former creates obligations between the HCP and the patient, the latter waives the obligation of non-interference with the patient’s bodily integrity and well-being.²⁵⁴

Other commentators have conceived of consent to treatment as a process of shared healthcare decision-making that can encompass both the ethical principles of respect for autonomy and beneficence, in the doctor-patient relationship.²⁵⁵ Ultimately, consent in medical law has the function of licensing that which would otherwise be regarded in some jurisdictions as battery.²⁵⁶ Further, consents other role during medical treatment is to provide the rights bearer with control of that right, by transforming an ordinarily illegitimate

²⁵² Moore v Webb (1961) 345 S.W.2d 239 (MO App) [para 243].

²⁵³ Maclean AR *Consent to medical treatment and the competent adult* [131-177].

²⁵⁴ Maclean AR *Consent to medical treatment and the competent adult* [132-161].

²⁵⁵ Meisel A and Kuczewiski M “Legal and ethical myths about informed consent” 1996 *Arch Intern Med* 2521-2522.

²⁵⁶ Grubb et al *Principles of Medical Law* 475

act into a permitted one.²⁵⁷ According to Alexander,²⁵⁸ consent functions as a moral transformative by altering the obligations and permissions that determine the rightness or wrongfulness of others actions.²⁵⁹ The concept of consent to treatment as being part of the fiduciary duty between doctors and patients was demonstrated in *Moore v Webb*, as summarized above.²⁶⁰ In this case, a patient brought an action in trespass against a defendant dentist for removing all her teeth without her permission. The facts were that the patient had agreed with her personal physician for partial removal of some teeth, which were contained in a referral note to a dentist to carry out the procedure. The patient presented the note to the dentist; whereby the dentist without obtaining additional IC or further discussion; and while the patient was under the influence of pre-anaesthetic drugs, requested that she sign a consent form. The dentists then proceeded to remove all of the patients' teeth. The patient brought an action in trespass against the dentist and she was awarded damages by a lower court. The dentists appealed the lower court decision based on the fact that she had signed a consent document entitled: "Permit for Operation", which stipulated that: "This is to certify that I, the undersigned, consent to the performing of whatever operation may be decided upon to be necessary or advisable, and the use of local or general anaesthetic as indicated. I desire to have Extraction or Surgery as shown upon the examination chart above".²⁶¹ The appellant dentists argued that this "permit" provided a general authority enabling them to take out all of plaintiff's teeth if required. They argued that such a written instrument which plaintiff should have read, and that she is estopped from avoiding it by her failure to do so. In support of this proposition defendants relied upon the general law of contract and cases involving commercial contracts and releases.²⁶² The Missouri Court of Appeals disagreed (citing various authorities); and stated in their judgment that consent to treatment agreements are to be viewed in the light of the physician-patient relationship which exists between both

²⁵⁷ Gillon R *Philosophical medical ethics-consent* 1985 *BMJ* 1700-1701 see also Maclean AR *Autonomy informed consent and medical law* (Cambridge University Press Cambridge 2009)100.

²⁵⁸ Alexander L "The moral magic of consent" 1996 *Legal Theory* 165.

²⁵⁹ Alexander 1996 *Legal Theory* 165.

²⁶⁰ *Moore v Webb* 1961 345 S.W.2d 239 (MO App) 243.

²⁶¹ *Moore v Webb* 1961 345 S.W.2d 239 (MO App) 242.

²⁶² *Moore v Webb* 1961 345 S.W.2d 239 (MO App) 243.

parties.²⁶³ The Court argued that physician occupies a position of trust and confidence as regards his patient, that is, a fiduciary position. It is therefore the doctor's duty to act with the utmost good faith. This duty of the physician flows from the relationship with his patient and is fixed by law and not by the contract of employment.²⁶⁴ Hence, all transactions between doctors and patients' are closely scrutinized by the courts, which must be assured of the fairness of those dealings, with regards to any contract between physician and patient. It is the rule that a doctor has the burden of proving that the patient entered into the agreement voluntarily and advisedly, and without undue influence.²⁶⁵ From the above one can conclude that the consent between a physician and the patient is governed not only by contractual obligations, but also by the professional and ethical rules of truth telling and fidelity, which go beyond the ordinary rules of general contractual agreements.

2.2 Consent to treatment

The question arises whether there is any self-evident principle, which compels patients to consent to medical treatment without their consent. In the United Kingdom, Judge LJ denied the existence of such an 'axiomatic principle' by borrowing the words of McCullough J in *R v Hallstrom* when he said:

There is... no canon of construction which presumes that Parliament intended that people should, against their will, be subjected to treatment which others, however professionally competent, perceive, however, sincerely and however correctly, to be in their best interests ...It goes without saying that unless clear statutory authority to the contrary exists, no one is to be detained in hospital or to undergo medical treatment or even to submit himself to medical examination without his consent. That is true for a mentally disordered person as that of anyone else.²⁶⁶

Similarly, in the American case of *Re Cruzan*,²⁶⁷ the United States Supreme Court averred with regard to an individual's right to autonomy and bodily integrity, where Rehnquist CJ

²⁶³ 41 *Am Jur Physicians and Surgeons* Section 88.

²⁶⁴ *Parkell v Fitzporter et al* (Mo Sup) 256 S.W. 239 as cited in *Moore v Webb* (1961) 243.

²⁶⁵ Gillon R *Philosophical medical ethics* 113 see also Maclean *Consent to medical treatment and the competent adult* [131-177].

²⁶⁶ McCullough J in *R v Hallstrom exp... W* (No.2) *R v Gardner, exp... L* (1986) 2 All ER 306 at 314.

²⁶⁷ *Cruzan, by her parents and co-guardians v Director Missouri Department of Health* Supreme Court of the United States 1990 497 US 261.

opined that: “[n]o right is held more sacred or is carefully guarded by the common law. Than the right of every individual to the possession and control of his own person, free from all restraint or interference of another;”²⁶⁸ quoting the judgment of the US Supreme Court in *Union Pacific Railway v Botsford* 1891 with agreement,²⁶⁹ where Gray J stated that “No right is held more sacred or is more carefully guarded in the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear unquestionable authority of law.”²⁷⁰ In this context, Gray J was citing Cooley J who averred that “*the right to one’s person may be said to be a right of complete immunity; to be let alone*”.²⁷¹ Therefore, it is an established ethical and legal principle that a medical doctor or other healthcare professional who provides medical treatment or performs a surgical procedure on a patient without his or her consent is prima facie guilty of both a tort (or a delict) and a crime.²⁷² The crime would be tantamount to an assault or trespass to the person, and the tort or delict would be based on negligence due to failure to follow established professional rules enforced by law.²⁷³ In this context, the UK Law Commission²⁷⁴ proposed that: “A person should not be guilty of an offence, notwithstanding that he or she causes injury to another, of whatever degree of seriousness, if such injury is caused during the course of proper medical treatment or care administered with the consent of that other person.” The commission goes further to define ‘medical treatment’ as:

Medical treatment or care administered by or under the direction of a duly qualified medical practitioner. This includes not only surgical and dental treatment or care, but also procedures taken for the purposes of diagnosis, prevention of disease, the prevention of pregnancy or ancillary to treatment.²⁷⁵

²⁶⁸ Cruzan v Director Missouri Department of Health Supreme Court of the United States 1990 497 U.S. 261.

²⁶⁹ Union Pacific Railway Co v Botsford 141 US 250 (1891) 251.

²⁷⁰ Union Pacific Railway Co v Botsford 141 US 250 (1891) 252.

²⁷¹ Cooley TM A treatise on *the law of torts or the wrongs which arise independently of contract* (Callaghan & Co 1907) 29.

²⁷² Grubb et al *Principles of Medical Law* 491.

²⁷³ Grubb et al *Principles of Medical Law* 491.

²⁷⁴ Law Commission *Consent in the criminal law* (UK Law Commission London 1995) 139.

²⁷⁵ Hocton A *The Law of consent to medical treatment* (Sweet & Maxwell London 2002) 15.

In this thesis 'medical treatment' will be applied as generic terminology covering all forms of medical examination, assessment, diagnosis, and all procedures whether surgical, medical or psychiatric, dental or nursing, which involve any physical touching or penetration of the patient's body, however trivial.²⁷⁶ Medical treatment should also be distinguished from 'medical research', which the Council for International Organizations of Medical Sciences (CIOMS) defines as a class of activity designed to develop or contribute to generalizable knowledge in the form of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference.²⁷⁷ In this context 'research' includes both medical and behavioural studies pertaining to human health. Usually research is modified by the adjective 'biomedical' to indicate its relation to health. However, sometimes, research and treatment are conducted simultaneously, such as when research is designed to obtain new information about the efficacy of new drugs or other therapeutic, diagnostic or preventive modality usually in clinical trials, most commonly in randomized clinical trials (RCT).²⁷⁸ Because of the conceptual difference between the regulations governing consent in biomedical research as opposed to medical treatment, in that consent to research is reviewed prospectively while consent to treatment is ordinarily subject to retrospective review, consent to treatment is mostly subject to judicial review while consent to research is reviewed by administrative bodies, such as research ethics committees (RECs). Therefore, the amount of information disclosed in research has been based on rules set up by regulatory bodies, ethical codes or statute.²⁷⁹ On the other hand the IC doctrine pertaining to medical treatment has developed out of judicial deference to individual autonomy in common law jurisdictions led by American courts and medico-legal jurisprudence. This is based on the prevalent belief that individuals ought to be free from non-consensual interference with their bodily integrity. It is also related to the ethical and moral principle that an individual's autonomy and right of self-determination must be respected, and the idea that it is wrong to force another to act

²⁷⁶ Grubb et al *Principles of Medical Law* 491.

²⁷⁷ Council for International Organizations of Medical Sciences (CIOMS) Guidelines on Research involving Human Subjects (CIOMS-World Health Organization Geneva 1993).

²⁷⁸ Chima SC *Consent and patients' rights in human biomedical research* (LLM dissertation Northumbria University 2006) 19.

²⁷⁹ Chima *Consent and patients' rights* 32.

against his or her will, or to undermine an individual's freedom of choice.²⁸⁰ In the American case of *Mohr v Williams* 1905, the Supreme Court of Minnesota asserted that "the free citizens first right and greatest right, which underlies all others [is] the right to himself."²⁸¹ Based on this opinion the court extended the concept of consent beyond intentional unauthorized touching regarded as trespass or assault to include the patients' rights to weigh reasonably the benefits and risks of treatment prior to consent. It has been suggested that it is important to distinguish between the medical and legal interpretations of IC. The first sense denotes autonomous action by the patient while the second notion conforms to institutionalized rules necessary to obtain legally effective IC.²⁸² The legal sense involves more of risk disclosure and preventing professional liability by HCPs, rather than promoting autonomous choices of patients.²⁸³ This observation may have prompted Pellegrino to proclaim that:

To obstruct the capacity for autonomy is to assault an essential part of a person's humanity, because the choices we make are so much an expression of our membership in the human community, of who we are or what we want to be as individual members of that community. [Therefore] human beings are owed respect for their autonomy because they have inherent dignity²⁸⁴

2.3 What makes consent valid?

Before a person can give a *valid or true consent* in the context of medical treatment, this requires that such a patient's decision must be based on an adequate understanding of what is involved in the medical procedure before giving permission to, or refusing the

²⁸⁰ Furrow BR et al (eds) *Health Law (Hornbooks) 3rd ed* (West Publishing Co St Paul MN 2014) see also Christman J "Autonomy in moral and political philosophy" *The Stanford encyclopedia of philosophy* (Spring 2015 Edition) Zalta EN et al (eds) <https://plato.stanford.edu/archives/spr2015/entries/autonomy-moral/> (Date of use: 15 November 2017).

²⁸¹ *Mohr v Williams* 104 N.W.12 25 105 N.E. 92 Sup Ct of MN (1905)14.

²⁸² Gordon E "Multiculturalism in medical decision-making: the notion of informed waiver" 1997 *Fordham Urb L J* 1321-1362.

²⁸³ Beauchamp T and Childress JF *Principles of biomedical ethics* 5th ed (Oxford University Press Oxford 2001) 77-83.

²⁸⁴ Pellegrino ED "Patient and physician autonomy: Conflicting rights and obligations in the physician-patient relationship" 1993 *J Contemp Health L & Pol'y* 47-54.

medical treatment in question. This generally requires broadly that such a decision must be made by a person with –

- (a) capacity,
- (b) based on adequate information, and
- (c) voluntarily, that is, without any undue influence or coercion.^{285, 286}

This is eloquently captured by the Court of Appeals of the District of Columbia (DC) in the case of *Canterbury v Spence*.²⁸⁷

True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible...the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice.

The court asserts further that the patient's reliance on the physician for information is "well-nigh abject" because of the asymmetry of knowledge between a learned/trained physician and a patient.²⁸⁸ Accordingly:

[...]To the physician, whose training enables a self-satisfying evaluation, the answer may seem clear, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie. To enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential...²⁸⁹

²⁸⁵ Carstens and Pearmain *Foundational Principles* 465.

²⁸⁶ Khan M, Robson M and Swift K *Clinical Negligence 2nd ed* (Cavendish Publishing London 2002) 44.

²⁸⁷ *Canterbury v Spence* (1972) 464 2d 772 [28-29].

²⁸⁸ *Canterbury v Spence* (1972) 464 2d 772 [para 31].

²⁸⁹ *Canterbury v Spence* (1972) 464 2d 772 [30].

The Court argues further that the duty of risk disclosure to a patient to enable an informed decision is part of the fiduciary duty entrenched within the doctor-patient relationship, which goes beyond the duty required in ordinary arm's length transactions²⁹⁰ as demonstrated in *Moore v Webb*.²⁹¹ This reinforces the observations made by other commentators that the physician-patient relationship consists of a type of 'special relationship' which makes consent in this context more than the consent or agreement as envisaged in ordinary contractual relationships. The *Canterbury* court²⁹² suggested that apart from the physician's overall obligation to the patient, there is an additional duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved. This disclosure requirement would reflect much more of a change in doctrinal emphasis than any substantive addition to malpractice law. It is trite law that a HCP must seek and secure the patient's consent before commencing any medical procedure. It is also an established rule that any therapy not authorized by a patient may amount to the common law tort of battery or assault. It therefore becomes self-evident that it would be normally impossible to obtain a valid or true consent worthy of its name unless the HCP first clarifies the options and the risks of the proposed treatment for the patient's enlightenment.²⁹³ Ultimately, doctors and other HCPs have long had a duty, on pain of liability for unauthorized treatment, to make adequate disclosure to their patients before commencing any medical treatment.²⁹⁴

Len Doyal²⁹⁵ has suggested that HCPs have three broad duties in healthcare:

- (i) To protect the life and health of their patients
- (ii) Respect the autonomy of patients
- (iii) And, to do both of these things in a fair and just way.²⁹⁶

²⁹⁰ *Canterbury v Spence* (1972) 464 2d 772 [31].

²⁹¹ *Moore v Webb* 1961 345 SW 2d 239 (MO App) 243.

²⁹² *Canterbury v Spence* (1972) 464 2d 772 [31-32].

²⁹³ Khan et al *Clinical Negligence* 44.

²⁹⁴ *Canterbury v Spence* (1972) 464 2d 772 see also Khan et al *Clinical Negligence* 44.

²⁹⁵ Doyal L "The moral foundation of the clinical duties of care: Needs, duties and human rights" 2001 *Bioethics* 520-535.

²⁹⁶ Doyal 2001 *Bioethics* 520-535 see also Maclean *Autonomy, informed consent and medical law: A relational challenge* (Cambridge University Press Cambridge 2009) 103.

However, it has been argued that though consent may give doctors permission, it cannot relieve them of their duty to take responsibility for an independent moral judgment. Therefore, a valid consent does not mean that the consentor has no right to complain if they are harmed by the act.²⁹⁷ According to Linde J in the Canadian case of *Allan v Mount Sinai Hospital*,²⁹⁸ “[i]t is the patient not the doctor who decides whether surgery will be performed, where it will be done, when it will be done, and by whom it will be done.” The judgment in *Canterbury v Spence*²⁹⁹ thus emphasises that true/real or valid consent must be based on adequate information disclosure, and that the extent and level of disclosure is shaped by the patients’ needs. This is echoed in the legal requirements for valid informed consent in South Africa and elsewhere, discussed later in this thesis.

I will now go on to analyse whether there are any other key issues or considerations that could impact on the patient’s understanding of the information disclosed by the HCP, to enable the patient make an informed decision in order to provide a legally valid consent.

2.4 Elements of a true, real or valid consent

Consent may be defined as the voluntary and continuing permission of an individual for a particular purpose, which in its ideal legal, regulatory, philosophical and ethical context requires five key elements to establish validity.^{300,301} These key elements generally comprise of:

- (i) Competence or capacity
- (ii) Voluntariness
- (iii) Information disclosure

²⁹⁷ Mclean *Consent to medical treatment in competent adults* 139.

²⁹⁸ *Allan v Mount Sinai Hospital* 1980 109 DLR (3d) [634 and 642].

²⁹⁹ *Canterbury v Spence* (1972) 464 2d 772

³⁰⁰ President’s Commission for the study of ethical problems in medicine and biomedical and behavioral research *A report on the ethical and legal implications of informed consent in the patient- practitioner relationship: Making healthcare decisions* volume one: Report (US Government Printing Office Washington DC 1982) 31-113.

³⁰¹ Beauchamp and Childress *Principles of biomedical ethics* 79.

- (iv) Understanding, and
- (v) Authorization or refusal to give consent³⁰²

Depending on whether consent involves medical treatment only, or is combined with research, or just non-therapeutic research, these elements could be broken down into:

- (A) Pre-conditional elements - capacity, competence and voluntariness.
- (B) Informational elements - disclosure of information such as a care plan for treatment and understanding of that information.
- (C) Consent elements - comprising of a decision by the patient to accept or refuse the proposed treatment, in the absence of coercion and any overriding influence, and finally authorization by the patient to proceed with treatment or participation in a research project.³⁰³ Based on the above criteria therefore, IC may be preliminarily defined as “an autonomous authorization by individuals of a medical intervention or participation in research based on full information disclosure and complete understanding of all the consequences.”³⁰⁴ Phrased differently, IC can be described as the social rules of consent in institutions that must obtain legally valid consent.^{305,306} In its ideal form the process of obtaining informed consent should consist of a conversation between a HCP and a patient, initiated by the HCP, which involves complete transparency, engagement by both parties and is continuous. This conversation may require evidence that it occurred, such a witnessed signature, a signed consent form or doctors medical notes.³⁰⁷ This consent may also be withdrawn at any time by the patient and could be vitiated by any changes in circumstances, which are not communicated to, or approved by the patient.³⁰⁸

³⁰² Beauchamp and Childress *Principles of biomedical ethics* 80

³⁰³ Chima 2009 *Trans J Coll Med S Afr* 39.

³⁰⁴ Chima *Consent and patients' rights* 35.

³⁰⁵ McCormick TR “Informed consent: Its basis, problems and uncertainties” University of Washington School of Medicine <https://depts.washington.edu/bioethx/tools/princpl.html> (Date of use: 28 February 2008) see also Chima *Trans J Coll Med S Afr* 39.

³⁰⁶ Beauchamp and Childress *Principles of biomedical ethics* 78.

³⁰⁷ McCormick TR “Informed consent: Its basis, problems and uncertainties” 2008 see also Chima *Trans J Coll Med S Afr* 39-40.

³⁰⁸ Chima *Trans J Coll Med S Afr* 39-40.

It has been suggested that the five-step definition of IC outlined above³⁰⁹ is superior to the legal connotation of IC which consists essentially of information disclosure or disclosure of risks.³¹⁰ This one item definition, focusing on risk disclosure, is based on legal convention and the adversarial litigation process, which does not take into consideration the moral and ethical requirements of the patient's rights of self-determination, moral agency and bodily well-being.³¹¹ The key elements of informed consent outlined above merit further analysis in order to establish their validity and importance in the IC process discussed further below.

2.4.1 Capacity or competence to make healthcare decisions or decision-making capacity (DMC)

It has been suggested that the doctrine of IC as founded on the premise that self-determination should not to be blind.³¹² That a patient's interests and well-being are best served when patients understand their medical situation and participate in decisions affecting their own health status or treatment.³¹³ Appelbaum and Roth³¹⁴ have argued that the requirement that consent to treatment be made by competent patients ensures that some policy goals regarding the IC doctrine are actually achieved. Firstly, that the autonomy of the competent patient is recognized; secondly that the rights of the incompetent patient is protected, and thirdly, that the mandate which requires that the wishes of a competent patient is respected fosters respect for individual autonomy.³¹⁵ Some commentators distinguish between judgments of capacity and judgments of competence by arguing that HCPs would normally determine capacity and incapacity, whereas the courts will usually make judgments about competence and incompetence.³¹⁶ However others have suggested that when doctors make a determination that a patient

³⁰⁹ Beauchamp and Childress *Principles of biomedical ethics* 57-112.

³¹⁰ Beauchamp and Childress *Principles of biomedical ethics* 81.

³¹¹ Lantos 1993 *Cancer Suppl* 2811-2815.

³¹² Alexander L 1996 *Legal Theory* 165-174.

³¹³ Alexander 1996 *Legal Theory* 165-174.

³¹⁴ Appelbaum PS and Roth LH "Clinical issues in assessment of competency" 1981 *Am J Psych* 1462-1467.

³¹⁵ Appelbaum and Roth 1981 *Am J Psychiatry* 1462-1467.

³¹⁶ Weinstock R Copelan R and Bagheri A "Competence to give informed consent for medical procedures" 1984 *Bull Am Acad Psych Law* 117-125.

lacks decision-making capacity (DMC), the practical effect is the same as a legal determination of incompetence.^{317,318} Nevertheless it has been established in English common law since the 1914 case of *Richmond v Richmond*³¹⁹ that:

Capacity is ultimately a legal not a medical decision... it is for the court to decide the question of capacity, although the court must pay attention to the evidence of experts in the medical profession who can indicate the meaning of symptoms and give some idea of the mental deterioration which takes place in cases of this kind...³²⁰

Further, it has been argued that although competency is a legal concept and all adults are presumed by law to be competent until proven otherwise by objective means, the practical realities of clinical practice require that doctors, especially psychiatrists or other mental health practitioners, make their own assessment as to whether a patient is competent or not, to consent to medical treatment. This has been described as “psychological capacity” rather than legal competence.³²¹ However, the impact of the doctor’s determination of patient capacity or competence is as important as the legal competence established by a court of law. In clinical practice, it is usually the psychiatrists who are often called upon during clinical care to assess patients DMC because frequent involvement of the courts is impracticable and not cost effective.³²² It is important to note that in South Africa, in terms of the Mental Health Care Act,³²³ all medical doctors in South Africa are also considered to be mental health care practitioners who may be legally required to assess and make determinations regarding patients DMC.

In view of the above observations and the simple definition of capacity as “the ability to perform a task”,³²⁴ I shall confine myself to the use of the terminology decision making capacity (DMC), as suggested by the President’s commission on bioethics, where the

³¹⁷ Grisso T and Appelbaum PS *Assessing competence to consent to Treatment: A guide for physicians and other health professionals* (Oxford university Press New York 1998) 11.

³¹⁸ Chima SC *Consent and patients’ rights* 35-36.

³¹⁹ *Richmond v Richmond* (1914) 111 LT 273 27.

³²⁰ *Richmond v Richmond* (1914) 111 LT 273 27 [148].

³²¹ Appelbaum and Roth 1981 *Am J Psychiatry* 1462-1467.

³²² Appelbaum PS and Grisso T “Assessing patients’ capacities to consent to treatment” 1988 *N Engl J Med* 1635-1638.

³²³ Mental Health Care Act 17 of 2002.

³²⁴ *Oxford South African concise dictionary* 170.

commission stated that the terms “decision making capacity and incapacity are used to avoid the sometimes confounding legal overtones associated with the terms competence and incompetence”.³²⁵ Generally, conclusions regarding a patient’s DMC reflects a balancing of two important, and sometimes competing objectives; the first is to enhance the patient’s well-being, and secondly, to respect the person as a self-determining individual.³²⁶

At common law, there is a presumption of capacity in that any adult is presumed to have the DMC to consent to, or refuse any medical treatment unless proven otherwise by acceptable objective evidence. However, this right to presumption of capacity is a rebuttable right, as argued by Lord Donaldson in *Re T*³²⁷

Prima facie every adult has a right and capacity to decide whether or not he will accept medical treatment, even if refusal may risk permanent injury to his health or even lead to premature death...However, the presumption of capacity to decide, which stems from the fact that the patient is an adult is rebuttable...An adult may be deprived of his capacity to decide either by long-term mental incapacity, or retarded development, or temporary factors such as unconsciousness or confusion, or the effects of fatigue, pain or drugs.³²⁸

The common law test for determining a patient’s mental capacity was outlined by the English Court of Appeals (CA) in *Re MB*³²⁹ as follows: “A person lacks capacity if some impairment or disturbance of mental functioning renders the person unable to make a decision whether to consent to or to refuse treatment. That inability to make a decision will occur when:

- a. The person is unable to comprehend and retain the information which is material to the decision, especially as to the likely consequences of having or not having the treatment in question.

³²⁵ President’s Commission *Making healthcare decisions* 55-60.

³²⁶ Alexander L 1996 *Legal Theory* 165-174

³²⁷ *Re T (An Adult) Consent to Medical Treatment* 1992 3 WLR 782 [115 and 483].

³²⁸ Hocton *Law of consent to medical treatment* [5-8].

³²⁹ *Re MB An adult: Medical treatment* 1997 2 FLR 426.

b. The patient is unable to use the information and weigh it in the balance as part of the process of arriving at a decision.”³³⁰

Similarly, it has been suggested that that any determinations of a patient’s ability decide on a course of treatment must relate to a patients individual ability, and the requirements of the task at hand. Thus, DMC, to greater or lesser extent depends on three things:

- i. The possession of a set of values and goals;
- ii. The ability to communicate and to understand information; and
- iii. The ability to reason and to deliberate about one’s choices.³³¹

It has been suggested that the third element of the above test, that is, reasoning and deliberation would include the ability to compare the impact of alternative healthcare choices on the individual’s personal goals and life plans.³³²

Thorpe J later summarized a three-way test for DMC in *Re C*³³³ as follows: He argued that the patient must be able to:

- (a) Comprehend and retain the information
- (b) Believe it
- (c) And weigh it in the balance so as to arrive at a choice.

The above test has been frequently applied in English case law, however due to some conflicting interpretations; the UK Mental Capacity Act 2005³³⁴ attempted to further simplify this into a single test. The current test states that a person is deemed incapable of making a decision or is lacking DMC and the ability to exercise autonomy rights where the person is unable:

³³⁰ Re MB An adult: Medical treatment 1997 2 FLR [436-437].

³³¹ President’s Commission *Making healthcare decisions* 55-60.

³³² President’s Commission *Making healthcare decisions* 55-60.

³³³ Re C (Adult refusal of medical treatment) 1994 1 All ER 891 [683] see also Hocton *Law of consent to medical treatment* 7.

³³⁴ The Mental Capacity Act 2005 United Kingdom.

- I. To understand the information relevant to the decision,
- II. To retain that information
- III. To use or weigh that information as part of the process of making the decision, or
- IV. To communicate his or her decision (whether by talking, using sign language or any other means).

It should be noted that the Mental Capacity Act³³⁵ only applies to competent adults accorded a presumption of capacity. Further, a basic understanding, demonstrated through any means including the use of sign language, visual aids or any other means, will suffice to satisfy the first part of the test.^{336,337}

2.4.2 Standards for assessing DMC

It has been argued that the actual measurement of the various abilities by a patient to demonstrate DMC may be quite complicated and complex, because virtually all conscious and competent adults are usually able perform some tasks but not necessarily others. In the context of IC however, what is critical is a patient's capacity to make a specific healthcare or medical decision.³³⁸ In other words, incompetence in one area does not mean incompetence in all areas. Generally, one can only speak of competence to do a particular thing.³³⁹ Therefore, the assessment of an individual's DMC must consider the nature of the particular decision to be made in light of considerations of whether the patient possesses the ability to understand the relevant facts and alternatives, as well as, whether the patient is weighing the decision based on his or her own personal values and goals. Further, it should be determined whether the patient can provide reasons for the decision, based on the facts of the case, the alternatives, and the impact of the decision on the patient's own objectives and value system.³⁴⁰ In some cases, it has been suggested that

³³⁵ The Mental Capacity Act 2005 <https://www.legislation.gov.uk/ukpga/2005/9> (Date of use: 9 November 2017).

³³⁶ UK Mental Capacity Act 2005 as amended (chapter 9).

³³⁷ Chima *Trans J Coll Med S Afr* 42-43.

³³⁸ President's Commission *Making healthcare decisions* 55-60.

³³⁹ Re C (Adult Refusal of Medical Treatment) 1994 1 All ER [683].

³⁴⁰ President's Commission *Making healthcare decisions* 55-60.

a patient may indeed possess these abilities, but may not be able to exercise them, or refuses to exercise these abilities. This may occur where the decision may be the result of a mistaken understanding of the facts or a defective reasoning process as shown in cases where a patient presents with false beliefs, or delusions, or bias against a particular physician or group of physicians that may preclude acceptance of any rational explanation.^{341,342} In such instances, the obligation of the HCP is not to declare, on the basis of a wrong or irrational decision, that the patient lacks DMC, but rather to work with the patient toward a fuller and more accurate understanding of the facts and a sound reasoning process.³⁴³

Since the assessment of capacity must balance competing considerations of well-being and self-determination, the prudent course is to take into account the potential consequences of the patient's decision. In view of this, some have recommended that where assessment of DMC is being conducted in a non-emergency setting, more than one evaluation session should take place to accurately evaluate a patient's DMC.³⁴⁴ Further, it has been suggested that where the consequences for well-being are substantial, there is a greater need to be certain that the patient possesses the necessary level of DMC. However, when little turns on the decision, then the level of DMC required may be appropriately reduced, even though the constituent elements of capacity or competence should remain the same.³⁴⁵ Thus, a particular patient may be capable of deciding about a relatively inconsequential medication, but not about the amputation of a gangrenous limb as demonstrated by the English CA in *Re C*.³⁴⁶ Here the court found that a patient with schizophrenia could subjectively refuse amputation of his gangrenous limb, based on the observation of the court that the patient possessed a 'conception of the good' amongst other personal moral values and subjective rights.³⁴⁷ Similarly, Weinstock

³⁴¹ Beauchamp and Childress *Principles of biomedical ethics* 91-92.

³⁴² Appelbaum and Roth 1981 *Am J Psychiatry* 1462-1467.

³⁴³ President's Commission *Making healthcare decisions* 62-63.

³⁴⁴ Appelbaum and Roth 1981 *Am J Psychiatry* 1462-1467.

³⁴⁵ Appelbaum and Roth 1981 *Am J Psychiatry* 1462-1467.

³⁴⁶ *Re C (Adult Refusal of Medical Treatment)* 1994 1 All ER 683.

³⁴⁷ Hocton *Law of consent to medical treatment* 65-69.

and others³⁴⁸ were able to show that most patients with schizophrenia and bipolar disorders in a hospital cohort were capable of consenting to medical treatment using relevant criteria, even if their consent were merely passive. They also reported that only patients with organic brain syndromes were found incompetent. Further, patients generally referred for psychiatric evaluation were those who refused recommended treatment. The authors concluded that sound DMC assessments are essential because consent or refusals of treatment would both be invalid in an incompetent patient.³⁴⁹ In light of the above, the President's Commission rejected as the standard for DMC, any test that looks solely to the content of the patient's decision, arguing that any standard based on "objectively correct" or "rational" decisions would only allow HCPs or other third parties to declare that a patient lacks DMC whenever such patients behaved wrongly, irrationally, or in any other way which appears incompatible with the evaluator's view of the patients' best interests.³⁵⁰ This supports arguments against giving doctors or other HCPs greater access to the use of the doctrine of "therapeutic privilege"^{351,352} or "therapeutic exception"³⁵³ during healthcare decision making. The doctrine of therapeutic privilege as an exception to IC³⁵⁴ will be discussed in more detail below. It has been suggested that use of an objective standard to determine DMC would be in sharp conflict with most of the values that support self-determination and individual autonomy because it would take the decision whether to consent to or refuse recommended treatment away from the patient and place it in the hand of others, such as HCPs. This would not adequately reflect the subjective nature of each individual's conception of what is they consider morally good or acceptable based on their own personal values.³⁵⁵ Accordingly, in English law, it has been suggested that in the case of refusal of medical treatment by a competent patient, the reasons for refusal need not be rationally defensible, as explained by Donaldson LJ in *Re*

³⁴⁸ Weinstock R, Copelan R and Bagheri A "Competence to give informed consent for medical procedures." 1984 *Bull Am Acad Psychiatry Law* 117-125.

³⁴⁹ Weinstock et al 1984 *Bull Am Acad Psychiatry Law* 117-125.

³⁵⁰ President's Commission *Making healthcare decisions* 55-62.

³⁵¹ Welz D "The boundaries of medical therapeutic privilege" 1999 *SALJ* 299-322.

³⁵² Coetzee LC *Medical therapeutic privilege* (LLM dissertation UNISA 2001).

³⁵³ Van Oosten *The doctrine of informed consent in medical law* (LLD thesis UNISA 1989) 167.

³⁵⁴ Van Oosten FFW "The so-called 'therapeutic privilege' or 'contra-indication': its nature and role in non-disclosure cases" 1991 *Med Law* 31-41.

³⁵⁵ President's Commission *Making healthcare decisions* 55-60.

7³⁵⁶: “It matters not whether the reasons are rational or irrational, unknown or even nonexistent...”³⁵⁷ Further, Butler-Sloss LJ opined in *Re MB* as follows:

A competent woman who has the capacity to decide, may for religious reasons, other reasons, for rational or irrational reasons or for no reason at all, choose not to have medical intervention, even though the consequence may be the death or serious handicap of the child she bears, or her own death. In that event the courts do not have the jurisdiction to declare medical intervention lawful and the question of her own interests objectively considered, does not arise[...].³⁵⁸

Other legal authorities have suggested that one must take other factors into consideration when assessing an individual’s capacity to consent to or refuse treatment. Based on an empirical study of competency to psychiatric hospitalization, Appelbaum *et al* concluded that though the evidence from empirical studies were supportive of the hypothesis that it is the patients underlying psychiatric illness which may have impaired such a patients DMC, other factors such as the stress surrounding hospitalization, whether psychiatric or medical, could contribute to a failure of rational modes of thought, in addition to relative ignorance about the medical issues involved in treatment.³⁵⁹ Therefore, one can summarize the following points with regards to determination of a person’s DMC:

- I. A person must be assumed to have capacity unless it is established that he or she lacks capacity by objective criteria
- II. A person is not to be treated as unable to make a decision unless all practicable steps to help him or her to do so have been taken without success.
- III. A person is not to be treated as unable to make a decision merely because he makes an unwise or irrational decision.
- IV. An act done or decision made for or on behalf of a person who lacks capacity must be done, or made, in his or her best interests.

³⁵⁶ Re T (An Adult) Consent to Medical Treatment) 1992 3 WLR 782.

³⁵⁷ Re T (An Adult) Consent to medical treatment) 1992 3 WLR 782 [115 and 483] see also Hocton *Law of consent to medical treatment* [5-8].

³⁵⁸ Re MB An adult: Medical treatment 1997 2 FLR 426 see also Hocton *Law of consent to medical treatment* [66-67].

³⁵⁹ Appelbaum PS, Mirkin SA and Bateman AL “Empirical assessment of competency to consent to psychiatric hospitalization” 1981 *Am J Psych* 1170-1176.

- V. Before such an act is done, or decision made, regard must be had as to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's autonomy.^{360,361}

Finally, a lack of DMC cannot be established merely by reference to a person's age, appearance, intelligence, level of education, or any condition or aspect of behavior, which might lead others to make unjustified assumptions about their DMC.^{362,363} It has been argued that judgments about DMC are pivotal to health care, since they determine the ability of patients to make choices about their care. Therefore HCPs, especially doctors, should understand the concept of DMC and how to assess it. Many patients clearly have the capacity to make health care decisions, and others, such as unconscious patients lack this capacity. In other cases, physicians may disagree about whether a patient has sufficient DMC. Therefore, DMC is a complex concept, since it is based on four abilities:

- (a) The ability to express a choice,
- (b) The ability to understand relevant information,
- (c) The ability to appreciate the significance of that information for one's own situation, and
- (d) The ability to engage in basic reasoning regarding treatment options.³⁶⁴

It has been argued that there is no simple algorithm for determining DMC, since the capacity to make a decision varies with the complexity of the decision to be made. Therefore, DMC must be assessed relative to the decision at hand. It has been suggested that HCPs must strive to avoid commonly held misconceptions about DMC, for example,

³⁶⁰ UK Mental Capacity Act 2005.

³⁶¹ Chima *Trans J Coll Med S Afr* 42-43.

³⁶² Chima *Trans J Coll Med S Afr* 43.

³⁶³ Annandale et al "Mental capacity and best interests-Annual review (2006)" www.bevanbrittan.com (Date of use: 27 March 2008).

³⁶⁴ President's Commission *Making healthcare decisions* 55-60.

that any patient with cognitive impairment or mental illness automatically lacks DMC.
365,366,367

2.4.3 The rights of incompetent patients

This category of patients would include temporarily or permanently incapacitated adults, infants and children below the legally defined age of consent, which will vary depending on individual jurisdictions and national laws. For example, the legal age of consent in England is 16:³⁶⁸ “The consent of a minor who has attained the age of while the age of 16 years, to any surgical, medical or dental treatment, which in the absence of consent, would constitute a trespass to the person shall be effective as it would be, if he were of full age.”³⁶⁹ On the other hand consent to routine medical treatment in South Africa is currently 12 years of age.³⁷⁰ As a general rule, patients who are incompetent should be treated based on the doctrines of ‘necessity’ and ‘best interests’ as explained by the English House of Lords in *Re F*:³⁷¹ “Not only must there be necessity to act when it is not practicable to communicate with the assisted person, but also, the action taken must be such as a reasonable person would in all the circumstances take in the best interests of the assisted person.”³⁷² Further, in *Re T*³⁷³ an English court concluded that though there is a prima facie presumption of capacity for all adult patients, such an assumption, which arises out of the fact that the person is an adult, is a rebuttable right, which can be compromised by short or long-term mental incapacity.³⁷⁴ With regards to the patients ‘best interests’, the House of Lords in *F v West Berkshire HA*³⁷⁵ stated while considering the sterilization of a mentally retarded patient that “...a doctor can lawfully operate on or give

³⁶⁵ Aulisio MP et al *Improving competence in clinical ethics consultation: A learner’s guide* (American Society for Bioethics and Humanities Clinical Ethics Task Force 2005).

³⁶⁶ President’s Commission *Making healthcare decisions* 55-62.

³⁶⁷ Chima *Trans J Coll Med S Afr* 43.

³⁶⁸ *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC [112].

³⁶⁹ UK Family Law Reform Act 1969 Section 8(1).

³⁷⁰ Children’s Act 38 of 2005 as amended 2015 [129-133].

³⁷¹ *Re F (Mental Patient: Sterilisation)* (1990) 2 AC 115.

³⁷² *Re F (Mental Patient: Sterilisation)* (1990) 2 AC 1 115 [55C-E].

³⁷³ *Re T (Adult) (Consent to medical treatment)* (1992) 2 FLR 458.

³⁷⁴ *Re T (Adult) (Consent to medical treatment)* (1992) 2 FLR 458 see also Hocton *Law of consent to medical treatment* 5.

³⁷⁵ *F v West Berkshire Health Authority* 1989 2 All ER 545.

treatment to adult patients who are incapable for one reason or another, of consenting to his doing so provided that the operation or other treatment concerned is in the best interests of the patient,³⁷⁶ especially where it is carried out to preserve the life or prevent deterioration of the patient's condition.³⁷⁷ Further, it has been argued that "[...] the imposition of medical treatment, without consent of a mentally competent adult patient, would interfere with a person's physical integrity in a manner capable of engaging the rights protected under Article 8 (1) of the European Convention on Human Rights (ECHR)".³⁷⁸

In the context of South African law, the Children's Act of 2005³⁷⁹ specifies that the legal age for consent to treatment in children aged less than 18 years is the age of 12 years, provided such children also have sufficient maturity to understand the information disclosed prior to providing consent. To clarify what constitutes medical treatment, it may be necessary to refer to the dictionary definitions of the word "treatment". Stedman's concise medical dictionary defines "treatment" as, "*medical or surgical management of a patient*".³⁸⁰ Furthermore, Harrap's medical dictionary defines 'operation' as "any form of surgical procedure major enough to require anaesthesia", while 'treatment' is defined as "care, in terms of medication, nursing and any other therapy, designed to cure a disorder".³⁸¹ Perhaps, to avoid such controversies and misunderstanding the Children's Act clearly stipulates as follows in section 129:³⁸²

Consent to medical treatment and surgical operation:

(1) Subject to section 5(2) of the Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996), a child may be subjected to medical treatment or a surgical operation only if consent for

³⁷⁶ F v West Berkshire Health Authority 1989 2 All ER 545 [55].

³⁷⁷ Payne-James J, Dean P and Wall I (eds) *Medicolegal essentials in healthcare* 2nd ed (Greenwich Medical Media Ltd London 2004).

³⁷⁸ European Convention on Human Rights 1950 Art 8(1).

³⁷⁹ Children's Act 38 of 2005 as amended s129.

³⁸⁰ Dirckx JH (ed) *Stedmans concise medical dictionary for the health professions* 4th ed (Lippincott Williams and Wilkins Philadelphia 1997) 1009.

³⁸¹ Harrap's *Dictionary of medicine and health* (Harrap London 1988) 288 and 395 as cited by McQuoid-Mason D 2006 *SAMJ* 531.

³⁸² Children's Act 38 of 2005 as amended s129.

such treatment or operation has been given in terms of either subsection (2), (3), (4), (5), (6) or (7).

(2) A child may consent to his or her own medical treatment or to the medical treatment of his or her child if-

(a) the child is over the age of 12 years; and

(b) The child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment.

(3) A child may consent to the performance of a surgical operation on him or her or his or her child if-

(a) the child is over the age of 12 years; and

(b) The child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation; and

(c) the child is duly assisted by his or her parent or guardian.

In simple terms one can conclude from the above that a child over the age of 12 years who is sufficiently mature and has the DMC to provide IC, can consent to or refuse medical treatment including 'surgical operations' not requiring 'anaesthesia' or those which are not life threatening which may require overriding of such consent or refusal by a parent, guardian or court of law, as the case maybe. Examples of such consent, which may require overriding by a parent, or guardian, or court of law, may include consent to organ transplantation, or amputation of a major limb, etc. The Children's Act further specifies in section 129 (4-10), the mechanisms to be followed in the case of children below the age of 12 years or in the case of children who are found incompetent.³⁸³ Details of such consent or refusal are further discussed below on pages 75-79.

³⁸³ Children's Act 38 of 2005 as amended s129 (4-10).

2.4.4 Refusal of treatment and the patients decision making capacity (DMC)

It is an established fact that every adult has the DMC to decide whether he or she will accept or refuse any medical treatment.³⁸⁴ However, this presumption of DMC is rebuttable in that sometimes an adult may be deprived of his or her DMC due to some forms of mental incapacitation. Generally, if an individual did not have the DMC to decide at the time of purported refusal, in such cases it becomes the duty of the doctors or other HCP to treat the patient in whatever way they consider, based on their clinical judgment, and prevailing circumstances, to be in the best interests of the patient.³⁸⁵ However, doctors faced with refusal of consent have to give very careful and detailed consideration to what was the patient's DMC at the time of refusing the proposed treatment, because sometimes it may not be a case of DMC or lack thereof, it may simply be a case of reduced capacity. In such situations, what matters most is whether the patient's DMC was reduced below the level required in the case of a refusal of that importance, due to the fact refusals can vary in importance. Some refusals may put the patient's life in danger to the extent of losing their life or causing an irreparable damage to the patients' health, while others may not.³⁸⁶ Therefore, incompetence or lack DMC in one area does not necessarily mean that the patient lacks DMC to make any decision whatsoever, because health care decisions may vary in importance, with some requiring only minimal DMC, while others will require all mental faculties of the patient to consider the consequences and arrive at decision. Therefore, a patient's lack of capacity in one area or instance does not mean the patient lacks DMC in all areas; one can merely speak of the competence or capacity to do a particular thing or act. This has led to suggestions in the case of psychiatric patients, that there may be need to do away with the requirements of giving meaningful/ true/ valid IC on admission or assessment, which would mean that a lower standard, such as 'assent', could be adopted instead. While this may diminish somewhat the requirements of respecting an individual's autonomy, it would have the virtue of avoiding pretence, and enhancing truth telling. Further, the lowered standard of patient consent or assent could be augmented by internal review

³⁸⁴ Airedale NHS Trust v Bland (1993) AC 789.

³⁸⁵ Re C (Adult: Refusal of medical treatment) 1994 1 All ER 819.

³⁸⁶ Re C (Adult: Refusal of medical treatment) 1994 1 All ER 819 [473].

processes,³⁸⁷ such as those embedded in the Mental Health Care Act,³⁸⁸ whereby each patient admitted due to suspected psychiatric illness or observation are subjected to review by two independent qualified mental health practitioners within 48 hours of admission,³⁸⁹ before a further 72-hour assessment, which must be reported to the Mental Health Review Board, before further decisions could be made regarding involuntary admission of the patient, or community based treatment by a HCP.³⁹⁰

Finally, the issue of a patient's right to refuse medical treatment was analysed by the Supreme Court of Nigeria in the case of *MDCN v Okonkwo* 2002.³⁹¹ In this case the Medical and Dental Council of Nigeria (MDCN) equivalent to the HPSCA in South Africa, brought charges against a medical doctor for failure to transfuse a Jehovah's Witness patient who had declined blood transfusion which eventually led to her death. The doctor was charged with two offences based on the Medical and Dental Practitioners Act.³⁹² On the first count, the doctor was charged with attending to the patient in a negligent manner and thereby conducting himself infamously in a professional respect contrary to the prevailing medical ethics code.³⁹³ In the second count, the doctor was charged with acting contrary to his oath as a medical practitioner and thereby conducting himself infamously in a professional respect contrary to the same section of the Act.³⁹⁴ In the first instance, the Medical and Dental Practitioners Tribunal found the doctor guilty of these charges. The doctor then appealed to the Nigerian Court of Appeals where the doctor was acquitted. The MDCN then appealed this judgment to the Nigerian Supreme

³⁸⁷ Appelbaum PS and Grisso T "Assessing patients' capacities to consent to treatment" 1988 *N Engl J Med* 1635-1638.

³⁸⁸ Mental Health Care Act 17 of 2002.

³⁸⁹ Mental Health Care Act 17 of 2002 as amended s33.

³⁹⁰ Mental Health Care Act 17 of 2002 as amended (s34-35) see also Ramlall S Chipps J and Mars M "Impact of the South African Mental Health Care Act No. 17 of 2002 on regional and district hospitals designated for mental health care in KwaZulu-Natal" 2010 *S Afr Med J* 667-670 and Burns JK "Implementation of the Mental Health Care Act (2002) at district hospitals in South Africa: Translating principles into practice" 2008 *S Afr Med J* 46-49.

³⁹¹ *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo* (2002) AHRLR 159 (NgSC2001).

³⁹² *Medical and Dental Practitioners Act* Cap 221 Laws of the Federation of Nigeria 1990.

³⁹³ *MDCN Code of medical ethics in Nigeria: Rules of professional conduct for medical and dental practitioners* [35-38] www.mdcn.nigeria.org (Date of use: 28 January 2018).

³⁹⁴ *Medical and Dental Practitioners Act* CAP M8 Laws of the Federation of Nigeria 2004 (s16).

Court. In arriving at its judgment, Ayoola JSC argued with regards to patients' refusal of proposed medical treatment as follows:

The scope and limit of the duty of a practitioner faced with a patient's refusal to give informed consent to life-saving medical treatment cannot be considered in isolation of the right of the patient. Although, there is a dearth of local authorities in this area of our law, there are ample provisions of the Constitution which show the basis on which the Court should proceed in these matters. It is expedient at the outset to recognize that a consideration of a religious objection to medical treatment involves a balancing of several interests, namely: the constitutionally protected right of the individual, state interest in public health, safety and welfare of society; and, the interest of the medical profession in preserving the integrity of medical ethics and, thereby, its own collective reputation.³⁹⁵

The Supreme Court further asserted that the patient's constitutional right to object to medical treatment is founded on fundamental rights protected by the Nigerian Constitution³⁹⁶ as follows: (i) right to privacy: section 34; (ii) right to freedom of thought, conscience and religion in section 35.³⁹⁷ According to the Supreme Court, the right to privacy implies a right to protect one's thought, conscience or religious belief and practice, from coercive and unjustified intrusion, and one's body from unauthorized invasion. The right to freedom of thought, conscience or religion implies a right not to be prevented, without lawful justification, from choosing the course of one's life, fashioned on what one believes in, and a right not to be coerced into acting contrary to religious belief.³⁹⁸ The limits of these freedoms, as in all cases, are where they impinge on the rights of others or where they put the welfare of society or public health in jeopardy. The sum total of the rights of privacy and of freedom of thought, conscience or religion which an individual has, put concisely, is that an individual should be left alone to choose a course for his life, unless a clear and compelling overriding state interest justifies the contrary.³⁹⁹ The law's role is to ensure the fullness or liberty when there is no danger to public interest. In arriving at its decision, the Supreme Court cited judgments from the

³⁹⁵ Medical and Dental Council (MDCN) Tribunal v Okonkwo (2002) AHRLR 159 (NgSC 2001) [72].

³⁹⁶ Constitution of the Federal Republic of Nigeria 1999.

³⁹⁷ Constitution of the Federal Republic of Nigeria 1999 s34 and s35.

³⁹⁸ MDCN v Okonkwo (2002) AHRLR 159 (NgSC 2001) [73].

³⁹⁹ MDCN v Okonkwo (2002) AHRLR 159 (NgSC 2001) [73].

“United States of America where this area of law has received considerable judicial attention.”⁴⁰⁰ In its judgment, the court referred to two pertinent cases including the case of *Re Yetter* (1973),⁴⁰¹ where upon evidence that the patient was a mature, competent adult, who had no children, and had not sought medical attention and then attempted to restrict it. The court concluded that the constitutional right of privacy includes the right of a competent, mature adult to refuse treatment that may prolong his or her life even though that refusal may seem unwise, foolish or ridiculous to others. Similarly, in the case of *Re Osborne* (1972),⁴⁰² an American superior Court affirmed a lower court's order refusing to appoint a guardian to give consent for the administration of a blood transfusion to a patient who had refused it on religious grounds, and whom the physician feared would die without blood. In coming to a conclusion, the Nigerian Supreme Court held that:

Since the patient's relationship with the practitioner is based on consensus, it follows that the choice of an adult patient with a sound mind to refuse informed consent to medical treatment, barring state intervention through judicial process, leaves the practitioner helpless to impose a treatment on the patient.⁴⁰³

The Nigerian Supreme Court concluded that the principle of the American cases is reflected in the opinions in the UK House of Lords in the *Sidaway case*,⁴⁰⁴ where Lord Scarman was of the opinion that “[t]he courts should not allow medical opinion of what is best for the patient to over-ride the patient's right to decide for himself whether he will submit to the treatment offered him.”⁴⁰⁵ In the same case, Lord Templeman concluded that:

The patient is free to decide whether or not to submit to treatment recommended by the doctor ... If the doctor making a balanced judgment advises the patient to submit to the operation, the

⁴⁰⁰ MDCN v Okonkwo (2002) AHRLR 159 (NgSC 2001) see also Chima *A primer on medical law* 70-75.

⁴⁰¹ *Re Yetter* (1973) 62 Pa D & C 2d 619.

⁴⁰² *Re Osborne* (1972, Dist Col App) 294 A 2d 372.

⁴⁰³ MDCN v Okonkwo (2002) AHRLR 159 (NgSC 2001) [75].

⁴⁰⁴ *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643.

⁴⁰⁵ *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643 [644-649].

patient is entitled to reject the advice for reasons which are rational or irrational or for no reason.⁴⁰⁶

From the above judgment, one can argue that the sentiments expressed by the Nigeria Supreme Court in the case of *MDCN v Okonkwo* (NgSC 2001)⁴⁰⁷ are consistent with the rights guaranteed under sections 12, 14 and 15 of the South African Constitution, which guarantees in section 12 “right to freedom and security of the person”, section 14 “right to privacy” and section 15 “right to freedom of religion, belief and opinion.”⁴⁰⁸

Again, in terms of South African law, there are very few cases, if any, where the issue of adult refusal of medical treatment has been adjudicated. However, the NHA provides some guidelines on refusal of medical treatment where it requires as part of the IC process that HCPs are obliged to inform patients of their right of refusal. In this case the NHA stipulates that HCPs must inform the user of “[t]he user’s right to refuse health services, including an explanation of the implications, risks and obligations of such refusal”.⁴⁰⁹ This form of refusal has been described as an “informed refusal”.⁴¹⁰ Furthermore, it has been argued that while competent adults are legally free to refuse any medical treatment, life-saving treatment can be administered to such patients if they are incompetent and in an emergency. However, this is only applicable where “the user has not expressly, impliedly or by conduct refused that service”.⁴¹¹ One can therefore conclude that once a legally competent patient has given ‘informed refusal’ to medical treatment, such a patient cannot be given emergency treatment against his or her will.⁴¹²

Similarly children who over the legal age to consent to medical treatment (that is, the age of 12 years as defined by South African law), who are legally competent to make that decision, can consent to medical treatment or surgical operation as

⁴⁰⁶ Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 1 All ER 643 [665-666].

⁴⁰⁷ *MDCN v Okonkwo* (2002) AHRLR 159 (NgSC 2001).

⁴⁰⁸ Constitution of the Republic of South Africa 1996 (s12, s14 and s15).

⁴⁰⁹ National Health Act s (6) (1).

⁴¹⁰ McQuoid-Mason D “The National Health Act and refusal of consent to health services by children” 2006 *SAMJ* 530-532.

⁴¹¹ National Health Act s7 (1).

⁴¹² McQuoid-Mason D 2006 *SAMJ* 531.

the case maybe, in accordance with the Children's Act 2005.⁴¹³ It has been argued that such children are also legally competent to refuse medical treatment,⁴¹⁴ except where such treatment is a life-saving treatment, in that case, such refusal could be overridden either by a parent, guardian, or a court as the upper guardian of all children,⁴¹⁵ based on the consideration that in all matters concerning children, the best interest of the child should be of paramount consideration.⁴¹⁶ In the case of minors under the age of 12 years who are not legally competent to refuse or consent to medical treatment or surgical operation, a parent or guardian, a hospital superintendent, or a court of law as the case maybe can provide such consent.⁴¹⁷ However it has been argued that such children under the age of 12 years who are capable of understanding should be provided with similar information as required by the NHA, and should then also give 'assent' to the proposed treatment.⁴¹⁸ The Children's Act 2005⁴¹⁹ provides an exception to age of consent or refusal of medical treatment in the context of termination of pregnancy. In terms of the Choice on termination of pregnancy Act 1996, "any woman of any age" can consent to termination of their pregnancy.⁴²⁰ It has been suggested that HCPs should consider that although age may not be a barrier to consent to TOP, lack of mental capacity to understand the consequences of the procedure, maybe a barrier to IC in these cases.⁴²¹ Furthermore, while female children of any age may refuse to undergo TOP, there is a need for HCPs to ensure that such children are fully aware of the risks and benefits of such a procedure through non directive counselling as required by the Act.⁴²² Finally, it has been suggested that where HCPs are unsure of the understanding or capacity of the female child to consent to termination of pregnancy in a life threatening situation, such TOP may be performed in the child's best interests.⁴²³

⁴¹³ Children's Act 38 of 2005 as amended s129.

⁴¹⁴ McQuoid-Mason D 2006 *SAMJ* 531.

⁴¹⁵ Children's Act 38 of 2005 as amended s129 (4-10).

⁴¹⁶ Children's Act 38 of 2005 as amended s6-9.

⁴¹⁷ Children's Act 38 of 2005 as amended s129 (4-10) see also McQuoid-Mason D 2006 *SAMJ* 531.

⁴¹⁸ National Health Act s (8)1 see also McQuoid-Mason D 2006 *SAMJ* 531.

⁴¹⁹ Children's Act 38 of 2005 as amended s129 (1).

⁴²⁰ Choice on Termination of Pregnancy Act 92 of 1996 s5 (2-3).

⁴²¹ McQuoid-Mason D 2006 *SAMJ* 531.

⁴²² Choice on Termination of Pregnancy Act 92 of 1996 see also McQuoid-Mason D 2006 *SAMJ* 531.

⁴²³ McQuoid-Mason D 2006 *SAMJ* 531.

However, one would like to suggest that in such cases the guidelines laid down in the Children's Act,⁴²⁴ should be followed by HCPs confronted by such dilemmas, in other cases, court adjudication maybe considered if there is sufficient time to do so.

Therefore, in the context of South African law the applicable legal principles on the issue of whether a court could authorise medical treatment for a child to preserve a child's life despite parental objection based on religious reasons were elucidated by Modiba AJ in the High Court of South Africa, Gauteng Lower Division, Johannesburg, in the case of *Life Healthcare and another v JMS 2014*.⁴²⁵ In this case, the Court held That:

In terms of section 129 (4) (a) of the Children's Act 38 of 2005 (the Act), the parents of a child under the age of 12 are authorised to consent to the child's medical treatment. In terms of section 129 (10), no parent may withhold consent for the medical treatment of a child by reason only of religious or other beliefs, unless the parent can show that there is a medically accepted alternative choice to medical treatment. Section 126 (9) gives the High Court or the Children's Court jurisdiction to consent to the medical treatment of a child in any instance where a person authorised by the Act to consent refuses or is unable to give consent.⁴²⁶

The court further argued that such cases create conflicts between parental rights and children's' rights. Such conflicts would include the parental rights to freedom of religion versus the child's right to life, and right to have best interests guide any decisions affecting all children.⁴²⁷ The court further held that under the Constitution, everyone has the right to freedom of conscience, religion, thought, belief and opinion.⁴²⁸ The court further held that everyone has a constitutional right to life,⁴²⁹ and that a child's best interests are of paramount importance in every matter concerning a child.⁴³⁰ The Gauteng High Court in this case cited with agreement the judgment of the court in the case of *Hay v B and others 2003*,⁴³¹ arguing that though the judgment in this case was rendered prior to the Children's

⁴²⁴ Children's Act 38 of 2005 as amended s129 (4-10).

⁴²⁵ *Life Healthcare Group (PTY) Ltd and Another v JMS and Another* [2014] 34758.

⁴²⁶ *Life Healthcare Group (PTY) Ltd and Another v JMS* [2014] 34758 [9].

⁴²⁷ *Life Healthcare Group (PTY) Ltd and Another v JMS* [2014] 34758 [10].

⁴²⁸ The Constitution s15 (1).

⁴²⁹ The Constitution s11.

⁴³⁰ The Constitution s28 (2).

⁴³¹ *Hay v B and others 2003* (3) SA 492 (W).

Act coming into effect, the dicta in *Hay v B* upholds the letter and spirit of the section 129 (10) of the Children's Act.⁴³² In the case of *Hay v B*, the court held that parental right to religion is not unfettered, and that the right to life is an inviolable right, to the extent that parental rights potentially violates the child's right to life. Moreover, the content of a child's right to life would include the right to receive medical treatment, especially where such treatment would preserve the child's life.⁴³³ The court opined that:

In my view, the limitation imposed by section 129 (10) on the parent's right to object to the medical treatment of a child for religious reasons reflects a balancing of the child's right to life and to have his best interests inform all decisions concerning the child against the parents' right to religion.⁴³⁴

In arriving at its decision, the Gauteng High Court cited the Constitutional Court judgment in *S v Makwayane*, where the court held that the right to life is the most constitutionally protected value.⁴³⁵ The court further cited the Constitutional Court judgment in *Christian Education South Africa v Minister of Education 2000* where the Court opined that:

Courts throughout the world have shown special solitude for protecting children from what they have regarded as the potentially injurious consequences of their parents religious practices. It is now widely accepted that in every matter concerning the child, the child's best interest must be of paramount importance.⁴³⁶

The Gauteng High Court therefore concluded that it was in the child's best interests that his life is preserved,⁴³⁷ even against parental objections. From the foregoing, one can conclude from South African law, those children below the legal age of consent and even up the age of consent and of sufficient maturity who refuse lifesaving treatment, such treatment can be administered against their will, in order to preserve the child's life. Finally, perhaps when interpreting or applying the new Children's Act,⁴³⁸ it may pertinent to keep in mind that one of the reasons for lowering the age of consent to treatment from 14 years to 12 years was to enable child-headed households which had increased in proportion in

⁴³² Children's Act 38 of 2005 as amended s129 (10).

⁴³³ Life Healthcare Group (PTY) Ltd and another v JMS and another (2014) 34758 [13].

⁴³⁴ Life Healthcare Group (PTY) Ltd and another v JMS and another [2014] 34758 [14].

⁴³⁵ *S v Makwayane* 1995 (3) SA 391 (CC) at para 144.

⁴³⁶ *Christian Education South Africa v Minister of Education 2000* (4) SA 757 (CC) at Para 41 and cited with approval in *Hay v B and others* 2003 (3) SA 492 (W).

⁴³⁷ Life Healthcare Group (PTY) Ltd and another v JMS and another [2014] 34758 [15].

⁴³⁸ Children's Act 38 of 2005 as amended

South Africa as a consequence of the AIDs epidemic, for such minor to have independent access to healthcare including HIV-AIDS treatment and counselling. Therefore it would be conceivable that such children should be able to consent to ‘minor’ surgical ‘operations’,⁴³⁹ independently, in the absence of parents or guardians within the household.⁴⁴⁰

2.4.5 DMC in children

With regard to children, the age of consent to treatment or refusal was legally defined as after the age of 18 in English law,⁴⁴¹ except where such children are regarded as mature minors based on *Gillick*⁴⁴² competence, or in accordance with other foreign regulations, such as US regulations.⁴⁴³ Similarly, in South Africa, the age of majority is 18, although the age of consent to routine medical treatment is currently pegged at 12 years.^{444,445} In the English case of *Gillick v West Norfolk AHA*⁴⁴⁶ the Court of Appeal ruled that children of a certain age, in this case girls under the age of 16, could be given prescriptions for contraceptive pills without parental consent. However, this ruling did not necessarily translate into the ability to consent to or refuse all medical procedures such as transplantation, or participation in biomedical research. As noted by an English court in *Re W*,⁴⁴⁷ “nothing in the above *Gillick* case shall be interpreted to include procedures which do not constitute treatment, such as organ donation, and blood procedures.”⁴⁴⁸ Commenting on the *Gillick* case, Lord Scarman stated that such a patient should have

⁴³⁹ Harrap’s *Dictionary of medicine and health* (Harrap London 1988) 288 as cited by McQuoid-Mason D 2006 *SAMJ* 531

⁴⁴⁰ Brand South Africa “Government explains new Children’s Act” 03 July 2007 <http://www.brandsouthafrica.com/governance/services/government-explains-new-childrens-act> (Date of use: 9 November 2017).

⁴⁴¹ Children’s Act 1989 s105.

⁴⁴² *Gillick v West Norfolk and Wisbech Area Health Authority* 1986 AC 112.

⁴⁴³ *Grimes v KKI* 2000.

³⁷⁵ McQuoid-Mason D “The National Health Act and refusal of consent to health services by children” 2006 *SAMJ* 530-532.

⁴⁴⁵ Children’s Act 38 of 2005 as amended.

⁴⁴⁶ *Gillick v West Norfolk and Wisbech Area Health Authority* 1986 AC 112.

⁴⁴⁷ *Re W (A Minor) Medical Treatment*. Courts Jurisdiction 1993 Fam 64.

⁴⁴⁸ *Re W (A Minor) Medical treatment-Courts jurisdiction* 1993 Fam 64 [83].

sufficient maturity to understand, the moral social and emotional impact of the decision.⁴⁴⁹ Similarly Van der Walt has suggested that “[...] the child must have the mental capability and maturity to evaluate responsibly the nature, and extent and implications of his consent or assumption of risk”.^{450,451} Similarly the Children’s Act 38 of 2005⁴⁵² was recently amended to take into consideration the considerable number of child-headed households in South Africa, and to give such child patients the opportunity to access treatment and voluntary counselling and testing for HIV-AIDs and contraceptives in the absence of parents or guardians.⁴⁵³

Further, in the American case of *Grimes v KKI*,⁴⁵⁴ the court was of the opinion that children should not necessarily be included in non-therapeutic research as a matter of course based on parental consent, since the most overriding issue was the best interests of the child. The court went further to suggest that such situations including organ or tissue transplantation and participation in non-therapeutic or therapeutic research with more than ‘minimal risk’ should be subjected to judicial review.⁴⁵⁵ The NHA⁴⁵⁶ stipulates that children or incompetent adults, who may not necessarily be capable of giving legal consent, should generally give “assent” to the proposed treatment.⁴⁵⁷ Therefore, competence to consent medical treatment is legally determined based on age, DMC of the patient, and the prevailing circumstances surrounding the decision to consent or refuse the proposed therapy.

⁴⁴⁹ Gillick v West Norfolk and Wisbech Area Health Authority 1986 AC 112 see also Children’s Act 38 of 2005 Section 129(2).

⁴⁵⁰ Van der Walt JC and Midgely JR *Delict: Principles and cases 2nd* ed (Butterworths Durban 1997) see also Du Plessis E, Govindjee A and Van Der Walt G “The constitutional rights of children to bodily and psychological integrity and autonomy” 2014 *Sabinet* 35 [1].

⁴⁵¹ Chetty PR *An examination of the rights of the child to refuse medical treatment: a South African perspective* (LLM dissertation UKZN 2016) 8.

⁴⁵² Children’s Act 2005 as amended 2015 [129-137].

⁴⁵³ Brand South Africa “Government explains new Children’s Act” 03 July 2007 <http://www.brandsouthafrica.com/governance/services/government-explains-new-childrens-act> (Date of use: 9 November 2017).

⁴⁵⁴ *Grimes v KKI* 2000[11-13].

⁴⁵⁵ *Grimes v KKI* 2000 [9-13].

⁴⁵⁶ National Health Act 61 of 2003

⁴⁵⁷ National Health Act 61 of 2003 s8 (2) (a-b) and (3).

The American *Guttmacher Report on Public Policy*⁴⁵⁸ emphasizes the notion “that many minors have the capacity and indeed the right to make important decisions about health care, has been well established in federal and state policy.”⁴⁵⁹ In South Africa, the currently prescribed age at which children can consent to routine medical treatment is 12 years, as codified in the Children’s Act.⁴⁶⁰ Section 17 of the Act further specifies that a child, whether male or female, attains majority upon reaching the age of 18 years.⁴⁶¹ However, this does not mean that minors below the age of 18 can generally refuse all medical treatment, as this refusal can be overridden by a person having parental authority or by a court of law, as upper guardian of children, based on the child’s best interests,⁴⁶² as demonstrated in the case of *Hay v B*,⁴⁶³ where a court overruled parents refusal of life-saving blood transfusion for a child because the parents were Jehovah witnesses.

2.4.6 Mature minors

The question as to whether a child is *Gillick*-competent or a mature minor is a question of fact, based on a developmental concept of sufficient maturity and intelligence to understand the nature and implications of the proposed medical treatment.⁴⁶⁴ The *Gillick*-competent child however does not have the power to consent to or refuse all forms of medical treatments.⁴⁶⁵ This is based on the concept of DMC and the magnitude of risk involved in the proposed medical procedure. In other words, the higher the magnitude of risk, the higher the DMC required to consent or refuse such treatment. Therefore it can be presumed that in cases of high-risk medical procedures, such as organ transplantation or donation and treatment using other types of human tissues e.g. lifesaving blood transfusion. The consent or refusal of a *Gillick*-competent or mature minor may be

⁴⁵⁸ Boonstra H and Nash E “Minors and the right to consent to health care” *Guttmacher report on public policy 1* (Guttmacher Institute New York 2000) 4-8.

⁴⁵⁹ Boonstra and Nash *Guttmacher report on public policy* 4.

⁴⁶⁰ Children’s Act 38 of 2005 as amended.

⁴⁶¹ Carstens and Pearmain *Foundational Principles* 904.

⁴⁶² McQuoid-Mason D “The National Health Act and refusal of consent to health services by children” 2006 *SAMJ* 531.

⁴⁶³ *Hay v B* 2003 (3) SA 492 (W).

⁴⁶⁴ *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112.

⁴⁶⁵ *Hocton Law of consent to medical treatment* 174.

overruled by a court of law or parent or guardian.⁴⁶⁶ As explained by Lord Donaldson in *Re W*⁴⁶⁷:

There can therefore be no doubt that [the court] has the power to override the refusal of a minor whether over the age of 16 or under that age but Gillick competent...such a refusal is a very important consideration in making clinical judgments and for parents in deciding whether themselves to give consent. Its importance increases with the age and maturity of the minor.⁴⁶⁸

2.4.7 Children under the legal age of consent who are not considered ‘mature minors’

Children under the age of consent who are not categorized as ‘mature minors’ generally do not have the capacity to consent to or refuse medical treatment. Under normal circumstances, consent has to be obtained from the parent or guardian. As a rule, any person with parental responsibility can give consent on behalf of a child who is below the age of consent. However, the treatment consented to must be in the child’s best interests. When there is dispute amongst parents with one refusing, and the other giving consent, the doctor or HCP is sometimes confronted by an ethical and professional dilemma. However, this is not a legal dilemma because the HCP has prima facie consent to treat children based on their best interests as shown in *Re R*.⁴⁶⁹ However, where such treatment is non-therapeutic, as in *Re J* (circumcision),⁴⁷⁰ judicial review may be required. This type of ethical dilemma was resolved by the court in the South African case of *Hay v B*,⁴⁷¹ where parents refused to give IC for blood transfusion to a child, basing their decision on the fact that they were practicing Jehovah’s witnesses. The court as upper guardian of all minors authorised the procedure against the parents’ wishes, based on the best

⁴⁶⁶ *Re R* (A minor) (Medical treatment: Consent to treatment) (1992) Fam 11.

⁴⁶⁷ *Re W* (A minor-Medical treatment: Courts discretion) 1992 2 WLR 758.

⁴⁶⁸ *Re W* (A minor-medical treatment: Courts discretion) 1992 2 WLR 758 [83].

⁴⁶⁹ *Re R* (A minor) (Wardship: Medical Treatment) 1992 1 FLR 190 [196] see also Chima *Consent and patients’ rights* 36-39.

⁴⁷⁰ *Re J* (A minor) (Prohibited steps order: Circumcision) 2000 1 FCR 305.

⁴⁷¹ *Hay v B* 2003 (3) SA 492 (W) 494-495.

interests of the child,⁴⁷² and as discussed in the above on pages 75-79 of this thesis, citing the court judgment in *Life Healthcare and another v JMS 2014*.⁴⁷³

Similarly, in non-therapeutic research the child's best interest should be the primary consideration as suggested by the Maryland Court of Appeals in *Grimes v KKI*.⁴⁷⁴ Here the Court held that consent to non-therapeutic research, entered into by parents, that exposed children to the danger of lead toxicity, was not in the children's best interest. Similarly, in *Ref F*,⁴⁷⁵ Lord Donaldson was of the opinion that consent entered into on behalf of a child by the parents was invalid and such treatment could constitute assault by the HCP. Arguing that the right of parents to make decisions on behalf of their children is a dwindling right, Lord Fraser in *Gillick*⁴⁷⁶ adopted the words of Lord Denning in *Hewer v Bryant*⁴⁷⁷ where the latter opined that "[t]he legal right of a parent to the custody of a child ends at the 18th birthday, and even up till then it is dwindling right which the courts will hesitate to enforce against the wishes of a child, and the more so the older he is. It starts with a right of control and ends with little more than advice."⁴⁷⁸ Similarly, the NHA⁴⁷⁹ provides that even if a person does not have the legal capacity to consent, he or she must still be consulted, and that children below the age of consent who could understand, should be asked to give "assent" to the treatment consented on their behalf by a parent or guardian.⁴⁸⁰ Jane Fortin concurred with the opinion of Lord Fraser in the *Gillick* case by suggesting that parental right yields to the child's right to make his or her own decisions when he or she reaches a sufficient understanding and intelligence.⁴⁸¹ In support of the best interests principle when dealing with children, the *UN Convention on Children's Rights*⁴⁸² states that: "In all actions concerning children, whether undertaken by public or

⁴⁷² McQuoid-Mason D "Parental refusal of blood transfusions for minor children solely on religious grounds-the doctor's dilemma resolved" 2005 *SAMJ* 29-30.

⁴⁷³ *Life Healthcare Group (PTY) Ltd and Another v JMS* [2014] 34758.

⁴⁷⁴ *Grimes v KKI* 2000 [9-13].

⁴⁷⁵ *Ref F* 1990 2 AC 1.

⁴⁷⁶ *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112.

⁴⁷⁷ *Hewer v Bryant* [1970] 1 QB 357.

⁴⁷⁸ *Hewer v Bryant* [1970] 1 QB 357 [369].

⁴⁷⁹ National Health Act 61 of 2003 s8.

⁴⁸⁰ National Health Act 61 of 2003 s (8) (2) (b).

⁴⁸¹ Fortin J *Children's rights and the developing law* (Butterworths London 2003) see also *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112 [169B].

⁴⁸² United Nations *Convention on the Rights of the Child* (United Nations 1989).

private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.”⁴⁸³ The best interest standard in all cases where a child’s rights and interests are affected is also entrenched in section 28(2) of the Constitution of the Republic of South Africa, 1996.

2.4.8 Consent to termination of pregnancy in South Africa

There is a unique situation in South African law, whereby the Choice on Termination of Pregnancy Act⁴⁸⁴ states that “any woman of any age” can legally consent to termination of pregnancy for various reasons.⁴⁸⁵ This may create a misunderstanding with the legal age of consent to treatment, which is stipulated as 12 years of age.⁴⁸⁶ It is established that this requirement is legally binding and that medical doctors and other HCP such as nurses and midwives ought to be conversant with this regulation. However, it has been demonstrated by recent research reports arising from this thesis, that only about 30% of medical doctors⁴⁸⁷ and 8% of professional nurses⁴⁸⁸ in South Africa can accurately answer the question regarding the age of consent to termination of pregnancy in South Africa. Therefore, as will be demonstrated later in part two of this thesis: doctors, professional nurses and patients in South Africa are not very conversant with the basic laws concerning medical treatment in South Africa. Therefore, such potential ambiguities should generally be explained or clarified to practicing HCPs, who are responsible for applying such laws during clinical practice, since most of them are not conversant with the fine nuances of interpreting the law.

⁴⁸³ *Convention on the Rights of the Child* (United Nations 1989) Art 3(1).

⁴⁸⁴ Choice on Termination of Pregnancy Act 92 of 1996.

⁴⁸⁵ Chima SC and Mamdoo F “Ethical and legal dilemmas around termination of pregnancy for severe fetal anomalies: A review of two African neonates presenting with ventriculomegaly and holoprosencephaly” 2015 *Niger J Clin Pract* 31-39 see also Choice on Termination of Pregnancy Act 92 of 1996.

⁴⁸⁶ Children’s Act 38 of 2005.

⁴⁸⁷ Chima 2013 *BMC Med Ethics* S3 [10].

⁴⁸⁸ Chima *Understanding and practice of informed consent by nurse by professional nurses in South Africa* 98.

2.4.9 Fluctuating capacity

A patient's capacity may fluctuate, and if so, this may mean that he or she effectively lacks capacity where there is a need to submit to regular treatment. In the English case of *Re D*,⁴⁸⁹ where D suffered from long standing psychiatric illness and was found to lack capacity to take decisions and exercise judgment with regard to his medical treatment, independent psychiatric evidence concluded that:

On consideration, I find the patient lacks capacity, although I believe he can at times understand the purpose and nature of his proposed treatment at considerable extent at others, I consider his appreciation and his understanding is critically defective and he is unable to retain information and weigh it in the balance. In circumstances where he needs to submit regularly and reliably to treatment, such fluctuating capability effectively means he lacks capacity.⁴⁹⁰

With regards with fluctuating capacity, the Health Professions Council of South Africa (HPCSA)⁴⁹¹ has made the following recommendations regarding IC and care of patients with fluctuating capacity:

- a. Where patients have difficulty retaining information, or are only intermittently competent to make a decision health care practitioners should provide any assistance they might need to reach an informed decision.
- b. Health care practitioners should record any decision made while the patients were competent, including the key elements of the consultation.
- c. Health care practitioners should review any decision made whilst the patients were competent, at appropriate intervals before treatment starts, to establish that their views are consistently held and can be relied on.⁴⁹²

Further, the National Health Act (NHA)⁴⁹³ makes provision for certain persons to consent on behalf of mentally incompetent patients to an operation or medical treatment where such patients are unable to give the necessary consent and have not mandated, while still

⁴⁸⁹ Re D (Medical treatment; mentally disabled patient) [1998] 2 FLR 22.

⁴⁹⁰ Re D (Medical treatment; mentally disabled patient) [1998] 2 FLR 22 see also Hocton *Law of consent to medical treatment* 69.

⁴⁹¹ HPCSA *Guidelines for good practice in the health care professions- Seeking patients informed consent: The ethical considerations* (HPCSA Pretoria 2008).

⁴⁹² HPCSA *Seeking patients consent* 7.

⁴⁹³ National Health Act 61 of 2003 s7.

mentally competent, somebody else in writing to give consent on their behalf. The Act sets out a priority list of persons who can give proxy consent in such circumstances:

- i. A person authorized by the court (e.g. a *curator personae*);
- ii. In order of priority, the patient's spouse, partner, parent, grandparent, major child or brother or sister.

The NHA also allows patients, while still mentally competent, to mandate another person in writing to give consent on their behalf.⁴⁹⁴ Therefore, where HCPs are treating a patient who has lost the capacity to consent to or refuse medical treatment, for example, after the onset or progress of a mental disorder or other disability, they should try to find out whether the patient has previously mandated someone else in writing to make decisions on their behalf; or has made a “living will” or provided “advanced directives” that could guide provision of care. Finally, the HPCSA suggests that HCPs must respect any refusal of treatment given when the patient was competent, provided the decision in the advance statement is clearly applicable to the present circumstances, and there is no reason to believe that the patient has changed his or her mind in the interim. Where an advance statement of this kind is not available, the patient's known wishes must be taken into account,⁴⁹⁵ as further discussed on pages 127-129 below.

2.4.10 Summary of criteria for determining DMC prior to informed consent

Finally, one can summarize the criteria that may disqualify a patient and could assist HCPs in determining a patient's competence or DMC to consent to medical treatment as follows:

- (a) Inability to express or communicate a preference
- (b) Inability to understand one's situation and its consequences
- (c) Inability to understand relevant information e.g. due to language differences, information not explained in simple language, or information overload due to excessive disclosure.

⁴⁹⁴ National Health Act 61 of 2003 s8 see also HPCSA *Seeking patients consent* 8.

⁴⁹⁵ HPCSA *Seeking patients consent* 8.

- (d) Inability to give reasons or rationalize reasons for a decision
- (e) Inability to analyse information and give risk/benefit-related reasons
- (f) Inability to reach reasonable decision
- (g) Coercion, undue influence, or manipulation interfering with capacity to comprehend or communicate a preference.^{496,497,498}

All of the above may have an impact on a patient's DMC or competence to consent to, or refuse any medical treatment, and may ultimately impact on and even invalidate such consent.

2.5 Voluntariness

Voluntary consent lies at the heart of respect for autonomy, based on the tenets of freedom and human rights as stipulated in the International Convention on Civil and Political Rights (ICCPR),⁴⁹⁹ the Universal Declaration of Human Rights (UDHR),⁵⁰⁰ and the International Covenant on Economic, Social and Cultural Rights (ICESCR),⁵⁰¹ which underlie contemporary theories on the interdependence and indivisibility of civil, political and socio-economic rights. It has been argued that the implications of this full conception of human rights and individual autonomy for effective enjoyment of these bundles of rights as enshrined in the above documents have not been fully explored. Consequently, the importance of individual autonomy for the enjoyment of socio-economic rights is rarely emphasized.⁵⁰² The ICCPR states that no one should be involved in research or scientific experimentation without his or her free and voluntary consent (Art 7 ICCPR).⁵⁰³ This element of voluntariness in research is also part and parcel of self-determination and autonomy in medical treatment. The voluntary consent of the individual has been adopted

⁴⁹⁶ Chima *Trans Coll Med S Afr* 42-43.

⁴⁹⁷ Beauchamp and Childress *Principles of biomedical ethics* 73.

⁴⁹⁸ President's Commission *Making healthcare decisions* 55-62.

⁴⁹⁹ International Convention on Civil and Political Rights (ICCPR) (United Nations 1966) Article 7.

⁵⁰⁰ Universal Declaration of Human Rights (United Nations 1948).

⁵⁰¹ International Covenant on Economic Social and Cultural Rights (ICESCR) (United Nations 1966).

⁵⁰² Piertese M "The interdependence of rights to health and autonomy in South Africa" 2008 *SALJ* 553-572.

⁵⁰³ ICCPR Article 7.

by all ethical codes and statutory laws regarding IC including the *Helsinki Declaration*,⁵⁰⁴ which states that human subjects of biomedical research must be volunteers and informed participants in the research project. Similarly the Nuremberg Code⁵⁰⁵ states unequivocally that:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.⁵⁰⁶

Some authorities have analysed voluntariness in IC in terms of the presence of adequate knowledge, absence of psychological compulsion or external constraints.⁵⁰⁷ Others have argued that such a broad application encompasses the whole gamut of autonomous action.⁵⁰⁸ Instead, Beauchamp and Childress have suggested that a patient acts voluntarily to the degree he or she wills that action into being, in the absence of external control. They further suggest that while all control by another person may represent some form of influence, not all influences can be considered as controlling. The broad category of influences may range from love, threat, persuasion, education, lies, emotional appeals, and manipulation. All of which can vary in their level of influence on the individual.⁵⁰⁹ However, according to Lord Donaldson in *Re T*,⁵¹⁰ not all influences will lead to involuntary action unless they lead to a change of will, in the individual concerned as explained below:

If his will was overborne; the refusal will not have represented a true decision. In this context the relationship of the persuader to the patient—for example, spouse, parents or religious adviser—will be

⁵⁰⁴ World Medical Association (WMA) “Declaration of Helsinki” *Ethical principles for medical research involving human subjects* (WMA Ferney Voltaire France 2013) Article 20.

⁵⁰⁵ *Trials of war criminals before the Nuremberg military tribunals under control council law No. 10* (2) (US Government Printing Office Washington DC 1949) 181-182.

⁵⁰⁶ The Nuremberg Code 1949 <https://history.nih.gov/downloads/nuremberg.pdf> (Date of use: 10 November 2017).

⁵⁰⁷ Feinberg J *Social philosophy* (Prentice-Hall Englewood Cliffs NJ 1973) 48-51.

⁵⁰⁸ Beauchamp and Childress *Principles of biomedical ethics* 57-105.

⁵⁰⁹ Beauchamp and Childress *Principles of biomedical ethics* 93-94.

⁵¹⁰ *Re T (Adult) (Consent to medical treatment)* (1992) 2 FLR 458.

important, because some relationships more readily lend themselves to overbearing the patient's independent will than others.⁵¹¹

Voluntariness is another important requirement for IC, based on the fact that the patient's participation in the ultimate decision to accept or refuse treatment must be voluntary. A choice that has been coerced, or that resulted from serious manipulation of a person's ability to make an intelligent and informed decision, will not be considered the person's own free choice. This has long been recognized in law, in that consent coerced or forced by threats or induced by fraud or misrepresentation is legally viewed as no consent at all. From the perspective of ethics, a consent that is substantially involuntary does not provide moral authorization for treatment because it does not respect the patient's autonomy and dignity and may not reflect the values and objectives of the patient.⁵¹²

2.5.1 Forms of undue influence

2.5.1.1 Coercion

Coercion occurs when one uses a credible threat or force to try and control another. For a threat to be real, both parties must believe it, and the perpetrator must convince the victim of the realness of the threat. Coercion occurs if a credible and intended threat displaces a person's self-directed actions or intentions. Coercion may void an act of autonomy by rendering even intentional and well-informed behaviour non-autonomous.⁵¹³ Concern is accordingly at its greatest effect when there is a disproportion in power or other significant inequality between one individual and another and this lends credibility to the threat of harm where the perceived interests of the individuals diverge.⁵¹⁴ The disparity in power or power asymmetry between a patient and the HCP could be slight or substantial, depending on the nature of the patient's illness, institutional setting, personalities of the individuals involved, and several other factors. It has been suggested that there are a

⁵¹¹ Re T (Adult) (Consent to medical treatment) (1992) 2 FLR 458.

⁵¹² President's Commission *Making healthcare decisions* 63-66.

⁵¹³ Beauchamp and Childress *Principles of biomedical ethics* 93-98.

⁵¹⁴ Beauchamp and Childress *Principles of biomedical ethics* 93-98.

number of reasons why power asymmetry exists between doctors and patients. These would include:

- (i) their social position
- (ii) the doctor's superior knowledge
- (iii) the control over access to healthcare
- (iv) the patient's illness, and
- (v) the fact that the patient has come to the HCP for help.^{515,516}

Further, it has been stated that in non-emergency settings, a patient can usually avoid this imbalanced power relationship by changing HCPs or simply foregoing treatment, thus avoiding the potential for coercion.⁵¹⁷ Although HCPs may sometimes have interests that are distinct from, and which may appear to be in conflict with those of their patients, strong social and professional norms usually ensure that priority is accorded to patients' welfare. Sometimes coercion can be exercised based on benevolent and paternalistic motives of the HCP where the HCP and the patient differ in their assessments of how the patient's welfare is best served. When isolated instances of abuse or coercion do occur, the law provides some remedies for the patient. It has been argued that patients' surrogates may play a useful role in this decision-making process.⁵¹⁸ Sometimes surrogates may also try to coerce a particular decision from the patient based on interests of their own.⁵¹⁹ This was demonstrated in the case of *Re T*⁵²⁰ where a Jehovah's Witness mother unduly influenced her daughter to the extent that her will was said to be overborne when the daughter rejected recommended life-saving blood transfusion. In such cases where there are differences of opinion between the patient and HCPs, it has been suggested that the HCP's first loyalty should be to the patient. HCPs should attempt to enhance the patient's

⁵¹⁵ Maclean AR *Consent to medical treatment and the competent adult* 161.

⁵¹⁶ Seeman M and Seeman TE "Health behavior and personal autonomy: A longitudinal study of sense of control and illness" 1983 *J Health Soc Behav* 144-160.

⁵¹⁷ President's Commission *Making healthcare decisions* 63-66.

⁵¹⁸ Beauchamp and Childress *Principles of biomedical ethics* 93-98.

⁵¹⁹ McCormick TR <https://depts.washington.edu/bioethx/tools/princpl.html> (Date of use: 28 February 2008).

⁵²⁰ *Re T (Adult) (Consent to medical treatment)* (1992) 2 FLR 458.

ability to make a voluntary, uncoerced decision and to overcome any coercive pressures.⁵²¹

2.5.1.2 Persuasion

In persuasion, a patient must come to believe in something based on the moral suasion and reasons another person advances, for example, the HCP or family member. Influence by appeal to reason is different from appeal to emotions. The key is to balance the information disclosed to patients who may be psychologically fragile so that their fear or panic would not overwhelm their ability to reason and to make a voluntary decision.⁵²²

2.5.1.3 Manipulation

Some HCPs have argued against IC by suggesting it is as mere window dressing on the basis that most doctors can usually manipulate a patient's decision to accede to any request made by a trusted physician. This can sometimes be achieved by persuasion, which may not be unethical. However, sometimes such conduct, capitalizes on the disparities in knowledge, position, and influence, and the power asymmetry between doctor and patient. It has been argued that such actions which are manipulative in character impair the voluntariness of the patient's choice.⁵²³ Manipulation is a generic term for many forms of undue influence, which are designed to get patients to behave in one way or another, which may not be necessarily coercive or persuasive.⁵²⁴ In healthcare, the primary form of manipulation is information manipulation, whereby the HCP can by tone of voice or careful selection of information, either negatively or positively presented, to influence patient choice. For example, a physician can say, "we succeed most of the time with this therapy" rather than "we fail in 30% of cases with this other therapy."⁵²⁵ HCPs that are aware of the effects of such minor variations can choose their language

⁵²¹ President's Commission *Making healthcare decisions* 63-66.

⁵²² Beauchamp and Childress *Principles of biomedical ethics* 94.

⁵²³ Beauchamp and Childress *Principles of biomedical ethics* 95.

⁵²⁴ President's Commission *Making healthcare decisions* 63-66.

⁵²⁵ Beauchamp and Childress *Principles of biomedical ethics* 95.

with care; if, during discussions with a patient, they sense any unintended or confused impressions being created, they can adjust their presentation of information accordingly and because many patients are often fearful and feel unequal to their physicians in status, knowledge, and power, they may be particularly susceptible to manipulations of this type.⁵²⁶ This type of potentially manipulative behaviour has been observed by studies amongst radiology resident physicians in the USA, with regard to the daily practice of IC in a healthcare setting.⁵²⁷ Other extreme forms of manipulative behaviour include lying and withholding of information as a form of “therapeutic privilege”,⁵²⁸ in order to get patients to act in one way rather than the other.^{529, 530} In view of the above, it has been proposed that HCPs should present information in a way that fosters patient understanding of their medical prognosis and the implications of different treatment options as recommended by the National Health Act.⁵³¹ The difficulty in distinguishing between rational persuasions on the one hand, and objectionable forms of influence or manipulation on the other, should be avoided.⁵³² Since voluntariness is one of the key elements of informed consent, HCPs have an ethical obligation to avoid coercion and manipulation of their patients. It has been argued that while the law may penalise those who ignore the requirements of IC, or who directly or indirectly coerce patients, it can do little about subtle manipulations of healthcare users, without disrupting fiduciary obligations of the doctor-patient relationship. Therefore true voluntariness and avoiding undue influences on patients would be best achieved through more ethical behaviour and practice by HCPs.⁵³³ This may involve elements of virtue ethics such as the requirement for truth-telling, honesty, and the character of HCPs coming into play in the doctor-patient alliance.⁵³⁴ It has been argued that socio-economic deprivation can make patients

⁵²⁶ Beauchamp and Childress *Principles of biomedical ethics* 93-98.

⁵²⁷ Olufowote JO “A structural analysis of informed consent to treatment: Societal evolution, contradiction, and reproductions in medical practice” 2008 *Health Communication* 292-303.

⁵²⁸ Mathew W “Invoking therapeutic privilege” 2004 *AMA Virtual Mentor* www.virtualmentor.ama-assn.org/204/02/msoc1-0402.html (Date of use: 29 January 2008).

⁵²⁹ Welz D “The boundaries of therapeutic privilege” 1999 *SALJ* 299-322.

⁵³⁰ Van Oosten FFW “The so-called ‘therapeutic privilege’ or ‘contra-indication’: Its nature and role in non-disclosure cases” 1991 *Med Law* 31-41.

⁵³¹ National Health Act 61 of 2003 s6.

⁵³² President’s Commission *Making healthcare decisions* 63-66.

⁵³³ Beauchamp and Childress *Principles of biomedical ethics* 93-98.

⁵³⁴ Cohen-Almagor “On the philosophical foundations of medical ethics: Aristotle, Kant, JS Mill and Rawls 2017 *Ethics Med Public Health* 1-26 [11-12].

vulnerable to these types of manipulations in healthcare.⁵³⁵ For example, where a patient is in desperate need, such that the lack of a particular medication could expose such an individual or a loved one to irreparable harm. Attractive offers such as extra money or free medication can leave such patients without a choice, which may influence their decision. Such patients are constrained by a desperate situation and not necessarily by the manipulation of another.⁵³⁶ Some have suggested that in certain circumstances, individuals can perceive excessive offers of either financial rewards or perhaps a rare experimental therapy as threat to patients in such desperate need.⁵³⁷ It has been suggested that while there is no evidence that HCPs routinely manipulate patients, it must be noted that some patients are susceptible to such manipulations and undue influence, and this has to be guarded against, or that patients may need to be protected from it.⁵³⁸

However, it has also been maintained that executional autonomy need not be accompanied by a decline in decisional autonomy. This observation was based on reports that caregivers in adult nursing homes often, neglect, misunderstand, or override resident's autonomous decisions in some geriatric nursing homes.⁵³⁹ Finally, HCPs must remember the observation by Brody that "the physician has the power to improve the patients' health status to the extent that he or she can alter the meaning that the patient attributes to the illness in a positive way."⁵⁴⁰

2.6 Information Disclosure

One of the more contested and controversial areas in IC and healthcare decision-making revolves around the amount of information to be disclosed to a patient to elicit true/real or valid consent. Generally, lawful consent is out of the question unless the consenting party knows and appreciates what it is that he or she is consenting to. The foundational requirements for lawful consent relate to the knowledge, appreciation and acquiescence

⁵³⁵ Piertese 2008 *SALJ* 553-572.

⁵³⁶ Beauchamp and Childress *Principles of biomedical ethics* 96.

⁵³⁷ Beauchamp and Childress *Principles of biomedical ethics* 96.

⁵³⁸ Beauchamp and Childress *Principles of biomedical ethics* 96.

⁵³⁹ Collopy J "Autonomy in long term care" 1988 *The Gerontologist* 10-17.

⁵⁴⁰ Brody H *The healer's power* (Yale University Press New Haven 1992)16-17.

on the part of the patient, and in the absence of knowledge and appreciation of information, real consent will be lacking.⁵⁴¹ The doctor or other HCP such as a physiotherapist,⁵⁴² as an expert, has the legal duty to provide the patient with the necessary information to enable an informed choice, as established in the landmark American case of *Canterbury v Spence*.⁵⁴³

[...] In our view, the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice... This disclosure requirement, on analysis, reflects much more of a change in doctrinal emphasis than a substantive addition to malpractice law. It is well established that the physician must seek and secure his patient's consent before commencing an operation or other course of treatment... It is a settled rule that therapy not authorized by the patient may amount to a tort -- a common law battery -- by the physician... it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification. Thus the physician has long borne a duty, on pain of liability for unauthorized treatment, to make adequate disclosure to the patient...⁵⁴⁴

Similarly in *Salgo v Leland Stanford Jr. University*, which pioneered the use of the terminology 'informed consent',⁵⁴⁵ the court held that:

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent.....The instruction given should be modified to inform the jury that the physician has such discretion consistent, of course, with the full disclosure of facts necessary to an informed consent.⁵⁴⁶

⁵⁴¹ Barit A *The doctrine of informed consent in South African medical law* (LLM dissertation University of Pretoria 2016) 16-17.

⁵⁴² Delany CM "In private practice, informed consent is interpreted as providing explanations rather than offering choices: a qualitative study." 2007 *Aust J Physiotherapy* 171-177.

⁵⁴³ *Canterbury v Spence* 464 F.2d 772 (DC Cir 1972).

⁵⁴⁴ *Canterbury v Spence* 464 F2d 772 (DC Cir 1972) [41].

⁵⁴⁵ *Salgo v Leland Stanford Board of Trustees* (1957) 154 Cal App 2d 560 317 P 2d 170.

⁵⁴⁶ *Salgo v Leland Stanford Etc. Bd Trustees* (1957) 154 Cal.App.2d 560 317 P 2d 170 [578].

Instructing the jury further, the *Salgo* court was of the opinion that there were exceptions to the IC rule such as extreme psychological threat or based on the different idiosyncrasies of individual patients, thereby recognizing the doctrine of 'therapeutic privilege'. The rule of information disclosure was further reinforced in *Natanson v Kline*⁵⁴⁷ where the court stated with regard to informed consent that:

This rule in effect compels disclosure by the physician in order to assure that an informed consent of the patient is obtained. The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances.⁵⁴⁸

In *Natanson* the court opined on the extent of disclosure required the physician or HCP as: to "[...] disclose and explain to the patient in language as simple as necessary the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body..."⁵⁴⁹ Therefore in, the American cases of *Canterbury v Spence*,⁵⁵⁰ *Natanson v Kline*,⁵⁵¹ and *Salgo v Leland Stanford Jr. University*,⁵⁵² the courts established a duty of information disclosure, albeit limited by exceptions for therapeutic privilege and the reasonable doctor standard.⁵⁵³ The *Canterbury* court went further to debate and rejected the objective reasonable doctor and reasonable patient standards as a basis for evaluating the extent of information disclosure, arguing that:

Consonantly with orthodox negligence doctrine, the physician's liability for nondisclosure is to be determined on the basis of foresight, not hindsight; no less than any other aspect of negligence, the issue on nondisclosure must be approached from the viewpoint of the reasonableness of the physician's divulgence in terms of what he knows or should know to be the patient's informational needs.⁵⁵⁴

⁵⁴⁷ Natanson v Kline 186 Kansas 393 (1960)350 P 2d 1093.

⁵⁴⁸ Natanson v Kline 186 Kansas 393 (1960)350 P 2d 1093[410].

⁵⁴⁹ Natanson v Kline 186 Kansas 393 (1960)350 P 2d 1093 [411].

⁵⁵⁰ Canterbury v Spence 464 F.2d 772 (DC Cir 1972).

⁵⁵¹ Natanson v Kline 186 Kansas 393 (1960)350 P 2d 1093.

⁵⁵² Salgo v Leland Stanford Board of Trustees (1957) 154 Cal App 2d 560 317 P 2d 170.

⁵⁵³ Faden and Beauchamp *A history and theory of informed consent* 114-150.

⁵⁵⁴ Canterbury v Spence 464 F.2d 772 (DC Cir 1972) [42].

The *Canterbury* court also alluded to the 'subjective patients' and 'material risk' standards, by adding that:

The scope of the physician's communications to the patient... must be measured by the patient's need, and that need is the information material to the decision. Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked. And to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure... Optimally for the patient, exposure of a risk would be mandatory whenever the patient would deem it significant to his decision, either singly or in combination with other risks. Such a requirement, however, would summon the physician to second-guess the patient, whose ideas on materiality could hardly be known to the physician. That would make an undue demand upon medical practitioners, whose conduct, like that of others, is to be measured in terms of reasonableness... If, but only if, the fact-finder can say that the physician's communication was unreasonably inadequate is an imposition of liability legally or morally justified...⁵⁵⁵

2.6.1 Standards of information disclosure: What must be disclosed to enable valid consent?

The amount and nature of the information given to a patient or research subject, in order to obtain valid consent is a critical issue in both treatment and research and has been the subject of both legal and ethical controversy in various jurisdictions.⁵⁵⁶ Previously it was alleged that English courts opted for a paternalistic approach by following the reasonable doctor standard which bases disclosure on the clinical judgement/accepted practice or substantial/normal/usual risk principles.⁵⁵⁷ English common law principles and jurisprudence with reference to information disclosure and medical negligence have generally revolved around the Bolam principle as outlined by McNair J in *Bolam v Friern HMC 1957*,⁵⁵⁸ where the judge stated that:

⁵⁵⁵ *Canterbury v Spence* 464 F.2d 772 (DC Cir 1972) [43-44].

⁵⁵⁶ Chima *Consent and patients' rights* 33-66.

⁵⁵⁷ Van Oosten FFW *The doctrine of informed consent in medical law* (Peter Lang Frankfurt 1991) 395-461.

⁵⁵⁸ *Bolam v Friern Barnet Health Management Committee* [1957] 2 All ER 118.

I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art... Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view...⁵⁵⁹

Therefore the true test for establishing negligence in diagnosis or treatment is defined in legal terms as, “whether the health professional has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care.”⁵⁶⁰ According to Lord Scarman in *Sidaway*,⁵⁶¹ the rule is expressed as follows:

The Bolam principle may be formulated as a rule that a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion even though other doctors adopt a different practice. In short, the law imposes the duty of care: but the standard of care is a matter of medical judgment.⁵⁶²

This means that a doctor, nurse or any other HCP, is expected to provide care that any other HCP practicing in the same specialty or branch of medicine would provide, i.e. the minimum expected standard for care and treatment. The test is “the standard of the ordinary skilled man exercising and professing to have that special skill”.⁵⁶³ Accordingly, Lord Templeman in *Sidaway* concluded that:

[...] At the end of the day, the doctor bearing in mind the best interests of the patient and bearing in mind the patient’s right to information which will enable the patient to make a balanced judgment, must decide what information should be given to the patient, and in what terms that information should be couched.”⁵⁶⁴

Therefore English common law practice has controversially been limited to the reasonable doctor standard which generally supported limited information disclosure as demonstrated in cases such as *Chatterton v Gerson*,⁵⁶⁵ where Bristow J said that the patient should

⁵⁵⁹ Bolam v Friern Barnet Health Management Committee [1957] 2 All ER 118 [587].

⁵⁶⁰ Bolam v Friern Hospital Management Committee (1957) 1 WLR [582].

⁵⁶¹ Sidaway v Governors of Bethlem Royal Hospital (1985) 1 AC 871.

⁵⁶² Sidaway v Governors of Bethlem Royal Hospital (1985) 1 AC 871 [881].

⁵⁶³ Bolam v Friern Hospital Management Committee (1957) 1 WLR [586].

⁵⁶⁴ Sidaway v Board of Governors of Royal Bethlem Hospital [1985] 1 All ER [643].

⁵⁶⁵ Chatterton v Gerson (1981) 1 All ER 257.

generally be informed in 'broad terms': "...Once the patient is informed in broad terms of the nature of the procedure which is intended, and gives consent that consent is rea."⁵⁶⁶ Thereby implying that not all information is required to be disclosed to patients and the nature and amount of information to be disclosed to a patient would be based on a reasonable doctor standard, rather than on the requirements of the patient.

However, in *Sidaway* Lord Scarman argued for a prudent patient standard as practiced in other jurisdictions such as Canada, USA, and even Germany.⁵⁶⁷ By contrast, the courts in North America have held in cases such as *Canterbury v Spence*⁵⁶⁸ and *Reibl v Hughes*⁵⁶⁹ that a patient must be informed of 'all material risks' subject to some form of therapeutic privilege. Where those 'material risks' consist of what a reasonable person, in such a patients position, would be likely to attach significance to, in deciding whether to accept or forego the proposed therapy.⁵⁷⁰ This requirement for a 'material risks' standard of information disclosure has been reaffirmed in more recent American cases such as *Grimes v KKI*⁵⁷¹ where Cathell J stated that a human subject is entitled to all material information.⁵⁷² The current situation in English common law is that Lord Scarman's prudent patient standard is becoming more recognized and accepted as shown in cases such as *Pearce v United Bristol Health Trust*,⁵⁷³ where Lord Woolf held that a doctor should inform the patient of any significant risks which would affect the judgment of a reasonable patient. Further, in *Chester v Afshar*,⁵⁷⁴ Sir Dennis Henry argued that it would be considered negligent if the omission to disclose risks fell below the professional standard, stating:

The purpose of the rule requiring doctors to give appropriate information to their patients is to enable the patient to exercise her right to choose whether or not to have the particular operation to which

⁵⁶⁶ Chatterton v Gerson (1981) 1 All ER 257 [265].

⁵⁶⁷ Giesen D "The patient's right to know- a comparative law perspective" 1993 *Med Law* 553-565.

⁵⁶⁸ *Canterbury v Spence* (1972) 464 2d 772.

⁵⁶⁹ *Reibl v Hughes* (1980) 114 DLR (3d) 1.

⁵⁷⁰ *Canterbury v Spence* (1972) 464 2d 772 [787].

⁵⁷¹ *Grimes v Kennedy Krieger Institute Inc.* 366 Md. 29 782 A.2d 807 (MD 2001).

⁵⁷² *Grimes v KKI* 2000 [64].

⁵⁷³ *Pearce v United Bristol NHS Healthcare Trust* [1998] 48 BMLR 18 [124].

⁵⁷⁴ *Chester v Afshar* [2004] 4 All ER 552 [para 15].

she is asked to give consent. English law has rejected the proposition that a failure to give adequate warning vitiates the patient's consent... But the patient does still have the right to choose what will and will not be done with her body and the doctor must take care expected of a reasonable doctor in the circumstances giving her the information relevant to that choice.⁵⁷⁵

In supporting the majority judgment in *Chester v Afshar*,⁵⁷⁶ Lord Steyn outlined a number of relevant factors that ought to be considered in disclosing information to patients:

- i. When assessing the rights and duties of patients, the departure point should always be patient autonomy because “every individual of adult years and sound mind has a right to decide what may or may not be done with his own body”, citing the maxim of Cardozo J in *Schloendorf v Society of New York Hospital*.⁵⁷⁷
- ii. He goes on further to say that even a decision which a physician regards as “ill-advised should be respected because in modern law medical paternalism no longer rules and the patient has a prima facie right to be informed by a surgeon of a small, but well established risk of serious injury as a result of surgery”.
- iii. He noted that all rights are not equally important but that a patient's right to an appropriate warning, must be given effective protection wherever possible.
- iv. Finally, the rule requiring a physician to obtain informed consent from a patient serves two purposes (a) it avoids occurrence of an injury for which the patient is not prepared and (b) it respects the autonomy and dignity of each patient.^{578,579}

In his dissenting opinion in *Sidaway*, Lord Scarman argued as follows:

In my view the question whether or not the omission to warn constitutes a breach of the doctor's duty of care towards his patient is to be determined not exclusively by reference to the current state of responsible and competent professional opinion and practice at the time, though both are, of course, relevant considerations, but by the court's view as to whether the doctor in advising his

⁵⁷⁵ *Chester v Afshar* (2004) 4 All ER 552 [593-594].

⁵⁷⁶ *Chester v Afshar* [2002] 3 All ER FR 552.

⁵⁷⁷ *Schloendorf v Society of New York Hospital* 105 NE 92 93 NY 1914.

⁵⁷⁸ *Chester v Afshar* (2004) 4 All ER 593 [594].

⁵⁷⁹ *Thomas* 2007 *SALJ* 188-215.

patient gave the consideration which the law requires him to give to the right of the patient to make up her own mind in the light of the relevant information whether or not she will accept the treatment which he proposes.⁵⁸⁰

In coming to this conclusion he referred to the north American cases of *Canterbury v Spence*⁵⁸¹ and *Reibl v Hughes*⁵⁸² which held that the "duty to warn" arises from the patient's right to know all material risks, a right which in turn arises from the patient's right to decide for himself or herself whether or not to submit to the medical treatment proposed.⁵⁸³ In *Chester v Afshar*⁵⁸⁴ the CA found a consultant surgeon negligent for failing to disclose a 1-2% risk of nerve damage even when this enquiry was made by the patient.⁵⁸⁵ The *Bolam* principle has persisted in English legal jurisprudence on IC and information disclosure despite the dissenting opinion of Lord Scarman in *Sidaway*⁵⁸⁶ and the more recent judgment of the House of Lords in *Bolitho v City and Hackney*,⁵⁸⁷ where it was finally suggested that decisions regarding information disclosure based on the reasonable doctor standard must be judicially reviewed for logicality and reasonableness.

In other common law jurisdictions, such as Australia, the standard of disclosure has tended towards the North American standards as established in *Reibl v Hughes*⁵⁸⁸ and *Canterbury v Spence*.⁵⁸⁹ Similarly, in the case of *F v R* 1983,⁵⁹⁰ the Australian Supreme Court per King CJ, was of the opinion that:

The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.⁵⁹¹

580 *Sidaway v Board of Governors of the Bethlem Royal Hospital* (1985) 1 AC 871 [885-889].

581 *Canterbury v Spence* ((18) (1972) 464 F 2d 772).

582 *Reibl v Hughes* ((19) (1980) 114 DLR (3d) 1.

583 *Sidaway v Board of Governors of the Bethlem Royal Hospital* (1985) 1 AC 871 [885-889].

584 *Chester v Afshar* [2002] 3 All ER FR 552.

585 *Chester v Afshar* [2004] 4 All ER FR 587.

586 *Sidaway v Bethlem Royal Hospital Governors and Others* [1985] 1 All ER 643.

587 *Bolitho v City and Hackney Health Authority* [1988] AC 232 [386].

588 *Reibl v Hughes* (1980) 114 DLR (3d) 1

589 *Canterbury v Spence* ((18) (1972) 464 F 2d 772)

590 *F v R* 26 (1983) 33 SASR 189.

591 *F v R* 26 (1983) 33 SASR 189 [194].

He further argues that the amount of information to be disclosed to a patient by a responsible doctor, was determined by many complex factors including “the nature of the matter to be disclosed; the nature of the treatment; the desire of the patient for information; the temperament and health of the patient; and the general surrounding circumstances.”⁵⁹² The judge therefore concluded that, “to allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty.”⁵⁹³ He suggested that while expert medical evidence was relevant to findings as to the risks that reside in or are a result of recommended surgery or other treatment, it will also have a bearing on their materiality, but this is not a question that is to be concluded on the basis of the expert medical evidence alone.⁵⁹⁴

The issue under consideration is a different issue from that involved where the question is whether the doctor carried out his professional activities by applicable professional standards. What is under consideration here is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment.⁵⁹⁵

The Australian court in *Rogers v Whitaker*,⁵⁹⁶ concurred with all the observations of King CJ in *F v R*, concluding that “ the law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. This duty is subject to the therapeutic privilege.”⁵⁹⁷ According to King J, the central argument regarding risk disclosure was based on a

⁵⁹² F v R 26 (1983) 33 SASR 189 [192-193].

⁵⁹³ F v R 26 (1983) 33 SASR 189 [192-193].

⁵⁹⁴ F v R 26 (1983) 33 SASR 189 [191-192].

⁵⁹⁵ F v R 26 (1983) 33 SASR 189 [201-205].

⁵⁹⁶ *Rogers v Whitaker* [1992] HCA 58 (1992) 175 CLR 479.

⁵⁹⁷ *Rogers v Whitaker* [1992] HCA 58 (1992) 175 CLR 479 [83].

balancing of the doctor's duty of beneficence and non-maleficence,⁵⁹⁸ otherwise doing what the HCP thinks would be in the best interest of the patient against the right of the patient to self-determination and freedom of choice. He therefore argued that the governing principle would be the right of every human being to decide what should happen to his or her own life, and in doing so to decide which risks he or she is willing or not willing to take.^{599,600} King CJ further argues that the court has an obligation to scrutinize professional practices, to make sure that they conform with the standard of reasonableness and disclosure required by the law, consistent with opinion of the English house of Lords in *Bolitho*,⁶⁰¹ because it is more than likely that some HCPs may resort to unreasonable practices especially in terms of information disclosure which may be more convenient or which better served their own personal interests.⁶⁰² Generally, Australian laws accord with the practice in Canada as outlined in *Reibl v Hughes*⁶⁰³ where the court held that information disclosure based on the reasonable doctor standard would only serve the effect of handing over to the medical profession the entire scope of the duty of disclosure, including the question of whether there had been a breach of that duty.^{604,605}

It has been reported that disclosure standards based on the prudent patient standard rather than the reasonable doctor standard, are prevalent in European countries such as Germany, Austria, Switzerland and France.⁶⁰⁶ In France, it has been stated that the individual's interest in his or her own bodily integrity requires that all medical procedures be based on the patients free and clear consent. Therefore, a doctor or other HCP is required to provide the patient with all the information which would enable the patient to conduct a cost/ benefit analysis on the possible consequences and risks entailed, before deciding whether to undergo or forego the proposed treatment. Similarly, in Germany the Federal Supreme Court was of the opinion that "the sick person who lacks experience in

⁵⁹⁸ Cohen-Almagor 2017 *Ethics Med Public Health* [10-12].

⁵⁹⁹ Giesen D "The patient's right to know- a comparative law perspective" 1993 *Med Law* 553-565.

⁶⁰⁰ F v R (26) (1983) 33 SASR 189 [192-194].

⁶⁰¹ *Bolitho v City and Hackney HA* (1998) AC 232 (HL).

⁶⁰² *Bolitho v City and Hackney HA* ((1998) AC 232 HL [386].

⁶⁰³ *Reibl v Hughes* (1980) 2 SCR 880 894 (1980) 14 CCLT 1 [16-17].

⁶⁰⁴ *Reibl v Hughes* (1980) 2 SCR 880 894 (1980) 14 CCLT 1 [16-17].

⁶⁰⁵ Giesen D 1993 *Med Law* 553-565.

⁶⁰⁶ Giesen D 1993 *Med Law* 554.

medical matters is dependent upon the doctor to provide expert advice and information. This would represent proper respect for the patient's right of self-determination and enhance the fiduciary nature of the doctor-patient relationship. To respect the patient's own will is to respect his freedom and dignity as a human being."^{607,608}

Further, in the newly emergent republics of South-eastern Europe such as Croatia, Croatian legislation governing IC, "The Act on the Protection of Patients' Rights",⁶⁰⁹ requires full information disclosure, stating "the patient has the right to all information, regarding his or her health condition, planned medical procedures, and all risks and complication of refusing and accepting them. To ensure complete comprehension of planned medical treatment, the information provided must be understandable, in a form adjusted to the patient's age, education and mental abilities. Only after having understood all the information, should patients express their acceptance or rejection of the medical procedure by signing the consent form."⁶¹⁰ Therefore, in terms of Croatian legislation, IC is required for all medical procedures, although implementation in practice is not fully compliant with the law.⁶¹¹ Therefore, in most European countries the standard of information disclosure required is based on the prudent-patient standard,⁶¹² except in some Scandinavian countries, such as Denmark, where it has been reported that the reasonable doctor standard is still relatively prevalent.⁶¹³

In a final analysis, based on the recent judgment of the UK Supreme Court (Scotland) in the case of *Montgomery v Lanarkshire Health Board*,⁶¹⁴ the court, having taken into consideration the various judgments by English courts in recent times, including the

⁶⁰⁷ BGH 9 Dec 1958 BGHZ 29, 46 [53-56].

⁶⁰⁸ Giesen D1993 *Med Law* 558-560.

⁶⁰⁹ Republic of Croatia *The Act on the protection of patients' rights* (Official Gazette No 160/2004 Government of Croatia 2004).

⁶¹⁰ Croatia *The Act on the protection of patients' rights* (Official Gazette No 160/2004 Government of Croatia 2004).

⁶¹¹ Vucemilo L et al "The quality of informed consent in Croatia- a cross-sectional study and instrument development." 2015 *Patient Educ Couns* <http://dx.doi.org/10.1016/j.pec.2015.08.03> (Date of use: 20 April 2016).

⁶¹² Giesen D 1993 *Med Law* 553-565.

⁶¹³ Segest E "The legal position with regard to informed consent in Denmark" 1995 *Med Law* 245-254.

⁶¹⁴ *Montgomery v Lanarkshire Health Board* Scotland [2015] UKSC 11.

Sidaway case,⁶¹⁵ *Pearce v United Bristol*,⁶¹⁶ subject to the opinion of the High Court of Australia in *Rogers v Whitaker*,⁶¹⁷ concluded that:

The correct position, in relation to the risks of injury involved in treatment, [...] An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.⁶¹⁸

The above position on information disclosure, is subject to certain exceptions including the doctrines of 'therapeutic privilege' and necessity, according to the Supreme Court.⁶¹⁹

2.6.2 Information disclosure in the context of South African law

In the context of South Africa, prior to the judgment in the *Castell* case⁶²⁰ and legal rules regarding IC introduced by the NHA,⁶²¹ one may argue from early case law, that doctors were not required by law to disclose all possible consequences and complications of medical treatment. It was enough that the patient was informed in broad terms about the serious risks and dangers inherent in the treatment. This was demonstrated in cases such as *Lymberg v Jeffries*⁶²² and *Richter v Estate Hamman*,⁶²³ where the court suggested that doctors were not expected to disclose to their patients unusual, uncommon or remote

⁶¹⁵ *Sidaway v Board of Governors of the Bethlem Royal Hospital* (1985) 1 AC 871 [885-889].

⁶¹⁶ *Pearce v United Bristol NHS Healthcare Trust* [1998] 48 BMLR 18 [124].

⁶¹⁷ *Rogers v Whitaker* [1992] HCA 58 (1992) 175 CLR 479 [83].

⁶¹⁸ *Montgomery v Lanarkshire Health Board Scotland* [2015] UKSC 11[87].

⁶¹⁹ *Montgomery v Lanarkshire Health Board Scotland* [2015] UKSC 11[75].

⁶²⁰ *Castell v De Greef* 1994 (4) SA 408.

⁶²¹ National Health Act 61 of 2003.

⁶²² *Lymberg v Jeffries* 1925 AD 236.

⁶²³ *Richter v Estate Hamman* 1976 (3) SA 226 (C).

risks or complications.⁶²⁴ However, in cases such as *Rompel v Botha*⁶²⁵ and the *Esterhuizen case*,⁶²⁶ the courts suggested that patients should generally be informed of any 'serious risks' related to the proposed treatment or medical procedure.⁶²⁷ It has been argued that the duty to disclose in South African common law consists in fully informing patients' of "the nature purpose and benefits and the probable, substantial and inevitable risks and consequences of the medical intervention, irrespective of whether it is therapeutic or diagnostic in nature."⁶²⁸ However, such information disclosure maybe subject to certain exceptions which would include:

- a. That the medical doctor may be obliged to inform the patient about medical treatment but not necessarily the diagnosis;⁶²⁹
- b. Where the patient waives the right to information disclosure, this would also be legally acceptable;⁶³⁰
- c. In certain circumstances, information may be withheld from the patient based on the doctrine of 'therapeutic privilege or contraindication'.⁶³¹ One example would be where a patient who is being treated for a serious condition would then after disclosure refuse further treatment, or where disclosure may unnecessarily distress the patient, or where disclosure would be contrary to the patients best interests.^{632,633}

More recently the South Africa standard for information disclosure appear to have changed with the judgment of the Ackerman J in the *Castell case*,⁶³⁴ where the court was of the opinion that for consent to be informed, the patient needs to fully appreciate the nature of the harm or the risk to which he or she is consenting. Further, the court

⁶²⁴ Van Oosten FFW "Informed consent: patient rights and the doctor's duty of disclosure in South Africa" 1989 *Med Law* [448].

⁶²⁵ *Rompel v Botha* 1953 (T) as cited in *Esterhuizen v Administrator Transvaal* 1957 [719].

⁶²⁶ *Esterhuizen v Administrator Transvaal* 1957(3) SA 710 (T) [719-722].

⁶²⁷ Van Oosten 1989 *Med Law* [448].

⁶²⁸ Van Oosten 1989 *Med Law* [449].

⁶²⁹ Strauss SA *Doctor, patient and the law* 3rd ed (Van Schaik Pretoria 1991) 6-14.

⁶³⁰ Millner MA "Fraudulent non-disclosure" 1957 (74) *SALJ* 177-200.

⁶³¹ Van Oosten 1991 *Med Law* 31-41.

⁶³² Welz D "The boundaries of medical-therapeutic privilege" 1999 *SALJ* 299-322.

⁶³³ Van Oosten 1989 *Med Law* [449-450].

⁶³⁴ *Castell v De Greef* 1994 (4) SA 408 (C).

suggested that the standard of disclosure required is the 'material risks' standard, where the test of materiality would be based on what a reasonable person in the patients' position would likely attach significance to in coming to a decision, or alternatively, what the doctor ought to have known would be of significance to that particular patient in arriving at decision with regards to information disclosure.⁶³⁵ It has been suggested that the rationale for the court's decision in the *Castell* case⁶³⁶ arose from the South African Constitution⁶³⁷ which recognizes the rights of autonomy, by entrenching and codifying the rights to human dignity and bodily integrity in sections 10 and 12(2) of the Constitution and the Bill of rights.⁶³⁸ Moreover, section 12 of the Constitution stipulates that everyone has a right to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experimentation without their informed consent.⁶³⁹ It has been suggested that when sections 12(2)(a), e.g. "everyone has the right to bodily and psychological integrity," and 12(2)(b), e.g. the right "to security in and control over their body" are read together it is clear that decisions regarding one's body relate to both a physical and psychological dimension.⁶⁴⁰ Generally, a patient can only be expected to take responsibility for a particular decision where the person has been provided with enough information to make an informed decision. Therefore, legal disclosure only sets out a minimum standard of information to be disclosed to enable informed decision-making. Based on the judgment in *Castell* case,⁶⁴¹ the minimum level of information required to render consent valid in terms of South African law should be that:

- i. the consenting party must have had knowledge and been aware of the nature and extent of the harm or risk
- ii. the consenting party must have appreciated and understood the nature and extent of the harm or risk

⁶³⁵ Thomas R *Where to from Castell v De Greef* 2007 SALJ 188-189.

⁶³⁶ *Castell v De Greef* 1994 (4) SA 408 (C).

⁶³⁷ The Constitution of the Republic of South Africa 1996.

⁶³⁸ The Constitution s10 and 12 (2).

⁶³⁹ The Constitution s12.

⁶⁴⁰ Mswela M "Cultural practices and HIV in South Africa: A legal perspective" 2009 *PER* 195-196.

⁶⁴¹ *Castell v De Greef* 1994 (4) SA 408 (C).

- iii. the consenting party must have consented to the harm or assumed the risk
- iv. the consent given by the consenting party must be comprehensive, that is, extends to the entire transaction, inclusive of the consequences^{642,643,644, 645,646}

Therefore in terms of South African law and based on *Castell* case,⁶⁴⁷ a doctor needs to disclose all material risks associated with the proposed treatment, based on a “prudent patient standard”, which is a subjective standard of information disclosure rather than an objective reasonable person standard. It has been suggested that the actual common law test for materiality is based on question whether “a risk is material if the person who consented would not have done so, had the risk been known to him or her”.⁶⁴⁸ This test was then applied by the Supreme Court of Appeal (SCA) in the case of *Broude v McIntosh*,⁶⁴⁹ without the SCA overruling the judgment of the High Court.⁶⁵⁰

The NHA⁶⁵¹ codified the requirements for IC and information disclosure as part of the legislative framework regulating healthcare services in South Africa. The law recognises the principle of individual autonomy and differentiates between ‘users’ of healthcare services or patients and ‘healthcare providers’ which refers to all providers of health care services registered in terms of the Health Professions Act,⁶⁵² and other related laws such as the Nursing Act.⁶⁵³ This means that the requirements for IC are not limited to doctors but includes all health care professionals (HCPs) *mutatis mutandis*, consistent with the

⁶⁴² Van Oosten 1989 *Med Law* [443-456].

⁶⁴³ *Castell v De Greef* 1994 (4) SA 408 (C) [425].

⁶⁴⁴ Carstens and Pearmain *Foundational Principles* 684.

⁶⁴⁵ Chima *BMC Med Ethics* 2013 S3 [3-4].

⁶⁴⁶ Van Oosten FFW “Castell v De Greef and the doctrine of informed consent: Medical paternalism ousted in favour of patient autonomy” 1995 *De Jure* 171-175.

⁶⁴⁷ *Castell v De Greef* 1994 (4) SA 408 (C) [426].

⁶⁴⁸ Thomas R *Where to from Castell v De Greef* 2007 *SALJ* 191.

⁶⁴⁹ *Broude v McIntosh and others* 1998 (3) SA 60 (SCA) [68-9].

⁶⁵⁰ Carstens and Pearmain *Foundational Principles* 892.

⁶⁵¹ National Health Act 61 of 2003.

⁶⁵² Health Professions Act 56 of 1974.

⁶⁵³ Nursing Act 33 of 2005.

opinion of the UK Supreme Court, Scotland in *Montgomery v Lanarkshire*.⁶⁵⁴ The NHA⁶⁵⁵ further stipulates that all healthcare users have a right to IC and that users have a right to participate in decisions affecting their personal health, and consequently must have full knowledge regarding the proposed treatment. The law further describes informed consent in section 7 as meaning “consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6”.⁶⁵⁶ This means that a healthcare user is required to have full knowledge and must be informed of:

- (a) The user health status [diagnosis];
- (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
- (d) The user’s right to refuse health services and the implications, risks, obligations of such refusal.⁶⁵⁷

However section 6(1)(a) of the NHA provides an exception which allows the HCP not to inform a user of the user’s health status, 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, thereby supporting the exception of therapeutic privilege.⁶⁵⁸ Other exceptions to information disclosure are noted in section 7 of the NHA; for example, where the user is unable to give IC and this is provided by a proxy previously mandated by the user in writing, or consent is given by another person mandated by law or by the patients recognized next of kin. IC can also be waived where such waiver is approved by law s7(c),⁶⁵⁹ or where failure to treat the user will lead to a serious risk to public health

⁶⁵⁴ *Montgomery v Lanarkshire Health Board* Scotland [2015] UKSC 11[75].

⁶⁵⁵ National Health Act 61 of 2003.

⁶⁵⁶ National Health Act 61 of 2003 s7 (3).

⁶⁵⁷ National Health Act 61 of 2003 S6 (a-d).

⁶⁵⁸ National Health Act 61 of 2003 S6 (1) (a).

⁶⁵⁹ National Health Act s 7(c).

s7 (d),⁶⁶⁰ or where delay in providing care to the user can cause irreversible damage to the user's health or may lead to patient's death.⁶⁶¹ As previously discussed on page 78 of this thesis, The Constitutional Court in the case of *S v Makwayane*, held that the right to life is the most constitutionally protected value.⁶⁶² However, it must be noted that in section 7 (e) of the NHA, lifesaving treatment may not be administered to an adult patient, where such a patient has 'expressedly or impliedly or by conduct refused such treatment'.⁶⁶³ The NHA further requires that if IC is provided by a proxy or surrogate decision-maker, such a proxy must consult the user if at all possible, or where the user is unable to participate in decisions regarding his or her health, the patient must be informed soon after the fact, except where such disclosure of information would be contrary to the users best interests.⁶⁶⁴ HCPs are also required to inform the user of all this information in a language the user understands, and in a manner that takes into account the user's literacy level, by implication the users' level of education.⁶⁶⁵ This level of detail as provided for by the NHA arguably supersedes the information disclosure requirements outlined in the *Castell* case.⁶⁶⁶ It is has been suggested that the requirement of full disclosure, and the right of users to participate in healthcare decision-making pertaining to their health, as well as the users right of refusal, ensures that the NHA⁶⁶⁷ gives effect to respect for patients autonomy and self-determination as well as enhancing patients' dignity, which is equally enshrined in section10 of the Constitution, where it states that "everyone has inherent dignity and the right to have their dignity respected and protected".⁶⁶⁸ However it has been reported that so far the disclosure requirements as outlined in the NHA have rarely been applied in any judicial decisions by South African courts.^{669,670,671}

660 National Health Act s 7(d).

661 National Health Act 2003 section 7(1) (a-e).

662 *S v Makwayane* 1995 (3) SA 391 (CC) [144].

663 National Health Act s 7(e).

664 National Health Act 2003 s8.

665 National Health Act 61 of 2003 section 6 (2).

666 *Castell v De Greef* 1994 (4) SA 408 (C) [425-426].

667 National Health Act 61 of 2003.

668 The Constitution s10.

669 Thomas 2007 *SALJ* 189.

670 Britz and Roux-Kemp *SAMJ* 2012 [746].

671 Carstens and Pearmain *Foundational Principles* 685-687.

2.6.3 The prudent patient standard of information disclosure and problems of 'hindsight'

It has been suggested that one of the problems militating against general adoption of the prudent patient standard in court decisions has been the fact that it places an unreasonable burden on doctors or other HCPs to try and unravel what would be the particular patient's interest with regards to information disclosure. As outlined in *Canterbury v Spence*.⁶⁷²

Optimally for the patient, exposure of a risk would be mandatory whenever the patient would deem it significant to his decision, either singly or in combination with other risks. Such a requirement, however, would summon the physician to second-guess the patient, whose ideas on materiality could hardly be known to the physician. That would make an undue demand upon medical practitioners, whose conduct, like that of others, is to be measured in terms of reasonableness. Consonantly with orthodox negligence doctrine, the physician's liability for nondisclosure is to be determined on the basis of foresight, not hindsight; no less than any other aspect of negligence, the issue on non-disclosure must be approached from the viewpoint of the reasonableness of the physician's divulgence in terms of what he knows or should know to be the patient's informational needs. If, but only if, the fact-finder can say that the physician's communication was unreasonably inadequate is an imposition of liability legally or morally justified.⁶⁷³

Generally, in order to prove causation in negligence cases where lack of IC or failure to provide adequate information disclosure by the HCP is alleged, and where such a risk eventually materialises, it has been argued that to substantiate such claims, patients would have to admit that, if such a risk had been disclosed, he or she would have not undergone the procedure or assumed the risk in question. It has been suggested that German law may have an answer for this conundrum. According to a German Supreme Court ruling in 1984,⁶⁷⁴ in order to defend the accusation that the claimant's decision was not based on the "hindsight" of the risk materializing, patients/ claimants should be obliged to substantiate and defend the allegation that they would not have undergone the treatment if the risk had been disclosed. The court would then evaluate these reasons

⁶⁷² *Canterbury v Spence* 18 (1972) 464 F 2d 772 [81].

⁶⁷³ *Canterbury v Spence* 18 (1972) 464 F 2d 772 [81].

⁶⁷⁴ BGH 7 Feb 1984 (VI ZR 174/82) BGHZ 90 103 [111-112].

against the patient's personal circumstances and the facts of the case. The reasons presented by the patient must be such, as to enable the court to be satisfied that the patient, had he or she received the information in question, would have been faced from their own perspective with a real conflict which would have made acceptance of such a risk impossible.^{675,676}

2.7 Some differences between consent to medical treatment versus biomedical research

Another contentious area with regards to determining the level of information disclosure to patients is the issue of the different standards of information disclosure required for involvement in biomedical research when compared to medical treatment. It has been suggested that these differences might seem obvious because research is generally experimental in nature, while standard medical therapy is based on tried and tested methods and medications.⁶⁷⁷ However, such arguments have been challenged by some others, who assert that the use of newer and better drugs may actually be more beneficial than older outdated therapy. Further, when a doctor compares a newer drug against an old established drug in a clinical trial, the physician/researcher is generally required to seek ethical approval from a research ethics committee (REC). However, when another doctor decides to change his or her patient's medication as part of standard treatment regimen in a clinic or medical ward, even though this is somewhat experimental in nature, this latter doctor is not required to obtain any approval other than routine IC from the patient. This has been viewed as contradictory because one could argue that the physician/ researcher who obtains regulatory approval prior to embarking on the clinical trial, may be more ethically astute and admirable, also the patient in this situation may be better protected.⁶⁷⁸ The question has been asked why international research ethical

⁶⁷⁵ BGH 7 Feb 1984 (VI ZR 174/82) BGHZ 90, 103 [111-112]

⁶⁷⁶ Giesen 1993 *Med Law* 553-565.

⁶⁷⁷ Lantos 1993 *Cancer Suppl* 2811-2815.

⁶⁷⁸ Lantos J 1993 *Cancer Suppl* 2811-2815.

codes^{679,680} focus more on the physician/researchers who are testing new drugs, rather than the new innovations which may be achieved in the process. The answer seems to lie in the belief that research is considered hazardous because the physician/researcher conducting research is only interested in gathering generalizable knowledge,⁶⁸¹ and is therefore using the patient as a means to an end.⁶⁸² Contrary to the moral philosophy and categorical imperative of Immanuel Kant who asserted that people should never be used as a means to an end,⁶⁸³ rather any decision taken must be generally universalisable and must be used for the benefit of the individual and not for others nor for benefit of society in general.^{684,685} Therefore biomedical research somehow changes the nature of the doctor-patient relationship from a fiduciary relationship which is designed to cater for the welfare and well-being of the individual patient, to a situation where the patient is now being used to further the aim of generalizable knowledge which may only benefit others, and society in general.^{686,687}

It has therefore been suggested that the role of ethical codes and regulatory approvals in medical research as opposed to treatment is to try and ameliorate this conflict.⁶⁸⁸ Therefore, the physician's role in the doctor-patient relationship may be regarded as different from the researcher's role in the researcher/ human subject relationship, even when the doctor and researcher are the same person. The physician's primary responsibility is usually the health and well-being of the patient, whereas the researcher's primary responsibility is the generation of new knowledge, which may or may not

⁶⁷⁹ World Medical Association (WMA) "Declaration of Helsinki-*Ethical principles for medical research involving human subjects*" (WMA Ferney Voltaire France 2013) Article 20.

⁶⁸⁰ Council for International Organizations of Medical Sciences (CIOMS) *International ethical guidelines for biomedical research involving human subjects* (CIOMS WHO Geneva 1993)

⁶⁸¹ Grimes v KKI 2000 [48-53].

⁶⁸² Morin K "The standard of disclosure in human subject experimentation" 1998 *J Leg Med* 157-221.

⁶⁸³ Cohen-Almagor 2017 *Ethics, Med Public Health* [3-9].

⁶⁸⁴ Kant I *Groundwork for the metaphysics of morals* (translated from the original by Wood AW) (Yale University Press New Haven 2002).

⁶⁸⁵ Hope T, Savulescu J and Hendricks J *Medical ethics and law-The core curriculum* (Churchill Livingstone Edinburgh 2008) 25-26.

⁶⁸⁶ World Medical Association *Declaration of Helsinki-Ethical principles for medical research involving human subjects* (Adopted by the 18th WMA General Assembly Helsinki Finland June 1964 as amended by the 64th WMA General Assembly Fortaleza Brazil 2013) 2.

⁶⁸⁷ Morin K 1998 *J Leg Med* 157-221.

⁶⁸⁸ Lantos J 1993 *Cancer Suppl* 2811-2815.

contribute to the research subject as patients' health and wellbeing.^{689,690} Thus, there is a potential for conflict between the two roles. When this occurs, the physician's role must take precedence over that of the doctor as researcher. According the National Bioethics Advisory committee (NBAC):⁶⁹¹

When research involves human participants, the uncertainties inherent in any research study raise the prospect of unanticipated harm...therefore, there can be a conflict between the need to test hypotheses and the requirement to respect and protect individuals who participate in research. This conflict and the resulting tension that can arise within the research enterprise suggest a need for guidance and oversight.⁶⁹²

Further, it has been suggested that because medical research is commercialized and well-funded, physicians can sometimes be lured by the financial or other benefits generated by research as shown in the case of *Moore v Regents of University of California*.⁶⁹³ In this case, full information disclosure was not provided to a patient whose tissues were used to generate commercial cell-lines, which generated enormous profit for the patient's physician and his employers. This led the Supreme Court of California to declare that "a physician who is seeking a patients consent for a medical procedure, [must] in order to satisfy his fiduciary duty and to obtain the patients 'consent, disclose personal interests unrelated to the patients' health, whether research or economic, that may affect his judgement."⁶⁹⁴ Therefore, it has been suggested that the HCPs interest in obtaining some of these ancillary benefits, can sometimes conflict with the duty to provide the patient with the best available information and treatment. It can also conflict with the right of the patient to receive all the necessary information to make a fully informed decision whether or not to participate in a research study.⁶⁹⁵ These observations led legal commentators like Morin⁶⁹⁶ to argue that:

⁶⁸⁹ WMA *Medical Ethics Manual* 3rd ed (World Medical Association Ferney-Voltaire France 2015).

⁶⁹⁰ Morin K 1998 *J Leg Med* 157.

⁶⁹¹ National Bioethics Advisory Commission (NBAC) *Ethical and policy issues in research involving human participants* (NBAC Washington DC 2000).

⁶⁹² NBAC *Ethical and policy issues in research involving human participants* (NBAC Washington DC 2000) 2-3.

⁶⁹³ *Moore v Regents of the University of California* (1990) 793 (P2d) 479.

⁶⁹⁴ *Moore v Regents of the University of California* (1990) 793 (P2d) 479-523.

⁶⁹⁵ *Moore v Regents of the University of California* (1990) 793 (P2d) 479.

⁶⁹⁶ Morin K 1998 *J Leg Med* 157-221.

It is essential to recognize that society's interest in knowledge may not coincide with an individual subject's interest. The individual subject stands to gain nothing and may lose everything including his or her right of self-determination...Failing to recognize that subjects who volunteer for the sake of advancing scientific knowledge are differently situated from patients who stand to benefit from treatment, results in an analysis that misconceives the purpose of disclosure. Beyond informing the patient as to the means available to treat him or her, a subject must become a voluntary and willing participant in an endeavor that may yield no direct benefit to him or her, or worse, that may cause harm."⁶⁹⁷

Reservations regarding these potential conflicts of interests may have prompted Cathell J to declare in *Grimes v KKI*⁶⁹⁸ that:

Researchers cannot ever be permitted to completely immunize themselves by reliance on consents, especially when the information furnished to the subject, or the party consenting, is incomplete in a material respect. A researcher's duty is not created by or extinguished by, the consent of a research subject or institutional review board approval. The duty to a vulnerable subject is independent of consent, although obtaining of consent is one of the duties a researcher must perform...Such legal duties, and legal protections, might additionally be warranted because of the likely conflict of interest between the goal of the research experimenter and the health of the human subject, especially, but not exclusively, when such research is commercialized."^{699,700}

Finally, in view of the above arguments the WMA has declared that "in medical research on human subjects, considerations related to well-being of the human subject should take precedence over the interests of science and society [...]"⁷⁰¹ It has been suggested that these ethical conflicts between biomedical research and medical treatment can be overcome based on the doctors and HCPs ethical behaviour and virtues, such as the ethical values of compassion, competence, autonomy, all of which should apply to the medical researcher as well. Consequently, there may be no inherent moral conflicts in the role of the biomedical researcher or physician, as long as doctors understand and follow the basic rules of research ethics; they should have no difficulty participating in research

⁶⁹⁷ Morin K 1998 *J Leg Med* 215-218.

⁶⁹⁸ *Grimes v KKI* 2000.

⁶⁹⁹ *Grimes v KKI* 2000 [76].

⁷⁰⁰ Chima 2006 *BMJ* 848-851.

⁷⁰¹ WMA Declaration of Helsinki-*Ethical principles for medical research involving human subjects* as amended 2013 [2].

as an integral component of their clinical practice and medical treatment.^{702,703} Nevertheless, the level of information disclosure required in research is somewhat higher than that of medical treatment and this can be ascertained by looking at case law from North American courts where cases involving biomedical research have been litigated over a long period of time.⁷⁰⁴ For example in the 1965 case of *Halushka v University of Saskatchewan*,⁷⁰⁵ Hall J argued that:

In order for consent to be effective, it must be informed consent, freely given and it is the duty of the doctor to give a fair and reasonable explanation of the proposed treatment including the probable effect thereof and any special or unusual risks. Such being the duty owed by a physician to his patient in ordinary medical practice, the duty to inform is at least as great if not greater in the case of those engaged in medical research. To persons who offer themselves as subjects for experimentation, because in the latter case, there can be no exception the requirements of full disclosure whereas it may be necessary to keep certain things from the patient, in the interest of peace of mind, when a medical operation is being performed.

Similarly in the case of *Weiss v Solomon*⁷⁰⁶ the Supreme Court of Quebec concluded that in a purely experimental research program (non-therapeutic research); the doctor must disclose all known risks, including those which are very rare or remote and *a fortiori* those whose consequences could be grave. This level of disclosure is somewhat different from that in therapeutic research where there may be some beneficial treatment accruing to the patient, as demonstrated in *Zimmer v Ringrose*⁷⁰⁷ where the Supreme Court of Alberta, Canada did not extend the full disclosure principle established in *Halushka* to a case of sterilization performed as part of experimental procedures, similarly also in *Moore v Regents of the University of California* (hereinafter the *Moore case*),⁷⁰⁸ regarding the misappropriation of a surgically removed diseased spleen for use in research. The patient had consented to the splenectomy as part of his medical treatment, but did not consent

⁷⁰² WMA *Medical ethics manual* 3rd ed (World Medical Association Inc. Ferney-Voltaire Cedex France 2015).

⁷⁰³ Lantos J 1993 *Cancer Suppl* 2815.

⁷⁰⁴ Chima 2006 *BMJ* 848-51 see also Chima *Consent and patients' rights* [67-75].

⁷⁰⁵ *Halushka v University of Saskatchewan* [1965] 52 WWR 608 Canada [para 29].

⁷⁰⁶ *Weiss v Solomon* (1989) Carswell Que 72.

⁷⁰⁷ *Zimmer V Ringrose* (1981) 124 DLR (3d) 215.

⁷⁰⁸ *Moore v Regents of the University of California* (1990) 793 (P2d) 479.

to its use for commercialized research. The Supreme Court of California held that though there may be some information that is so remote from the patient's decision that it would not need to be disclosed in some cases, medical research would not fall into this category. Rather, the Court held that a physician who has an interest in research on tissue taken from a patient has potentially conflicting interests, which may render the physician to consciously or unconsciously recommend a particular procedure or treatment as opposed to the other. Therefore, disclosure of any research and other related interests is required.⁷⁰⁹ On the issue of misappropriation of patient's tissue however, the Court found that a patient has no proprietary rights to his or her own tissue. While acknowledging that the patient has rights of privacy and autonomy to his own body, the Court felt that these rights were fully and equally protected under the right of full information disclosure and informed consent.⁷¹⁰ The *Moore* case⁷¹¹ illustrates the fact that information disclosure is necessary to comply with a physician's fiduciary duty to respect the patient's autonomy, and to protect his or her property and privacy rights. It illustrates further that where the patient has derived some benefit from medical treatment combined with research, the so-called "therapeutic research", the courts may be reluctant to rule against HCPs. The requirements for information disclosure were earlier analysed by an American court in *Salgo v Leland Stanford (1957)*⁷¹² where the term "informed consent" was first introduced into legal parlance. The *Salgo* court argued that the duty to disclose the risks and alternatives of treatment was a logical extension of the already established duty to disclose the treatments nature and consequences. The court hence focused not only on whether consent had been given, but whether that consent was based on adequate information.⁷¹³ Similarly, in *Natanson v Kline (1960)*,⁷¹⁴ which pioneered the legal charge of "negligence" in informed consent cases, the Kansas Appeals Court required the physician to disclose and explain to the patient in language as simple as necessary, the nature of the ailment, the nature of the proposed treatment, success, failure,

⁷⁰⁹ Moore v Regents of the University of California (1990) 793 (P2d) 479-523.

⁷¹⁰ Biering JR "Informed consent in the practice of pathology" 2001 *Arch Pathol Lab Med* 1425-1429.

⁷¹¹ Moore v Regents of the University of California (1990) 793 (P2d) 479.

⁷¹² *Salgo v Leland Stanford Jr. University Board of Trustees* 317 P 2d 170 CA (1957).

⁷¹³ *Salgo v Leland Stanford Jr University Board of Trustees* 317 P 2d 170 CA (1957) 154 Cal App 2d 578 [para 12-15].

⁷¹⁴ *Nathanson v Kline* 186 Kansas 393 350 P2d 1093 (1960)

alternatives.⁷¹⁵ More recent American cases point to an even stricter standard of disclosure in “non-therapeutic research” as shown in *Whitlock v Duke University*.⁷¹⁶ Here a District Court in North Carolina held that the applicable standard in research was that established in *US v Karl Brandt*⁷¹⁷ as stipulated by the Nuremberg Code.⁷¹⁸ The *Whitlock* court was of the opinion that the Nuremberg standard is higher than the ‘informed consent’ standard used in medical treatment, in that the researcher is put under a duty to disclose *all* the ‘material risks’ which are reasonably foreseeable; and not just the most frequent, most common, or most severe risks.⁷¹⁹ In addition, the Nuremberg code puts the researcher under an obligation to disclose to the subject all the risks, which he or she may *personally* suffer, as opposed to those risks which a reasonable person may be expected to suffer during participation in research. This means that the level of disclosure is specific for each individual participating in a research project based on a subjective prudent patient’s standard. Therefore, one may conclude that the requirements in the *Nuremberg code*⁷²⁰ are based on a ‘subjective’ patient’s standard as opposed to the reasonable doctor standard adopted in the *Declaration of Helsinki*.⁷²¹ The *Whitlock* court therefore concluded that the degree of disclosure of risks is higher in non-therapeutic research than that required in therapeutic research.⁷²² It appears, however, that United States courts have been reluctant to impose the *Nuremberg* code standard in private actions for research conducted in violation of US regulations as being in violation of the subject’s rights to privacy and dignity as demonstrated by the case of *Robertson v McGee* 2002.⁷²³ Here the court held that the standard in the United States for conducting research on human

⁷¹⁵ Nathanson v Kline 186 Kansas 393 350 P2d 1093 (1960) [para 41-43].

⁷¹⁶ *Whitlock v Duke University* (NC 1986) 637 Suppl 1463.

⁷¹⁷ *US v Karl Brandt* "Trials of war criminals before the Nuremberg military tribunals under control council law No 10" (U.S. Government Printing Office Washington DC 1949).

⁷¹⁸ Nuremberg Code (1948) "Trials of war criminals before the Nuremberg military tribunals under control council law" (Washington DC US Government Printing Office 1949)181-182.

⁷¹⁹ *Chima Consent and patients' rights* 42-45.

⁷²⁰ Office of Human Research Protections-Nuremberg Code (US Department of Health and Human Services Washington DC) <http://www.hhs.gov/ohrp/archive/nurcode.html> [Date of use: 4 March 2016].

⁷²¹ World Medical Association. *Declaration of Helsinki-Ethical principles for medical research involving human subjects* (Adopted by the 18th WMA General Assembly Helsinki Finland 1964.

⁷²² *Whitlock v Duke University* (NC 1986) 637 Suppl 1463.

⁷²³ *Robertson v McGee* Oklahoma District Court (2002) WL 5350-45.

subjects was limited to the *US Code of Federal Regulations*,⁷²⁴ and there was no need to resort to international law to impute another standard.

On the other hand, English common law has still not fully differentiated between the requirements for full information disclosure in research, from that in medical treatment, preferring to lump both together under the *Bolam*⁷²⁵ principle, based on the reasonable doctor standard. In view of the above analysis, one can conclude that the amount of information disclosure required to comply with IC in research, appears to be more rigorous and higher than those required for medical treatment, especially where such research is considered to be non-therapeutic or commercialized research.⁷²⁶ Some commentators have argued that while the standards of IC in research are unnecessarily exhaustive, the requirements with regards to medical treatment are uneven, being alternatively scanty or comprehensive, depending on individual HCPs. Therefore, the artificial dichotomy between IC in research compared to treatment may be fundamentally flawed and does not really serve the best interests of patients.⁷²⁷

Finally, the extent of information disclosure required can also be influenced by socio-cultural factors, leading the NBAC to recommend that “researchers should develop culturally appropriate ways to disclose information that is necessary for adherence to the substantive ethical standards of informed consent.”⁷²⁸

2.8 What should generally be disclosed to a patient by healthcare professionals?

It has been shown that certain factors influence the ability or willingness of HCPs to disclose healthcare information to patients. These would include the patient’s ability to understand the disclosed information and cope with the disclosure, the seriousness of the

⁷²⁴ US Code of Federal Regulations (CFR 46.116) <http://www.hhs.gov/ohrp/regulations/45-cfr-46/index.html> (Date of use: 10 November 2017).

⁷²⁵ *Bolam v Friern Barnet Health Management Committee* [1957]1 WLR 582.

⁷²⁶ *Grimes v KKI* 2000 [63-64].

⁷²⁷ Lantos J1993 *Cancer Suppl* 2811-2815.

⁷²⁸ NBAC *Ethical and policy Issues in research involving human participants* (NBAC Washington DC 2000) 2-3.

patient's health condition, and the patient's desire to know about their current health status.⁷²⁹ From the foregoing one can summarize the requirements for information disclosure to patients, which can be generally classified into several broad areas:

- I. The patient's current medical status- this would include current medical diagnosis, prognosis, and the need or otherwise of medical treatment at this time and the likely course of the patient's condition if no treatment is administered.
- II. The medical interventions or treatment that might improve the patients prognosis, including a description of the potential procedures involved, a characterization of the associated risks and benefits, and the likely course of the patient's condition with or without therapy.
- III. The doctors or HCPs professional opinion as to the best course of action in this case in light of their expert knowledge, taking into consideration what they know about the patient's personal values and condition including for example, the costs of the different types of treatment based on the HCPs knowledge of the patients' economic situation, health insurance status or family situation.
- IV. The uncertainties associated with the proposed treatment and the likelihood of success or failure and the likely consequences of treatment or non-treatment, including any 'bad news' which may be associated with the patient's current condition e.g. quality of life issues, life expectancy or the impact of any experimental therapy. Where the overall effects of the therapy may be associated with the patient's idiosyncrasy, or where the proposed therapy would be part of a clinical trial, which would require the patient to be randomized to a placebo or treatment group, in which case the eventual outcome could be unknown.
- V. The patient's right of refusal. Patients should also be informed of their right to refuse the proposed medical intervention and the likely consequences of such refusal. The idea of IC is to enhance and respect the patient's right of self-determination and autonomy,⁷³⁰ as suggested by Lord Goff in *Airedale NHS Trust v Bland*⁷³¹ when he stated:

⁷²⁹ President's Commission *Making healthcare decisions* 70-99.

⁷³⁰ President's Commission *Making healthcare decisions* 96-99.

⁷³¹ *Airedale NHS Trust v Bland* [1993] AC 78.

It is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if a patient of sound mind refuses, however unreasonably to consent to treatment or care by which life would or might be prolonged, the doctors responsible for his case must give effect to his wishes, even though they do not consider it to be in his best interests to do so.⁷³²

Overall, one can conclude by saying that generally the law requires disclosure of risks that are material as judged by the seriousness or chance of occurrence.⁷³³ Material information was described in the case of *McKinney v Nash* 1981⁷³⁴ by the California CA as follows:

Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding whether to accept or reject the recommended medical procedure. To be material, a fact must also be one which is not commonly appreciated. If he physician knows or should know of a patient's unique concerns or lack of familiarity with medical procedures, this may expand the scope of required disclosure.^{735,736}

A comparative analysis of the above disclosure requirements will show that they are generally consistent with the requirements adumbrated in the National Health Act⁷³⁷ and in the *Castell* case,⁷³⁸ as well as the criteria outlined by various South African legal scholars.^{739,740,741,742}

⁷³² Airedale NHS Trust v Bland [1993] AC 78 [864].

⁷³³ Hartman M and Liang BA "Exceptions to informed consent in emergency medicine" 1999 *Hospital Physician* 53-59.

⁷³⁴ *McKinney v Nash* (1981) 120 Cal App 3d 428 174 Cal Report 642.

⁷³⁵ *McKinney v Nash* (1981) 120 Cal. App.3d 441 174 Cal Report 642 [para 7].

⁷³⁶ *Cobbs v Grant* 8 Cal 3d 229 (1972) 243-245.

⁷³⁷ National Health Act 61 of 2003

⁷³⁸ *Castell v De Greef* 1994 (4) SA 408 (C) [425-426].

⁷³⁹ Thomas 2007 *SALJ* 188-215.

⁷⁴⁰ Carstens and Pearmain *Foundational Principles* 685-687.

⁷⁴¹ Britz and Roux-Kemp *SAMJ* 2012 746-749.

⁷⁴² Van Oosten 1989 *Med Law* 443-456.

2.9 Exceptions to full information disclosure during informed consent

Informed consent is derived from the ethical principle of respect for autonomy, which together with the principles of beneficence, non-maleficence and justice, form the core principles of the principlism account of ethical reasoning as postulated by authorities such as Beauchamp and Childress.⁷⁴³ Some have argued against the principlism methodology because of the presumed elevation and pre-eminence of “respect for autonomy” above all other ethical principles or moral theories. However, Beauchamp and Childress⁷⁴⁴ have firmly denied these observations and argue that the principle of respect for autonomy has only prima facie right which can lawfully and ethically overridden when in competition with other equally compelling ethical principles. Therefore, in the realm of medical practice with particular reference to the IC doctrine, one can argue that respect for autonomy can be overridden in certain circumstances when there are other equally compelling ethical reasons. Hence the right to IC is only a rebuttable right which may be set aside when there are other overriding moral considerations and ethical dilemmas,⁷⁴⁵ as noted by Lord Donaldson in *Re T*.⁷⁴⁶

Despite the overriding importance of information disclosure in order to obtain valid informed consent during medical practice, overriding patient autonomy and the requirements of informed consent can create a moral dilemma where a conflict arises between two equally compelling moral imperatives. This constitutes a central dilemma in biomedical ethics and medical practice, whereby a moral dilemma is created by the doctors’ duty of professional beneficence and non-maleficence versus respect for the patient’s autonomy. The principles of beneficence and non-maleficence require a doctor or other HCP to maximize the good and minimize harm to the patient, while respect for autonomy requires the HCP to respect the patients’ right to self-determination and freedom of choice.⁷⁴⁷ It is said that persistence or overreliance on the doctrine of

⁷⁴³ Beauchamp and Childress *Principles of biomedical ethics* 57-282.

⁷⁴⁴ Beauchamp and Childress *Principles of biomedical ethics* 57.

⁷⁴⁵ Chima 2009 *Trans J Coll Med S Afr* 40-42.

⁷⁴⁶ *Re T Adult (Consent to medical treatment)* (1992) 2 FLR 458.

⁷⁴⁷ Cohen-Almagor 2017 *Ethics Med Public Health* [1-12].

beneficence by the HCP may promote or encourage paternalism.^{748, 749, 750} Despite the above observations, it has been recognised that there are certain circumstances in medical practice where the overriding of a patient's IC could be legally and morally justified. Such situations can be grouped into five general categories, which are the following:^{751,752,753,754}

- I. Based on legal requirements or public policy
- II. Based on the doctrine of necessity or emergency
- III. Based on the patient's best interests or incompetency
- IV. Based on the doctrine of therapeutic privilege
- V. Based on patient's waiver of information disclosure or informed consent

2.9.1 Public policy or legal requirements

In cases of public policy generally, utilitarian principles take precedence over respect for autonomy. Globally, legal statutes or international human rights conventions generally support or guarantee a right to life⁷⁵⁵ and a right to health.⁷⁵⁶

In the United Kingdom, the UK Human Rights Act (1998)⁷⁵⁷ states that “[e]veryone’s right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following conviction of a crime for which this penalty is provided.”⁷⁵⁸ However in certain medical situations, for example where a patient has

⁷⁴⁸ McCormick <https://depts.washington.edu/bioethx/tools/princpl.html> (Date of use: 28 February 2008)

⁷⁴⁹ Chima SC *A primer on medical law* [70-75].

⁷⁵⁰ Chima 2009 *Trans J Coll Med S Afr* 40-42.

⁷⁵¹ Meisel A “The ‘exceptions’ to the informed consent doctrine: striking a balance between competing values in medical decision-making” 1979 *Wis L Rev* 413.

⁷⁵² Chima 2009 *Transactions (CMSA)* 39-45.

⁷⁵³ Presidents Commission *Making healthcare decisions* [47 and 182].

⁷⁵⁴ National Health Act 61 of 2003 S6-S8

⁷⁵⁵ Universal Declaration of human rights (UDHR) (United Nations 1949).

⁷⁵⁶ United Nations International Covenant on Economic Social and Cultural Rights (2000) Article 12 para 9.

⁷⁵⁷ Human Rights Act 1998 c42.

⁷⁵⁸ Human Rights Act 1998 Article 2.

been declared to be in a persistent vegetative state (PVS), legal authorities have derogated from these guaranteed rights by sanctioning the withholding and withdrawal of life sustaining nutrition and hydration which usually lead to the patient's death. This was demonstrated in diverse jurisdictions such as the English cases of *Airedale NHS Trust v Bland*,⁷⁵⁹ and *NHS Trust A v; NHS Trust B v H*,⁷⁶⁰ and similarly also in the American cases of *Cruzan*⁷⁶¹ and *Re Conroy*,⁷⁶² as well in the South African case of *Clarke v Hurst*.⁷⁶³

Some legal and ethical authorities have argued against of these actions by suggesting that it might be in the interests of society to conserve scarce resources, rather than utilizing such resources to maintain patients with terminal diseases or irreversible conditions at public expense.^{764,765} However, other arguments supporting these decisions have centred on the need to respect those patients' rights of autonomy and dignity.⁷⁶⁶ Some professional authorities such as the Health Professions Council of South Africa (HPCSA) have supported the view that there may be circumstances where withholding treatment even if it not in the best interests of the patient, may be justifiable in the face of resource scarcity.⁷⁶⁷ In addition, while the European Convention on Human Rights (ECHR) guarantees a right to liberty and security of the person;⁷⁶⁸ similar to the South African Constitution which guarantees individual rights in section 12(a) "not to be deprived of freedom arbitrarily or without just cause; (b) not to be detained without trial, and (c) to free

⁷⁵⁹ *Airedale NHS Trust v Bland* (1993) AC 789.

⁷⁶⁰ *NHS Trust A v M; NHS Trust B v H* (2001) 2 WLR 942 1All ER 801.

⁷⁶¹ *Cruzan et ux v Director Missouri Department of Health* Supreme Court of the United States (1990) 497 US 261.

⁷⁶² *Re Conroy* 98 NJ 321 (1985) 486 A2d 1209 Supreme Court of New Jersey United States.

⁷⁶³ *Clarke v Hurst* (1992) NO (4) SA 636 (D).

⁷⁶⁴ Brock DW and Winkler D "Ethical issues in resource allocation, research and new product development" in Jamison DT et al (eds) *Disease Control Priorities in Developing Countries 2nd* ed (The International Bank for Reconstruction and Development /The World Bank Washington DC co-published with Oxford University Press New York 2006) See also Lopez AD et al "The global burden of disease: A response to the need for comprehensive consistent and comparable global information on disease and injuries (WHO 2001) See also Chima SC "Ethical issues in public health and resource allocation" in *A Primer on medical law* 196-206.

⁷⁶⁵ HPCSA *Guidelines for the withholding and withdrawing of treatment* (HPCSA Pretoria 2007).<http://www.hpcsa.co.za> (Date of use: 20 February 2016).

⁷⁶⁶ Cohen-Almagor 2017 *Ethics, Medicine and Public Health* [7-9].

⁷⁶⁷ HPCSA <http://www.hpcsa.co.za> (Date of use: 20 February 2016).

⁷⁶⁸ European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14 (Council of Europe 1950).

from all forms of violence from either public or private sources.”⁷⁶⁹ The ECHR, on the other hand, provides an exception where a person’s liberty could be curtailed including “the lawful detention of persons for the prevention of the spreading of infectious disease, of persons of unsound mind, or drug addicts or vagrancy.”⁷⁷⁰ This may justify the detention of patients for the treatment of infectious disease such as extremely drug resistant tuberculosis (XDR-TB), or compulsory immunization in school children, based on the utilitarian principle of limiting an individual autonomy rights to prevent harm to another. As postulated by JS Mill in his treatise *On Liberty*, where he argued that “the only part of conduct of anyone for which he is amenable to society is that which concerns others.”^{771,772}

2.9.2 The doctrine of necessity

The second criterion under which IC may be legally overridden is based on the doctrine of necessity, which is a recognized doctrine in common law jurisdictions and is routinely applied during emergency medical treatment. This doctrine allows doctors or other HCPs to treat patients within the limits of what is medically necessary to preserve life or prevent irreversible damage to the patients’ health. As outlined in section 7(e) of the NHA.⁷⁷³ This doctrine maybe applied where “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.”⁷⁷⁴ As explained by Lord Golf in *F v Berkshire HA*⁷⁷⁵: “That there exists in the common law a principle of necessity which may justify action, which would otherwise be unlawful, is not in doubt”.⁷⁷⁶ Further,

⁷⁶⁹ Constitution of the Republic of South Africa 1996 s12

⁷⁷⁰ European Convention for the Protection of Human Rights and Fundamental Freedoms (Council of Europe 1950).

⁷⁷¹ Mill JS *On Liberty* 1859 (Batoche Books Kitchener Ontario Canada 2001) [52-53 and 69-70].

⁷⁷² Burrows RC and Hodgson RE “De facto gatekeeping and informed consent in intensive care” 1997 *Med Law* 17-27.

⁷⁷³ National Health Act 61 of 2003 s7 (e).

⁷⁷⁴ National Health Act 61 of 2003 s7.

⁷⁷⁵ *F v Berkshire Health Authority (Mental Health Act Commission intervening)* 1989 2 All ER 545.

⁷⁷⁶ *F v Berkshire Health Authority* 1989 2 All ER 545.

Lord Brandon in the case of *Re F*⁷⁷⁷ also agreed that “in many cases, however, it will not only be lawful for doctors, on the ground of necessity, to operate on or give other medical treatment to adult patients disabled from giving their consent; it will also be their common law duty to do so.”⁷⁷⁸ Brooke LJ later summarized three requirements for the application of the doctrine of necessity in *Re A*⁷⁷⁹ as follows:

- a. The act is needed to avoid inevitable or irreparable evil
- b. No more should be done than is reasonably necessary for the purpose to be achieved
- c. The evil inflicted must be disproportionate to the evil avoided.^{780,781}

Some other authorities have argued that the harm caused should be weighed against the potential benefit before deciding on the best course of action via a risk/benefit analysis.⁷⁸² Lord Goff LJ however cautioned in the same case that “[e]mergency is however not the criterion or even a pre-requisite: it is simply a frequent origin of the necessity, which impels intervention. The principle is one of necessity, not of emergency”.⁷⁸³ He also added that the doctrine should be strictly confined to “action taken to preserve the life, health or well-being of another who is unable to consent to it”.⁷⁸⁴ Based on the above considerations, two basic requirements for applications of the doctrine of necessity were outlined in English common law:

1. There must be necessity to act when it is not practicable to communicate with the assisted person.
2. The action taken must be such as a reasonable person would in all circumstances take, acting in the best interests of the assisted person.⁷⁸⁵

⁷⁷⁷ Re F 1990 2 AC 1.

⁷⁷⁸ Re F 1990 2 AC [55-56].

⁷⁷⁹ Re A (Children. Conjoint Twins: Surgical separation) 2000 4 All ER 961.

⁷⁸⁰ Re A (Children. Conjoint twins: Surgical separation) 2000 4 All ER 961[962].

⁷⁸¹ Chima *A primer on medical law* 91-92.

⁷⁸² Grubb et al *Principles of Medical Law* 454.

⁷⁸³ Re F 1990 2 AC 1 [75].

⁷⁸⁴ Re F 1990 2 AC 1 [74].

⁷⁸⁵ Re F 1990 2 AC 1 [75H] see also Hocton *Law of consent to medical treatment* 10.

South African law is derived in part from Roman Dutch Law⁷⁸⁶ (to which the concept of negotiorum gestio belongs), and English common law to which the doctrine of necessity belongs. One can argue that the NHA does not specify which derivative of South African law is applicable when providing treatment in an emergency situation. One can assume that either the Roman-Dutch principle of negotiorum gestio, or the doctrine of necessity is equally applicable with regards to interpretation of the exceptions to IC outlined in s7(a-e) of the NHA.⁷⁸⁷ As previously discussed in the introduction to chapter two of this thesis, the reasons for the frequent citation of foreign case law to support arguments in this thesis is based on the fact that many of the legal principles outlined in the NHA have not been tested in South African courts, and the courts in many cases have been reluctant to delve into detailed interpretations of the IC doctrine even where litigants have requested the courts to do so.⁷⁸⁸ Again, there may be no contradiction as the common law does not distinguish between negotiorum gestio and the doctrine of necessity, under English common law the doctrine applicable is the doctrine of necessity, as outlined by the dictum of Lord Goff in *Re F* where he said that “*emergency is however not the criterion or even a pre-requisite: it is simply a frequent origin of the necessity which impels intervention. The principle is one of necessity, not of emergency*”.⁷⁸⁹ One can therefore conclude that the NHA does not specifically differentiate between the doctrine of necessity, or negotiorum gestio. One can argue that either principle is applicable when interpreting this regulation depending on the jurisdiction concerned. Having regards to the observations above, the principle of negotiorum gestio is further discussed below with some differences to the doctrine of necessity highlighted.

⁷⁸⁶ Carstens and Pearmain *Foundational Principles* 7-8.

⁷⁸⁷ National Health Act 2003 section 7(1) (a-e).

⁷⁸⁸ Louwrens v Oldwage 2006 (2) SA 161 (SCA) see also Britz R and Roux 2012 *SAMJ* 746-748 and Thomas R 2007 *SALJ* 188-215.

⁷⁸⁹ *Re F* 1990 2 AC 1 [75C].

2.9.2.1 *Negotiorum gestio* (unauthorized administration)

This is another condition, which may allow provision of medical treatment to an ailing individual in Roman-Dutch law, which is distinguishable from the doctrine of necessity, but is more closely aligned to the best interests of the patient as will be discussed further below. *Negotiorum gestio* is distinguished from the doctrine of necessity based on the following criteria:

- A. Necessity involves the sacrifice of the interests of a harmless third party, whereas *negotiorum gestio* involves two parties, the caretaker and the beneficiary.
- B. Necessity protects the interests of society, whereas *negotiorum gestio* protects the rights and interests of the individual.⁷⁹⁰

Based on the above considerations unauthorized treatment or *negotiorum gestio* may be justified under the following circumstances:

- a) There must be a situation of emergency, which necessitates the intervention or action taken.
- b) The patient must be incapable of consenting or unaware of the situation. If the patient has some capacity to provide consent, then it must be obtained. The defence is only allowable where it is impossible to obtain the patients consent.
- c) The intervention must not have been expressly prohibited by the patients will. For example, if there is an advance directive or a living will which prohibits such intervention, then the HCP cannot go against the prohibited action.

This may be illustrated by the landmark Canadian case of *Malette v Shulman*.⁷⁹¹ In this case, Mrs Malette was carrying with her an unsigned Jehovah's Witness card, which prohibited blood transfusion. She was involved in a motor vehicle accident and was unconscious, but required blood transfusion to save her life. Dr. Shulman authorized a blood transfusion that saved her life, even when he became aware of corroborative

⁷⁹⁰ Carstens and Pearmain *Foundational Principles* 909 see also Barit *The doctrine of informed consent in South African medical law* 60.

⁷⁹¹ *Malette v Shulman* (1991) 2 Med LR 162.

information from a family member to confirm that she was indeed a Jehovah's Witness. The patient recovered and sued the doctor for violation of her rights. The Canadian court awarded damages against the doctor, not for negligence, but for violation of the patient's rights to privacy and bodily integrity, arguing that the presence of the Jehovah's Witness card served as an advance directive that prohibited the blood transfusion, and ought not to have been ignored by the doctor. According to Robins J of the Ontario Court of Appeals, "the instructions imposed a valid restriction on the emergency treatment that could be provided...and precluded blood transfusions."⁷⁹²

It has been suggested that the doctrine of *negotiorum gestio* or unauthorized treatment is recognized by the National Health Act in section 7, where it states:

- (1) Subject to section 8, a health service may not be provided to a user without the User's informed consent unless-
- (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.⁷⁹³

Other factors, which may apply to the doctrine of *negotiorum gestio*, may include:

- i. That the HCP or doctor who comes to treat a patient based on unauthorized administration has a duty to complete the treatment; that is, the healthcare professional is under obligation to complete the care based on a 'reasonable doctor standard' of care.
- ii. The HCP is also entitled to just remuneration, provided that the HCP acted with the intention of obtaining compensation for such action, he or she may claim compensation for the treatment administered to the patient.
- iii. The right to compensation: that if the HCP were to come to some harm while assisting the patient, then the HCP may claim compensation from the patient, if the

⁷⁹² Malette v Shulman (1991) 2 Med LR 162[166] see also Khan et al *Clinical Negligence* 42.
⁷⁹³ National Health Act 61 of 2003 s7 (1) (e).

patient or individual assisted was negligent in creating the conditions that necessitated the assistance or unauthorized administration in the first place.⁷⁹⁴

However, it must be observed that while South African law is derived in part from Roman Dutch Law,⁷⁹⁵ to which the concept of *negotiorum gestio* belongs, and English common law to which the doctrine of necessity belongs. One can argue that the NHA does not specify which derivative of South African law is applicable when providing treatment in an emergency as previously noted on pages 125-126 of this thesis.

With regards to surrogate decision-making on behalf of incompetent patients. One can argue that, substituted judgment is only one aspect of the options that are applicable during surrogate decision-making. Generally, surrogate decision-making can be based on either:

- (a) Substituted judgment standard
- (b) Pure autonomy standard, or
- (c) Best interests standard

It has been argued that the 'substituted judgment standard' would require that the surrogate decision-maker to 'don the mantle of the incompetent' as referred to in the American case of *Superintendent of Belckerton State School v Sackewicz*.⁷⁹⁶ The substituted judgment standard is generally viewed as autonomy based, however, it does not apply to never competent persons. In these cases, the types of evidence required for substituted judgment would be (i) written evidence, (ii) verbal evidence, or (iii) relational evidence.⁷⁹⁷

The second basis on which decisions can be made on behalf of people lacking decisional capacity is the 'pure autonomy standard'. It has been argued that this

⁷⁹⁴ Carstens and Pearmain *Foundational Principles* 908 see also Barit *The doctrine of informed consent in South African medical law* 58-59.

⁷⁹⁵ Carstens and Pearmain *Foundational Principles* 7-8.

⁷⁹⁶ *Superintendent of Belckerton State School v Sackewicz* 93 ALR 3d [67-85] see also *MDCN v Okonkwo* *MDCN v Okonkwo* (2002) AHRLR 159 (NgSC 2001) [75-76].

⁷⁹⁷ McCormick "Informed Consent: Its basis, problems and uncertainties" <https://depts.washington.edu/bioethx/tools/princpl.html> (Date of use: 28 February 2008) see also Chima *A primer on medical law* 89-97.

standard generally eliminates the ‘ghost’ autonomy created by substituted judgment. However, it only applies to previously competent individuals and in such cases, the types and strength of evidence must be weighed to decide what the person would have wanted.⁷⁹⁸

The third basis on which surrogates can make decisions on behalf of an individual lacking decisional capacity would be the ‘best interests standard’. In such cases, the surrogate determines what is in the patient’s best interests. Here, the goal is to maximize benefits to incompetent persons while minimizing risks. It is generally suggested that in such cases the surrogate should not consider his or her own interests or the interests of others besides the incompetent person. However, this standard is also complicated by the ‘myth of the disinterested other’, whereby, surrogates with ‘interests of their own’ could end up substituting their own objective with that of the incompetent person/s.⁷⁹⁹

2.9.3 The doctrine of best interests

Another legally acceptable reason for overriding patients’ autonomy or IC is based on the patient’s best interest.⁸⁰⁰ This will usually occur where the patient is incompetent either by being mentally incapacitated such as occurs in severe mental retardation in an adult patient, or during infancy or during states of unconsciousness. In such cases, the patient is lacking the necessary and required DMC to give IC. In such instances, according to the analogy of Lord Brandon in *Re F*:⁸⁰¹

[T]hey will normally be received into the casualty department of a hospital, which thereby undertakes the care of them. It will then be the duty of the doctors at that hospital to use their best

⁷⁹⁸ McCormick “Informed Consent: Its basis, problems and uncertainties” <https://depts.washington.edu/bioethx/tools/princpl.html> (Date of use: 28 February 2008).

⁷⁹⁹ McCormick “Informed Consent: Its basis, problems and uncertainties” <https://depts.washington.edu/bioethx/tools/princpl.html> (Date of use: 28 February 2008) see also Chima *A primer on medical law* 96-97 and Chima 2015 *Niger J Clin Pract* 2.

⁸⁰⁰ Chima 2009 *Trans J Coll Med S Afr* 41.

⁸⁰¹ *Re F* 1990 2 AC 1.

endeavours to do, by way of an operation or other treatment, that, which is in the best interests of such patients.⁸⁰²

It has been argued that the legal concept of best interests is centred on respecting and promoting patients autonomy, and is therefore aligned with the desire-fulfilment theory which is related to a person's well-being and having one's desires fulfilled, according to the concept of well-being and self-interest. In this case, a person's well-being is what is good for them. Health could be considered a constituent of a person's well-being, but it may not be all that matters to that individual's well-being. "One correlate term worth noting here is 'self-interest': my self-interest is what is in the best interests of me, and not others."⁸⁰³ In other words, to maximize an individual's well-being, one ought to give them whatever they want. Opponents of this theory have argued that there could be a conflict between what an individual wants and what is actually good for them. Based on this conflict between wants and needs, the best interests' argument can be divided into 'subjective' and 'objective' categories.⁸⁰⁴

A. Objective view of best interests- Advocates of the objective view argue that best interests can be explained in terms of maximizing an individual's welfare, well-being or good. Based on this view, any action or omission that brings about the maximization of my well-being in a particular situation is that which is in that person's best interests.⁸⁰⁵ Others have argued that the decision would only be considered the 'best' if such an action would bring about the most good for the individual concerned.⁸⁰⁶

B. Subjective view of best interests- Advocates of the subjective view of best interests on the other hand argue that the best interests' standard should be determined by what that particular individual would have chosen if they were

⁸⁰² Re F 1990 2 AC 1 [55].

⁸⁰³ Crisp R "Well-Being" 2015 *The Stanford encyclopaedia of philosophy* Zalta EN (ed) <http://plato.stanford.edu/archives/sum2015/entries/well-being/> (Date of use: 18 February 2016).

⁸⁰⁴ Chima 2009 *Trans J Coll Med S Afr* 41.

⁸⁰⁵ Dawson A "The determination of the best interests in relation to childhood immunization" *Bioethics* 1467-1485.

⁸⁰⁶ Buchanan AE and Brock DW *Deciding for others: The ethics of surrogate decision making* (Cambridge University Press Cambridge 1989) 122.

competent to do so. This would of course apply to only previously competent patients. Further, if those patients were incompetent, what they would have chosen if they were in a position to do so. In practical terms it could be argued that where knowledge is available of that person's wishes e.g. by means of an advance directive, or living will, or arguably corroborative anecdotal evidence. Those individuals' best interests would be determined based on this. The central idea in the subjective view of best interests would be that, if an individual values certain types of beliefs e.g. religious beliefs as exemplified by Jehovah's witnesses. Actions that tend to take account of these views would be in my best interests and enhance my autonomy, while actions that ignore these beliefs would tend to compromise my best interests.⁸⁰⁷

2.9.4 The doctrine of therapeutic privilege

This is an exception to the IC doctrine, which allows a doctor under certain circumstances to withhold distressing information from a patient in his or her best interests. It is a controversial exception that could undermine the very essence of patient's autonomy and self-determination.⁸⁰⁸ Generally, doctors or other HCPs are under a legal-ethical obligation to procure patients valid and fully informed consent before proceeding with treatment. At the same time, the HCP is bound by medical-ethical rules of the profession to heal or cure the patient if he or she can, based on the ethical principles of beneficence and non-maleficence, which bind the doctor to promote good and minimize harm.⁸⁰⁹ Therefore, the doctrine of therapeutic privilege creates an ethical conflict and moral dilemma for the HCP. The doctrine of therapeutic privilege is a somewhat controversial formulation, which attempts to resolve this dilemma-albeit unsuccessfully in most cases. The doctrine of therapeutic privilege was recognized as an exception to the IC in *Canterbury v Spence*,⁸¹⁰ where the court held that: "Informed consent is a basic social

⁸⁰⁷ Buchanan and Brock *Deciding for others* 126-132.

⁸⁰⁸ Chima 2009 *Trans J Coll Med S Afr* 42.

⁸⁰⁹ Welz D 1999 *SALJ* 299-322.

⁸¹⁰ *Canterbury v Spence* 18 (1972) 464 F 2d 772.

policy for which exceptions are permitted. These exceptions would include intellectual capability such as unconsciousness and extreme psychological threat [...]"⁸¹¹

The precise use of the therapeutic privilege exception to IC though recognized by most common law jurisdictions differs in application in various countries. While some jurisdictions would permit a physician to withhold information, where it would be contrary to the therapeutic intent and lead to a deterioration in the patient's condition. For example, when a patient with unstable cardiac arrhythmias would have his or her condition exacerbated by anxiety attendant on full disclosure of the risks of treatment.⁸¹² However, the exception in this case must be narrowly constructed so that it does not swallow up the general doctrine of IC and respect for patient's autonomy.⁸¹³

Others appear to permit the withholding of information only if the patients knowledge of that information would have health-related effects, by impairing the patients DMC to give informed consent.⁸¹⁴ In terms of psychological distress as a basis for therapeutic privilege, Robertson⁸¹⁵ has suggested four possible scenarios where information could arguably be withheld from the patient:

- i. Where the information may be counterproductive in that the resulting psychological distress might prevent rational decision making;
- ii. Where the patient is being treated for emotional or psychological problems and the added distress caused by disclosure may compromise such treatment;
- iii. Where disclosure would be likely to cause serious distress or psychological harm. It would be in the best interests of the patient that the information should not be disclosed.

⁸¹¹ Canterbury v Spence 18 (1972) 464 F 2d 772 [para 47-49].

⁸¹² Mathew 2004 *AMA Virtual Mentor* www.virtualmentor.ama-assn.org/204/02/msoc1-0402.html (Date of use: 29 January 2008).

⁸¹³ Welz D 1999 *SALJ* 299-322.

⁸¹⁴ Chima *Trans J Coll Med S Afr* 42.

⁸¹⁵ Robertson G "Informed consent to medical treatment" 1981 *Law Quarterly Review* 102-121.

- iv. Where a doctor or HCP believes that the treatment is in the patient's best interests and the patient might refuse consent if told of the risks.⁸¹⁶

Further, some authorities have argued that the doctrine of therapeutic privilege can be legitimately invoked where the HCP has sufficient reasons to believe that disclosure would render the patient incompetent to give valid IC.⁸¹⁷ To invoke the privilege under this condition, it is argued, does not conflict with the patient's autonomy rights, because at this point the patient is incapable of making an autonomous decision.⁸¹⁸ Other authorities contend that therapeutic privilege, as an exemption from IC is a frank exercise in paternalism.⁸¹⁹ As outlined by Coetzee,⁸²⁰ the doctrine of therapeutic privilege may have the following negative impacts on the patient:

- a. It undermines the patients' rights to freedom of choice and self-determination.
- b. It may undermine patients' trust in doctors/HCP and fiduciary duty inherent in the doctor-patient relationship.
- c. Applying the doctrine of therapeutic privilege may cause significant harm to the patient, where the patient eventually learns the truth despite efforts to shield him or her from it.
- d. Non-disclosure can affect the patient's well-being.
- e. It may lead to dignity harm due to 'loss of self-esteem' when the true condition of the patient is later revealed, following initial non-disclosure.
- f. The doctrine may afford an easy defence after the fact by a HCP of failure to obtain informed consent and thus may shield cases of medical negligence.
- g. The privilege may be used to legitimise the doctor's Hippocratic aversion to delivering bad news.

⁸¹⁶ Robertson 1981 *Law Quarterly Review* 102-121.

⁸¹⁷ Van den Heever P "Pleading the defence of therapeutic privilege" 2005 *SAMJ* 420-421.

⁸¹⁸ Van den Heever 2005 *SAMJ* 420-421.

⁸¹⁹ Mathew www.virtualmentor.ama-assn.org/204/02/msoc1-0402.html (Date of use: 29 January 2008).

⁸²⁰ Coetzee LC "A critical evaluation of the therapeutic privilege in medical law: some comparative perspectives" 2003 *CILSA* 268-288.

- h. It may have cost implications in healthcare because the patients may not be given an opportunity to evaluate the cost/ benefit analysis of undergoing or refusing futile treatment, while on the hand , the HCP may proceed with such treatment based as it where on his own judgment of what would be in the patients best interests.
- i. Generally, physicians lack the ability or empirical evidence to conclude on whether disclosure would be harmful to a particular patient. It has been argued that the therapeutic privilege exception rests on a false assumption, that patients would automatically reject and refuse the recommended treatment once they are apprised of the truth.⁸²¹

It has been suggested that the doctrine of therapeutic privilege should be applied within very narrow boundaries because of its potential for abuse and overuse by HCPs. According to the Presidents' Commission on Bioethics,⁸²² the potential for abuse arises from its inherent inconsistency with the patient's right to know in order to authorize or refuse the proposed treatment. Further, the privilege may sometimes allow doctors and other HCPs to unethically manipulate patients into giving consent to the proposed treatment.⁸²³ Van Oosten has argued that the wider the scope the doctrine of therapeutic privilege is defined, the narrower the scope of IC and information disclosure and the difficulty of obtaining a valid consent which respects the patient's autonomy.⁸²⁴

The American Medical association (AMA) Code of Medical Ethics suggests that physicians may withhold information about a patient's diagnosis or treatment when disclosing it would pose such a serious psychological threat, as to be medically contra-indicated. However, the code also warns that the doctrine of therapeutic privilege should not be used to prevent patients from exercising their free choice.⁸²⁵ Berg and others maintain that it is likely the therapeutic privilege exception lends false legitimacy to the natural aversion of doctors to giving information to patients. Therefore, if the scope of this

⁸²¹ Coetzee 2003 *CILSA* 282-287.

⁸²² The President's Commission *Making healthcare decisions* [93-99].

⁸²³ The President's Commission *Making healthcare decisions* 96.

⁸²⁴ Van Oosten 1991 *Med Law* 31-41.

⁸²⁵ AMA Council on Ethics and Judicial Affairs *Code of medical ethics: Current opinions with annotations* (American Medical Association Chicago 2012-2013) [8.08-8.082].

privilege is not circumscribed it has the potential to swallow the HCPs ethical-legal obligation of disclosure, which may in fact permit HCPs to substitute their own judgment for that of patients in any instance of healthcare decision-making. They further suggest that because of the overlap between the doctrine of therapeutic privilege and the allowances provided by waiver and incompetence, the doctrine of therapeutic privilege should be abolished.⁸²⁶

In the context of South African jurisprudence, therapeutic privilege as an exception to information disclosure have been cited in cases such as the *Castell* case⁸²⁷ where Ackerman J recognized its existence as a defence against information disclosure in South African law, but did not provide a detailed analysis of its application in practice. According to Welz, the court in this case appeared to suggest that the existence of therapeutic privilege is incompatible with the current practice of enhancing patient's autonomy and self-determination.⁸²⁸ Further, in *SA Medical and Dental Council v McLouglin*,⁸²⁹ Watermeyer J observed, "it may sometimes even be advisable for a medical man to keep secret from his patients the form of treatment he is giving them", whilst in *Richter v Estate Hamman*,⁸³⁰ the court opined that "a doctor whose advice is sought about an operation in which certain dangers are attached is in a dilemma because if he fails to disclose the risks he may render himself liable to an action for assault. On the other hand if he discloses all the possible risks, he might well frighten the patient into refusing treatment which the doctor knows would be in the patient's best interest to accept."⁸³¹ The full extent of the doctrine of therapeutic privilege has never been litigated in South African courts. The more recent NHA 2003 codified this exception into law by providing that "every healthcare provider must inform a user of the user's health status except in circumstances where there is substantial evidence that the disclosure of the users health status would be contrary to the best interests of the user."⁸³² Therefore, while the exception of therapeutic

⁸²⁶ Berg JW et al *Informed consent: Legal theory and clinical practice* 2nd ed (Oxford University Press Fairlawn NJ 2001) 80.

⁸²⁷ *Castell v De Greef* 1994 (4) SA 408 (C) [418].

⁸²⁸ Welz 1999 *SALJ* 321.

⁸²⁹ *SA Medical and Dental Council v McLouglin* (1948) (2) SA 355 (A) 366.

⁸³⁰ *Richter and Another v Estate Hamman* (1976) (3) SA 226 (C) 232.

⁸³¹ Van Oosten FFW 1991 *Med Law* 31-41.

⁸³² National Health 61 of 2003 s6 (1) (a).

privilege is now legally recognized in South Africa, it is still advisable that HCPs use this exception with caution subject to the following recommendations:

1. Non-disclosure or incomplete disclosure can only be justified in exceptional circumstances.
2. There must be a real threat of detriment to a patient's physical or mental health.
3. Information could be withheld where the HCP judges the patient's emotional state to be such that the patient is unable to use the information in arriving at a rational decision.
4. The HCP must bear the onus of justifying that inadequate or non-disclosure was based on a sound clinical judgment.
5. The legal-ethical principles relating to the HCPs use of the therapeutic privilege exception must still protect the patient's autonomy within the overall objective of achieving the goals of treatment and enhancing the patient's dignity rights of self-determination.⁸³³

2.9.5 Waiver of information disclosure

The final criterion and perhaps least controversial exception to information disclosure is based on the concept of waiver. In the case of *Miranda v Arizona*,⁸³⁴ the US Supreme Court defined waiver as the voluntary and intentional relinquishing of a known right. In exercising waiver, a patient voluntarily relinquishes the right to information disclosure and IC by delegating the decision-making to either the HCP or another surrogate decision maker.⁸³⁵ In making such a decision, some patients may express a decision to trust their doctor's professional judgment, whereas others may feel unable or lack the confidence to analyse the risk disclosed.⁸³⁶ Sometimes a waiver may occur or apply where a patient who was previously competent initiates an 'advance directive' or 'living will', which

⁸³³ Van den Heever 2005 *SAMJ* 420-421 see also Carstens and Pearmain *Foundational Principles* 316.

⁸³⁴ *Miranda v Arizona* (1966) 384 US 436 [475-76].

⁸³⁵ Beauchamp and Childress *Principles of biomedical ethics* [92-93].

⁸³⁶ Gordon E "Multiculturalism in medical decision-making" 1997 *Ford Urb L J* 1321-1362.

transfers the right to IC or healthcare decision-making to another person if, and when such a person is no longer competent to do so. The law generally allows patients to waive their right to give IC, so long as it made after full information disclosure, or where a patient chooses not have negative information disclosed due to personal cultural beliefs. In other words, the patient makes a decision not to make an informed decision. The waiver exception may also be applicable based on religious or other cultural beliefs, for example amongst Navajo Indians of North America who abhor 'bad news'- this exception may enable them to revoke their right to hear bad news by relieving the HCP from the duty of disclosure.⁸³⁷

This exception has been legally accepted in some instances, in that courts have been of the opinion that doctors need not make disclosures of risks where the patient requests that he or she be not so informed.⁸³⁸ It has also been suggested by some ethicists that the bearer of rights can always waive that right.⁸³⁹ Others have argued that it is appropriate to recognize waivers of rights because an individual always enjoys a discretion when and whether to exercise those rights.⁸⁴⁰ It is possible that with regard to the issue of advance directives and living wills, that exercising these options allows the patient as the rights bearer to still be active in the decision-making process by choosing who will exercise those rights on his or her behalf, and that this enhances patient autonomy and right of self-determination. It has been said that patient consent can act as a waiver, for example, when a patient gives consent to a surgeon to operate. This does not actually give the surgeon the right to operate, since the patient retains the right to bodily integrity and sufficient control of his or her body to withdraw that permission at any time. In such situations, it may be argued that consent can operate as a waiver.⁸⁴¹ Accordingly, the impact of the waiver exception is that if a waiver is properly obtained, the patient will remain the ultimate decision-maker. However, the content of this decision is shifted from the decisional level to the meta-decisional level, for example, the decision may change

⁸³⁷ Carrese JA and Rhodes LA "Western bioethics on the Navajo reservation: Benefit or harm?" 1995 *JAMA* 826-829.

⁸³⁸ *Cobbs v Grant* (1972) 502 P2d 1 12.

⁸³⁹ Brody B *Life and death decision making* (Oxford University Press New York 1988) 22.

⁸⁴⁰ Beauchamp and Childress *Principles of biomedical ethics* [92-93]

⁸⁴¹ Maclean *Consent to medical treatment and the competent adult* 141.

from 'I want this treatment or I do not want this treatment' to 'I do not want any information about the treatment I am about to receive.'⁸⁴² However, the legal requirements for effective waiver during the informed consent process have never been clearly articulated by the courts. While it has been suggested that the court would generally approve of properly obtained and applied waivers, there is a concern that such waivers must be morally and legally acceptable. In the absence of clear judicial guidance, HCPs are advised to exercise this exception with appropriate caution.⁸⁴³ Further, it has been argued that a general acceptance of waivers of information disclosure and IC could lead to its abuse and overuse, because most patients have an inordinate trust in their doctors and a general acceptance of waivers could expose patient to exploitation and abuse.

Therefore, it is generally accepted that a rule could be established whereby waivers would be overruled, except where it has been analysed and approved by an independent body, such as a research ethics committee or hospital ethics committee. This procedure could minimize or generally eliminate the potential abuse of the waiver exception by HCPs and others.⁸⁴⁴

2.10 Understanding or comprehension of information disclosed

Although information disclosure and knowledge of that information are necessary for the comprehension of information, plain knowledge is generally not sufficient. Real comprehension would involve the ability to use information rationally. Therefore, for a patient to understand the information imparted by a HCP, the patient must not only be able to listen attentively to the HCP. Doctors must also appreciate that for information to have been communicated successfully, it needs not only disclosure, but the patient must also pay attention to that information, understand it, accept, retain the information, and then put that information to use in a rational manner.⁸⁴⁵ Some commentators have argued that the true test for comprehension is the patient's capacity to understand, and that the

⁸⁴² The President's Commission *Making healthcare decisions* 33.

⁸⁴³ The President's Commission *Making healthcare decisions* [93-99].

⁸⁴⁴ Beauchamp and Childress *Principles of biomedical ethics* [92-93].

⁸⁴⁵ The President's Commission *Making healthcare decisions* [87-89].

HCP needs to ascertain that the patient actually has the capacity to understand the information conveyed in a non-technical language.⁸⁴⁶ Accordingly, in *Re C*,⁸⁴⁷ Thorpe J was of the opinion that there are three stages to a decision and understanding of information:

- (i) to take in and retain the information,
- (ii) to believe it, and
- (iii) to weigh that information balancing risks and needs.

Based on these criteria, the court ruled that a schizophrenic patient, who had refused amputation of his infected leg, had the capacity to understand information disclosed.⁸⁴⁸ Further, the *British Medical Association (BMA)*⁸⁴⁹ guidelines stipulate with regards to understanding that the patient must be shown to:

- Understand in simple language what the medical treatment is, its purpose and nature and why it is being proposed
- Understand its principal benefits, risks and alternatives
- Understand in broad terms what will be the consequences of not receiving the proposed treatment
- Retain the information for long enough to make an effective decision
- Make a free choice (free from pressure or undue coercion)

This was further explained by Morland J in *Smith v Tunbridge Wells*⁸⁵⁰ as follows:

⁸⁴⁶ Francis R and Johnston C *Medical decisions and the law* (Butterworths London 2001) see also Kanj M and Mitic W "Health Literacy" Paper presented at the 7th Global Conference on Health Promotion, "Promoting Health and Development: Closing the Implementation Gap", Nairobi, Kenya, 26-30 October 2009 http://www.who.int/healthpromotion/conferences/7gchp/Track1_Inner.pdf (Date of use: 15 November 2017).

⁸⁴⁷ *Re C* (Adult: Refusal of medical treatment) [1994] 1 All ER 819.

⁸⁴⁸ *Re C* (Adult: Refusal of medical treatment) [1994] 1 All ER 819 [822].

⁸⁴⁹ British Medical Association BMA *Consent Toolkit* 2009 www.bma.org.uk/-/media/files/pdfs/.../consenttoolkitdec2009_full.pdf (Date of use: 20 February 2016)11.

⁸⁵⁰ *Smith v Tunbridge Wells Health Authority* 1994 5 Med LR 334.

When recommending a particular type of surgery or treatment, the doctor, when warning of the risks, must take reasonable care to ensure that his explanation of the risks is intelligible to this particular patient. The doctor should use language, simple but not misleading, which the doctor perceives from what knowledge and acquaintanceship that he may have of the patient (which may be slight), will be understood by the patient so that the patient can make an informed decision.⁸⁵¹

In finding a surgeon guilty of negligence in this case, the court held that surgeon had “failed to explain with sufficient clarity...the risk of impotence...and on this occasion was negligent.”⁸⁵² In another English case *Re L (Medical treatment: Gillick competency)*,⁸⁵³ the court ordered that a 14-year old Jehovah’s witness who was considered mature for her age, should be given blood transfusion against her will, because the court considered that she did not fully appreciate the consequences of her decision. According to Van Oosten, information as a *sine qua non* of informed consent entails both knowledge and appreciation by the consentor.⁸⁵⁴ Some have argued that the NHA⁸⁵⁵ is somewhat deficient in this respect, by emphasizing in section 6(1) “that users must have full knowledge”, without the corollary requirement that they must also appreciate such information, although this is implied in section 6(2) where the Act stipulates that HCPs must take into consideration the language and literacy level of the user. It has been suggested that the legislation may need to be remedied by including a requirement for not only understanding, but also appreciation by the consent giver.⁸⁵⁶

The UK General Medical Council (GMC), in explaining this, states as follows:⁸⁵⁷

Effective communication is the key to enabling participants to make informed decisions. When providing information you must do your best to find out participants individual needs and priorities e.g. the participants current understanding of their condition and treatment, beliefs, culture, occupation or other factors, may have a bearing on the information they require. You must not make

⁸⁵¹ Smith v Tunbridge Wells Health Authority 1994 5 Med LR 334 [339].

⁸⁵² Hocton *The law of consent to medical treatment* 46.

⁸⁵³ Re L (Medical treatment: Gillick competency) (1998) 2 FLR 810 see also Khan et al *Clinical Negligence* 68.

⁸⁵⁴ Van Oosten *The doctrine of informed consent in South African law* 20.

⁸⁵⁵ National Health 2003 s6.

⁸⁵⁶ Barit *The doctrine of informed consent in South African medical law* 16-18.

⁸⁵⁷ GMC *Research: The role and responsibilities of doctors* (General Medical Council London 2000).

assumptions about participant's views but discuss matters with them and ask whether they have concern about the treatment or the risks involved in the research programme.⁸⁵⁸

From the above, one may argue that HCPs are required to actively seek to ensure that patients truly understand the information disclosed to them. In furtherance of the requirements for understanding and comprehension, some authorities such as the National Bioethics Advisory Commission, USA (NBAC)⁸⁵⁹ have suggested that part of ensuring complete understanding of information may even include community participation.⁸⁶⁰ Such involvement may vary from providing written information sheets for potential participants to take home and discuss with family members, holding community meetings during which information is presented and community consensus is obtained,⁸⁶¹ in the context of research.⁸⁶² It is suggested that when a patient wishes to involve family members in the consent discussion, the HCP should take appropriate steps to accommodate this desire by the patient, but the patient should be cautioned that such family member's permission should not replace the requirement for a competent individual's voluntary informed consent.^{863,864} Finally, it has been proposed that:

Improving people's understanding of what is provided in the realm of medical services is seen as a major factor that contributes to increased quality of care and adherence to expert advice. Measurement of health literacy is needed to identify those patients that do not understand medical information or the range of services offered. Only if we know about those patients or subgroups with low degrees of health literacy, we can adjust our services respectively or provide specific teaching programs for patients.⁸⁶⁵

⁸⁵⁸ GMC *Good medical practice* 2013 <https://www.gmc-uk.org/guidance/index.asp> (Date of use: 12 November 2017).

⁸⁵⁹ National Bioethics Advisory Commission *Presidential bioethics commission issues report on clinical trials research in developing countries* (NBAC Bethesda MD 2001) [recommendation 3.4].

⁸⁶⁰ NBAC *Presidential bioethics commission issues report on clinical trials research in developing countries* (NBAC Bethesda MD 2001) [recommendation 3.5].

⁸⁶¹ NBAC *Presidential bioethics commission issues report on clinical trials research in developing countries* (NBAC Bethesda MD 2001) [recommendation 3.8].

⁸⁶² Tindana et al 2006 *IRB* 1-6.

⁸⁶³ NBAC *Presidential bioethics commission issues report on clinical trials research in developing countries* (NBAC Bethesda MD 2001) [3.8].

⁸⁶⁴ Chima *Consent and patients' rights* 47.

⁸⁶⁵ Abel T "Measuring health literacy: moving towards a health-promotion perspective" 2008 *Int J Public Health* 169-170 see also Kanj and Mitic "Health Literacy" Paper presented at the 7th

2.10.1 Language and effective communication

It is arguable that while the above requirements are generally applicable in medical treatment the magnitude of difficulty for understanding required in complex multicultural and multilingual developing African countries could be even higher,⁸⁶⁶ especially in a country like South Africa, which has 11 official languages.⁸⁶⁷ Further, the population using public healthcare services in South Africa are not highly educated⁸⁶⁸ and many do not speak the same language as the HCP providing treatment, especially doctors.⁸⁶⁹ In these types of settings it may be necessary to obtain the services of an interpreter or an intermediary, or to put the information in the patient's local language in other words, 'in language understandable to the patient', in order to fulfil the obligation for understanding prior to IC. This would be consistent with the requirement in the NHA, which states that, "The health care provider concerned must, where possible, inform the user...in a language that the user understands and in a manner which takes into account the user's level of literacy."⁸⁷⁰

Language barriers may have a negative impact on healthcare services, leading to errors such as misdiagnosis, failure of preventive healthcare and non-adherence by patients to prescribed medications.⁸⁷¹ This could ultimately lead to accusations of negligence and claim of damages against doctors and other HCPs.⁸⁷² Problems with language difficulties and IC or other healthcare services are not limited to South Africa,⁸⁷³ where previous reports indicate that the absence of appropriately trained interpreters is a major barrier to IC for doctors working in public hospitals.⁸⁷⁴ In another study in a South African district

Global Conference on Health Promotion, "Promoting health and development: Closing the implementation gap", Nairobi, Kenya, 26-30 October 2009 [26].

⁸⁶⁶ Bhan A, Majid M and Adejumo A "Informed consent in international research: Perspectives from India, Iran and Nigeria" 2006 *MUMJ* 36-41.

⁸⁶⁷ Schlemmer A and Mash B "The effects of a language barrier in a South African district hospital" 2006 *SAMJ* 1084-1087.

⁸⁶⁸ Chima 2015 *Niger J Clin Pract* S46-S56.

⁸⁶⁹ Chima 2013 *BMC Med Ethics* S3.

⁸⁷⁰ National Health Act 61 of 2003 s6(2)

⁸⁷¹ Schlemmer and Mash 2006 *SAMJ* 1084-1087.

⁸⁷² Flores 2006 *N Engl J Med* 229-331.

⁸⁷³ Clark S et al "The informed consent: A study of the efficacy of informed consents and the associated role of language barriers" 2011 *J Surg Edu* 143-147.

⁸⁷⁴ Chima 2013 *BMC Med Ethics* S3 [8-11].

hospital, the authors concluded that language difficulties create significant problem for HCPs and could influence the patients' rights to IC and confidentiality in the healthcare setting.^{875,876}

In light of the above observations, the Council for International Organizations of Medical Sciences (CIOMS)⁸⁷⁷ has provided the following recommendations concerning language and comprehension of information, albeit with particular reference to biomedical research. However, these guidelines are equally applicable to medical treatment scenarios.

Language – Informing the individual subject must not be simply a ritual recitation of the contents of a written document. Rather, the investigator must convey the information, whether orally or in writing, in language that suits the individual's level of understanding. The investigator must bear in mind that the prospective subject's ability to understand the information necessary to give informed consent depends on that individual's maturity, intelligence, education, and belief system. It depends also on the investigator's [HCPs] ability and willingness to communicate with patience and sensitivity.⁸⁷⁸

Comprehension – The investigator must then ensure that the prospective subject has adequately understood the information. The investigator should give each one full opportunity to ask questions and should answer them honestly, promptly and completely. In some instances, the investigator may administer an oral or a written test or otherwise determine whether the information has been adequately understood.⁸⁷⁹

⁸⁷⁵ Tate RC et al "Strategies used by prehospital providers to overcome language barriers" 2016 *Prehosp Emerg Care* 404-414.

⁸⁷⁶ Schlemmer and Mash 2006 *SAMJ* 1084-1087

⁸⁷⁷ The Council for International Organizations of Medical Sciences (CIOMS) *International ethical guidelines for biomedical research involving human subjects-Guideline 9* (CIOMS-WHO Geneva 2016) 33-36.

⁸⁷⁸ CIOMS *International ethical guidelines for biomedical research Involving human subjects* (WHO Geneva 2016) 34 (Note, the exact terminology of the 2016 version may be slightly different in the 2002 version which is quoted here).

⁸⁷⁹ CIOMS *International ethical guidelines for biomedical research involving human subjects* (WHO Geneva 2016) 34 (Note, the exact terminology of the 2016 version may be slightly different in the 2002 version which is quoted here).

2.10.2 Information overload

Excessive information, which the patient barely understands, can also be a barrier to processing of disclosed information. In such cases, too much information as opposed to inadequate information can prevent understanding especially where unfamiliar terminology or medical jargon is used and the patient cannot make any sense of such information.⁸⁸⁰ This is of particular importance amongst less educated patients or low socio-economic classes as prevalent in developing countries like South Africa.^{881,882}

In another study from South Africa, it was reported that patients in a rural setting could not understand basic technological terminology because these are new technologies for which words do not exist in the local language. The authors concluded that this might affect the patients understanding and ability to render IC.⁸⁸³ In this situation, it has been argued that patients may come to rely on selective information processing within their own personal value systems or level of knowledge, making it increasingly difficult to determine whether patient preconceptions and beliefs distort the information disclosed or when other biases may intrude.^{884,885}

2.10.3 Other factors that may impact on patient comprehension-false beliefs

DMC can also be compromised where a patient's ability to accept information which is factually true, even when they comprehend such information, could be impacted based on false beliefs, plain ignorance, or unexplained bias against the HCP. Such false beliefs can occur for example; (a) where a patient who is capable and understands information provided, but may still agree to participate in non-therapeutic research project under the

⁸⁸⁰ Beauchamp and Childress *Principles of biomedical ethics* 90.

⁸⁸¹ Chima 2015 *Niger J Clin Pract* S46-S56.

⁸⁸² Oduro AR et al "Understanding and retention of the informed consent process among parents in rural northern Ghana" 2008 *BMC Medical Ethics* 9 12.

⁸⁸³ Jack C et al "Language, cultural brokerage and informed consent-will technological terms impede telemedicine use?" 2014 *S Afr J Bioeth Law* 14-18.

⁸⁸⁴ Beauchamp and Childress *Principles of biomedical ethics* 90.

⁸⁸⁵ Pace C et al "Quality of parental consent in a Ugandan malaria study" 2005 *Am J Public Health* 1184-1189.

false belief that it is therapeutic, that is, the so-called therapeutic misconception.⁸⁸⁶ (b) A seriously ill-patient who has been presented with factual information that they have a serious medical diagnosis e.g. lung cancer, may falsely believe that he or she does not have lung cancer because he or she has not been a smoker and from her own personal knowledge only smokers can get lung cancer. In such a case, the patient's perception is clouded by strongly held misinformation and belief, and where such a patient refuses the necessary treatment this will not be an informed refusal because it is based on a false belief. Finally, ignorance or bias can impact on a patient's understanding and acceptance of information, for example, where a patient of a different racial background from the HCP refuses to accept factually accurate information simply because such a person has preconceived notions regarding the intellectual capacity or otherwise of the other race.⁸⁸⁷ This is sometimes related to the inability to accept the otherness of the other,⁸⁸⁸ such as occurs in situations where xenophobia and other racial biases exist. Similarly, in a country like South Africa or Nigeria, ancestral beliefs systems including ancestor worship which is prevalent amongst Bantu speaking peoples.⁸⁸⁹ This may impact negatively on patients' acceptance of factual medical or healthcare disclosures, if such individuals harbour the false or real belief that their illness are caused by the ancestors or evil spirits.^{890, 891,892}

As illustrated in the English case of *Re MB*,⁸⁹³ where the court opined that a misperception of reality, such as the blood is poisoned because it is red; could result in some impairment or disturbance of mental functioning, which renders the person unable to make a decision whether to consent to or refuse treatment.⁸⁹⁴

⁸⁸⁶ Sugarman J et al "Evaluating the quality of informed consent" 2005 *Clinical Trials* 34-41.

⁸⁸⁷ Beauchamp and Childress *Principles of biomedical ethics* 91-92.

⁸⁸⁸ Chima SC "Religion politics and ethics: Moral and ethical dilemmas facing faith-based organizations and Africa in the 21st century-implications for Nigeria in a season of anomie" 2015 *Niger J Clin Pract* S1-S7.

⁸⁸⁹ Dan-Fulani UHD "Religious conflict on the Jos Plateau: The interplay between Christianity and traditional religion during the early missionary period" 2001 *Swedish Missiological Themes* 8-40.

⁸⁹⁰ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

⁸⁹¹ Booyens JH "Traditional health care in South Africa- Diverse ideas and convergent practice" 1991 *Koers* 479-497.

⁸⁹² Bogopa D "Health and Ancestors: The case of South Africa and beyond" 2010 *Indo-Pacific Journal of Phenomenology (IPJP)* 1-7.

⁸⁹³ *Re MB* (1997) 2 FLR 426.

⁸⁹⁴ *Re MB* (1997) 2 FLR 426 [437].

2.11 Consent, agreement or authorization of treatment

Having evaluated all the key elements of informed IC as described above, a patient can legally authorize or give permission for the proposed treatment or otherwise refuse to authorize the proposed treatment. As previously defined, IC is an autonomous authorization by a patient to accept or refuse a medical intervention. Based on this definition, the US Department of Health and Human Services (DHHS) regulations require that consent should be sought “only under circumstances that provide the prospective patient or patients legally authorized representative, sufficient opportunity to consider whether or not to give permission, and that HCPs must minimize the possibility of coercion or undue influence.”⁸⁹⁵

Similarly, the English Department of Health (DOH) has set out requirements for consent, which include the absence of coercion.⁸⁹⁶ Therefore, before a patient can give valid consent in the context of medical treatment, this requires that a patient’s decision must be made without any form of coercion or undue influence. Undue influence was classically demonstrated in *Re T*,⁸⁹⁷ where Lord Donaldson held that it was lawful to have transfused a Jehovah’s Witness patient in order to save her life, despite her refusal of consent. Here the court was of the opinion that the patient’s refusal to give consent was unduly influenced by her mother’s wishes, who was a staunch Jehovah’s Witness, in contrast to her ailing daughter, for whom evidence from close relatives were that, had she not been influenced by her mother, she would have given consent to save her life if she had the capacity to do so. In this case, the court overrode the patient’s refusal by stating that it was not a ‘valid or real refusal’ because the patient’s will was “overborne” by that of her mother.⁸⁹⁸

⁸⁹⁵ Appelbaum PS, Lidz CW and Meisel A “Consent to research” in *Informed consent: Legal theory and clinical practice* (Oxford University Press Oxford 1987) 211-237.

⁸⁹⁶ DOH *Guidelines on consent: Reference guide to consent for examination or treatment* (HMSO London 2001). See also Hocton *Law of consent to treatment* 164-183.

⁸⁹⁷ *Re T* (An adult): Consent to Medical Treatment [1992] 2 FLR 458.

⁸⁹⁸ *Re T* (An adult): Consent to Medical Treatment [1992] 2 FLR 458 [113-114] see also Grubb et al *Principles of Medical Law* 534.

Further, the question of justifying or identifying whether consent is 'real' or valid also brings up the moral issue of consenting to illegal, immoral or ethically questionable activities. In analysing these issues, Cathell J in *Grimes v KKI*⁸⁹⁹ put it this way:

One can say first, consent is justified whatever it consents to, so case closed, second, this particular consent is deficient-you did not really consent and so the result or action is not justified, or third, you consented, but your consent cannot justify the action or result [...]⁹⁰⁰

Similarly, it has been argued that one can only consent to what is socially or morally acceptable or justifiable, based on public policy, law or custom. Real or valid consent can only apply to what is morally acceptable within a particular society's "*boni mores*".^{901,902} Whatever is consented to generally has to be consistent with good morals, public good or accepted cultural values.⁹⁰³

2.12 So, what is valid or true consent?

Having analysed the various legal, ethical, and moral issues, which may affect the validity of consent. One may now attempt to define what constitutes valid IC:

Valid, true or real consent to medical treatment may be described as a voluntary and autonomous authorization by a competent individual after disclosure of all material risks by the HCP, with full understanding by the patient, in the absence of any physical or moral pressure or undue influence.

To put it another way, any form of undue influence, misrepresentation of facts, non-disclosure of material risks, or lack of capacity to consent either by virtue of age, or mental incapacity due to any organic/inorganic/temporary/permanent incapacitation, fraud or lack

⁸⁹⁹ Grimes v KKI 2000.

⁹⁰⁰ Grimes v KKI [88] citing Garnett RW "*Why informed consent? Human experimentation and the ethics of autonomy*" 1996 *Catholic Lawyer* 455-512 [459].

⁹⁰¹ Carstens and Pearmain *Foundational Principles* 308.

⁹⁰² Slabbert MN "South Africa" in *International encyclopaedia of laws: Medical law* Nys H and Aan den Rijn A (eds) (Wolters Kluwer Netherland 2014) 69.

⁹⁰³ Chima *A primer on medical law* [88] see also Dyer C "Surgeon amputated healthy legs" 2000 *BMJ* 332.

of time to fully consider the implications of consenting, may render consent invalid. Valid consent may also be given by a person with proxy responsibility under applicable laws, but is also subject to validity based on the above criteria being fulfilled. Similarly, a person with parental responsibility may give consent for minor under the age of consent although the minor's assent should be obtained as well.

However, where an individual is considered a 'mature minor', he or she may consent to his or her own treatment. Further, minors who are within the accepted age of consent (currently 12 years in South Africa);⁹⁰⁴ may consent on their own behalf to routine medical treatment, but may not necessarily be able to refuse all treatment since such refusal can be overridden by the parent, guardian, or a court of law as the case may be, because the court is considered the upper guardian for children. Generally, where there is a dispute on the children's consent or refusal, court opinion must be sought. This requirement was demonstrated in some American cases such as *Strunk v Strunk*⁹⁰⁵ where a mentally incompetent organ donor who was nominated to donate an organ to a sibling was granted permission to consent, through the parents, by the court to allow transplant of one kidney from mentally incompetent adult to 26-year old healthy sibling. Similarly, in *Hart v Brown*,⁹⁰⁶ court intercession and permission was sought to transplant one kidney from 7-year old to an identical twin. In another case, *Bonner v Moran*,⁹⁰⁷ court permission was sought for a skin graft from a minor donor to a cousin. In all the above cases, consent was granted by the courts, based on humanitarian as well as other legal reasons. It is possible that these situations may be addressed by court jurisdiction in the 'best interests' of the minor as suggested by Lord Donaldson in *Re W*.⁹⁰⁸

There can therefore be no doubt that [the court] has the power to override the refusal of a minor whether over the age of 16 or under that age but Gillick competent... such a refusal is a very

⁹⁰⁴ Children's Act 38 of 2005.

⁹⁰⁵ *Strunk v Strunk* (445 S.W.2d 145) 1969.

⁹⁰⁶ *Hart v Brown* 29 Conn Supp. 368, 289 A 2d (1997).

⁹⁰⁷ *Bonner v Moran* 75 US App DC 156, 126 F 2d 121 (1941).

⁹⁰⁸ *Re W* (A minor) (Medical treatment: Courts discretion) [1992] 2 WLR 758.

important consideration in making clinical judgments and for parents in deciding whether themselves to give consent. Its importance increases with the age and maturity of the minor.⁹⁰⁹

Any such consent or refusal, which does not have the support of appropriate legal authority, may be considered invalid. For adults lacking the capacity to consent, UK law stipulates that no other individual can give consent except as established by the *Mental Capacity Act 2005*.⁹¹⁰ To all intents and purposes, such individuals must be treated under the doctrine of 'best interests'.⁹¹¹ Similar criteria are used in other jurisdictions such as the where a surrogate's consent to treatment may be given by a legally responsible adult based on kin-ship relationships,⁹¹² or individuals with power of attorney or a similar person. Consent given while the patient is fully capable, in a 'living will' or 'advance directives', for example where a person consents to donate their body or remains for research or anatomical demonstration after death, may also be legally valid, though any limitations must be adhered to.⁹¹³ These guidelines are also consistent with the law as outlined sections 6 to 9 of the NHA.⁹¹⁴

In addition and by way of comparison, the UK GMC has described valid consent as follows: "Patients consent is legally valid and professionally accepted only where patients are competent to give consent, have been properly informed, and have agreed without coercion."⁹¹⁵ Finally, phrasing it in another way, informed consent may be described as the social rules of consent in institutions that must obtain legally valid consent, such as HCPs from patients. Any consent, which is not obtained within legally defined rules of obtaining consent, is therefore invalid.

⁹⁰⁹ Re W (A minor) (Medical treatment: Courts jurisdiction) [1993] Fam 64 [83] see also Re L (Medical treatment: Gillick competency) (1998) 2 FLR 810.

⁹¹⁰ UK Mental Capacity Act 2005.

⁹¹¹ UK Children's Act 1989 see also Hocton *Law of consent to treatment: Children and parents* 74-94.

⁹¹² National Health Act 61 of 2003 s7.

⁹¹³ National Health Act 61 of 2003 s8.

⁹¹⁴ National Health Act 61 of 2003 s6-9.

⁹¹⁵ GMC Good medical practice 2013 <https://www.gmc-uk.org/guidance/index.asp> (Date of use: 12 November 2017).

2.13 Types of consent and the validity of consent forms

Validity of consent is not dependent upon the form in which it is given. There is no requirement in law that consent should be in writing, except when this has been legally specified e.g. in the conduct of biomedical research in South Africa.⁹¹⁶ The UK DOH⁹¹⁷ has recommended the use of consent forms as good practice where interventions, such as surgery, are planned. Similarly, the US Code of Federal regulations,⁹¹⁸ as well as the CIOMS guidelines,⁹¹⁹ and the Declaration of Helsinki,⁹²⁰ all consider this good practice in the research setting. Proplewell J, however, demonstrated the limits of written consent for surgical procedures in *Taylor v Shropshire*⁹²¹ where he stated that:

For my part I regard the consent form immediately before operation as pure window dressing in this case and simply designed to avoid the suggestion that a patient has not been told. I do not regard the failure to have specialized consent form at the time to be any indication of negligence.⁹²²

Similarly, Bristow J stated in *Chatterton v Gerson* as follows:⁹²³ “Getting the patient to sign a proforma expressing consent...would be no defence to an action based on trespass, if no explanation had in fact been given [and] consent obtained in ‘form only’ is no consent at all”.⁹²⁴

Lord Donaldson MR in *Re T* explained with regard to consent forms authorizing or refusing blood transfusion as follows: “They will be wholly ineffective...if the patient is incapable of understanding them, they are not explained to him and there is no good evidence (apart from the patients signature) that he had that understanding and fully appreciated the

⁹¹⁶ National Health Act 61 of 2003 [s11].

⁹¹⁷ DOH *Guidelines on consent to treatment or examination* (HMSO London 2001) see Hocton *Law of consent to medical treatment* [164-176].

⁹¹⁸ United States Government *US Code of Federal Regulations* 45 CFR 46.116

⁹¹⁹ Council for International Organizations of Medical Sciences *International ethical guidelines for biomedical research involving human subjects* (CIOMS-WHO Geneva 2016).

⁹²⁰ World Medical Association *Declaration of Helsinki-Ethical principles for medical research involving human subjects as amended at Fortaleza Brazil 2013* (WMA Geneva 2013).

⁹²¹ *Taylor v Shropshire Health Authority* [1998] Lloyds Rep Med 395 QBD.

⁹²² *Taylor v Shropshire Health Authority* [1998] Lloyds Rep Med 395.

⁹²³ *Chatterton v Gerson* [1981] All ER 257.

⁹²⁴ *Chatterton v Gerson* [1981] All ER 257 [265H].

significance of signing it.”⁹²⁵ Therefore for the patients consent to amount to valid legal defence against trespass or negligence, the consent may be express, implied, oral or written, or part oral-part written, so long as the conditions described under valid consent above have been fulfilled. The signing of consent forms, however, is a legal requirement in accordance with certain statutory laws and regulations, such as the UK *Mental Health Act 1983*⁹²⁶ and the *Human Fertilization and Embryology Act (HFEA) 1990*.⁹²⁷ Where a patients’ capacity is in doubt, the patient’s DMC to validly sign a consent form must be ascertained in accordance with the *Mental Capacity Act 2005*.⁹²⁸ Furthermore, in South Africa, the HPCSA suggests that written consent should be obtained in the following circumstances:

Except in an emergency, where the patient has the capacity to give consent HCPs should obtain written consent in the following cases, although this list is not exhaustive: (a) Where the treatment or procedure is complex or involves significant risks and/or side effects; (b) Where providing clinical care is not the primary purpose of the investigation or examination; (c) where there may be significant consequences for the patient's employment, social or personal life; (d) where the treatment is part of a research programme.⁹²⁹

One legal scholar asserts that hospital consent forms may impose contractual obligations between the doctor and the patient, which allow exclusion from any indemnities or failures that arise during medical treatment.⁹³⁰ However, one disagrees with this last observation, because as previously explained, consent agreements between doctors and patients creates a special relationship, which goes beyond the usual arm’s length contracts,⁹³¹ in the sense that usually the HCP cannot unilaterally withdraw from a patients’ consented treatment while the patient still retains that right even after signing a consent form-the right to withdraw at any time from the proposed medical treatment.⁹³² Interestingly, the United

⁹²⁵ Re T (1992) 4 All ER 649 [668].

⁹²⁶ UK Mental Health Act 1983.

⁹²⁷ UK Human Fertilization and Embryology Act 1990.

⁹²⁸ UK Mental Capacity Act 2005.

⁹²⁹ HPCSA *Guidelines for good practice in the healthcare professions- Seeking patients informed consent: The ethical considerations* (HPCSA Pretoria 2008) Booklet 9.

⁹³⁰ Van Dokkum N “Hospital consent forms” 1996 *STELL LR* 249-255.

⁹³¹ Moore v Webb 1961 345 SW 2d 239 (MO App).

⁹³² Mclean AR *Consent to medical treatment and the competent adult* [132-161].

States code of federal regulations⁹³³ has stipulated that any exculpatory statements contained in consent forms, especially with regard to biomedical research, would have the effect of rendering such an agreement or consent invalid.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.⁹³⁴

2.13.1 Implied or inferred consent

Consent could be implied or inferred based on a patient's conduct. For example, when a patient holds out his or her arm for the administration of an injection as demonstrated in the case of *O'Brien v Cunard*.⁹³⁵ In this classical case, a patient joined a queue on a ship and extended her arm to receive immunization from the ship's doctor, but later sued the doctor based on trespass to the person. The court held that her actions implied consent whatever her unexpressed feelings might have been, although there were other corroborative evidence, such as wide advertisement of the place and time for the vaccination exercise on the ship in question. Other authorities have suggested that consent may have been inferred from her behaviour, as consent is a state of mind personal to a patient, whereby he or she agrees or gives permission to a HCP to interfere with his or her bodily integrity.⁹³⁶ However, since it is not possible to determine what the patient's state of mind is, one can draw an inference from his or her behaviour or actions.⁹³⁷ Silence on the part of the patient however, does not necessarily imply consent, as argued in the case of *Schweitzer v Central Hospital*.⁹³⁸ Consent can also not be inferred where the patient is incompetent. In such cases the patient is treated based on the 'best interests' standards. According to the UK Mental Health Act 1983, " the consent of a

⁹³³ United States Government *US Code of Federal Regulations* 45 CFR 46.116.

⁹³⁴ US Code of federal regulations 45 CFR 46.116 *General requirements for informed consent* <https://www.law.cornell.edu/cfr/text/45/46.116> (Date of use: 23 April 2016).

⁹³⁵ *O'Brien v Cunard SS Co* [1891] 28 NE 266 (Supreme Court of Massachusetts).

⁹³⁶ Mclean AR *Consent to medical treatment and the competent adult* [132-161].

⁹³⁷ Grubb et al *Principles of medical law* [455-458].

⁹³⁸ *Schweitzer v Central Hospital* (1974) DLR (3d) 494.

patient shall not be required for any medical treatment given to him for the mental disorder from which he is suffering...if the treatment is given under the direction of the approved clinician in charge of the treatment.”⁹³⁹ According to Lord Goff in *Re F*, lawfulness of treatment under such circumstances is derived from the principle of necessity, “the doctor has to act in the best interests of the assisted person. In the case of routine treatment of mentally disordered persons, there should be little difficulty in applying this principle.”⁹⁴⁰

The Health Professions Council of South Africa (HPCSA), states as follows with regard to implied consent:

Health care practitioners should be careful about relying on a patient's apparent compliance with a procedure as a form of consent. Submission in itself may not necessarily indicate consent. For example, the fact that a patient lies down on an examination couch does not indicate that the patient has understood what the health care practitioner proposes to do and why. Consent must at all times be expressed and not implied.⁹⁴¹

2.13.2 Express consent

Express consent occurs where the consent is given once without limitations to its use. It extends through the entire transaction including all its consequences. In this case, the patient must:

- (a) Have had knowledge and been aware of the nature and extent of the harm or risk
- (b) Must have appreciated and understood the nature and extent of the harm or risk
- (c) Must have consented to the harm or assumed the risk, and
- (d) The consent must be comprehensive that it extends to the entire transaction inclusive of all its consequences.⁹⁴²

⁹³⁹ Mental Health Act (United Kingdom 1983) Part IV.

⁹⁴⁰ *Re F* (1990) 2 AC 1 [78].

⁹⁴¹ HPCSA *Guidelines for good practice in the healthcare professions- Seeking patients informed consent: The ethical considerations* (HPCSA Pretoria 2008).

⁹⁴² Carstens and Pearmain *Foundational Principles* [479-480].

2.13.3 Presumed consent

This occurs where the individual gives consent and it is assumed that this patient has given consent for all purposes, unless he or she chooses to 'opt out' if he or she does not consent to other uses or future activities. This type of consent has recently been applied in jurisdictions attempting to increase organ donations, where patients are presumed to have given consent, except where they 'opt out'.⁹⁴³ However, it would be wrong to presume that simply when a patient shows up to the clinic or hospital or consulting rooms or is admitted to a hospital ward, that they have somehow impliedly consented to whatever a doctor or HCP decides to do, as observed by the HPCSA above,⁹⁴⁴ and neither can it be presumed that they have consented to all types of treatment or physical contact from the HCP. As noted by Watermeyer J in *Stoffberg v Elliot*.⁹⁴⁵

A man by entering a hospital does not submit himself to such surgical operations as the doctors in attendance upon him might think necessary...by going into hospital he does not waive or give up his right of absolute security of the person...he retains his rights of control and disposal of his own body; he still has the right to say what operation he will submit to, and unless consent to an operation is expressly obtained, any operation performed on him without his consent is an unlawful interference with his right of security and control of his own body.⁹⁴⁶

2.13.4 Open or Broad consent and other types of consent related to DNA biobanking

Open consent refers to the situation where a person gives future consent to the use of his bodily fluids or tissues containing DNA, to a biobank or for personal genomic studies, pending the discovery of new ways of dealing with such material.⁹⁴⁷ This type of consent

⁸⁴⁰ A report of the presumed consent subcommittee on ethics. *An evaluation of the ethics of presumed consent* (US Department of Health and Human Services). <https://optn.transplant.hrsa.gov/resources/ethics/an-evaluation-of-the-ethics-of-presumed-consent/> (Date of use: 16 April 2016).

⁹⁴⁴ HPCSA *Guidelines for good practice in the healthcare professions- Seeking patients informed consent: The ethical considerations* (HPCSA Pretoria 2008) Booklet 9.

⁹⁴⁵ *Stoffberg v Elliot* 1923 CPD 148.

⁹⁴⁶ *Stoffberg v Elliot* 1923 CPD 148-150. See also Carstens and Pearmain *Foundational principles* [500].

⁹⁴⁷ Liddell K and Skopek JM "Informed consent for research using biospecimens, genetic information and other personal Data" University of Cambridge Faculty of Law Legal Studies

has acquired additional implications with the advent of new biotechnologies such as DNA storage and analysis and tissue bio-banking, especially with the advent of the Human Genome project, Personal Genome project, International Hap Map project and Genome-wide association studies (GWAS).⁹⁴⁸ It has been asserted that ‘human subjects’ research no longer consists primarily of research on people, as advances in big data and biobanking have transformed the research landscape.⁹⁴⁹ Much research now focuses on personal data and bio-specimens, some of which is collected a long time ahead of the research and initially for other purposes. This shift has given rise to difficult questions about how to apply legal and ethical principles that were developed to govern biomedical research on people.⁹⁵⁰ The implications of this type of consent has created new controversies, ethical debate and moral dilemmas because of the on-going process of establishing human DNA databases in countries such as Iceland, Estonia, Tonga as well as the UK Biobank and others.⁹⁵¹ It is also has implications for tissue bio banking generally, with future and current implications for regulations regarding individual confidentiality, privacy and the process of IC, especially in the context of human biomedical research.⁹⁵² Some of the moral and ethical issues arising from these new developments include:

- a) Personal data and bio-specimens are increasingly at the centre of research, giving rise to difficult questions about whether and how to apply legal and ethical principles that were originally developed for a research model in which people were at the core.
- b) The requirement to obtain informed consent for research on personal data and bio-specimens can be grounded in many of the same considerations that justify requiring consent for research on people—e.g. autonomy, distributive justice and public policy, although there could be important differences in the application of these ethical principles.

Research Paper Series Number 27/2017) <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

⁹⁴⁸ Lunshof JE et al “From genetic privacy to open consent” 2008 *Nature Rev Genet* 406-411.

⁹⁴⁹ Lunshof et al 2008 *Nature Rev Genet* 406-411. See also Liddell and Skopek <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

⁹⁵⁰ Liddell and Skopek <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

⁹⁵¹ Hallinan D and Friedewald M “Open consent, biobanking and data protection law: Can open consent be ‘informed’ under the forthcoming data protection regulation? 2015 *Life Sci Soc Policy* doi.10.1186/s40504-014-0020-9.

⁹⁵² Chima SC and Mamdoo F “Ethical and regulatory issues surrounding umbilical cord blood banking in South Africa” 2011 *SAJBL* 79-84.

- c) The requirement of “specific consent” appears to be a poor fit for long-term research on personal data and bio-specimen; since the future research uses will often be inconceivable at the time of obtaining IC, thereby raising questions about whether alternative models, such as broad or dynamic consent, would be preferable options.
- d) The fact that research using genetic material and information will often reveal information about both the individual donor and a broader group of related individuals,⁹⁵³ has generated controversial proposals for requiring “community consent” in addition to individual consent.
- e) While the anonymization of personal data and bio-specimens may eliminate the requirement to obtain IC based on regulatory requirements, this approach has been criticized potentially infringing the informational autonomy of the sources and undervaluing the potential harms of re-identification, which could reduce the public’s trust in biomedical research.
- f) Stating that they did not consent to commercialization or patent protection is one of several ways individuals have sought to limit how their bio-specimens are used and commercialized; another approach has been to claim residual property rights in their bio-specimens.⁹⁵⁴

The moral dilemmas arising from these new biotechnologies have arisen because current IC regulations require that the nature, purpose and methods to be used be disclosed to any potential research subjects prior to IC.⁹⁵⁵ However in the case of human DNA and genome studies, it is possible and generally acknowledged that the potential consequences of future use of such materials cannot be fully anticipated during and prior to the collection of tissues containing human DNA.⁹⁵⁶ Therefore, all the potential future uses cannot be anticipated or disclosed, creating conflicts with current IC regulations and the potential for abuse of personal information, confidentiality and privacy.⁹⁵⁷ Due to these moral and ethical dilemmas, new types of consent have been suggested such as:

- (a) **Presumed consent** - also called democratic community consent; whereby the individual is not usually asked to give consent, but has the option to ‘opt-out’ in the future if they do not want to participate in the project. This type of consent has been

⁹⁵³ Chima and Mamdoo 2011 *SAJBL* 82.

⁹⁵⁴ Liddell and Skopek <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

⁹⁵⁵ US Code of federal regulations 45 CFR 46.116 *General requirements for informed consent* <https://www.law.cornell.edu/cfr/text/45/46.116> (Date of use: 23 April 2016).

⁹⁵⁶ Grady C et al “Broad consent for research with biological samples: Workshop conclusions” 2015 *AJOB* 34–42.

⁹⁵⁷ Hallinan and Friedewald *Life Sci Soc Policy* doi.10.1186/s40504-014-0020-9.

used to increase general participation in organ donation, or to collect nationwide genomic information and DNA samples, as was done in Iceland.^{958,959}

- (b) **Dynamic consent** - refers to a 'personalised, digital communication interface' which allows biobank or researchers to establish continuous communication with human research subjects whereby research participants can be presented with specific project information and then, be able to continuously tailor their consent preferences according to their desires and needs.⁹⁶⁰ Dynamic consent has however been criticized for being inefficient, with the potential to burden human research subjects, exacerbate therapeutic misconceptions, and over-individualize ethical reviews.⁹⁶¹
- (c) **Sectoral consent** - This refers to a situation where human research subjects can give consent to a specific project or research area while refusing or denying use of their donated tissues or DNA for other projects outside of the specified area without additional IC.⁹⁶²
- (d) **Open or Broad consent**⁹⁶³ - Of all the proposed new forms of consent, 'open consent', also known as 'broad consent', 'general consent' or 'blanket consent' appears to differ significantly from the accepted model of IC.⁹⁶⁴ Multiple definitions of open consent have been proposed including one by Lunshof et al,⁹⁶⁵ who defined 'open consent' in relation to the Personal Genome Project in the following way:

Open consent means that volunteers consent to unrestricted [research] re-disclosure of data originating from a confidential relationship, namely their health records, and to

⁹⁵⁸ Árnason V and Árnason G "Informed democratic consent? The case of the Icelandic database" 2004 *Trames* 164–177.

⁹⁵⁹ Rithalia et al "Impact of presumed consent for organ donation on donation rates: Systematic review" 2009 *BMJ* doi: <http://dx.doi.org/10.1136/bmj.a3162>.

⁹⁶⁰ Kaye et al "Dynamic consent: A patient interface for twenty-first century research networks" 2015 *EJHG* 141-146.

⁹⁶¹ Steinsbekk KS, Myskja BK and Solberg B "Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?" 2013 *EJHG* 21 897-902.

⁹⁶² American Society of Human Genetics "Statement on informed consent for genetic research" 1996 *Am J Hum Genet* 471-474.

⁹⁶³ Grady et al 2015 *AJOB* 15 34-42.

⁹⁶⁴ Hallinan and Friedewald 2015 *Life Sci Soc Policy* doi:10.1186/s40504-014-0020-9.

⁹⁶⁵ Lunshof et al 2008 *Nature Rev Genet* doi: 10.1038/nrg2360 [5].

unrestricted [research] disclosure of information that emerges from any future research on their genotype-phenotype data set, the information content of which cannot be predicted.⁹⁶⁶

Further, in relation to population-based biobanks, Nomper has defined ‘open consent’ as “the research subject’s affirmative agreement to participate in a population genetic database and in research projects that use tissue and data from that database.”⁹⁶⁷ Similarly, the recently codified US federal regulations for protection of human subjects which comes into effect in January 2018,⁹⁶⁸ requires that research subjects be informed if their bio-specimens may be used for commercial profit and whether or not they are likely to share in this profit.⁹⁶⁹ This inclusion in the new ‘Common Rule’ probably arose from the contrasting judgments by two United States High Courts in the *Moore* case,⁹⁷⁰ and *Greenberg v Miami Children’s Research Hospital*.⁹⁷¹ In the former case, the California Supreme Court held that physician-researchers must inform patients about economic rights or interests prior to obtaining informed consent, while in the latter case a United States Federal Court sitting in Florida held that this did not apply in a purely research context.⁹⁷² Whilst there may be certain differences between the different definitions of ‘open consent’, there are certain core concepts, which are common across all definitions. These characteristics differentiate ‘open consent’ from other forms of consent. The salient features are as follows:

- i. The human research subject usually gives consent only once to the biobank or to the data or tissue collector.
- ii. The research participant is not usually required to give IC to a specific research project, or to a particular project or research area. The participant gives consent to the use of their tissue sample or DNA and data for all future research purposes; without knowing which research projects, research areas, or technologies, for which the sample will be used, because sometimes even the biobank or researcher

⁹⁶⁶ Lunshof et al 2008 Nature Rev Genet doi: 10.1038/nrg2360 [5].

⁹⁶⁷ Nomper A *Open consent - A new form of informed consent for population genetic databases* (Doctor Juris dissertation University of Tartu 2005).
<http://dspace.ut.ee/bitstream/handle/10062/818/nomper.pdf> (Date of use: 23 April 2016).

⁹⁶⁸ Federal policy for the protection of human subjects 2017 US Federal Register 82 7149-7274.

⁹⁶⁹ Liddell and Skopek <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

⁹⁷⁰ *Moore v Regents of the University of California* 51 Cal 3d 120 (CA 1990).

⁹⁷¹ *Greenberg v Miami Children’s Research Hospital* 264 F sup 2d 1064 (SD Florida 2003).

⁹⁷² Liddell and Skopek <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

may not be able to predict the potential future uses of the collected sample in the future.

- iii. In most biobanks operating based on 'open consent', researchers wishing to conduct research on samples generally have to apply to the biobank for the opportunity to use stored tissue and data. The biobank through its governance mechanisms will then decide whether a research project will be permitted to use the requested material. The research subject plays no role in this decision.

Open consent has become the most widely used of the new forms of consent because of certain reasons, including the fact that it has the maximum research utility, by allowing the most possible amount of data to be extracted from the tissue or DNA sample since there are no restrictions. Further, the consent procedure demands minimal administrative effort, since based on a singular meeting with the research participant/human subject; permission can be sought and granted, and consent forms signed for all future usage. It has been reported that open consent has become popular with population biobank projects, such as the Estonian gene bank where the consent form simply states that: "By signing this document, I give my free and informed consent to... have the tissue sample, description of my state of health and my genealogy entered in the Gene Bank in coded form. The use thereof for genetic, public health research, statistical and other purposes in accordance with the law."⁹⁷³ Similarly, the donor consent form for the UK Biobank simply states, "I give permission for long-term storage and use of my blood and urine samples for health-related research purposes (even after my incapacity or death)".⁹⁷⁴

The ethical implications of open/presumed/ sectoral/dynamic consent which individuals are forced to comply with, either because of local laws and regulations, lack of understanding of giving such consent when the uses have not been clearly stated, have not been clearly established. Based on the IC guidelines described above, these types of consent may not fulfil the criteria for valid or true IC because the patients are not informed

⁹⁷³ TÜ Eesti Geenivaramu *Gene Donor Consent Form* (Gene Bank Estonia 2007)

⁹⁷⁴ Biobank UK *Consent Form: UK Biobank 2013*
http://www.ukbiobank.ac.uk/wpcontent/uploads/2011/06/Consent_form.pdf (Date of use: 05 June 2014).

of any new changes in information derived from the patients tissues or DNA, which would ordinarily render such IC invalid. However, these types of consent are still being applied in certain jurisdictions, not only for research but for medical treatment as well. It has been rightfully argued that such types of consent may be inconsistent with current EU laws and directives regarding confidentiality, data protection, information disclosure and privacy, and that these laws and regulations may need to be modified, if the open consent model can be made compliant with current laws and regulations.^{975,976,977, 978}

Another area of debate is the right of individuals who may be diagnosed with rare disorders affecting other members of the community or other family members. The moral and ethical dilemma on how to balance the privacy and self-determination rights of the individual consenting against the rights of others, who might benefit from that information either now or in the future, arises.⁹⁷⁹ The implications of open consent for new biotechnologies have been discussed by commentators such as Kegley,⁹⁸⁰ who has argued that, “new scientific discoveries and new technologies will soon challenge our old ways of proceeding and thinking. It is no surprise then that new knowledge in molecular genetics and the ensuing developments in genetic technology bring with them new modes of thought, not just in science and medicine, but also in ethics, law and public policy.”⁹⁸¹ The above statement has implications not only for on-going discoveries in DNA biotechnology, but for medical treatment and forensic science such as paternity tests and criminal prosecutions, as well as for gene therapy and cloning, including DNA and tissue

⁹⁷⁵ Hallinan and Friedewald 2015 *Life Sci Soc Policy* doi.10.1186/s40504-014-0020-9.

⁹⁷⁶ European Commission “Proposal for a regulation of the European parliament and of the council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)” (European Commission 2012).

⁹⁷⁷ European Commission “Impact assessment accompanying the general data protection regulation” SEC 72 final (European Commission 2012).

⁹⁷⁸ European Parliament and Council Directive 95/46/E “On the Protection of individuals with regard to the processing of personal data and on the free movement of such data” (European Union 1995).

⁹⁷⁹ Chima and Mamdoo 2011 *SAJBL* 81-83.

⁹⁸⁰ Kegley JAK “Challenges to informed consent: New developments in biomedical research and healthcare may mark the end of the traditional concept of informed consent” 2004 *EMBO Reports* 832-836.

⁹⁸¹ Kegley JAK 2004 *EMBO Reports* 832.

bio banking in South Africa and elsewhere.^{982,983} However it must be noted that under the UK Human Fertilization and Embryology Authority (HFEA) regulations, consent for storage and use of gametes must be in writing after requirements for consent and parental donors have been fulfilled.⁹⁸⁴ In addition, the UK Human Tissue Act (HTA) established a criminal offence for the crime of ‘DNA theft’.⁹⁸⁵ According to Lunshof et al:

Open consent means that volunteers consent to unrestricted re-disclosure of data originating from a confidential relationship, namely their health records, and to unrestricted disclosure of information that emerges from any future research on their genotype–phenotype data set, the information content of which cannot be predicted. No promises of anonymity, privacy or confidentiality are made.⁹⁸⁶

Some authors have suggested that the leading moral principle in this case should be veracity or truth telling which ideally should precede autonomy. Although in medicine truth telling is the required moral and legal norm in many jurisdictions, doctors and other HCPs may try to justify the withholding of information by invoking the controversial ‘therapeutic privilege’ exception as previously discussed.⁹⁸⁷ Albeit, in biomedical research, there is no such privilege arguably allowed by law when seeking informed consent during biomedical research. Generally, distorted or incomplete information disclosure could undermine trust in researchers and in science. It has been argued that this leaves individuals consenting, open to breach of confidentiality and infringement of their right to privacy and dignity, which are all against international ethical codes and local regulations, and may require new or modified regulations to protect potential human research subjects and patients.^{988,989,990}

982 Chima and Mamdoo 2011 *SAJBL* 79-84.

983 Liddell and Skopek <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

984 Grundy R et al “Fertility preservation for children treated for cancer: ethics of consent for gamete storage and experimentation” 2001 *Arch Dis Child* 360–362.

985 UK Human Tissue Act 2004.

986 Lunshof 2008 *Nature Rev Genet* doi: 10.1038/nrg2360 [5].

987 Van Oosten 1991 *Med Law* 31-41 see also Chima *Trans J Coll Med S Afr* 44.

988 Chima *Consent and patients’ rights* [32-52].

989 Hallinan and Friedewald 2015 *Life Sci Soc Policy* doi.10.1186/s40504-014-0020-9.

990 Liddell and Skopek <http://www.law.cam.ac.uk/ssrn/> (Date of use: 24 September 2017).

2.14 Limits, duration, withdrawals, and refusal of consent

For consent to be truly autonomous, then any patient giving consent must be free to withdraw such consent at will. When a subject gives IC for a medical intervention or research, until such a time as the patient/subject withdraws such consent; it remains valid. The UK GMC recommends that HCPs should inform a patient when there is a change surrounding the circumstances for which consent was given.^{991,992} The requirement for renewal of consent was demonstrated by a US court in the case of *Mohr v Williams*,⁹⁹³ where the court found a surgeon negligent for operating on a patient's left ear, when in fact permission was given only for operation on the right ear. Similarly, in *Williamson v East London and City HA*,⁹⁹⁴ Butterfield J found surgeons negligent in performing more extensive surgery than the patient had consented to. Therefore a patient's consent to treatment is only limited to what has been consented to and no more can be done without additional consent even if the doctor considers it to be in the patient's best interests to do so.

According to the Royal College of Obstetricians and Gynaecologists (RCOG) guidance document, "[w]ith the exception of an unanticipated emergency, the practitioner should not exceed the scope of the authority given by the patient."⁹⁹⁵ This is of course subject to the exceptions, which have been described above, such as emergency, waiver, *negotiorum gestio*, amongst others. Therefore, a patient with DMC is entitled to withdraw consent at any time, including during the procedure without reprisal as demonstrated in the Canadian case of *Ciarlariello v Schactr*:⁹⁹⁶

An individual's right to determine what medical procedures will be accepted must include the right to stop a procedure...It is not beyond the realm of possibility that the patient is better able to gauge the level of pain or discomfort that can be accepted or that the patient's premonitions of tragedy or

⁹⁹¹ UK General Medical Council *Good medical practice 2013* <https://www.gmc-uk.org/guidance/index.asp> (Date of use: 12 November 2017).

⁹⁹² UK GMC *Consent: patients and doctors making decisions together* (GMC London 2008).

⁹⁹³ *Mohr v Williams* (1905) 104 N.W. 12 (Sup Ct Minnesota).

⁹⁹⁴ *Williamson v East London and City HA and Others* [1998] Lloyds Law Rep Medical 6.

⁹⁹⁵ RCOG *Obtaining valid consent clinical governance advice* No. 6 (Royal College of Obstetricians & Gynaecologists London 2015).

⁹⁹⁶ *Ciarlariello v Schactr* (1993) 1000 DLR 4th 609 (SCC).

mortality may have a basis in reality. In any event, the patient's right to bodily integrity provides the basis for the withdrawal of consent to a medical procedure even while it is underway. Thus, if it is found that the consent is effectively withdrawn during the course of the procedure, then it must be terminated.⁹⁹⁷

Generally, if an adult with capacity makes a voluntary and informed decision to refuse treatment, this decision must be respected except when there are legally acceptable reasons such as those contained in the UK Mental Health Act 1983 or the South African Mental Healthcare Act.⁹⁹⁸ However limitations have been placed on reliance on the UK Mental Health Act as a mechanism for the involuntary treatment of patients, based on the judgment of the *European Court of Human Rights* (ECtHR) in *HL v UK* (The Bournemouth case).⁹⁹⁹ This case involved the detention of a 49-year old autistic man without DMC, in his own best interests. The ECtHR overturned the UK House of Lords decision by indicating the patient's detention was at variance with the "right to liberty" as enshrined in the ECHR.¹⁰⁰⁰ Further, it held that detention under the common law and the Mental Health Act¹⁰⁰¹ were incompatible with Article 5 of the ECHR, because it was too arbitrary and lacked sufficient safeguards. Article 5 of the ECHR guarantees everyone the right to liberty and security of the person,¹⁰⁰² similar to section 12 of the South African Constitution.¹⁰⁰³ The ECtHR held that judicial review (administrative); which was the only way the patient was able to challenge his detention, did not provide the kind of rigorous challenge that was required by ECHR.¹⁰⁰⁴ A patient's refusal may also be legally overridden where it could result in death of a temporarily incapacitated patient¹⁰⁰⁵ or in injury to a minor.¹⁰⁰⁶ Such patients must be treated under the doctrine of 'best interests' and necessity as previously discussed.¹⁰⁰⁷ However, as cautioned by the UK GMC: "[HCPs] must respect

⁹⁹⁷ Ciarlariello v Schactr (1993) 1000 DLR 4th 609 (SCC) 618.

⁹⁹⁸ Mental Health Care Act no 17 of 2002.

⁹⁹⁹ R (L) v Bournemouth Community and Mental Health NHS Trust (1998) UKHL 24.

¹⁰⁰⁰ European Union *European Convention on Human Rights* (Council of Europe 1950) Article 5.

¹⁰⁰¹ Mental Health Act 1983.

¹⁰⁰² European Union *European Convention on Human Rights* (Council of Europe 1950) Article 5.

¹⁰⁰³ Constitution of the Republic of South Africa 1996.

¹⁰⁰⁴ HL v UK 45508/99 (2004) ECHR 471.

¹⁰⁰⁵ National Health Act 61 of 2003 s7 (1) (e).

¹⁰⁰⁶ McQuoid-Mason D "The National Health Act and refusal of consent to health services by children" 2006 *SAMJ* 530-532 [531].

¹⁰⁰⁷ Chima *Trans J Coll Med S Afr* 40.

a patient's decision to refuse an investigation or treatment, even if you think their decision is wrong or irrational."¹⁰⁰⁸ The only exceptions would be in an emergency and when the patient lacks DMC due to mental incapacity, in which case such patients can be involuntarily treated for their mental disorder only, based on the regulations in the Mental Health Act 2007.¹⁰⁰⁹

2.15 Summary of chapter 2

This chapter provides an analysis of relevant laws and ethical guidelines pertaining to the legal and ethical doctrine of informed consent in medical practice, derived from the principle of respect for autonomy in comparable common law jurisdictions and South Africa. In this chapter, I have critically examined different understandings of consent; key elements of informed consent, including standards for information disclosure, decision-making capacity, and an understanding of information disclosed, voluntariness, what constitutes valid IC and the criteria to establish it. I have also considered the ethical and legally accepted exceptions to the IC doctrine, and have explored some general problems associated with obtaining valid IC in clinical practice and the different forms of consent used during medical treatment, including new problems associated with IC practice due the development of new biotechnologies including DNA storage and analysis. This chapter sets the background and provides the context as a basis for this study and some relevant objectives to be determined via an empirical research study, which is described in detail, in part 2 of this thesis.

¹⁰⁰⁸ GMC *Consent: Patients and doctors making decisions together* (GMC London 2008) <https://www.gmc-uk.org/guidance/index.asp> (Date of use: 12 November 2017).

¹⁰⁰⁹ UK Mental Health Act 2007 as amended.

CHAPTER 3 - REVIEW OF LITERATURE

3.1 Introduction

This chapter will discuss the literature review that was undertaken for this thesis. A review of the relevant literature will encompass an analysis of the doctrine of informed consent as applied in South Africa jurisprudence, followed by the socio-legal aspects of IC in South Africa and the potential impact of the cultural milieu and multiculturalism on IC practice in South Africa. This will be followed by an analysis of the Hippocratic tradition and the evolution of the IC doctrine, as well as a critical discussion of the philosophical concepts of autonomy from a Kantian (duty based),¹⁰¹⁰ and Millian or utilitarian¹⁰¹¹ perspectives.¹⁰¹² This is followed by analysis of the concept of patients' rights, shared healthcare decision-making, and the rights of vulnerable population groups.

According to Polit and Beck,¹⁰¹³ a literature review is usually done to assist the researcher to comprehend and extend his or her knowledge regarding the phenomenon under study. It also helps the researcher to determine whether the phenomenon is worth studying and assists in determining the scope of the study, so that research can be limited to a needed area of inquiry.¹⁰¹⁴ A review of the literature may also help the researcher to determine the extent to which the topic under study is covered in the existing body of knowledge.¹⁰¹⁵ Moreover, the literature review shares with the reader the results of other studies that are closely related to the topic under study, it relates the current study to other larger and ongoing debates in the literature, in this case the medico-legal cases and analysis regarding the doctrine of IC, by filling in gaps and extending prior studies. Hence a literature review provides a framework for establishing the importance of the present study

¹⁰¹⁰ Kant I *Groundwork for the metaphysics of morals* (translated from the original by Wood AW) (Yale University Press New Haven 2002) see also Hope et al *Medical ethics and law-The core curriculum* 2nd ed (Churchill Livingstone Edinburgh 2003) 22-33.

¹⁰¹¹ Mill JS *Utilitarianism Liberty and Representative Government* (JM Dent & Sons Ltd London 1910).

¹⁰¹² Cohen-Almagor 2017 *Ethics Med Public Health* [1-26].

¹⁰¹³ Polit D and Beck CT *Nursing research: Generating and assessing evidence for nursing practice* 8th ed (Lippincott William & Wilkins Philadelphia 2008)105.

¹⁰¹⁴ Creswell JW *Research design-Qualitative, quantitative and mixed methods approaches* 3rd ed (Sage Publications Thousand Oaks California 2009) 25-29.

¹⁰¹⁵ Babbie E and Mouton J *The practice of social research* (Oxford University Press Cape Town 2001) 565.

and a basis for comparison of the results of the present study to findings by other researchers working on the same phenomenon or in the same area of inquiry.^{1016,1017}

3.2 The legal doctrine of informed consent in South Africa

3.2.1 Constitutional rights to informed consent

Informed consent before medical procedures is a constitutionally protected right in South Africa. These constitutionally protected rights to bodily integrity and security have been tested in South African courts in the cases of *Minister of Safety and Security v Gaqa*¹⁰¹⁸ and *Minister of Safety and Security v Xaba* (hereinafter the *Xaba* case).¹⁰¹⁹ In both cases, the police sought a court order to compel an accused person to undergo a surgical procedure in order to extract a bullet to be used as evidence in their prosecution. In the *Xaba* case,¹⁰²⁰ the court ruled that granting such an order would violate the defendant's constitutional rights to a fair trial, bodily integrity and privacy.¹⁰²¹ By contrast, such an order was granted by a judge in the case of *Minister of Safety v Gaqa* (hereinafter the *Gaqa* case),¹⁰²² where the judge felt that there were grounds within the Criminal Procedure Act,¹⁰²³ which allowed use of reasonable force by the police in the public interest.¹⁰²⁴ In both cases, the defendants sought protection under the constitutionally protected rights to bodily and psychological integrity as enshrined in section 12(2) of the Constitution.¹⁰²⁵ In the *Gaqa* case, Desai J granted the order for the extraction of the bullets, basing his judgment on the fact that the rights enshrined in section 12 were limited rights when read together with section 36 of the Constitution, which provides that rights in

¹⁰¹⁶ Creswell *Research design* 25.

¹⁰¹⁷ Mugisha E *Delivery and utilization of voluntary HIV counselling and testing services among fishing communities in Uganda* (D Litt et Phil thesis University of South Africa 2008)16.

¹⁰¹⁸ *Minister of Safety and Security v Gaqa* (2002) (1) SACR 654 (C).

¹⁰¹⁹ *Minister of Safety and Security v Xaba* (2003) 2 703 D.

¹⁰²⁰ *Minister of Safety and Security v Xaba* (2003) 2 703 D.

¹⁰²¹ *Minister of Safety and Security v Xaba* 2003 (2) SA 703 (D) see also Carstens and Pearmain *Foundational Principles* 31-32.

¹⁰²² *Minister of Safety and Security v Gaqa* 2002 (2) SACR 654 (C)

¹⁰²³ Criminal Procedure Act 51 of 197 as amended s27, 37(1) (c) and 37(2) (a).

¹⁰²⁴ Carstens and Pearmain *Foundational Principles* 544.

¹⁰²⁵ Constitution of the Republic of South Africa 1996

the constitution could be limited by a law of general application in a democratic society.¹⁰²⁶ The court further held that this limitation was supported by the Criminal Procedure Act,¹⁰²⁷ which stipulates that the police could use any reasonable force to procure evidence from suspected criminals.¹⁰²⁸ On the other hand, Southwood J denied the police the right in the *Xaba* case,¹⁰²⁹ basing his decision on the rights to bodily and psychological integrity enshrined within the Constitution, arguing that the judgment in the former case was wrong in terms of section 12 of the Constitution.¹⁰³⁰ Further, it was held that relief could not be provided by the Criminal Procedure Act since the Act did not allow forced surgical removal of an object from the body of a person.¹⁰³¹

Some commentators argued that the limitation of rights applied in *Gaqa* case by Desai J refers only to the limitation of rights in the Bill of Rights and specifies that those limitations apply “only in terms of law of a general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.”¹⁰³² The authors contend that court adjudication may not be considered a law of general application and such abrogation should probably be done via legislative mandate, as suggested by Southwood J in the *Xaba* case.¹⁰³³

One may conclude this section by noting what has been suggested by others, namely that: “The ease with which any jurisdiction is capable of upholding patient’s rights depends on its history and jurisprudence as it does on its willingness to make appropriate modifications or enthusiasm for change.”¹⁰³⁴ In South Africa, the constitutionally protected rights to bodily integrity and security as well as the right to IC have been codified in the

¹⁰²⁶ Constitution of the Republic of South Africa 1996 s36 (limitation of rights).

¹⁰²⁷ Criminal Procedure Act 51 of 1977 as amended.

¹⁰²⁸ Criminal Procedure Act 51 of 1977 s27.

¹⁰²⁹ Minister of Safety and Security v Xaba (2003) 2 703 D.

¹⁰³⁰ Constitution of the Republic of South Africa 1996 s12.

¹⁰³¹ Carstens and Pearmain *Foundational Principles* 975.

¹⁰³² Bill of Rights Constitution of the Republic of South Africa 1996 s36.

¹⁰³³ Carstens and Pearmain *Foundational Principles* 976-977.

¹⁰³⁴ McLean SAM *A patient's right to know: Information disclosure, the doctor and the law* (Dartmouth London 1989) see also Brazier M and Lobjoit M *Protecting the vulnerable: Autonomy and consent in health care* (Routledge London 2005) [introduction] and Chima *Consent and patients' rights* 54.

NHA,¹⁰³⁵ and further enshrined in the Constitution and disseminated in the Patients Right Charter.¹⁰³⁶ These provisions and regulations are designed to assist in achieving the right of access to healthcare by all South African citizens. The Patients' charter formally recognizes the patients' right to IC during medical treatment. It has been advanced that the Charter provides an officially sanctioned baseline standard that can be referred to as tool for accountability to patients, HCPs and the broader civil society.¹⁰³⁷ Under South African law, health related autonomy rights are constitutionally protected as outlined in section 12 of the Constitution, with section 12(1) stating that "everyone has the right to freedom and security of the person," whilst section 12(2) stipulates that:

Everyone has the right to bodily and psychological integrity, which includes the right to:

- (a) To make decisions concerning reproduction
- (b) To security in control over their body; and
- (c) Not to be subjected to medical and scientific experiments without their informed consent.¹⁰³⁸

3.2.2 Historical origins of informed consent in South Africa

According to Van Oosten, patient consent, as a requirement for all lawful medical interventions, is a well-established principle in South African common law.¹⁰³⁹ The earliest leading cases in this area were the cases of *Stoffberg v Elliot*¹⁰⁴⁰ and the *Esterhuizen* case.¹⁰⁴¹ In the former case, a patient whose penis was wrongfully amputated without his consent sued his doctors for damages in action for assault. The court agreed that any treatment done without the necessary consent is an interference with an individual's bodily integrity and can lead to charges of assault and award of damages.¹⁰⁴² In the *Esterhuizen* case a 10-year-old child who was diagnosed with Kaposi's sarcoma, a form of skin cancer was initially treated with superficial radiation for the condition with both

¹⁰³⁵ National Health Act 61 of 2003.

¹⁰³⁶ HPCSA *Guidelines for good practice in the health care professions: National patients' rights charter* (HPCSA Pretoria 2008) Book 3.

¹⁰³⁷ Thomas Where to from Castell v De Greef? 2007 SALJ 188-215.

¹⁰³⁸ Constitution of the Republic of South Africa 1996 s12.

¹⁰³⁹ Van Oosten FFW *The doctrine of informed consent in medical law* [445-446].

¹⁰⁴⁰ *Stoffberg v Elliot* 1923 CPD 148-150.

¹⁰⁴¹ *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T).

¹⁰⁴² *Stoffberg v Elliot* 1923 CPD 148.

parents' consent. Later, however, because of recurrence of the tumour, she was subjected to extensive radiation therapy, which resulted in severe burns and tissue damage necessitating amputation of her limbs. This was done without the express consent of her guardians. In action for damages for assault against the treating physician, the court held that while the superficial radiation was duly performed with appropriate consent from the parents, the latter procedure was performed without full disclosure, knowledge and consent of the child's mother although there was adequate time to obtain such consent. The court rejected the treating doctor and hospital's argument that the fact that her grandfather and parents had brought the child to hospital and previously consented to a similar treatment implied consent for the more radical procedure. The court also rejected arguments that the treatment was in the best interests of the child. The court held rather, that because the radical treatment was vastly different from the former superficial radiation given to the child, it was necessary that the child's mother should have been adequately informed of the dangers inherent in the radical treatment for such consent to be considered valid.¹⁰⁴³

More recently in the *Castell* case,¹⁰⁴⁴ it has been argued that the judgment of the court in this case seems to have introduced the prudent patient standard of information disclosure and IC into South African medical jurisprudence.¹⁰⁴⁵ Further, the SCA revisited this judgement in the case of *Broude v McIntosh*,¹⁰⁴⁶ but did not overrule this decision despite some technical reservations, thereby reaffirming the prudent patient and material risks standards as the required standard for information disclosure in South Africa.¹⁰⁴⁷ The consequences of the court's decision in the *Castell* case¹⁰⁴⁸ on South African medical jurisprudence were that the following principles were generally accepted, according to Van Oosten:¹⁰⁴⁹

¹⁰⁴³ Esterhuizen v Administrator Transvaal 1957 (3) SA 710 (T) 723-724.

¹⁰⁴⁴ Castell v De Greef 1993 (3) SA 501.

¹⁰⁴⁵ Carsten and Pearmain *Foundational Principles* 688-689.

¹⁰⁴⁶ Broude v McIntosh 1998 (3) SA 60 (SCA).

¹⁰⁴⁷ Carsten and Pearmain *Foundational Principles* 681-695.

¹⁰⁴⁸ Castell v De Greef 1993 (3) SA 501.

¹⁰⁴⁹ Van Oosten *De Jure* 164-179.

- a shift from medical paternalism to patient autonomy
- A shift from the 'reasonable doctor' standard to the 'prudent patient' standard
- A shift in disclosure to the 'material risk' standard, where the level of disclosure required is what a reasonable patient would consider pertinent before making a decision
- The court appears to place the patients' informed consent within the framework of *volenti non fit injuria* or voluntary assumption of risk rather than delict.

In 2004, enactment of the NHA¹⁰⁵⁰ codified the requirements for IC into South African healthcare law specifying the nature and aspects of information to be disclosed prior to IC as discussed in chapters 1 and 2 of this thesis. In terms of South African common law, the issue of how much information should be disclosed to a patient has been the subject of debate starting from the case of *Lymberg v Jeffries* 1925,¹⁰⁵¹ where the court was of the opinion that a "doctor is not obliged to disclose all the conceivable complications that may arise during a medical procedure." However the judgment of Ackerman J in *Castell v De Greef*,¹⁰⁵² suggested that a doctor is obliged to warn the patient of all the 'material risks' inherent in the treatment, where the material risks are based on a 'prudent patient standard'.¹⁰⁵³ Therefore, the requirement for information disclosure in South Africa tends towards the practice in North America where libertarian rights-based autonomy is predominant. Furthermore, section 6 of the NHA requests that as part of IC, "every HCP should inform the user of the user's health status except where it would be contrary to the user's best interests," which would include "the range of diagnostic procedures and treatment options available, the benefits, risks, costs and consequences generally associated with each option. The user's right to refuse health services and the implications thereof".¹⁰⁵⁴ It may be said that this appears to reaffirm the requirement for disclosure of all material risks with appropriate exceptions.

¹⁰⁵⁰ National Health Act 61 of 2003.

¹⁰⁵¹ *Lymberg v Elliot* 1925 AD 236.

¹⁰⁵² *Castell v De Greef* 1994 (4) SA (408) C.

¹⁰⁵³ *Castell v De Greef* 1994 (4) SA (408) C [425-426].

¹⁰⁵⁴ National Health Act 61 of 2003 sections 6-8.

3.3 Developments in South African common law on informed consent since the judgment in the *Castell v De Greef* and enactment of the National Health Act 2003

As outlined in chapter one, following the judgment of Ackerman J in the *Castell* case,¹⁰⁵⁵ legal scholars from South Africa have argued that South African courts have not endeavoured to develop the common law on informed consent as envisaged by the Constitution.¹⁰⁵⁶ Such commentators have suggested that in several cases brought to South African courts after the NHA¹⁰⁵⁷ was implemented, the courts have been reluctant to apply the regulations laid down in the NHA with regard to the legal application of the IC doctrine in medical practice.^{1058,1059} Some of the pertinent cases which have been tried by South African Courts following the *Castell* case, include *Broude v McIntosh and Another*.¹⁰⁶⁰ In this case, a claimant brought an action against a surgeon for negligence following facial paralysis developing secondary to an operation, which the claimant alleged, had been wrongfully performed. The claimant also alleged that the defendant surgeon had also failed to obtain appropriate informed consent, and had failed to warn of the risk of facial paralysis prior to surgery. The provincial High Court dismissed the claim, based on the fact that the claimant had failed to prove any negligent conduct on the part of the surgeon.¹⁰⁶¹ The claimant then appealed to the Supreme Court of Appeal (SCA) based on two heads of argument: (a) That the respondent wrongfully failed to obtain the appellants real or informed consent for the surgical procedure and that the respondent therefore committed an assault on the claimant by performing the surgery; and (b) alternatively, that in carrying out the surgical procedure on the patient, the surgeon acted in a negligent and unskilful manner by failing to inform the claimant before performing the surgery regarding the risks and hazards involved in the procedure and the availability of alternative treatments.¹⁰⁶² In arriving at a decision, the SCA was of the view that while the sole interest of the surgeon or doctor was to alleviate the suffering of the patient, it was somewhat strange that the doctors' actions in this case should be considered an assault

¹⁰⁵⁵ *Castell v De Greef* 1994 (4) SA (408) C.

¹⁰⁵⁶ Constitution of the Republic of South Africa 1996 s39.

¹⁰⁵⁷ National Health Act 2003.

¹⁰⁵⁸ Britz and Roux-Kemp *SAMJ* 2012 746-748.

¹⁰⁵⁹ Thomas 2007 *SALJ* 189.

¹⁰⁶⁰ *Broude v McIntosh and another* 1998 (3) SA 60 (SCA).

¹⁰⁶¹ *Broude v McIntosh and another* 1998 (3) SA 60 (SCA) 68-69.

¹⁰⁶² Carstens and Pearmain *Foundational principles* 681.

due to failure to disclose some risks, which if disclosed may have caused the patient to abandon the surgery by withholding consent. The Court suggested that this was unusual and concluded in part that such an approach might be unsound. However, on the facts of the case the SCA rightfully held that failure to obtain real informed consent would in fact be considered an assault. The SCA also considered in detail the judgment of Ackerman J in the *Castell* case, but did not overrule the judgment in that case. However, Marais J made an *obiter dictum* remark regarding his reservations about the observation that failure to disclose material risks which were in the opinion of a doctor likely to lead to a patient withholding consent, could constitute assault.^{1063,1064} In a more recent South African case *Louwrens v Oldwage 2006*¹⁰⁶⁵ (hereinafter the *Oldwage case*), Yekiso J sitting in the High Court found that based on a preponderance of the evidence, there was a failure to obtain informed consent by a vascular surgeon in performing a procedure on a patient, based on several grounds including the fact that the said surgical procedure as noted on the informed consent document signed by the patient and submitted as evidence in court, was different from the procedure that was eventually performed on the patient. Secondly, that the surgeon could not recall when such consent was obtained from the patient, and thirdly that the doctor's clinical notes regarding his consultations with the patient could not be found and could not be presented as evidence in court, and might have been shredded by the surgeon prior to expiry of the time legally required for the preservation of medical notes. Despite noting the *obiter dictum* of Marais J in *Broude v McIntosh*,¹⁰⁶⁶ the trial Judge Yekiso J concluded that he was legally bound by the opinion of the full bench of the High Court in the *Castell* case which held that failure to disclose material risks to a patient and obtain valid informed consent prior to surgery amounted to assault.¹⁰⁶⁷ In the subsequent appeal heard by the SCA, the higher court overruled the judgment of Yekiso J, arguing that on the issue of informed consent, the surgeon had duly informed the patient of the appropriate surgery based on the opinion of expert witnesses who stated that the difference between the surgical procedure stated on the informed

¹⁰⁶³ Broude v McIntosh and another 1998 (3) SA 60 (SCA).

¹⁰⁶⁴ Carstens and Permian *Foundational Principles* 682.

¹⁰⁶⁵ Louwrens v Oldwage 2006 (2) SA 161 (SCA) 173.

¹⁰⁶⁶ Broude v McIntosh and another 1998 (3) SA 60 (SCA) [671].

¹⁰⁶⁷ Castell v De Greef 1994 (4) SA (408) C [425].

consent document as ‘femoro-femoro bypass’ and the procedure subsequently performed by the surgeon described as an ‘illio-femoral bypass’ was merely semantic in that the two expert witnesses for the defence and prosecution concurred that both procedures were generally referred to as ‘femoro-femoro bypass’.¹⁰⁶⁸ Similarly on the issue of whether the illio-femoral bypass was the cause of the patients subsequent development of a ‘steal syndrome’, the SCA held that the patients expert witness’ argument based on 1976 clinical evidence that the incidence of such complications occurred in 4% of cases, was not acceptable in the year 2000. Rather the court preferred the evidence of the appellants’ expert witness who contended that because of modern techniques now available, the incidence of such complications was more in the region of 2%.¹⁰⁶⁹ The claimant had argued that based on the judgment reached by the court in the *Castell* case, the patient ought to have been warned based on the material risks as outlined Ackerman J, where he said that for consent to be used as a defence, certain conditions must be satisfied.¹⁰⁷⁰ In arriving at its decision in the *Oldwage* case, the SCA referred to the ‘reasonable doctor standard’ as elucidated in *Richter v Estate Hamman* (hereinafter the *Richter* case),¹⁰⁷¹ rather than the subjective prudent patient’s standard of information disclosure as arrived at in the *Castell* case.¹⁰⁷²

South African legal scholars have since argued that the SCA erred in its judgment in the *Oldwage* case,¹⁰⁷³ because it applied the discredited reasonable doctor standard of information disclosure rather than the more accepted and current prudent patient standard as established in *Castell*.¹⁰⁷⁴ It can be further be advanced that in arriving at its decision in the *Oldwage* case, the SCA did not pay attention to the judgments from similar cases in other common law jurisdictions like England, where the English Court of Appeals (CA), held in cases such as *Chester v Afshar*,¹⁰⁷⁵ that failure of a doctor to disclose serious risks

¹⁰⁶⁸ Louwrens v Oldwage 2006 (2) SA 161 (SCA) [para 21].

¹⁰⁶⁹ Louwrens v Oldwage 2006 (2) SA 161 (SCA) [para 23-25].

¹⁰⁷⁰ Castell v De Greef 1994 (4) SA (408) C [425-426].

¹⁰⁷¹ Richter and Another v Estate Hamman 1967 (3) SA 226 (C) [232].

¹⁰⁷² Castell v De Greef 1994 (4) SA (408) C.

¹⁰⁷³ Louwrens v Oldwage 2006 (2) SA 161 (SCA).

¹⁰⁷⁴ Britz and Roux-Kemp 2012 *S Afr Med J* 746-748 see also Thomas 2007 *SALJ* 189-192 and Carstens and Pearmain *Foundational principles* 685-687.

¹⁰⁷⁵ *Chester v Afshar* [2002] 3 All ER FR 552 (CA) see also Cartens and Pearmain *Foundational principles* 835.

in the range of 1-2% amounted to negligence. Similarly, in the Canadian case of *Reibl v Hughes*,¹⁰⁷⁶ the Canadian Supreme Court held that failure to disclose material risks in the range of 1% could also amount to actionable negligence. Therefore, the judgment of the SCA in the *Oldwage* case has been generally criticized by some legal scholars based on several grounds.^{1077,1078,1079} Firstly, it has been argued that though the SCA first set out to answer the question of whether “the claimant gave informed consent to the surgical procedure performed by the defendant, in the absence of that, whether such a surgical intervention would have amounted to assault.”¹⁰⁸⁰ The court did not address this question, rather it concluded that the absence of informed consent was not proven, and failure to obtain consent did not amount to assault. Secondly, in *Broude v McIntosh*,¹⁰⁸¹ the Court had alluded to the need for the SCA to review the issue of whether failure by a doctor to obtain informed consent amounted to assault at a later date. When confronted with this argument, the SCA did not refer to this particular issue in its judgment; neither did it review the arguments from that case or answer the query from the lower court. Thirdly, while the SCA accepted and applied the principles elucidated by Ackerman J in the *Castell case*,¹⁰⁸² on the prudent patient and material risks standards of information disclosure; it also accepted and eventually applied the discredited ‘reasonable doctor standard’ arrived at in the *Richter case*¹⁰⁸³ in its judgment, thereby creating some confusion in the interpretation of cases regarding informed consent in South African Courts. It has been maintained that by doing so, the SCA did not provide further clarity as to whether the principle of respect for autonomy should take precedence over medical paternalism.¹⁰⁸⁴ Further, it has been suggested that this failure to clarify issues does not appear to be consistent with constitutional provisions for respect for privacy and bodily integrity as elucidated in sections 12(2) of the Constitution.¹⁰⁸⁵ Furthermore, the SCA judgment in the *Oldwage* case also appears inconsistent with the constitutional provisions to expand the common

¹⁰⁷⁶ *Reibl v Hughes* (1980) 114 DLR (3d) 1 (SCC).

¹⁰⁷⁷ Carstens and Pearmain *Foundational Principles* 685-687.

¹⁰⁷⁸ Britz and Roux-Kemp 2012 SAMJ 746-748.

¹⁰⁷⁹ Thomas 2007 SALJ 188-215.

¹⁰⁸⁰ Carstens and Pearmain *Foundational Principles* 685-687.

¹⁰⁸¹ *Broude v McIntosh and another* 1998 (3) SA 60 (SCA).

¹⁰⁸² *Castell v De Greef* 1994 (4) SA (408) C [425-426].

¹⁰⁸³ *Richter and Another v Estate Hamman* 1967 (3) SA 226 (C) [232E].

¹⁰⁸⁴ Carstens and Pearmain *Foundational Principles* 686.

¹⁰⁸⁵ Constitution of the Republic of South Africa 1996 s12 (2).

law by reference to judgments from foreign legal jurisdictions, and the need to promote the values of human dignity, equality and freedom when interpreting the bill of rights or when interpreting any South African legislation.¹⁰⁸⁶

The SCA has also been criticized for not taking into consideration the current regulations and legislation regarding informed consent as elucidated in the National Health Act 2003.¹⁰⁸⁷ In a more recent judgment in the case of *McDonald v Wroe* 2006,¹⁰⁸⁸ a Western Cape High Court judge found that failure by a dentist to warn the patient of the risk of permanent nerve damage subsequent to extraction of an infected wisdom tooth amounted to violation of the patients right to bodily integrity as enshrined in section 12(2) of the Constitution.¹⁰⁸⁹ Further, the Court held that the patient was subjected to surgery without real informed consent due to incomplete disclosure of the material risks.¹⁰⁹⁰ In arriving at its decision, the judge applied the rule established by Ackerman J in the *Castell case*,¹⁰⁹¹ while emphasizing that in South African law there is a duty upon a medical practitioner to disclose the material risks of a planned procedure to the particular patient. Further, that in order for consent to be used as a defence, the patient must have knowledge of the risks, understood the risks, and assumed the attendant risks and all its consequences.^{1092,1093,1094} Expert opinion in this case was that there was about a 1% risk of injury to the inferior alveolar nerve and facial palsy occurring especially where such a procedure is not performed by a maxillo-facial surgeon. The dentist appealed the decision of the judge to a full bench of the Cape High Court. The decision of the judge a quo was recently overturned by a full bench of the Cape High Court,¹⁰⁹⁵ based on the question of causation. In its judgment the High Court agreed that appellants were wrong by not warning the patient of all the risks involved, which resulted in the plaintiff consenting to the dentist

¹⁰⁸⁶ The Constitution s39.

¹⁰⁸⁷ National Health Act 61 of 2003 s6-9.

¹⁰⁸⁸ *McDonald v Wroe* [2006] 3 All SA 565 (C)

¹⁰⁸⁹ The Constitution s12 (2).

¹⁰⁹⁰ Carstens and Pearmain *Foundational Principles* 687.

¹⁰⁹¹ *Castell v De Greef* 1994 (4) SA (408) C [425-426].

¹⁰⁹² Baron M "The medical duty of care revisited: *McDonald v Wroe* [2006] 3 All SA (C) Deneys Reitz http://www.deneysreitz.co.za/directors/Monique_baropn.html (Date of use: 15 July 2017).

¹⁰⁹³ Van Oosten 1995 *De Jure* 178.

¹⁰⁹⁴ Van den Heever P "The patients right to know" 1995 *De Rebus* 53.

¹⁰⁹⁵ Esterhuysen S "Medical Negligence" www.bowmanslaw.com/insights/tax/medical-negligence (Date of use: 25th October 2017).

performing the surgery. However, he performed the surgery correctly without negligence. The experts were unable to fault the manner in which he performed the surgery in any way. The harm which the plaintiff suffered, is due to a risk which is inherent in the surgical procedure in question, and which could ensue without negligence on the part of the practitioner, be it a general practitioner or a specialist. The harm, which the plaintiff suffered, is harm she might equally probably have suffered in any event if the surgery had been performed by a specialist surgeon. There was, therefore, no direct causal link between the defendant's negligence (in failing to warn the plaintiff of the risk) and occurrence of the harm, unless it can be shown that the plaintiff, upon being warned of risk, would not have undergone the procedure at all. That was not the plaintiff's case.¹⁰⁹⁶ Based on the above considerations the full bench of the High Court overturned the judgment of Fourie J by reaffirming causation as an element deeply entrenched in the South African law of delict. A patient who intends relying on lack of informed consent bears the onus to prove on a balance of probabilities that: (1) the medical practitioner was negligent in so far he failed to warn his patient of the particular risk or complication; and (2) the medical practitioner's negligent omission as such caused the damages suffered by the patient.^{1097,1098} The implications of this judgment on South African medical jurisprudence are further discussed in chapter 8 of this thesis.

3.3.1 **Sibisi NO v Maitin (311/13) [2014] ZASCA 156** ¹⁰⁹⁹

In a more recent reportable case of *Sibisi NO v Maitin*¹¹⁰⁰ of October 2014 (hereinafter the *Sibisi* case), the SCA held that where a plaintiff did not discharge the onus of proving negligence on the part of the doctor accused of failure to obtain valid informed consent; informed consent would not be an issue once negligence is not proved. Further, the SCA held that "that the question of informed consent goes to the wrongfulness element of the

¹⁰⁹⁶ McDonald v Wroe (2006) 3 All SA 565 (C) [para 34].

¹⁰⁹⁷ Esterhuysen www.bowmanslaw.com/insights/tax/medical-negligence (Date of use: 25 October 2017).

¹⁰⁹⁸ Baron [http:// www.denysreitz.co.za/directors/monique_baron.html](http://www.denysreitz.co.za/directors/monique_baron.html) (Date of use: 25 October 2017).

¹⁰⁹⁹ *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156 1 October 2014.

¹¹⁰⁰ *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156 1.

Aquilian action. Negligent conduct on the part of the doctor will be wrongful if the patient has not given informed consent. However, proof of negligence is still a requirement. The court argued that this concept was established in the *Castell* case,¹¹⁰¹ that where there is no negligence proved, the test for wrongfulness does not even arise.¹¹⁰² The SCA further refused to develop South African law regarding informed consent by establishing that the prudent patient standard ought to be the required standard for information disclosure, by following the example of other common law jurisdictions despite a request by the plaintiff to do so,¹¹⁰³ arguing that, “[I]n this matter Mrs Sibisi did not prove that Dr Maitin was negligent. In the circumstances there is no need for this court to determine which test should be adopted in relation to informed consent.”¹¹⁰⁴ To evaluate how South African Courts are faring with regard to the constitutional injunction to extend the common law,¹¹⁰⁵ it would be helpful to further evaluate the SCA judgment in the Sibisi case.¹¹⁰⁶

Facts of the case

Mrs Sibisi brought the action for damages suffered by her daughter Yandiswa, as a result of the negligent conduct of the respondent, Dr Maitin, during the birth of Yandiswa. The negligent conduct alleged had resulted in injury to Yandiswa’s brachial plexus, which had in turn resulted in Erb’s palsy-defined as “a type of brachial birth palsy in which there is paralysis of the muscles of the upper arm and shoulder girdle...due to a lesion of the upper trunk of the brachial plexus or of the roots of the fifth and sixth cervical roots”.¹¹⁰⁷ The brachial plexus is a network of nerve fibres that run from the spine through the shoulder and down the arm to the hand. The injury to the brachial plexus was considered to be a result of the baby being very big or macrosomic, and shoulder dystocia having occurred. Shoulder dystocia occurs when the anterior shoulder cannot pass below the pubic symphysis and requires manipulation to release the shoulder and allow the baby to

¹¹⁰¹ *Castell v De Greef* 1994 (4) SA (408) C [426].

¹¹⁰² *Sibisi NO v Maitin* 311/13 [2014] 156 1 [50].

¹¹⁰³ *Sibisi NO v Maitin* 311/13 [2014] 156 1 [45].

¹¹⁰⁴ *Sibisi NO v Maitin* 311/13 [2014] 156 1 [51].

¹¹⁰⁵ The Constitution s39.

¹¹⁰⁶ *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156 1.

¹¹⁰⁷ Dirckx JH (ed) *Stedman’s concise medical dictionary for the health profession* 4th ed (Lippincott Williams & Wilkins Philadelphia 2001) 329.

pass through the mother's pelvis. Yandiswa was indeed very large at birth weighing 4.68kg; it was probably her size that caused the shoulder dystocia experienced during labour and delivery of the baby. It was reported that Dr Maitin had to perform a special procedure, called a McRoberts' manoeuvre, in order to enable delivery of the baby. In this case, the McRoberts' manoeuvre was done in a modified format because the mother was given epidural anaesthesia during labour to relieve pain, therefore she did not have full control of her limbs, leading to the McRoberts' manoeuvre being done in a lithotomy position. This manoeuvre together with an episiotomy, were used to deliver the baby as an emergency procedure. Mrs Sibisi argued that a combination of the doctors' failure to accurately estimate the weight of the baby, or to perform a Caesarean section (C-section), instead of a vaginal delivery, and the incorrect use of the McRoberts' manoeuvre amounted to negligent conduct that caused the injury to the brachial plexus and the resultant Erb's palsy. After delivery, Yandiswa, the baby was referred to paediatricians for further care, but her condition did not improve and she is currently living with the physical disability, and an accompanying difficulty of vision due to drooping of her left eyelid. The consequences of the injury to the brachial plexus have been very serious indeed for both Mrs Sibisi and Yandiswa resulting in the baby's right shoulder and arm being paralysed so that she has very little control and movement, despite ongoing therapy. In addition, the effect of the injury at the root of the damaged nerve is that her one eye is sunken, affecting her appearance.¹¹⁰⁸

Legal arguments at the High Court

Mrs Sibisi alleged (among other arguments) that Dr Maitin had a duty to inform her prior to inducing labour of the material risks and complications associated with vaginal delivery and of alternative procedures, such as the option of undergoing a C-section, which could have minimised the risks. She also alleged that Dr Maitin should have foreseen the risks of vaginal delivery given the size of the baby *in utero*. She therefore alleged that she had not provided Dr Maitin with valid informed consent, as he had not informed her of all the inherent 'material' risks associated with her delivery. It was pleaded further that as a result

¹¹⁰⁸ Sibisi NO v Maitin 311/13 [2014] 156 [16].

of Dr Maitin's negligent conduct, Yandiswa had suffered a right brachial plexus palsy that had led to her requiring continued medical treatment. Mrs Sibisi also asked the court to develop the common law in line with the constitutional rights to bodily integrity and autonomy, by establishing that the test for whether a doctor has obtained a patient's informed consent is whether, a patient in the position of the plaintiff would have elected not to undergo the procedure and instead elect another one. The High Court found in favour of Dr Maitin in that his conduct was not negligent and therefore found no need to develop the common law with regard to informed consent.¹¹⁰⁹

SCA Judgment

On appeal, Mrs Sibisi relied on her rights to have been informed of the risks of vaginal delivery based on the estimated and actual weight of the baby. The Court adopted the approach that in order to found liability, the plaintiff would have to establish negligence on the part of the doctor. Judge Lewis commented in the opening line of his judgement that "giving birth is an inherently risky process" and in order to determine whether Dr Maitin was negligent, the Court focused their attention on the testimony of the relevant experts. The Court found that Dr Maitin's misestimating of Yandiswa's weight was not negligent, as it is difficult to correctly estimate a baby's weight when they are over 4kg as averred by expert witnesses.¹¹¹⁰ On the additional grounds advanced by the plaintiff, the Court found that shoulder dystocia was not foreseeable and that a C-section had not been a viable option in the circumstances, although it was alleged that in utilising the McRoberts' manoeuvre, Dr Maitin might have used too much force to pull the baby from her mother. Counsel for the defendant advanced the argument that an obstetrician who is required to utilise the McRoberts' manoeuvre only has minutes to do so and must "use as much force as necessary", failing which this may result in serious brain damage to the baby or even death. Mrs Sibisi therefore did not discharge the onus of proving negligence on the part of Dr Maitin.¹¹¹¹ Mrs Sibisi also asked the court to extend the common law test for informed

¹¹⁰⁹ Hogan Lovells "The doctors duty to inform" <http://www.hoganlovells.com/en/publications/the-doctors-duty-to-inform> (Date of use: 28 September 2017).

¹¹¹⁰ Sibisi NO v Maitin 311/13 [2014] 156 [34].

¹¹¹¹ Sibisi NO v Maitin 311/13 [2014] 156 [39-44].

consent, by arguing that a reasonable patient, who was informed of all the risks of a vaginal delivery, would have elected to undergo a C-section if given that option by the doctor. It was common cause that Dr Maitin did not, at any time, advise Mrs Sibisi of the possibility of shoulder dystocia occurring, which could lead to a brachial plexus injury. The Court referred to the test for informed consent as established in the *Castell case*.¹¹¹² The court in that instance found that:

For a patient's consent to constitute a justification that excludes the wrongfulness of medical treatment and its consequences, the doctor is obliged to warn a patient so consenting of a material risk inherent in the proposed treatment. A risk will be material where: (a) a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or (b) a medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk would be likely to attach significance to it.

The SCA based its judgment on the reasonable doctor standard of information disclosure as adumbrated in the case of *Van Wyk v Lewis*¹¹¹³ and later applied in the *Richter case*¹¹¹⁴ The Court in the *Sibisi case* found that the test for informed consent goes to the wrongfulness of the matter. Since Mrs Sibisi had failed to prove any negligence on the part of Dr Maitin, the Court therefore found that there was no need to assess the wrongfulness of the matter. Mrs Sibisi did not place any argument before the Court that had she known of the risk; she would have opted for a C-section. The appeal was dismissed and the SCA again found in Dr Maitin's favour. Perhaps the Court would have elaborated further, should argument have been advanced as to the fact that Mrs Sibisi would have decided on a C-section had she been informed of the risks associated with vaginal delivery. According to the Court:

No evidence was led to show what the reasonable patient in Mrs Sibisi's position would have done had she been warned of the risk of shoulder dystocia (a risk that was lower than one per cent), and advised about the choice between a vaginal delivery or a C-section. Would she have taken the far

¹¹¹² *Castell v De Greef* 1994 (4) SA (408) C [425-426].

¹¹¹³ *Van Wyk v Lewis* 1924 AD 438 [444].

¹¹¹⁴ *Richter & another v Estate Hamman* 1976 (3) SA 226 (C) [232].

greater risks attendant on a C-section or the very minor risk of shoulder dystocia occurring? We do not know.¹¹¹⁵

Moreover, Mrs Sibisi herself said, when asked if she knew about delivery by C-section, and about the risks associated with it, that she did not know of such risks and knew nothing about shoulder dystocia, brachial plexus injury or Erb's palsy. It was suggested to her that both Dr Maitin and she had to weigh up the respective risks. She responded: "I don't believe that. I placed all my trust in him in the sense that it was he who was going to make a decision as to the correct procedure to adopt."¹¹¹⁶ The evidence placed before the Court was that shoulder dystocia, while a risk of vaginal delivery, couldn't be reasonably foreseen based on the weight of a foetus. This was based on the evidence by two expert witnesses invited to assist the Court in this case. In addition, the Court relied on a guideline issued by the Royal College of Obstetricians and Gynaecologists (RCOG) on the foreseeability of shoulder dystocia, which advised that while there is a relationship between foetal size and shoulder dystocia, it is not a good predictor. The large majority of infants with a birth weight of 4500g or more do not develop shoulder dystocia and, equally importantly, 48% of incidences of shoulder dystocia occur in infants who weigh less than 4000g at birth. Further, the guideline also pointed out that clinical foetal weight estimation is unreliable, and even ultrasound scans have a ten per cent margin of error. The guideline further advised that "elective caesarean section is not recommended for suspected fetal macrosomia (estimated fetal weight over 4.5 kg) without diabetes".¹¹¹⁷

The SCA concluded that the question of informed consent goes to the wrongfulness element of the Aquilian action. Negligent conduct on the part of the doctor will be wrongful if the patient has not given informed consent. However, negligence is still a requirement as established in the *Castell* case.¹¹¹⁸ Where there is no negligence proved, however, the test for wrongfulness does not even arise.¹¹¹⁹ It has been argued that the Courts have

¹¹¹⁵ Sibisi NO v Maitin 311/13 [2014] 156 [52].

¹¹¹⁶ Sibisi NO v Maitin 311/13 [2014] 156 [52].

¹¹¹⁷ Royal College of Obstetricians and Gynaecologists (RCOG) Shoulder dystocia-Green-top guideline No. 42 (RCOG London 2012) <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg42/> (Date of use: 14 November 2017).

¹¹¹⁸ *Castell v De Greef* 1994 (4) SA (408) C [426].

¹¹¹⁹ Sibisi NO v Maitin 311/13 [2014] 156 [49-50]

now conclusively demonstrated that informed consent falls within the element of wrongfulness relating to a claim based on delict. However, in order to found this element of wrongfulness on a doctors' conduct, the conduct must be negligent. You cannot have one without the other, or else there would be no claim in delict.¹¹²⁰ It has also been averred that although Mrs Sibisi was not successful in her claim against Dr Maitin, the case has highlighted the importance of HCPs gaining their patient's informed consent.¹¹²¹ The implications of the *Sibisi* case and extension of the common law will be further discussed in Chapter 8 of this thesis.

3.3.2 **Pane v MEC Free State Department of Health [2016] ZAFSHC 99**¹¹²²

In another recent case by the High Court of the Free State sitting in Bloemfontein, the issue of lack of informed consent during medical treatment was again debated and argued by a South African court with the conclusion being that patients have the dual responsibility of proving negligence in addition to proving failure to obtain valid informed consent.

Facts of the case

The plaintiff Ms. Boniswa Pane instituted action against the Member of the Executive Council (MEC) responsible for the Department of Health, Free State; seeking damages in the sum of R3 000 000 (three million rand) and costs of the suit. In bringing her action, she alleged that "the employees of the defendant were negligent by cutting the plaintiff's intestine and removing her womb."¹¹²³ She later amended the particulars of her claim to state that on the 23rd of January 2010, she suffered an incomplete miscarriage of a pregnancy and was admitted to a regional hospital the same day where she was treated by evacuation of the contents of the womb by doctors on duty and discharged the next day, with a course of antibiotics and pain killers. However, a week later on the 1st of

¹¹²⁰ Castell v De Greef 1994 (4) SA (408) C [425-426].

¹¹²¹ Hogan Lovells <http://www.hoganlovells.com/en/publications/the-doctors-duty-to-inform> (Date of use: 28 September 2017).

¹¹²² Pane v MEC Free State Department of Health [2016] ZAFSHC 99.

¹¹²³ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [2].

February, she showed up at a local clinic with complaints of abdominal pain, nausea and vomiting and she was then referred back to the original treating hospital. On this occasion, she was admitted and tests were done to determine the cause of her illness, it was found that she had “suspicion of a perforated uterus”. The diagnosis on this occasion read: “perforated uterus + bowel obstruction or urinary retention.”¹¹²⁴ On the 4th of February, the plaintiff alleged that she was discharged by the hospital despite still feeling sick and experiencing the same symptoms. She further testified that on the 10th of February she was re-admitted to the hospital with the same symptoms she displayed on the 2nd of February. She was then operated on the 11th of February. When she regained consciousness, she was informed that the doctors had removed her whole uterus and inserted a colostomy bag, in which she was to relieve herself; which was supposed to be a temporary arrangement until a specialist from Australia came to South Africa to investigate how this could be reversed. She also testified that the colostomy bag caused her a lot of discomfort and embarrassment as it leaked from time to time and left a foul smell in the process. Consequently, she lost her job and her children found the condition unbearable. She is currently subsisting on the usual state grant to make ends meet, as she could no longer work as a seamstress.¹¹²⁵

Legal arguments at court

Both the plaintiff and the defendant called expert witnesses to support their arguments. The plaintiff's witness was a qualified obstetrician and gynaecologist, and after evaluating the hospital records reported that, the defendant doctors were negligent in the manner that they treated the patient on 2 February. In that having diagnosed perforated uterus, she should have been admitted immediately for surgery, and that had this been done at that time, her womb might have been preserved. He concluded: “The standard of care was neglected during her second admission as she should have been operated on during that admission but instead she was discharged again.”¹¹²⁶ The points of disagreement arise from the fact that it could not be established whether or why the patient was

¹¹²⁴ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [5].

¹¹²⁵ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [7].

¹¹²⁶ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [9].

discharged after readmission on the 2nd or 4th of February. The plaintiff's expert witness contented that in the absence of discharge documents or clinical notes to the effect that the patient absconded, and then he had no option but to conclude that the doctors who treated the patient on the 4th of February were negligent for discharging her without proper treatment. The expert witness for the defendant argued that absence of the clinical records or discharge records meant that the patient had absconded. The hospital legal administrator then testified that the hospital records disappeared in 2013 and the only records available were those provided by the plaintiff. During cross-examination, the plaintiff maintained that she was not given any treatment on 2nd of February. She was challenged with the hospital report that had an inscription that on 2nd of February the doctor had taken her for a scan, put her on a drip, and gave her medication including voltaren™ as well as antibiotics to relieve the pain. She refused to admit the correctness of such entry but was forced to admit that she was treated on the 2nd of February. She denied that she consented to the operation of 11th February which led to her whole uterus being removed. She indicated that the only operation she agreed to was an explorative laparoscopy. However, she maintained that even in that respect, nothing was explained to her including the risks and consequences of such operation.¹¹²⁷ Concerning the patient's readmission on February 10th, the doctors testified that when the patient was taken to the operating theatre, her condition was critical; and that the only option available to save her life was a total abdominal hysterectomy (complete removal of the womb).¹¹²⁸ Since the patient was unconscious under anesthesia, they obtained the necessary consent for the procedure from the hospital superintendent as required by regulations and operated on the patient based on the doctrine of necessity and in her own best interests.¹¹²⁹

Judgment

The Court in this case argued that the issue of medical negligence revolves in most instances around whether proper consent was obtained before any operation or medical

¹¹²⁷ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [5-8].

¹¹²⁸ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [4-20].

¹¹²⁹ Chima *Trans J Coll Med S Afr* 41-42 see also National Health Act 2003 (s7 and s8).

procedure could be embarked upon.¹¹³⁰ The expert witness in this case bemoaned the quality of the consent forms used across the country and complained that he has even had to develop his own, for his personal use, to address all the necessary issues including the risks, foreseen and not foreseen but likely, that are related to the medical procedure undertaken.¹¹³¹ He argued that if a consent form is not properly explained before the operation is undertaken, no matter the good intentions and oath of the medical practitioners, if proper consent was not obtained prior to a procedure, the practitioner will be liable for whatever happened during that procedure adopted, consistent with the National Health Act.¹¹³² Proper consent includes consent given after all the apparent risks and the obvious steps that the medical team will take in any emergency have been explained to the patient as established in the case of *Sibisi v Maitin*.¹¹³³ By appending his or her signature, the patient indicates that she or he understood what was explained to him or her and accepted the risks. In the event that the patient is in no condition or state of mind to do so, his or her next of kin must be consulted in accordance with the National Health Act.¹¹³⁴ In arriving at a judgment in this case the judge held that negligence is a requirement for delictual liability and the plaintiff must allege and prove that the defendant was negligent as established in the case of *Oppelt v Department of Health*.¹¹³⁵ According to the judge, it is not sufficient to allege negligence alone. The particular grounds of negligence must also be detailed as explained in the case of *Honikman v Alexander Palace Hotels*.¹¹³⁶ It is an implied term of the contract that the medical practitioner who undertakes the treatment of the patient will exercise the reasonable skill and care of a practitioner in her or his field as established in *Mitchell v Dixon*.¹¹³⁷ In deciding what is reasonable, the evidence of qualified physicians is of greatest assistance; however, what is reasonable under the circumstances is a matter for the court to decide as established the case of *Oppelt v Department of Health Western Cape*.¹¹³⁸ Should the practitioner fail

¹¹³⁰ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [21-23].

¹¹³¹ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [11-13, 21].

¹¹³² National Health Act 61 of 2003 (s6 and s7).

¹¹³³ Sibisi NO v Maitin 2014 (6) SA 533 (SCA) [49-50].

¹¹³⁴ National Health Act 61 of 2003 (s6 and s7).

¹¹³⁵ Oppelt v Department of Health Western Cape 2016 (1) SA 325 (CC) [17].

¹¹³⁶ Honikman v Alexander Palace Hotels (Pty) Ltd 1962 (2) SA 404 (C).

¹¹³⁷ Mitchell v Dixon 1914 AD [525].

¹¹³⁸ Mukheiber v Raath 1999 (3) SA1065 (SCA) See also Oppelt v Department of Health Western Cape 2016 (1) SA 325 (CC) [36].

in his or her duty and the patient suffer damages in consequence thereof, the practitioner is bound to compensate the patient for the damages caused by the breach of contract. If a plaintiff relies on a breach of duty of care, she or he must set out the facts that could or should have been foreseen by the defendant. Therefore, the onus rests on the plaintiff to establish that a reasonable person (*diligens paterfamilias*) in the position of the defendant as established in *Van Wyk v Lewis*:¹¹³⁹ “(i) would foresee the reasonable possibility of the conduct (whether an actor omission) injuring another’s person or property, and causing that person patrimonial loss; (ii) would take reasonable steps to guard against such occurrence; and (iii) that the defendant failed to take such reasonable steps.”¹¹⁴⁰ Whether a reasonable person would have taken steps to guard against foreseeable harm involves a value judgment.¹¹⁴¹ Four useful considerations courts rely on are: “(i) the degree or extent of the risk created; (ii) the gravity of the possible consequences; (iii) the utility of the actor’s conduct; and (iv) the burden of eliminating the risk.”¹¹⁴² The Court accepted the opinion of the expert witnesses, but could not establish why there were no forms filled out for discharge or refusal of treatment as done on her previous admission on January 24 or as required by law. The case then turned on the credibility of the plaintiff. The Court held that despite the fact that she had a remarkable memory regarding what transpired on other occasions or throughout her medical saga, she conveniently could not remember what happened on the 4th of February when she claimed to have been discharged by the hospital staff. The Court concluded that she was an unreliable witness in this instance having referred to the law on a dispute of facts as established by the SCA in the case of *Stellenbosch Farmers’ Winery Group Ltd v Martell et Cie*.¹¹⁴³ The Court concluded that the decision on which version of the facts to accept would be based on an evaluation of the credibility of the witnesses, their reliability and probabilities, as established in the *Oldwage* case.¹¹⁴⁴ The Court then found that the plaintiff had been unable to prove her charge of negligence on a balance of probabilities and her action was thus dismissed.¹¹⁴⁵

¹¹³⁹ Van Wyk Appellant v Lewis 1924 AD 438 [444].

¹¹⁴⁰ Oppelt v Department of Health, Western Cape 2016 (1) SA 325 (CC) [107-108].

¹¹⁴¹ Cape Metropolitan Council v Graham 2001 (1) SA 1197 (SCA) [7].

¹¹⁴² McIntosh v Premier KwaZulu-Natal and Another 2008 (6) SA 1 (SCA) [para 14].

¹¹⁴³ Stellenbosch Farmers’ Winery Group Ltd and Another v Martell et Cie and Others 2003 (1) SA 11 SCA [5].

¹¹⁴⁴ Louwrens v Oldwage 2006 (2) SA 161 SCA [14].

¹¹⁴⁵ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [41-50].

The implications of these new rulings by South African courts in the above two cases and other recent court judgments with regards to the development of the doctrine of informed consent in South African jurisprudence will be further discussed and elaborated in chapter 8 of this thesis.

3.4 Other legal issues pertaining to the doctrine of informed consent in the context of comparative international laws

3.4.1 Rights to bodily integrity and individual autonomy

The rights to bodily and psychological integrity enshrined in the South African Constitution appear relevant to the protection of the individual's autonomy. It has been argued that the right to bodily integrity underlies the right to pursue lifestyle choices including freedom to obtain medical care when needed, as well as autonomy choices regarding reproduction consistent with section 12(a) of the Constitution "to make decisions concerning reproduction".¹¹⁴⁶ This right to reproductive choices is reminiscent of articles 8 and 12 of the ECHR¹¹⁴⁷, which were adopted into UK law under the Human Rights Act 1998.¹¹⁴⁸ These articles guarantee an individual's "right to respect for private and family life" in article 8 and; right to marry and found a family in article 12.¹¹⁴⁹ The South African constitutional guarantee of "security in and control over their body" provides protection to individuals over all forms of non-consensual touching, which extends to bodily integrity and self-determination, whereas section 12(2)(c) specifically protects the rights of the individual not be subjected to medical and scientific experiments without their informed consent. This later requirement would appear to include protection from many forms of medical treatment including where treatment and research are combined as in randomized clinical trials (RCTs) or clinical trials. Section 72(7) of the NHA defines "clinical trials" as "a systematic study, involving human subjects that aims to answer specific

¹¹⁴⁶ The Constitution s12 (a).

¹¹⁴⁷ Council of Europe *European Convention on Human Rights* (European Union 1950).

¹¹⁴⁸ UK Human Rights Act 1998.

¹¹⁴⁹ Chima *Consent and patients' rights* 2006 [60-62].

questions about the safety or efficacy of a medicine or method of treatment”.¹¹⁵⁰ This is a form of therapeutic research in which medical treatment and research are conducted simultaneously in the same patient as previously discussed in section 2.8 of this thesis. It could be argued further that a combined reading of these subsections of the legislation as well as the common law interpretations would mean that individuals are also entitled to participate in any decision-making process pertaining to their healthcare.¹¹⁵¹ Again, this is consistent with Article 5 of the ECHR, which guarantees a person’s “right to liberty and security”.¹¹⁵² Further, an explanatory note in article 5 of the European Convention to Human Rights and Biomedicine (CHRB)¹¹⁵³ explains that:

Human beings must therefore be able to give or refuse their consent to any intervention involving their person. This rule makes clear patients autonomy in their relationship with healthcare professionals and restrains the paternalistic approaches which might ignore the wish of the patient...An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.¹¹⁵⁴

3.4.2 The legal doctrine of informed consent in the context of South African and international jurisprudence

The Roman law maxim of *volenti non fit injuria* (no harm is done to someone who consents or agrees), is generally regarded as the ultimate justification of consent to treatment. This is subject to any legal or moral considerations and exceptions. For example, one can only consent to something that is consistent with public policy or good societal morals *bone mores*.^{1155,1156} It has also been argued that what is good and moral in society may be controversial, because people sometimes have values that may diverge from traditional

¹¹⁵⁰ National Health Act 61 of 2003 s72 (7).

¹¹⁵¹ Piertese M “The interdependence of rights to health and autonomy in South Africa”2008 *SALJ* 553-572.

¹¹⁵² Council of Europe *European Convention on Human Rights* (European Union 1950) Article 5.

¹¹⁵³ European Convention on Human Rights and Biomedicine Oviedo 1997.

¹¹⁵⁴ European Convention on Human Rights and Biomedicine Explanatory notes (Strasbourg 1997).

¹¹⁵⁵ Pearmain and Carstens *Foundational Principles* [294].

¹¹⁵⁶ Slabbert MN “*South Africa*” in *International encyclopaedia of laws: Medical law* Nys H and den Rijn A (eds) (Kluwer Law International Netherlands 2014) 107-108.

norms.¹¹⁵⁷ Ideally, informed consent is a prerequisite for any medical intervention or treatment, but it has been suggested that the only justification for something that would otherwise be considered illegal is consent or agreement to it.¹¹⁵⁸ For example, the only mechanism that would allow a surgical incision on a patient, which would ordinarily be considered infringement of the guaranteed right to bodily integrity, and would ordinarily result in a charge of battery or assault, is the patient's consent or agreement to such a procedure.¹¹⁵⁹ Legal and ethical guidelines in health care therefore provide qualifications of information disclosure and focus on procedures to obtain valid consent.^{1160,1161} According to Ackerman J in the *Castell* case,¹¹⁶² for consent to operate as a defence for a medical procedure, the following criteria must be fulfilled by the consenting party, that is, he or she:

- (a) Must have had knowledge and been aware of the nature and extent of the harm or risk;
- (b) Must have appreciated and understood the nature and extent of the harm or risk;
- (c) Must have consented to the harm or assumed the risk, and
- (d) The consent must be comprehensive that it extends to the entire transaction inclusive of all its consequences.¹¹⁶³

The doctrine of informed consent comprises the key elements of information disclosure, capacity, comprehension and voluntariness followed by a decision to accept or refuse the proposed treatment as previously described in the foregoing chapters of this thesis.^{1164,1165}

¹¹⁵⁷ Savulescu J "Autonomy, the good life, and controversial choices" in *The Blackwell guide to medical ethics* Rhodes R, Francis LP and Silvers A (eds) (Blackwell Publishing Ltd Oxford 2007)17-37 see also Shandu A "Julian Savulescu and the issue of controversial choices" 2013 *Procedia Soc Behav Sci* 222-226 [223].

¹¹⁵⁸ Earle MA "Informed consent: Is there room for the reasonable patient in South African law?" 1995 *SALJ* 629-631.

¹¹⁵⁹ Thomas 2007 *SALJ* 188-215.

¹¹⁶⁰ Verheggen FWS and Wijmen FCB "Myth and reality of informed consent in clinical trials" 1997 *Med Law* 53-67.

¹¹⁶¹ Van Oosten FFW Patients' rights and the doctor's duty of disclosure in South Africa" 1989 *Med Law* 443-456.

¹¹⁶² *Castell v De Greef* 1994 (4) SA 408 (C).

¹¹⁶³ *Castell v De Greef* 1994 (4) SA 408 (C) [425].

¹¹⁶⁴ Jones B "Legal aspects of consent" 2006 *BJU International* 275-279.

¹¹⁶⁵ Beauchamp and Childress *Principles of biomedical ethics* 80.

A decision may be described as choices between various options which are usually made based on a balance of probabilities.¹¹⁶⁶ In the case of medical treatment, patients with capacity can only make a valid decision after full information disclosure and understanding of the options available, in an atmosphere that is free of coercion or undue pressure. Ideally, the IC process begins when the initial contact is made with the patient and extends throughout the entire treatment process or clinical encounter.¹¹⁶⁷ Accordingly, the US NBAC has emphasised that the process of IC should ensure that information is fully disclosed, that competent participants fully understand the treatment in order to make informed choices, and that decisions to participate or are not made involuntarily.¹¹⁶⁸

A few exceptions to IC exist and these would include; based on the best interests of the patient or unauthorized administration. Based on necessity-such as emergency cases where the patient is unconscious or incapable of giving consent, or based on public policy and therapeutic privilege as previously discussed in the preceding chapter.^{1169,1170} The duty on the HCP to disclose information prior to medical treatment arises from the principle that an individual's right to self-determination and free choice entails a right to know the truth and to receive all information that would enable the individual to make an intelligent choice.^{1171,1172} The Kansas Supreme Court in *Natanson v Kline* pioneered the use of the legal charge of negligence in informed consent cases, rather than battery, requiring from HCPs a duty "to disclose and explain to the patient in language as simple as necessary the nature of the proposed treatment...chances of success, failure, and any alternatives."¹¹⁷³ In the case of *Salgo v Leland Stanford University*,¹¹⁷⁴ the California

¹¹⁶⁶ Burrows RC and Hodgson RE "De facto gatekeeping and informed consent in intensive care" 1997 *Med Law* 17-27.

¹¹⁶⁷ McCormick <http://depts.washington.edu/bioethx/> (Date of use: 23 April 2016).

¹¹⁶⁸ National Bioethics Advisory Commission Ethical and policy issues in research involving human participants (NBAC Bethesda MD 2015) recommendation 5.1. <https://bioethics.georgetown.edu/nbac/human/overvol1.pdf> (Date of use: 15 November 2017).

¹¹⁶⁹ National Health Act 61 of 2003 [s7-s9].

¹¹⁷⁰ Chima 2009 *Trans J Coll Med S Afr* 39-45 see also Hocton *Law of consent to medical treatment* 10 and Carstens and Pearmain *Foundational Principles* 909 and Barit *The doctrine of informed consent in South African medical law* 60.

¹¹⁷¹ Svoboda JS et al "Informed consent for neonatal circumcision: An ethical and legal conundrum" 2000 *J Contemp Health L & Pol'y* 61-133.

¹¹⁷² *Canterbury v Spence* 18 (1972) 464 F 2d 772 [81].

¹¹⁷³ *Natanson v Kline* (1960) 154 CA App 2d 560 [404-408].

¹¹⁷⁴ *Salgo v Leland Stanford Junior University Board of Trustees* 317 P 2d 170 CA (1957) 578.

Supreme Court ruled that, “a physician violates his duty to the patient and subjects himself to liability if he withholds any facts that are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.” Generally, the standard of information disclosure must be based on that of a ‘reasonable patient’ rather than that of the ‘reasonable doctor’¹¹⁷⁵ or based on a ‘prudent patient standard’ as suggested by Lord Scarman in the *Sidaway case*.¹¹⁷⁶ In this case a patient claimed damages against a doctor based on injuries sustained after a surgical procedure. While the patient did not allege negligence on the part of the doctor in performance of the operation, the patient’s case was that she was not informed of the inherent material risks, put at about 1-2% of likelihood of nerve damage to the spinal cord resulting in paralysis. According to Lord Scarman, this case raised important questions on medico-legal jurisprudence, which include the following question:

Has the patient a legal right to know, and is the doctor under a legal duty to disclose, the risks inherent in the treatment which the doctor recommends? If the law recognises the right and the obligation, is it a right to full disclosure or has the doctor discretion as to the nature and extent of his disclosure. ¹¹⁷⁷

Lord Scarman concluded that there was room in the law for a legal duty to warn a patient of risks inherent in a proposed treatment, especially in cases of surgery, and that this was part of the doctor’s duty of care to the patient. In arriving at this conclusion, he relied on the propositions in the American case of *Canterbury v Spence*¹¹⁷⁸ where the doctrine of informed consent was applied based on certain premises:

- (a) The root premise is that every human being of adult years and of sound mind has a right to determine what shall be done with his own body.
- (b) That consent is an informed exercise of choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.

¹¹⁷⁵ Mason JK and Laurie GT *Law and medical ethics* 6th ed (Oxford University Press Oxford 2006) 348-393.

¹¹⁷⁶ *Sidaway v Board of Governors of the Bethlem Hospital* [1985] 1 All ER 643.

¹¹⁷⁷ Hocton *Law of consent to medical treatment* 35.

¹¹⁷⁸ *Canterbury v Spence* 18 (1972) 464 F 2d 772.

(c) The doctor must therefore disclose all 'material risks'. What risks are 'material' is determined by the 'prudent patient' test formulated by the Court as follows: "[A] risk is...material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy".¹¹⁷⁹

Lord Scarman in *Sidaway*¹¹⁸⁰ therefore suggested that there is an obligation on the part of a doctor or other healthcare professional to disclose all the necessary information to enable a patient make an informed choice. Putting it another way, due to the asymmetry of knowledge that exists between a physician and his patients, the former has an obligation to provide sufficient and accurate information so that the patient can make an intelligent and informed decision.¹¹⁸¹ A doctor or other HCP must therefore fully explain the proposed procedure, the short-term risks and long-term consequences, the available alternatives, their risks and benefits, and the consequences of delaying or declining treatment.¹¹⁸² The patient should also be made aware of both short term costs such as pain, recovery time, and length of confinement to the hospital. Long term costs such as loss of functioning and physical scarring or loss of function must also be divulged.¹¹⁸³ The HCP must disclose all information that would be regarded as 'material' by a reasonable person, with material defined as any information that would make a particular patient choose a different option.¹¹⁸⁴ Legally obtaining consent without providing adequate information may constitute redressable negligence or assault.^{1185,1186} Despite this stated reality, in developing countries such as South Africa, where the doctor-patient ratio is high, though it may be ethically desirable, and legally required for patients to be as fully informed

¹¹⁷⁹ Canterbury v Spence 18 (1972) 464 F 2d 772 [41-46].

¹¹⁸⁰ Sidaway v Board of Governors of the Bethlem Hospital [1985] 1 All ER 643.

¹¹⁸¹ Angell M "The ethics of clinical research in the third world" 1997 *New Engl J Med* 847-849.

¹¹⁸² National Health Act 61 of 2003 section 6(1).

¹¹⁸³ Grubb et al *Principles of medical law* [465-470].

¹¹⁸⁴ Pelias MK "Research in human genetics: The tension between doing no harm and personal autonomy" 2005 *Clin Genet* 1-5 see also Castell v De Greef 1994 (4) SA 408 (C) [426].

¹¹⁸⁵ Svoboda et al 2000 *J Contemp Health L & Pol'y* 61-133 see also

Canterbury v Spence 18 (1972) 464 F 2d 772 [41-46] and Stoffberg v Elliot 1923 CPD 148-150.

¹¹⁸⁶ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11.

as stipulated by the NHA,¹¹⁸⁷ and the HPCSA guidelines,¹¹⁸⁸ doctors may not have the time to spend on unduly lengthy explanations of all the ramifications of treatment.¹¹⁸⁹ This presents a challenge in ensuring that patients are armed with sufficient, relevant, and accurate information before they consent to any medical procedure or treatment.

Comprehension is another key element of IC that focuses on ensuring that a patient is not only informed, but that the patient understands the information provided. According to the *Belmont Report*,¹¹⁹⁰ information must be provided in a language that can be understood bearing in mind the level of intelligence, rationality, education and maturity of the patient. This refers to *cognitive and communicative vulnerability* of human subjects of research,¹¹⁹¹ or medical treatment. The ability to comprehend information may be determined by the language of communication and the literacy levels of the patient concerned as alluded to in section 6 of the NHA, where the Act requires HCPs to take into consideration patients' language and literacy levels when obtaining consent.¹¹⁹² Discussions on a clinical procedure therefore needs to be carried out in a non-technical language so that maximal interchange of information between the patient and a doctor or another HCP can occur.¹¹⁹³ Even when dealing with regard to educated people, explanations of the details of the medical procedure are mandatory.¹¹⁹⁴ The requirement of comprehension imposes on a doctor the duty to assess whether a person is capable of making a rational decision based upon the information provided by evaluating whether the patient understands the information. While it may be easier to assess the adequacy of information disclosed and imparted, it is far more difficult to assess whether the information has been understood by

¹¹⁸⁷ National Health Act 61 of 2003.

¹¹⁸⁸ HPCSA *Guidelines for good practice in the healthcare professions-Seeking patients informed consent: The ethical considerations* (HPCSA Pretoria 2008).

¹¹⁸⁹ Chima 2013 *BMC Med Ethics* S3 [8-10].

¹¹⁹⁰ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research* (Department of Health Education and Welfare US Government 1979).

¹¹⁹¹ National Bioethics Advisory Commission *Ethical and policy issues in research involving human participants* Report volume 1 (NBAC Bethesda MD 2001) 88.

¹¹⁹² National Health Act 61 of 2003 s6 (2).

¹¹⁹³ Bailey PB "Informed consent" in *Legal Medicine Annual* Wecht CH (ed) (Appleton-Century-Crofts New York 1978) 271-284.

¹¹⁹⁴ Kyambi JM "Issues involved in pre-operative consent" 2004 *East Afr Med J* 329-330.

the patient or research subject.¹¹⁹⁵ The causes of misunderstanding among such patients include differences in language, culture, level of education,¹¹⁹⁶ and lack of a shared understanding between the HCP and the patient about health and disease.¹¹⁹⁷

In an African study on the application of IC in Nigeria, it was reported that 18 patients (1.5%) out of 133 patients had difficulties understanding the information given to them. They complained that the doctors used technical terminology.¹¹⁹⁸ Nevertheless, the patients gave consent to prevent their operations or surgical procedures being cancelled. These findings make it clear that even where consent is given, it may not always be fully informed or valid based on the legal requirements for validity. Another important component of IC is voluntariness. Volition is concerned with having the capacity required to make conscious choices or decisions or desire to make a choice. It is designed to protect the patient's right to make health care choices free of coercion or undue influence.¹¹⁹⁹ In medical law, consent obtained through threat or intimidation for a clinical procedure may not be valid and the doctor can be held liable for assault or trespass to the person.¹²⁰⁰ The power imbalance between a patient and a doctor also creates a danger of undue influence,¹²⁰¹ since a patient cannot obtain treatment without an agreeable medical professional.¹²⁰² In such cases the patient can do little more than respond to treatment offered by the HCP lest they are labelled as rude and uncooperative.^{1203,1204} It has also been reported that in South Africa, patients may consent to treatment without asking questions where they are afraid to lose free treatment benefits.¹²⁰⁵ Patients are also often anxious at the time consent is sought, thereby making them even more

¹¹⁹⁵ Lindegger G and Richter LM "HIV vaccine trials: critical issues in informed consent" 2000 South African Journal of Science 313-317 [315].

¹¹⁹⁶ Agu et al 2014 *BMC Med Ethics* 77.

¹¹⁹⁷ Lindegger and Richter 2000 *S Afr J Sci* 314.

¹¹⁹⁸ Osime et al 2004 *East Afr Med J* 331-335 [334].

¹¹⁹⁹ Svoboda et al 2000 *J Contemp Health L & Pol'y* 61-133 see also Beauchamp and Childress *Principles of biomedical ethics* 93-98.

¹²⁰⁰ Carstens and Pearmain *Foundational Principles* 676.

¹²⁰¹ Beauchamp and Childress *Principles of biomedical ethics* 94-98.

¹²⁰² Grubb et al *Principles of medical law* 497.

¹²⁰³ Molyneux et al 2004 *Soc Sci Med* 2551-2552.

¹²⁰⁴ Osime 2004 *East Afr Med J* 334.

¹²⁰⁵ Chima 2015 *Niger J Clin Pract* 51-53.

vulnerable and subject to undue influence, easy coercion¹²⁰⁶ and manipulation¹²⁰⁷ by HCPs during the IC process. An example of this would occur when consent is sought from women in labour, leading the RCOG to caution HCPs about taking due consideration when obtaining IC from women in labour.¹²⁰⁸ In the case of *Diaz v Hillsborough County*,¹²⁰⁹ doctors were charged with the offence of ‘*dignity harm*’ for infringing on patients’ rights to human dignity, where they obtained informed consent during labour from vulnerable, poorly educated immigrant women, for a clinical trial without full information disclosure.¹²¹⁰

In African countries, unlike more developed countries of the West, the appropriateness of first person IC has been questioned in the cultural context, where individuals are seen a part of a community and not only as individuals.¹²¹¹ In these traditional settings, consent may first be sought from community elders, and in the case of married women, permission is sought from their husbands. It is therefore doubtful whether such consent is truly autonomous and free from coercion or undue influence.^{1212,1213} The real question regarding volition then, is whether patients’ consent is freely given or whether their decision is influenced by their relationship to the HCP or surrogate/persuader, as demonstrated in *Re T*,¹²¹⁴ where a Jehovah’s witness mother was alleged to have unduly influenced her vulnerable daughter and ‘overbore’ her will.¹²¹⁵ In view of this, some legal authorities have argued that sometimes the influence of parents on their children, or of one spouse on another, or of an employer over a servant, may result in coercion or undue influence.¹²¹⁶

¹²⁰⁶ Molyneux et al 2005 *Soc Sci Med* 443-454.

¹²⁰⁷ Beauchamp and Childress *Principles of biomedical ethics* 94-98.

¹²⁰⁸ RCOG *Obtaining valid consent* -Clinical governance advice No. 6 (RCOG London 2015).

¹²⁰⁹ *Diaz v Hillsborough County Hospital Authority* (2000) U.S Dist 140617

¹²¹⁰ Hanlon S and Shapiro RS “Ethical issues in biomedical research: *Diaz v Hillsborough County Hospital Authority* (Section of individual rights and responsibilities American Bar Association Washington DC 2000) see also Chima *Consent and patients’ rights* [63-64].

¹²¹¹ Metz and Gaie “The African ethic of Ubuntu/Botho: Implications for research on morality” 2010 *J Moral Educ* 274-275 see also Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

¹²¹² Ijsselmuiden and Faden 1992 *N Eng J Med* 830–834 see also Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

¹²¹³ Tindana et al 2006 *IRB* 1-6.

¹²¹⁴ *Re T (An adult) (Consent to Medical Treatment)* [1992] 2 FLR 458.

¹²¹⁵ *Re T (An adult) (Consent to Medical Treatment)* [1992] 2 FLR 458 [799].

¹²¹⁶ Jones M *Textbook on torts* 8th ed (Oxford University Press Oxford 2002) 531.

From the foregoing, it is clear that there are challenges that exist in the process of obtaining IC. In some instances the information given is insufficient and/or is inaccurate. In other instances the information may be so technical that it cannot be understood by an ordinary patient based on language barriers, low education levels, poverty or other cultural beliefs; or even sickness which may make the patient feel vulnerable. In yet other instances, patients may feel intimidated by the power asymmetry between the patient and the HCP or become intimidated by the hospital environment so that they do not consent freely. Finally, it is debatable whether all individuals giving consent have the legal capacity to give consent. The empirical part of this thesis will endeavour to investigate and explain how these factors play themselves out in clinical practice in South Africa. Therefore, this thesis seeks to shed some light on these aspects of the IC process in an urban setting in South Africa.

3.5 Informed consent, the socio-cultural milieu and patients' rights in South Africa

In developing countries such as South Africa, educational standards and literacy levels are low, knowledge and power asymmetry on healthcare issues usually exist between patients and HCPs.^{1217,1218} It has been suggested that in such settings “[...] it is critically important to recognize the historical backdrop of colonialism and racism, and ongoing challenges of poverty and exploitation. In this light, building and maintaining trust among researchers, communities, and participants can be a critical element of informed consent.”¹²¹⁹ However, despite such considerations, it has been observed that a doctor or other HCP still has a duty to explain a clinical procedure without turning the patient or their surrogate decision makers into students of medicine.¹²²⁰ Debates continue on how much information a HCP should give to a patient before they feel informed enough to make a valid decision.¹²²¹ It is trite that the ability to use written information is important

¹²¹⁷ Mhlongo and Mdingi 1997 *BMJ* 252.

¹²¹⁸ Agu et al 2014 *BMC Med Ethics* 77 see also Osime et al 2004 *East Afr Med J* 331-335.

¹²¹⁹ McGrory CE et al *Informed consent in HIV prevention trials: Report of an international workshop* co-hosted by the Population Council and Family Health International New York City May 16-18 2005 (The Population Council 2006).

¹²²⁰ Lore “Medical ethics in the protection of patients’ rights” 1993 *Medicus* 227-229.

¹²²¹ Burrows RC and Hodgson RE “De facto gatekeeping and informed consent in intensive care” 1997 *Med Law* 17-27.

to comprehension and understanding,^{1222,1223} and barriers to communication arising from illiteracy and language differences may prevent a common understanding of medical procedures, thereby putting a patient at risk of providing consent without comprehension.^{1224,1225} How can HCPs ensure that patients understands a proposed treatment or procedure prior to providing consent? Some authorities have suggested a verbal or written test to ascertain patient capacity, competence or understanding before considering IC valid.^{1226,1227} In South Africa, around 25% of the population is unemployed, with low labour force participation rate of 54% compared to a global average of 69%;^{1228,1229,1230} compounded by historical inequities within population groups.^{1231,1232,1233} Basic health care is unaffordable and out of reach for a majority of the population.¹²³⁴ Therefore, any offer of medical assistance maybe seen as better than nothing, thus encouraging undue influence, therapeutic misconception, and medical paternalism.^{1235,1236} Further, there is a dichotomy in the organization of the South African healthcare system, which is dual in nature, consisting of private hospitals/medical

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- 1222 Green JB et al “Putting the ‘informed’ into ‘consent’: A matter of plain language” 2003 *J Paediatric Child Health* 700-703.
- 1223 National Bioethics Advisory Commission *Ethical and policy issues in research involving human participants* Report volume 1 (NBAC Bethesda MD 2001) 88.
- 1224 Richter ML et al *Guidelines for the development of culturally sensitive approaches to obtaining informed consent for participation in HIV vaccine-related trials* (Discussion Document) (1999) University of Natal Scottsville South Africa).
- 1225 Agu et al 2014 *BMC Med Ethics* 77
- 1226 Appelbaum PS “Assessment of patients’ competence to consent to Treatment” 2007 (357) *N Engl J Med* 1834-1840.
- 1227 Charland L “Decision making capacity” In: *Stanford encyclopaedia of philosophy* 2008 Zalta EN et al (eds) <http://www.science.uva.nl/~seop/archives/fall2008/entries/decision> (Date of use: 22 March 2011).
- 1228 Vollgraaff R “Little hope of hitting job-creation target” 20-02-011 *Sunday Times* South Africa.
- 1229 Merten M “Great reversal: Stats SA claims black youth are less skilled than their parents” 18-04-2016 *Daily Maverick* <https://www.dailymaverick.co.za/article/2016-04-18-the-great-reversal-stats-sa-claims-black-youth-are-less-skilled-than-their-parents/> (Date of use: 20 November 2017).
- 1230 Trading Economics “South Africa unemployment rate 2000-2014” <http://www.tradingeconomics.com/south-africa/unemployment-rate> (Date of use: 19 August 2014).
- 1231 Mhlongo and Mdingi 1997 *BMJ* 252.
- 1232 Truth and Reconciliation Commission Report *Institutional hearings: The health sector* (CTP Book Printers Cape Town 1998)109-164.
- 1233 Maphai VT “Affirmative action in South Africa -a genuine option?” 1989 *Social Dynamics* 1-24.
- 1234 Rowe and Moodley 2013 *BMC Med Ethics* 15.
- 1235 Annas GJ and Grodin MA “Human rights and maternal-fetal HIV transmission prevention trials in Africa” in *Health and Human Rights* Mann JM et al (eds) (Routledge New York 1999) 373-380.
- 1236 Chima 2015 *Niger J Clin Pract* S46-S56 see also Sugarman et al 2005 *Clinical Trials* 34-41.

practice which is patronized by more affluent patients (about 20%); representing those who have health insurance or the financial means to pay for private healthcare services, compared with the public health services which accounts for the majority (80%) of indigent patients and citizens.^{1237,1238,1239} This dual healthcare system is further characterized by better infrastructure in private hospitals because of commercial competition and better funding, and arguably better educated and more knowledgeable patients and consumers of healthcare services.

In a recent Canadian case of *Chaoulli v Attorney General Quebec*,¹²⁴⁰ the court, by a narrow majority, held that the prevention of the right of more affluent Canadians from accessing healthcare services from the private sector, and therefore ostensibly preventing the development of a two-tier healthcare system in Canada, which would have prejudiced the ability of poorer or less affluent Canadians from obtaining equal health care services, was an infringement on those affluent Canadians' rights to life, liberty and security of the person as enshrined in the Canadian Charter of Rights and Freedoms.¹²⁴¹ The author concluded that the judgment in the *Chaoulli* case shows that there may be circumstances in which lack of access to certain forms of medical treatment, could be a violation of an individual's autonomy rights.¹²⁴² By contrast, the Constitutional Court of South Africa held in the case of *Soobramoney v Minister of Health KwaZulu-Natal*,¹²⁴³ that the right of access to healthcare as enshrined in the Constitution,¹²⁴⁴ is a gradually attainable right subject to the availability of resources with regards to access to healthcare services.¹²⁴⁵ One can therefore conclude that the dual healthcare system in South Africa may influence indigent patients' autonomy rights as well as their right to the best possible healthcare

¹²³⁷ DOH *KwaZulu-Natal Strategic Plan 2010-2014* (Department of Health KZN 2010).

¹²³⁸ Pieterse 2008 *SALJ* 553-572.

¹²³⁹ Chima 2015 *Niger J Clin Pract* S46-S56.

¹²⁴⁰ *Chaoulli v Attorney General Quebec* (2005) 254 DLR 4th 577.

¹²⁴¹ Pieterse M "The legitimizing/insulating effect of socio-economic rights" 2007 *CJLS* 1-20.

¹²⁴² Pieterse M 2007 *CJLS* 1-20.

¹²⁴³ *Soobramoney v Minister of Health (KZN)* 1998 910 SA 430 (D).

¹²⁴⁴ Constitution of the Republic of South Africa 1996 (sections 11 and 27(1) a).

¹²⁴⁵ *Soobramoney v Minister of Health (KZN)* [1997] ZACC 17 1998 (1) SA 765 (CC) 773-774.

services as enshrined in the UDHR¹²⁴⁶ and the International Covenant on Economic, Social and Cultural Rights (ICESCR).¹²⁴⁷

This evident dichotomy of healthcare service delivery may in some ways influence the practice of IC in South Africa, since the more affluent and arguably more knowledgeable patients, may have the means to purchase private healthcare services and therefore maybe more attuned to demanding their consumer rights when accessing healthcare,¹²⁴⁸ since the consumer protection also guarantees the rights fair dealing and full disclosure during healthcare, including disclosure of costs.¹²⁴⁹ Furthermore, most African societies being culturally complex and paternalistic in nature may require that consent or approval be obtained from community elders/extended family members, or men as heads of households before the actual patients or research subjects can provide consent.^{1250,1251} The challenge here then is to ensure that IC is truly voluntary and that community or surrogate consent is not substituted for individuals' consent, which ideally should be obtained in the absence of undue influence and coercion.^{1252,1253}

3.6 The relationship between multiculturalism, right to health, and individual autonomy

It has been argued that the IC doctrine is primarily based on the Western notion of individualism over the rights of the community and communalism, which is practiced in some African communities as exemplified by the Ubuntu philosophy that emphasizes communal rights and brotherhood over individual rights.¹²⁵⁴ It has been argued that

¹²⁴⁶ United Nations *Universal Declaration of Human Rights* (United Nations 1948).

¹²⁴⁷ United Nations *International Covenant on Social Economic and Cultural Rights* (United Nations 1966) see also UNCESCR General comments 14 "The Right to the highest attainable standard of Health" (United Nations ICESCR 1966) Article 12 .

¹²⁴⁸ Rowe K and Moodley K "Patients as consumers of health care in South Africa: the ethical and legal implications" 2013 *BMC Med Ethics* 15.

¹²⁴⁹ Consumer Protection Act 68 of 2008.

¹²⁵⁰ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

¹²⁵¹ Tindana et al 2006 *IRB* 1-6.

¹²⁵² Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

¹²⁵³ Oduro AR et al "Understanding and retention of the informed consent process among parents in rural northern Ghana" 2008 *BMC Medical Ethics* 12.

¹²⁵⁴ Metz and Gaie 2010 *J Moral Educ* 274-275.

traditionally, the ontology of African culture is communitarian in nature,^{1255,1256} which was characterized by John Mbiti as follows: “[In African culture], only in terms of other people does the individual become conscious of his own being, his own duties, his privileges and responsibilities towards himself and towards other people”, summarized by the maxim “I am because we are, and since we are, therefore I am”.¹²⁵⁷ It has been argued that the doctrine of IC as currently formulated favours self-reliance over interdependence, action over passiveness, rationalism over spirituality, and uncertainty and forthrightness over collective harmony.^{1258,1259} This is in contrast to deep religious and ancestral belief systems prevalent in most African cultures, which points to an omnipotent, universalizing and fatalistic view of the world that cannot be easily controlled or influenced by mortal human beings.^{1260,1261} This Western notion of autonomy, as paraphrased in the maxim of Cardozo which states that “every human being of adult years and sound mind has a right to determine what shall be done with his own body [...]”¹²⁶² is further characterized by the Cartesian maxim of “I think, therefore I am.”¹²⁶³ This view overlooks that fact that in some non-western cultures, including those in Africa, individuals may expect and even desire that others make decisions regarding their healthcare and that some individuals may not even want to receive any ‘negative’ information on which such decisions maybe based.^{1264,1265} According to Frimpong-Mansoh the question to be asked is “how can the requirement of voluntary informed consent be addressed in African community oriented culture”.¹²⁶⁶

¹²⁵⁵ Frimpong-Mansoh 2008 *Dev World Bioeth* 107.

¹²⁵⁶ Hope et al *Medical ethics and law-The core curriculum* 2nd ed 2008 [29].

¹²⁵⁷ Mbiti JS *African Religions and Philosophy* (Heinemann London 1969) 108-109 see also Frimpong-Mansoh 2008 *Dev World Bioeth* 107.

¹²⁵⁸ Gordon E 1997 *Fordham Urb L J* 1321-1362.

¹²⁵⁹ Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

¹²⁶⁰ Chima 2015 *Niger J Clin Pract* S1-S7.

¹²⁶¹ Mbiti JS *African Religions and Philosophy* (Heinemann London 1969).

¹²⁶² *Schloendorf v Society of New York Hospital* 105 NE (NY 1914) 92.

¹²⁶³ Frimpong-Mansoh 2008 *Dev World Bioeth* 107.

¹²⁶⁴ Carrese JA and Rhodes LA “Western bioethics on the Navajo reservation: Benefit or harm?” 1995 *JAMA* 826-829.

¹²⁶⁵ Susilo et al “Nurses role in informed consent in a hierarchical and communal context” *Nurs Ethics* 2013 413-425.

¹²⁶⁶ Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

The tradition of rugged individualism prevalent in American culture reinforces the view that healthcare is a matter of private interests which is best left to determination by market forces within a free market economy.¹²⁶⁷ Unfortunately, this state of affairs has led to a category of underprivileged healthcare recipients within the American system, leading to observations that levels of ill-health are comparatively higher amongst the disadvantaged minorities and other vulnerable population groups in modern American society.¹²⁶⁸ Individuals who do not identify with Western cultural values may be more spiritual and more family oriented and communal in their decision making processes.^{1269,1270} Therefore imposing western beliefs and practices with regards to the IC doctrine and respect for individual autonomy may in fact create deleterious and negative health consequences for such patients, and risks viewing them as oddities stripped of their cultural belief systems. This view ignores the fact that such individuals' perception of health and illness and medical decision-making choices are part of who they are as individuals.¹²⁷¹ Therefore, imposing a singular Western view of autonomy and IC may not actually respect such people's rights to autonomy and their rights to make decisions about their own personal welfare within the context of their traditional customs, morals and belief systems.^{1272,1273,1274 ,1275}

Individual autonomy has been generally recognized as a core value of legal and constitutional order.¹²⁷⁶ Further, it has been suggested that human beings require a minimum level health and physical well-being amongst other rights, as enshrined in the UDHR¹²⁷⁷ and ICESCR,¹²⁷⁸ in order to be fully autonomous and fulfil their personal goals

¹²⁶⁷ Giesen D "Right to healthcare? A comparative perspective" 1994 *Health Matrix* 277-295 [282].

¹²⁶⁸ Giesen 1994 *Health Matrix* 282-284.

¹²⁶⁹ Tindana et al 2006 *IRB* 1-6 see also Oduro et al 2008 *BMC Medical Ethics* 12.

¹²⁷⁰ Susilo et al *Nurs Ethics* 2013 413-425

¹²⁷¹ Gordon E 1997 *Fordham Urb L J* 1321-1362.

¹²⁷² Gordon E 1997 *Fordham Urb L J* 1321-1362.

¹²⁷³ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

¹²⁷⁴ Chima 2015 *Niger J Clin Pract* S1-S7.

¹²⁷⁵ Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

¹²⁷⁶ Giesen D "From paternalism to self-determination to shared decision-making "1988 *Acta Juridica* 107-127 see also Giesen 1994 *Health Matrix* 280.

¹²⁷⁷ United Nations *Universal Declaration of Human Rights* (1948) Article 25.

¹²⁷⁸ United Nations *International Covenant on Social Economic and Cultural Rights* (United Nations 1966) See UNCESCR General comments 14: The Right to the highest attainable standard of health (UN ICESCR 1966) Art 12.

consistent with their own personal values.¹²⁷⁹ Therefore, good health may be described as a basic social good, which enhances human flourishing and individual autonomy.¹²⁸⁰ Thus, any society that denies individuals access to basic healthcare services or standards, disvalues personal autonomy and opens itself up to moral criticism and public opprobrium. In view of the above observations, good health and the right to health cannot simply be viewed as issues under an individual's autonomous control, because a person's health status is generally impacted on by other complex variables such as genetic inheritance, or good or bad genes, coupled with other factors such as individuals' psychological makeup, cultural, environmental, economic, as well as available health care resources both at the individual and societal levels.¹²⁸¹ Hence it is important to recognize the linkages between social vulnerability and individual choices, not just whether the individual is an innocent or unfortunate victim of disease, and not based only on the view that the individual has brought a disease on him or herself because of so-called 'bad choices' or poor decision-making in life.^{1282,1283} It should also be recognized that the health-affirming personal choices are invariably linked to various factors as alluded to above. Hence, one may argue that empowering individuals to exercise their personal autonomy must generally acknowledge the underlying socio-cultural factors and structural violence,^{1284,1285} prevalent in that particular society, and this means that the state must sometimes play an active role in providing access to health and enabling individuals to exercise their right to autonomy.^{1286,1287,1288,1289} Finally, it must be acknowledged that socio-economic factors, as well as cultural belief systems, may play a big role in the

¹²⁷⁹ Giesen 1988 *Acta Juridica* 120-121.

¹²⁸⁰ Giesen 1994 *Health Matrix* 277-295.

¹²⁸¹ Pieterse M "The interdependence of rights to health and autonomy in South Africa" 2008 *SALJ* 553-572.

¹²⁸² Metz T "Respect for persons permits prioritizing treatment for HIV/AIDS" 2008 *Dev World Bioeth* 89-103

¹²⁸³ Savulescu J "Autonomy, the good life and controversial choices"
http://www.philosophy.ox.ac.uk/__data/assets/pdf_file/0007/28168/controversial_choices.pdf.
 (Date of use: 22 February 2016).

¹²⁸⁴ Chima SC, Mduluzi T and Kipkemboi J "Viewpoint discrimination and contestation of ideas on its merits, leadership and organizational ethics: Expanding the African bioethics agenda" 2013 *BMC Medical Ethics* S1.

¹²⁸⁵ Farmer PE et al "Structural violence and clinical medicine" 2006 *PLOS Med* 1686-1691.

¹²⁸⁶ Metz T 2008 *Dev World Bioeth* 89-103.

¹²⁸⁷ Pieterse *SALJ* 553-572.

¹²⁸⁸ Giesen 1994 *Health Matrix* 277-295.

¹²⁸⁹ Gordon E 1997 *Fordham Urb L J* 1321-1362.

development of human capabilities including the ability to fulfil life plans and participate effectively in political economic and social life and exercise one's choices in life including the right to autonomy. Respect for autonomy forms the cornerstone of IC and is seen to be derived from the Western liberal notions of dignity, integrity, individuality and independence. However, it must be remembered that other societies may have a different worldview in terms of their interpretation of the rights to autonomy, which may include communalism rather than rugged individualism.¹²⁹⁰ In view of these observations; Schuck has suggested that IC "is impoverished by a lack of context within which patients can exercise meaningful choice about difficult options [...] that the goal should be to further contextualize informed consent-both the process and the legal doctrine that regulates it" [emphasis added].¹²⁹¹ One can therefore conclude that IC should be considered "as a normative variable, not an empirical constant" because of its cultural plasticity.¹²⁹² Thus, the implementation of IC should; if it is to be effective, allow for changes in the way it is defined to attune to the local or prevailing medical culture.¹²⁹³

The issues and considerations outlined above present challenges to ensuring that IC provided in clinical practice in South Africa is informed, comprehensible, voluntary and autonomous. For the purposes of this thesis, the emphasis is on the investigation of the role of HCPs, specifically medical doctors and professional nurses in the ensuring that IC provided by patients during routine healthcare services in South Africa is valid, while taking into consideration the various key elements of IC namely; information disclosure, competence, voluntariness and comprehension.

¹²⁹⁰ Gordon E 1997 *Fordham Urb L J* 1321-1362.

¹²⁹¹ Schuck P "Rethinking informed consent" 1994 *Yale LJ* 951.

¹²⁹² Chima *Consent and patients' rights* 2006 [56].

¹²⁹³ Schuck P 1994 *Yale LJ* 951-959 see also Chima *Consent and patients' rights* 56.

3.7 The Hippocratic tradition and the historical origins of IC in medical practice

An ethical code of behaviour is central to the ‘*Corpus Hippocraticum*’ attributed to the ancient physician Hippocrates and other writers of the 5th-3rd century B.C.^{1294,1295} The Hippocratic tradition was predicated on benevolent paternalism based on the ethical principle of beneficence,¹²⁹⁶ which opined, ‘Speak to the patient carefully and adroitly, concealing most things...comfort with solitude and attention, revealing nothing of the patients’ future or present condition.’^{1297,1298} Providing benefit to the patient by relieving suffering and avoiding harm were chief concerns.¹²⁹⁹ *Primum non nocere* (above all do no harm), based on the ethical principle of non-maleficence, was of paramount importance; therefore full information disclosure, as required by modern IC doctrines was considered harmful.

Medieval physicians in the West expanded Hippocratic texts, so that by the 15th century, rules of conduct had been established in medical schools of the time. In the 18th century, American physicians such as Benjamin Rush and Thomas Percival stressed the need for primary moral rules of medical practice and began to wrestle with questions of truth-telling in the doctor-patient relationship. However, these physicians still maintained a rigid paternalistic attitude as shown by this quote from Benjamin Rush in 1786, “Yield to patients in matters of little consequence, but maintain an inflexible authority...in matters essential to life”.¹³⁰⁰ Rush wanted patients educated to the point where they could

¹²⁹⁴ Hippocrates *Hippocrates collected works* I Jones WHS (ed) <http://www.perseus.tufts.edu/hopper/text?doc=Perseus%3Atext%3A1999.01.0251%3Atext%3Dintro%3Achapter%3D2> (Date of use: 23 April 2016).

¹²⁹⁵ 2 Hippocrates *Decorum* 297- 299 (translated from the original by Jones W 1967).

¹²⁹⁶ Cohen-Almagor “On the philosophical foundations of medical ethics: Aristotle, Kant, JS Mill and Rawls 2017 *Ethics Med Public Health* 1-26.

¹²⁹⁷ Katz J *The silent world of doctor and patient* (Free Press New York 1984)1-29.

¹²⁹⁸ Olufowote JO “A structural analysis of informed consent to treatment: Societal evolution, contradiction, and reproductions in medical practice” 2008 *Health Communication* 292-303.

¹²⁹⁹ Katz J “Limping is no sin: Reflections on making health care decisions” 1984 *Cardozo Law Review* 243-265.

¹³⁰⁰ Leitch A “Rush, Benjamin (1746-1813)” in *A Princeton companion* (Princeton University Press Princeton NJ 1978) see also Haakonssen L “Benjamin Rush: Medical ethics for a new Republic” in *Medicine and morals in the enlightenment: John Gregory, Thomas Percival and Benjamin Rush* (Rodopi Amsterdam/Atlanta 1997) 187-199.

understand and comply with physicians' recommendations, but no further. In 1803, Thomas Percival published a book called "*Medical Ethic*"¹³⁰¹ where he stated:

To a patient who makes inquiries which if faithfully answered, might prove fatal to him, it would be a gross and unfeeling wrong to reveal the truth. His right to it is suspended and even annihilated...the balances of truthfulness yield to beneficence in critical situations.¹³⁰²

Percival felt that beneficent deception for the purpose of protecting the hope of the patient was a prior duty to the truth when he stated:

The only point at issue is whether the practitioner shall sacrifice that delicate sense of veracity, which is so ornamental to, and indeed forms a characteristic of excellence of the virtuous man, to this claim of justice and social duty."¹³⁰³

Percival's writings became the basis for the first American Medical Association (AMA) code of ethics issued in 1847.¹³⁰⁴ Despite Percival's insistence on concealing the truth from patients, other writers such as Thomas Gisborne¹³⁰⁵ championed the need for truth-telling in medicine when he wrote in 1794: "The physician...is invariably bound never to represent the uncertainty or danger as less than he actually believes it to be,"¹³⁰⁶ thereby encouraging full disclosure as required by current IC doctrines. Other 19th century physicians such as Worthington Hooker¹³⁰⁷ of Connecticut and William Osler¹³⁰⁸ continued to refine a primarily beneficence based understanding of medical ethics. Osler argued that physicians should be broadly educated in the liberal arts, so as to practice medicine properly, while Hooker was more concerned about the effect of deception

¹³⁰¹ Percival T *Medical Ethic or a code of institutes and precepts adapted to the professional conduct of physicians and surgeons* (Printed by S Russell Manchester 1803).

¹³⁰² Faden and Beauchamp *A history and theory of informed consent* 68.

¹³⁰³ Haakonssen L "Thomas Percival: The duty of public office" in *Medicine and morals in the enlightenment: John Gregory, Thomas Percival and Benjamin Rush* (Rodopi Amsterdam/Atlanta 1997) 170.

¹³⁰⁴ AMA Council on Ethics and Judicial Affairs *Code of medical ethics: Current opinions with annotations* (American Medical Association Chicago 2006-2007).

¹³⁰⁵ Porter R "Thomas Gisborne: Physicians, Christians and gentlemen" 1993 *Clio Med* 252-73.

¹³⁰⁶ Porter 1993 *Clio Med* 252-73.

¹³⁰⁷ Musto DF "Worthington Hooker (1806-1867): Physician and educator" 1984 *Conn Med* 569-574.

¹³⁰⁸ Cushing H "Sir William Osler" in *Life of Sir William Osler* (Clarendon Press Oxford 1925).

generally, than on the importance of patient consent. In the 1950s, following the revelations of research abuse and the use of human patients as guinea pigs during the doctors' trial at Nuremberg, Germany,¹³⁰⁹ efforts to codify ethical principles increased and the *Nuremberg Code* were introduced in 1947-1948¹³¹⁰ to prohibit experiments against humans without their consent. As such, the first principle of the Nuremberg code provides in part: "*The voluntary consent of the human subject is absolutely essential.*"¹³¹¹ The code suggests that the consent of the research subject must have at least four characteristics; it must be voluntary, competent, informed, and comprehending.¹³¹²

Following publication of the Nuremberg Code, medical ethics began to move away from being primarily self-regulating to increased public scrutiny based upon the views of non-physicians such as Joseph Fletcher,¹³¹³ who began to examine the impact of medical technology on the moral fabric of society. The World Medical Association (WMA) *Declaration of Helsinki* 1964¹³¹⁴ departed from the strictly legal focus of the Nuremberg code, as a guideline for physicians in the ethical practice of medical research. Despite the publication of these ethical codes, Beecher¹³¹⁵ and Katz¹³¹⁶ were able to document unethical research practices involving human subjects. Because of these controversies, a United States National Commission published the *Belmont Report*,¹³¹⁷ which proposed broad ethical principles to guide researchers in designing research studies. The primary ethical principles suggested by the Belmont report are the principles of respect for autonomy, beneficence, non-maleficence and justice. In addition, various US federal

¹³⁰⁹ Trials of war criminals before the Nuremberg military tribunals under control council law No. 10 vol 2 (Washington DC US Government Printing Office 1949).

¹³¹⁰ Trials of war criminals before the Nuremberg military tribunals under control council law (Washington DC US Government Printing Office 1949) 181-182.

¹³¹¹ Faden et al *History and theory of informed consent* (Oxford University Press New York 1986) 192.

¹³¹² Nuremberg Code (1948) "Trials of war criminals before the Nuremberg military tribunals under control council law" (Washington DC US Government Printing Office 1949) 181-182.

¹³¹³ Fletcher J *Situation ethics* (The Westminister Press Philadelphia 1966).

¹³¹⁴ World Medical Association *Declaration of Helsinki-Ethical principles for medical research involving human subjects* (Adopted by the 18th WMA General Assembly Helsinki Finland June 1964 and amended by the 64th WMA General Assembly Fortaleza Brazil October 2013).

¹³¹⁵ Beecher H "Ethics and clinical research and experimentation in man" 1966 *N Engl J Med* 1354-1360.

¹³¹⁶ Katz J *Experimentation with human beings* (Russell Sage Foundation New York 1972).

¹³¹⁷ National Commission for the Protection of Human Subjects of Biomedical Research *The Belmont Report* (DHHS USA 1979).

agencies published regulations guiding experimental research such as the Food and Drug Administration (FDA) in 1981 and the Department of Health and Human Services (DHHS) in 1983.¹³¹⁸ These regulations required that Institutional Review Boards (IRBs), review research proposals and monitor execution of federally funded research projects.¹³¹⁹

Similarly in England in 1967, the Royal College of Physicians committee on the supervision of the ethics of clinical investigation called for the formation of research ethics committees (RECs).¹³²⁰ In the same year, Papworth published his book “Human Guinea Pigs”¹³²¹ which documented hundreds of unethical research practices in the United Kingdom and USA. In the later part of the 20th century until present, biomedical research has been dominated by new technological advances, which are currently influencing the ethics of contemporary biomedical research and medical treatment. The 1960s and 70s brought an emphasis on patient autonomy to the consideration of biomedical ethics in the USA.¹³²² Medical paternalism gradually gave way to respect for autonomy. The ascendancy of respect for autonomy paralleled the rise in technological advancement in medicine and pronounced affluence in the West. Institutions dedicated to the study of biomedical ethics were established in Washington DC¹³²³ and New York,¹³²⁴ leading to challenges of the medical establishment as the sole participant in medical decision-making. With the 1980s and 1990s came the prospect of scarcity of healthcare resources, which led to dramatic ethical debates regarding distributive justice in the context of the HIV-AIDS pandemic. Such questions as healthcare rationing, post-trial benefits to HIV-AIDS drugs and redistribution of the risk and burdens of biomedical research became more prominent.¹³²⁵ The last few decades have been preoccupied with the moral, ethical

¹³¹⁸ National Bioethics Advisory Commission *Ethical and policy issues in research involving human participants* (NBAC Washington DC 2001).

¹³¹⁹ US Code of federal regulations 45 CFR 46.116 *General requirements for informed consent* <https://www.law.cornell.edu/cfr/text/45/46.116> (Date of use: 23 April 2016).

¹³²⁰ DOH *Guidelines on consent to treatment or examination* (HMSO London 2001).

¹³²¹ Papworth MH *Human guinea pigs: Experimentation in man* (Beacon Press Boston 1967).

¹³²² National Bioethics Advisory Commission *Ethical and policy issues in research involving human participants* (NBAC Washington DC 2000).

¹³²³ Kennedy Institute in Washington DC.

¹³²⁴ Hastings Center in New York.

¹³²⁵ Chima 2006 *BMJ* 848-51.

and legal issues associated with new medical advances in cloning, stem-cell research, DNA analysis, the human genome and gene therapy.¹³²⁶

As discussed above, concerning information disclosure, from Hippocratic times, the medical profession has always been reluctant to disclose information to patients fearing that “for many patients through this cause have taken a turn for the worse” (*Decorum*, XVI).¹³²⁷ Similarly, up until the judgment of the UK House of Lords in the case of *Sidaway* where Lord Templeman opined that “the provision of too much information may prejudice the attainment of the objective of restoring the patient’s health,”¹³²⁸ this opinion has been maintained by many medical and legal authorities. However, in recent times there has been somewhat of a paradigm shift in the doctor-patient relationship, whereby patients have acquired more rights, and become imbued with the rights of the consumer of healthcare services, rather than passive recipients of benevolent healthcare service from doctors and other HCPs.¹³²⁹ As patients have become more aware of their rights, they have become more knowledgeable and inquisitive, making comments, such as: “ I want to know what the options are, and weigh them myself,” or “ I want to know what is going to happen or why; I also look up info on the internet.”¹³³⁰ The law such as the Human Rights Act¹³³¹ in the UK and the Constitution in South Africa¹³³² have enshrined these rights of dignity, privacy, confidentiality, and bodily integrity within codified legal instruments, which doctors and other HCPs are obliged to adhere to. As summarized by the WMA:¹³³³

¹³²⁶ Chima SC and Mamdoo F “Ethical and regulatory issues surrounding umbilical cord blood banking in South Africa” 2011 *SAJBL* 79-84.

¹³²⁷ Hippocrates *Hippocrates collected works* I Jones WHS (ed) <http://www.perseus.tufts.edu/hopper/text?doc=Perseus%3Atext%3A1999.01.0251%3Atext%3Dintro%3Achapter%3D2> (Date of use: 23 April 2016).

¹³²⁸ *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643 [904].

¹³²⁹ Chima *A primer on medical law* 18-19 see also *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11 para [75-81].

¹³³⁰ Chima 2015 *Niger J Clin Pract* 52.

¹³³¹ UK Human Rights Act 1988.

¹³³² The Constitution of the Republic of South Africa 1996.

¹³³³ Williams JR World Medical Association *Manual on ethics* 3rd ed (WMA Ferney-Voltaire France 2005).

Until recently, physicians generally considered themselves accountable only to themselves, to their colleagues in the medical profession and for religious believers, to God. Nowadays, they have additional accountabilities to their patients, to third parties such as hospitals and managed healthcare organizations, to medical licensing and regulatory authorities, and often to courts of law. These different accountabilities can conflict with one another.¹³³⁴

In view of the above, the professional practice of medicine has changed from its Hippocratic roots, with doctors and other HCPs being urged to involve patients in healthcare decision-making, as stated by the GMC guidance documents on good medical practice:

Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care.¹³³⁵

Similarly, the HPCSA has urged HCPs in South Africa to ensure voluntary healthcare decision-making by patients' stating:

It is for the patient, not the health care practitioner, to determine what is in the patient's own best interests. Nonetheless, practitioners may wish to recommend a treatment or a course of action to patients, but they must not put pressure on patients to accept their advice. In discussions with patients, health care practitioners should give a balanced view of the options and explain the need for informed consent.¹³³⁶

The recent judgment of the UK Supreme Court (Scotland) in *Montgomery v Lanarkshire*,¹³³⁷ including certain social and legal developments in medical practice, signal a departure from a doctor-patient relationship based on medical paternalism towards a relationship based on respect for the autonomy and rights of patients as intelligent individuals who are capable of being involved in the healthcare decision

¹³³⁴ WMA *Medical ethics manual* 3rd ed (WMA. Ferney-Voltaire Cedex France 2015) 22.

¹³³⁵ UK General Medical Council *Good medical practice 2013* <https://www.gmc-uk.org/guidance/index.asp> (Date of use: 12 November 2017).

¹³³⁶ HPCSA *Guidelines - Seeking patients informed consent* (HPCSA Pretoria 2008) 6.

¹³³⁷ *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11.

¹¹²¹ *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11 para [82]

making process The current law and jurisprudence regarding IC and negligence point towards a situation where, instead of patients being placed in the hands of doctors under the reasonable doctor standard of care, whereby the patients may turn around to sue the doctor or HCP when things go wrong. A shift is noticeable to one where the patients are recognized as capable of assessing the risks involved in healthcare, and making a conscious decision to accept such risks which might impact on their individual lives. “In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment.”¹³³⁸

In light of the above considerations and new developments in human rights, medical law and ethics; full information disclosure based on the prudent patient and material risks standards has become the required standard of care for IC since the latter part of the 20th century to the present.¹³³⁹ However, other commentators have argued for a shift from informed decision-making to shared healthcare decision-making by distinguishing informed decision-making as “an individual’s overall process of gathering relevant information from both the clinician and other clinical and non-clinical sources with or without independent clarification of values.”¹³⁴⁰ Whereas shared healthcare decision-making can be characterized as a particular process of decision-making by the patient and clinician in which the patient:

- a) Understands the risk or seriousness of the medical condition;
- b) Understands the medical procedure including the risks, benefits, alternatives, and uncertainties;
- c) Has weighed his or her personal values regarding the potential benefits and harms associated with the healthcare service;
- d) Has engaged in decision-making at a level at which he or she feels comfortable;

¹³³⁸ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 82].

¹³³⁹ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 87].

¹³⁴⁰ Kaplan RM “Shared medical decision making: A new tool for preventive medicine” 2004 *Am J Prev Med* 81.

e) Has come to a joint decision in association with the healthcare provider.¹³⁴¹

Advocates of shared decision-making have suggested that it promotes patient comprehension and autonomy, reduces unwanted medical procedures, and malpractice claims, improves patient compliance, and decreases overall costs of healthcare service delivery.^{1342,1343,1344, 1345}

3.8 Sociohistorical phases of informed consent based on structural analysis

Using the technique of structural analysis, Olufowote has delineated the historical evolution of the IC doctrine into three overlapping phases or structures.¹³⁴⁶ The first phase or structure, known as the “traditionalist phase or structure”, favoured physician control over the medical decision making process and information disclosure which accompanied the emergence of the IC doctrine in the 1950s. Laws prevalent during this phase include the doctrine of therapeutic privilege and the reasonable doctor standard of information disclosure.^{1347,1348} The second phase is described as the “liability structure”, which favoured the interests of states and administrative entities, which emerged in the 1970s to challenge the traditionalist structure. Informed consent laws prevalent during this period included the ‘objective’ reasonable patient standard of information disclosure, legal rules, standardized risk disclosure, and the presumptive effect of consent forms as reflecting true informed consent.¹³⁴⁹ The third phase or structure is described as the “decision-making structure”, which now emphasises patients’ rights and emerged in the 1980s. The

¹³⁴¹ Kaplan 2004 *Am J Prev Med* 81-83.

¹³⁴² King JS and Moulton BW “Rethinking informed consent: The case for shared medical decision-making” 2006 *Am J Law Med* 429-501.

¹³⁴³ Charles C, Gafni A and Whelan T “Shared decision-making in the medical encounter: What does it mean? (Or it takes at least two to tango)” 1997 *Soc Sci Med* 681-692.

¹³⁴⁴ Chima 2015 *Niger J Clin Pract* S46-S56.

¹³⁴⁵ Katz J *The silent world of doctor and patient* (The Free Press New York 1984).

¹³⁴⁶ Olufowote JO “A structural analysis of informed consent to treatment: (Re) productions of contradictory sociohistorical structures in practitioners’ interpretive schemes” 2009 *Qualitative Health Research* 802-814.

¹³⁴⁷ Faden and Beauchamp A *History and theory of informed consent* 86-91.

¹³⁴⁸ Meisel A “The ‘exceptions’ to the informed consent doctrine: Striking a balance between values in medical decision making” 1979 *Wis L Rev* 413-488.

¹³⁴⁹ Olufowote JO 2008 *Health Communication* 292-303 see also Olufowote 2009 *Qualitative Health Research* 802-814.

laws constituting this phase or structure are the ‘subjective’ patients standard of information disclosure, waiver of IC, where written consent alone may not prove that valid IC was obtained, and the ‘material risks’ standard of information disclosure.¹³⁵⁰ In the decision-making phase, which is currently prevalent in modern medical practice, IC emphasizes oral communication and an ongoing conversation between doctors or other HCPs and the patient, which enhances patients’ understanding and comprehension. Patients are now seen as idiosyncratic and unique participants in decisions regarding their healthcare, and decisions are seen as an intertwining of the technical knowledge and skills of the HCP, with the personal values of the patient concerned, thereby facilitating shared healthcare decision making.^{1351,1352,1353,1354}

3.9 Some philosophical arguments related to autonomy and the informed consent doctrine

3.9.1 The concept of autonomy

“I am autonomous if I rule me and no one else rules I”,¹³⁵⁵ therefore “I act autonomously if I, as the agent, am the power that freely and competently achieves my own ends by choosing what I have good grounds to believe to be, the best means to my ends”.¹³⁵⁶ Autonomy, as a concept, was initially introduced to describe self-governing nation states. In medical law and ethics, it refers to self-determination or freedom of choice.¹³⁵⁷ This ethical principle that each person has a right to decide what can be done to his or her own body during medical treatment has found expression in some legal statutes, such as the

¹³⁵⁰ Olufowote 2008 *Health Communication* 292-303 see also Olufowote 2009 *Qualitative Health Research* 802-814.

¹³⁵¹ Braddock CH “Advancing the cause of informed consent: Moving from disclosure to understanding” 1998 *Am J Med* 354-355.

¹³⁵² Braddock CH et al “How doctors and patients discuss routine clinical decisions: Informed decision making in the outpatient setting” 1997 *J Gen Intern Med* 339-345.

¹³⁵³ Olufowote 2008 *Health Communication* 292-303.

¹³⁵⁴ Chima 2015 *Nig J Clin Pract* 55.

¹³⁵⁵ Dworkin G *The theory and practice of autonomy* (Cambridge University Press Cambridge 1988) 8.

¹³⁵⁶ Kihlbom U “Autonomy and negatively informed consent” 2008 *J Med Ethics* 146-149.

¹³⁵⁷ Chima 2009 *Trans J Coll Med S Afr* 38.

NHA,¹³⁵⁸ and international ethical codes such as the UNESCO code on bioethics.¹³⁵⁹ The concept of autonomy has also been given some legal recognition via court decisions in common law jurisdictions through the legal doctrine of informed consent.^{1360,1361} In cases such as *Canterbury v Spence*,¹³⁶² *Rogers v Whitaker*,¹³⁶³ *Reibl v Hughes*,¹³⁶⁴ and *Castell v De Greef*,¹³⁶⁵ common law courts from South Africa to the USA, Canada, and Australia, have come to enforce patients autonomy rights through landmark judgments, thereby reinforcing the doctrine of IC.

It has been argued that autonomy by itself has never been fully recognized as a legally enforceable right.¹³⁶⁶ Instead, two other rights, derived from the principle of respect for autonomy, have been universally accorded legal protection.¹³⁶⁷ The first is the right to bodily integrity, protected by legal rules against assault or battery. The second is the right to bodily wellbeing, protected by professional negligence laws.¹³⁶⁸ According to Keith LJ in *Airedale NHS Trust v Bland*:¹³⁶⁹

The first point to make is that it is unlawful so as to constitute both the tort and crime of battery, to administer medical treatment to an adult, who is conscious and of sound mind, without his consent... such a patient is completely at liberty to decline to undergo treatment, even if the result of his doing so will be that he will die.¹³⁷⁰

As explained further by Watermeyer J in the South African case of *Stoffberg v Elliot*,¹³⁷¹ any operation performed on a person without his consent is an unlawful interference with

¹³⁵⁸ National Health Act 61 of 2003.

¹³⁵⁹ UNESCO *Universal Declaration on Bioethics and Human Rights* (UNESCO Geneva 2005).

¹³⁶⁰ Schultz MM 1985 *Yale L J* 219.

¹³⁶¹ Jennings S "Medical law and individual autonomy- Competing perspectives" 2003. <http://www.nuigalway.ie/law/GSLR/2003/MedicalNegligence.pdf> (Date of use: 20 February 2008).

¹³⁶² *Canterbury v Spence* (1972) 464 F 2d 772 (DC Cir).

¹³⁶³ *Rogers v Whitaker* (1992) HCA 58; (1992) 175 CLR 479 (Australian High Court).

¹³⁶⁴ *Reibl v Hughes* (1980) 114 DLR (3d) 1 (SCC).

¹³⁶⁵ *Castell v De Greef* 1994 (4) SA 408 (C).

¹³⁶⁶ Schultz 1985 *Yale L J* 219-299.

¹³⁶⁷ Chima 2013 *BMC Med Ethics* S3 [2].

¹³⁶⁸ Jennings <http://www.nuigalway.ie/law/GSLR/2003/MedicalNegligence.pdf> (Date of use: 20 February 2008).

¹³⁶⁹ *Airedale NHS Trust v Bland* (1993) AC 789.

¹³⁷⁰ *Airedale NHS Trust v Bland* (1993) 2 WLR 316 [859].

¹³⁷¹ *Stoffberg v Elliot* (1923) CPD 148-150.

his right of security to his person. Cardozo J classically summarized a patient's right to autonomy during medical treatment in the *Schloendorff* case,¹³⁷² where he opined: "Every person being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patients consent commits an assault, for which he is liable in damages."¹³⁷³ Rehnquist CJ of the US Supreme Court later reaffirmed these sentiments in the *Cruzan* case¹³⁷⁴ when he noted that "[n]o right is held more sacred or is more carefully guarded by the common law. Than the right of every individual to the possession and control of his own person, free from all restraint or interference of another".¹³⁷⁵ Therefore, a physician who exceeds the consent given by a patient will generally be guilty of infringing the patients' right to bodily integrity and well-being,¹³⁷⁶ as summarized by Lord Donaldson in *Re F*:¹³⁷⁷

Prima facie, therefore, in the absence of consent all, or almost all, medical treatment and all surgical treatment of an adult is unlawful, however beneficial such treatment might be. This is incontestable.¹³⁷⁸

Therefore respecting patient's autonomy requires that HCPs recognize that:

It is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if a patient of sound mind refuses, however unreasonably to consent to treatment or care by which life might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so.¹³⁷⁹

¹³⁷² *Schloendorff v Society of New York Hospital* (1914) 211 NY 105 NE 92.

¹³⁷³ *Schloendorff v Society of New York Hospital* 211 NY 105 NE (1914) 93.

¹³⁷⁴ *Cruzan, by her parents and co-guardians v Director Missouri Department of Health* (Supreme Court of the United States 1990) 497 U.S. 261.

¹³⁷⁵ *Re Cruzan* Supreme Court of the United States 1990 497 US 261 see also *Union Pacific Railway Co v Botsford* 141 US 250 (1891) [251].

¹³⁷⁶ Chima 2013 *BMC Med Ethics* S3 [2].

¹³⁷⁷ *Re F* (1992) 2 AC1.

¹³⁷⁸ *Re F* (1992) 2 AC1 [12D].

¹³⁷⁹ *Airedale NHS Trust v Bland* (1993) AC 789 [865].

3.9.2 Kantian or principled autonomy

The 18th century philosopher, Immanuel Kant, postulated the moral basis for the principle of respect for autonomy.¹³⁸⁰ Kant argued that the ability of humans to consider the possible consequences of their actions, form intentions, and then act on them, rather than reacting to circumstances, are what distinguish humans from machines or lower animals. Therefore, unthinking choices do not represent autonomy. Kant argued that autonomous action can be theoretically harnessed for universal good. This is based on his identification of a “categorical imperative”, which he formulated into two major maxims. The first of these maxims asks us to, “act only on that maxim which you can at the same time will, that it becomes a universal law”. In the second maxim he urges us to, “act as to treat humanity, whether in your own person or in that of any other, never solely as a means but always as an end.”^{1381,1382}

This idea that people should be treated as ‘ends in themselves’ has influenced liberal political philosophy by stressing the principle that people should not have their individual freedoms compromised for the sake of others or for the good of society in general. Kant believed that these “categorical imperatives”, which may be described as duties that should never be renounced, could be used to derive the specific moral duties that make up a complete ethical framework. To illustrate this, he derived the following argument for the duty of keeping promises: “Suppose one is considering breaking his promise. One could not will that breaking promises would become universal law because that would result in a total breakdown of the trust needed for promises to mean anything at all”.¹³⁸³ Therefore based on Kant’s theory, immoral actions such as telling lies, coercion, deception and control or enslavement of others, are not universalisable, because if everybody acted in this way, the end result would be a breakdown in societal morals. This Kantian form of

¹³⁸⁰ Kant I *Groundwork for the metaphysics of morals* (translated by Wood AW (ed) (Yale University Press New Haven 2002).

¹³⁸¹ Hope et al *Medical ethics and law-The core curriculum 2nd ed* (Churchill Livingstone Edinburgh 2008) 25-26.

¹³⁸² Cohen-Almagor “On the philosophical foundations of medical ethics: Aristotle, Kant, JS Mill and Rawls 2017 *Ethics, Medicine and Public Health* [4-9].

¹³⁸³ Hope et al *Medical ethics and law* 25-26.

autonomy has been described as principled autonomy.^{1384,1385} By contrast to Kant, another philosophical school of thought based on consequentialism argues that right or wrong actions should balance on their good or bad consequences. The proponents of this moral philosophy postulate that the right act in any circumstance is that which produces the best overall good as determined by an impersonal perspective that gives equal weight to the interests of each affected party.¹³⁸⁶ This moral philosophy, called utilitarianism, accepts a significant role for the principle of utility in formulating public policy and one of its principal proponents John Stuart Mill¹³⁸⁷ formulated a form of utilitarian philosophy called Millian autonomy.¹³⁸⁸

3.9.3 Millian autonomy

There is another conception of autonomy, which, while it gives consideration to reason, like Kantian autonomy, it accords, however, more weight to the exercise of choice and liberty. According to JS Mill, “the only part of conduct of anyone for which he is amenable to society is that which concerns others; in the part which merely concerns himself, his independence of right is absolute...Over himself, his own body and mind, the individual is sovereign.”¹³⁸⁹ Further:

That the individual is not accountable to society for his actions, in so far as these concern the interests of no person but himself. Advice, instruction, persuasion, and avoidance by other people if thought necessary by them for their own good, are the only measures by which society can justifiably express its dislike or disapprobation of his conduct...The reason for not interfering, unless for the sake of others, with a person’s voluntary acts, is consideration for his liberty. His voluntary

¹³⁸⁴ Stirrat GM and Gill R “Autonomy in medical ethics after O’Neill” 2005 *J Med Ethics* 127–130.

¹³⁸⁵ Furness PN “Ethical aspects of histopathology” 2003 *Recent Advances in Histopathology* 115-122.

¹³⁸⁶ Hope et al *Medical ethics and law* 22-24 see also Mill JS “Utilitarianism” in Ryan A (ed) *Utilitarianism and other essays: JS Mill and J Bentham* (Penguin Hammondsworth London 1987) 278.

¹³⁸⁷ Mill JS *Utilitarianism liberty and representative government* (JM Dent & Sons Ltd London 1910).

¹³⁸⁸ Cohen-Almagor “On the philosophical foundations of medical ethics: Aristotle, Kant, JS Mill and Rawls 2017 *Ethics Med Public Health* [10-13].

¹³⁸⁹ Mill JS *On Liberty* 1859 (Batoche Books Kitchener Ontario Canada 2001) [chapter 5].

choice is evidence that what he so chooses is desirable, or at least endurable, to him, and his good is on the whole best provided for by allowing him to take his own means of pursuing it...¹³⁹⁰

Mills was the most famous proponent of this notion of autonomy, or individuality as he called it. He was also a strong advocate of originality. According to Mills:

[...]he who lets the world, or his own portion of it, choose his plan of life for him, has no need of any other faculty than the ape-like one of imitation. He, who chooses his plan for himself, employs all his faculties. He must use observation to see, reasoning and judgment to foresee, activity to gather materials for decision, discrimination to decide, and when he has decided, firmness and self-control to hold to his deliberate decision...It is possible that he might be guided in some good path, and kept out of harm's way, without any of these things. But what will be his comparative worth as a human being? It really is of importance, not only what men do, but what manner of men they are that do it. Among the works of man, which human life is rightly employ in perfecting and beautifying, the first in importance is surely man himself... individuality is the same thing with development, and ... it is only the cultivation of individuality which produces, or can produce, well-developed humans ...¹³⁹¹

3.9.4 Millian autonomy and controversial choices

There is no agreement in the world on what is good and moral in society. Questions have been asked about how far people should be allowed to pursue choices which are not judged to be in their best interests. Should people be allowed act in such controversial ways or make such controversial choices? Common examples are those who practice apotemnophilia and other body dysmorphisms such as limb amputations, body piercings, tattooing and other controversial choices. How should society respond to these controversial choices? The answer, it has been argued, turns on how these people arrive at such choices. People often have values, which diverge from the dominant social values. These values lead them to make choices that are judged by some to be imprudent or irrational.

¹³⁹⁰ Mill JS *On Liberty* 1859 (Batoche Books Kitchener Ontario Canada 2001) 52-68.

¹³⁹¹ Savulescu J "Autonomy, the good life, and controversial choices" in *The Blackwell guide to medical ethics* Rhodes R, Francis LP and Silvers A (eds) (Blackwell Publishing Ltd Oxford 2007) see also Mill JS *On liberty* 1859 [chapter 3].

According to Savulescu, controversial choices can be divided into three categories: (a) refusal of assistance to which one has a legitimate entitlement (b) requests for assistance for enhancement or for assistance to which one does not have a clear legitimate entitlement, and (c) requests for liberty to engage in activities which may result in future requests for assistance or demands on others or society.¹³⁹² According to JS Mill who championed the right to individual freedom and liberty:

I have said that it is important to give the freest scope possible to uncustomary things, in order that it may appear in time which of these are fit to be converted into customs. But independence of action, and disregard of custom, are not solely deserving of encouragement for the chance they afford that better modes of action, and customs more worthy of general adoption, may be struck out; nor is it only persons of decided mental superiority who have a just claim to carry on their lives in their own way. There is no reason that all human existence should be constructed on someone or small number of patterns. If a person possesses any tolerable amount of common sense and experience, his own mode of laying out his existence is the best, not because it is the best in itself, but because it is his own mode.^{1393,1394}

3.9.5 Implications of respect for autonomy and liberty on the informed consent doctrine

Current arguments on informed consent in healthcare are based on libertarian rights-based autonomy, designed to safeguard individual freedoms and liberty, above considerations related to the rights of others and society. John Locke wrote as follows: "The natural liberty of man is to be free from any superior power on earth and not to be under the will or legislative authority of man, but to have only the law of nature for his

¹³⁹² Savulescu J "Autonomy, the good life and controversial choices"
http://www.philosophy.ox.ac.uk/__data/assets/pdf_file/0007/28168/controversial_choices.pdf.
(Date of use: 22 February 2016)

¹³⁹³ Savulescu
http://www.philosophy.ox.ac.uk/__data/assets/pdf_file/0007/28168/controversial_choices.pdf.
(Date of use: 22 February 2016).

¹³⁹⁴ Mill JS *On liberty* 1859 (Batoche Books Kitchener Ontario Canada 2001) 63.

rule.”¹³⁹⁵ This may be compared to a statement by Karin Morin concerning the rights of human subjects in biomedical research:

It is essential to recognize that society’s interest in knowledge may not coincide with an individual subject’s interest; the individual subject stands to gain nothing and may lose everything, including his or her right of self-determination...¹³⁹⁶

As discussed earlier in this thesis, the doctrine of informed consent is essentially derived from two moral principles, namely respect for autonomy and liberty, which some consider to be synonymous with autonomy. Some scholars distinguish between liberty as the condition of being independent from controlling influences; and autonomy as having both liberty and agency, that is, the capacity for intentional action.¹³⁹⁷ The idea of liberty in healthcare decision-making can be surmised from this statement attributed to Isaiah Berlin where he said that:¹³⁹⁸

Those who have ever valued liberty for its own sake believed that to be free to choose, and not to be chosen for, is an inalienable ingredient, in what makes human beings human, and that this underlies... the demand... to be accorded an area... in which one is one’s own master, a ‘negative’ area in which man is not obliged to account for his activities to any man so far as this is compatible with the existence of organized society.¹³⁹⁹

Mill’s arguments also defend liberty of the individual from being controlled by society except where it interferes with the rights of other members of society.¹⁴⁰⁰ Therefore, the Western moral tradition of individualism, as exemplified by works of Locke, Mills, Berlin and others, has strongly dominated the modern concept of autonomy and healthcare

¹³⁹⁵ Locke J *Second treatise of government* 2010-2015

<http://ezeg.nationallibertyalliance.org/files/books/locke/Locke%20-%20Early%20Modern%20Philosophy.pdf> (Date of use: 23 April 2016).

¹³⁹⁶ Morin K “The standard of disclosure in human subject experimentation” 1998 *J of Leg Med* 167 see also *Grimes v KKI* [51-52].

¹³⁹⁷ Hope et al *Medical ethics and law* 2008 [40-41].

¹³⁹⁸ Berlin I “Two concepts of liberty” in Berlin I *Four essays on liberty* (Clarendon Press Oxford 1969).

¹³⁹⁹ Berlin I *Four essays on liberty* (Oxford University Press Oxford 1969) lix-lx.

¹⁴⁰⁰ Mill JS *On liberty* 1859 (Batoche Books Kitchener Ontario Canada 2001) 69-71.

decision-making.¹⁴⁰¹ This is reflected in the IC doctrine and respect for autonomy, which favor individualism over communalism, self-reliance over interdependence, and truth-telling and forthrightness over group harmony.¹⁴⁰² Other justifications for IC may include increasing numbers of more inquisitive and knowledgeable patients, who in exercising their rights as healthcare consumers have demanded more involvement in medical decision-making.¹⁴⁰³ To explain further, as medical care has become more industrialized and sophisticated, patients have become consumers rather than involuntary recipients of benevolent healthcare services. Patients have begun to ask questions and demand consumer rights, resulting in increasing ethical and legal analyses of healthcare decision-making.^{1404,1405} As a consequence of these questions and demands by patients and analysts, modern medical practice is evolving from a practice based on beneficence, towards rights based autonomy and shared healthcare decision making.¹⁴⁰⁶ Moreover as argued by Murray:¹⁴⁰⁷

In the development of bioethics, respect for autonomy emerged as powerful catalyst for protest against thoughtless researchers and paternalistic doctors. It found ideological resonance within American civil rights movements and popular legal and political culture. The celebration of the individual, anger at the infringement of others, constitutionalized protections of personal liberty and faith in the free market economy as a fair and efficient method for distributing social goods.¹⁴⁰⁸

One may rightfully conclude that the practice of medicine has changed significantly from its Hippocratic roots. While the requirement of competence endures, the doctor–patient relationship has changed, with more knowledgeable and demanding patients, explaining the formal requirements of informed consent and respect for patients’ autonomy. Thus, the patient’s welfare has become complex and contested. Hence the obligation of HCPs

¹⁴⁰¹ Cohen-Almagor “On the philosophical foundations of medical ethics: Aristotle, Kant, JS Mill and Rawls 2017 *Ethics Med Public Health* [1-26].

¹⁴⁰² Gordon 1997 *Fordham Urb L J* 1321-1362.

¹⁴⁰³ *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11 [75].

¹⁴⁰⁴ Bastian H “Gains and losses for rights of consumer and research participants” 2001 *BMJ* 1417-1421.

¹⁴⁰⁵ Schuck 1994 *Yale LJ* 899-959.

¹⁴⁰⁶ Chima *A primer on medical law* 18-19.

¹⁴⁰⁷ Murray T “Communities need more than autonomy” 1994 *Hastings Cent Rep* 32-33.

¹⁴⁰⁸ Murray T 1994 *Hastings Cent Rep* 32-33.

to recommend interventions based on evidence of benefit, and the advent of harm which is challenged by patients who have the expectations of consumers of healthcare services, rather than the recipients of benevolent care.^{1409,1410, 1411,1412}

3.10 Patients' Rights

Patient's rights may be defined as a combination of claims, liberties, powers and immunities that ensure the protection of the patient's dignity and moral autonomy.¹⁴¹³ This definition forms the foundation for the claims that a patient might have in respect of a doctor or other HCP and it also assists in defining the duties of the HCP to the patient. It ensures access to data and information, protection from most kinds of unauthorized activities including involvement in medical procedures without consent, and suggests that the patient does no wrong by choosing to accept or refuse any medical intervention or participation in biomedical research.¹⁴¹⁴ Wear and others¹⁴¹⁵ have described patient's rights and IC as enabling and empowering a patient population that has traditionally been largely powerless and mute in the face of medical expertise and authority. When put this way, the notion of patient's rights while remaining based on the legal autonomy model also extends beyond the confines of a particular legal system. As described by Beauchamp and Childress,¹⁴¹⁶ rights per se are not absolute, but only assert *prima facie* claims that individuals can make upon other individuals or society. Therefore, the exercise of rights and making of claims are governed by rules. These rules may be legal, moral, or institutional rules, and some rights will exist or fail to exist because the relevant system either allows or disallows the claims in question.¹⁴¹⁷ The challenge for medical practice and

¹⁴⁰⁹ World Medical Association *Manual on ethics* (WMA Ferney-Voltaire France 2005) 22.

¹⁴¹⁰ Chima *A primer on medical law* 18-19.

¹⁴¹¹ Chima 2015 *Niger J Clin Pract* S46-S56.

¹⁴¹² *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11.

¹⁴¹³ Chima *Consent and patients' rights* 53.

¹⁴¹⁴ Chima *Consent and patients' rights* 53.

¹⁴¹⁵ Garcia-Bollester L "Medical ethics in transition in the Latin medicine of the thirteenth and fourteenth centuries: New perspectives on the physician-patient relationship and the doctors fee" in Wear A, Geyer-Kordesch J and French R (eds) *Doctors and ethics: The earlier historical setting of professional ethics* (Rodopi Amsterdam/Atlanta 1993) 38-71 [41].

¹⁴¹⁶ Beauchamp and Childress *Principles of biomedical ethics* 355-361.

¹⁴¹⁷ Beauchamp and Childress *Principles of biomedical ethics* 357.

biomedical research has hence been the development of a set of justifiable rules which could protect patients and human subjects, and upon which they can base their claims of rights or violations of same. The issue of patient's rights in medical practice and research has only come to the fore in the later part of the twentieth century, especially arising after the abuse of research subjects as described during the Nuremberg trials¹⁴¹⁸ and afterwards.¹⁴¹⁹

Recent advances in biomedical technology have also led to a constant rethinking of the rights of individuals utilizing the beneficial aspects of modern science.¹⁴²⁰ Prior these events and subsequent challenges to the status quo, the rights of patients have only been based on the beneficence or non-maleficence of the benevolent physician. In other words, a patient's right was solely dependent on the goodwill of the medical doctor or HCP, with the presumption that 'doctor knows best' and would act in the best interests of patients. With the revelations of doctor/researcher abuses in biomedical research, and ethical violations during medical treatment culminating in negligence claims as shown in *Canterbury v Spence*,¹⁴²¹ *Castell v De Greef* ¹⁴²² and other common law cases; commentators, such as McLean,¹⁴²³ began to question whether it was still appropriate for patients to rely solely on the judgment of doctors and other HCPs, and if not, how patients should be involved in the decision-making process regarding medical treatment or participation in research. In addition, as medical care became more industrialized and sophisticated, patients became consumers of healthcare services rather than involuntary participants in the healthcare process. Against this background, the issue of IC has consequently become more complex than ever before, intensified by the impact of the rights of patients as consumers of healthcare, and their entitlements.¹⁴²⁴

¹⁴¹⁸ Trials of war criminals before the Nuremberg Military tribunals under control council law (US Government Printing Office Washington DC 1949).

¹⁴¹⁹ Papworth MH *Human guinea pigs: Experimentation in man* (Beacon Press Boston 1967).

¹⁴²⁰ Hallinan and Friedewald 2015 *Life Sci Soc Policy* DOI 10.1186/s40504-014-0020-9.

¹⁴²¹ *Canterbury v Spence* 464 F 2d 772 (DC Cir 1972).

¹⁴²² *Castell v De Greef* 1994 (4) SA 408 (C).

¹⁴²³ McLean SAM *A patient's right to know: Information disclosure, the doctor and the law* (Dartmouth Aldershot 1995).

¹⁴²⁴ Schuck 1994 *Yale LJ* 899-959 see also Bastian H 2001 *BMJ* 1417-1421 and Rowe and Moodley "Patients as consumers of health care in South Africa: the ethical and legal implications" 2013 *BMC Med Ethics* 15.

The increased complexity of decision-making in contemporary medicine has stimulated an extensive literature on patients' rights in medical practice and increasing debate on the ethics of research.¹⁴²⁵ One aspect of the recognition of the moral autonomy of the patient has been the recognition of the need for adequate information disclosure, which would enable the patient to accept or reject therapy or medical interventions, or choose between therapies as first recognized in cases such as *Canterbury v Spence*,¹⁴²⁶ or more recent cases,¹⁴²⁷ or as debated by the English House of Lords in the *Sidaway* case.¹⁴²⁸ One aspect of this debate in the latter case has been whether to persist with the 'reasonable doctor standard' as established in *Bolam*¹⁴²⁹ or to follow the 'prudent patient standard' as suggested by Lord Scarman in *Sidaway*¹⁴³⁰ and Ackerman J in the *Castell* case.¹⁴³¹ Information disclosure is an important aspect of enhancing the patient's moral autonomy or ability to choose. As suggested by McLean, its potential invasiveness and its social and political potential make it an area ripe for rights discourse.¹⁴³² Debates in this area have therefore focused on several issues, including whether the doctors' duty to disclose based on the patients right to receive information can be tested independently of patient understanding, however, if the patient is unable to understand, what then is the point of disclosure? Is there a duty on the doctor or HCP to ensure patient understanding? There are also problems with the rationality of a patient's decision-making, leading to questions of competence especially about incapacitated patients, minors, and individuals in dependent positions such as prisoners, students and vulnerable people from developing

¹⁴²⁵ Chima *Consent and patients' rights in human biomedical research* 2006 see also Chima "The importance of ethics, human rights and medical law to Africa in the 21st century" *Arab Health Magazine*, Issue 3 August 2014. [www.arabhealthmagazine.com](http://arabhealthmagazine.com) <http://arabhealthmagazine.com/the-importance-of-ethics-and-human-rights-to-africa-in-the-21st-century/> (Date of use: 15 November 2014).

¹⁴²⁶ *Canterbury v Spence* 464 F 2d 772 (DC Cir 1972).

¹⁴²⁷ *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11.

¹⁴²⁸ *Sidaway v Bethlem Royal Hospital Governors and Others* [1985] 1 All ER 643.

¹⁴²⁹ *Bolam v Friern Barnet Health Management Committee* [1957] 2 All ER 118.

¹⁴³⁰ *Sidaway v Bethlem Royal Hospital Governors and Others* [1985] 1 All ER 643 see also Hocton *Law of consent to medical treatment* 34-39.

¹⁴³¹ *Castell v De Greef* 1994 (4) SA 408 (C) see also Carstens and Pearmain *Foundational Principles* 681-694.

¹⁴³² McLean SAM *A patient's right to know* 1989 see also Mclean SAM and Mason JK *Legal and ethical aspects of healthcare* (Cambridge University Press Cambridge 2003) chapter 4.

countries with poor resources.¹⁴³³ Therefore, the contemporary debate on patients' rights in medicine has been dominated by issues of competence, information disclosure, understanding of that information, the rights of vulnerable populations and issues of distributive justice.

3.10.1 The rights of patients during medical treatment

The need to formulate internationally recognized standards of rights relevant to patients as championed by the UN ICCPR¹⁴³⁴ led to the formulation of the "Rights of Patients" by the WMA in 1981,¹⁴³⁵ where the following sets of defined rights were articulated as the core principles pertaining to the doctrine of IC in WMA patients' rights charter:

Core Principles:

1. Right to medical care of good quality

- a) Every person is entitled without discrimination to appropriate medical care.
- b) Every patient has the right to be cared for by a physician whom he/she knows to be free to make clinical and ethical judgements without any outside interference.
- c) The patient shall always be treated in accordance with his/her best interests.
- d) The treatment applied shall be in accordance with generally approved medical principles.

2. Right to freedom of choice

- a) The patient has the right to choose freely and change his/her physician and hospital or health service institution, regardless of whether they are based in the private or public sector.
- b) The patient has the right to ask for the opinion of another physician at any stage

3 Right to self-determination

- a) The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions.
- b) A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any

¹⁴³³ Chima 2006 *BMJ* 848-851.

¹⁴³⁴ United Nations *International Convention on Civil and Political Rights* (United Nations 1966).

¹⁴³⁵ WMA *Declaration of Lisbon on the Rights of the Patient* (WMA Lisbon 1998 Reaffirmed Oslo 2015).

test or treatment is, what the results would imply, and what would be the implications of withholding consent.

- c) The patient has the right to refuse to participate in research or the teaching of medicine.

4. The unconscious patient

- a) If the patient is unconscious or otherwise unable to express his/her will, informed consent must be obtained whenever possible, from a legally entitled representative.
- b) If a legally entitled representative is not available, but a medical intervention is urgently needed, consent of the patient may be presumed, unless it is obvious and beyond any doubt on the basis of the patient's previous firm expression or conviction that he/she would refuse consent to the intervention in that situation.

5. The legally incompetent patient

- a) If a patient is a minor or otherwise legally incompetent, the consent of a legally entitled representative is required in some jurisdictions. Nevertheless the patient must be involved in the decision-making to the fullest extent allowed by his/her capacity.
- b) If the legally incompetent patient can make rational decisions, his/her decisions must be respected, and he/she has the right to forbid the disclosure of information to his/her legally entitled representative.

6. Right to information

- a) The patient has the right to receive information about himself/herself recorded in any of his/her medical records, and to be fully informed about his/her health status including the medical facts about his/her condition. However, confidential information in the patient's records about a third party should not be given to the patient without the consent of that third party.
- b) Exceptionally, information may be withheld from the patient when there is good reason to believe that this information would create a serious hazard to his/her life or health.
- c) Information should be given in a way appropriate to the patient's culture and in such a way that the patient can understand. d. The patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life. e.g. The patient has the right to choose who, if anyone should be informed on his/her behalf.

7. Right to confidentiality

- a) All identifiable information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death. Exceptionally, descendants may have a right of access to information that would inform them of their health risks.
- b) Confidential information can only be disclosed if the patient gives explicit consent or if expressly provided for in the law. Information can be disclosed to other health care

providers only on a strictly "need to know" basis unless the patient has given explicit consent.

- c) All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of its storage. Human substances from which identifiable data can be derived must be likewise protected.

8. Right to dignity

- a) The patient's dignity and right to privacy shall be respected at all times in medical care and teaching, as shall his/her culture and values.
- b) The patient is entitled to relief of his/her suffering according to the current state of knowledge.
- c) The patient is entitled to humane terminal care and to be provided with all available assistance in making dying as dignified and comfortable as possible.¹⁴³⁶

The above principles led to the formulation of a patient's charter of rights in other countries such as the UK¹⁴³⁷ by the *American Hospital Association (AHA)* 1992,¹⁴³⁸ and later in South Africa.¹⁴³⁹ While these principles were originally proposed in the context of medical treatment rather than research, such principles as freedom of choice, information disclosure, and right to privacy and confidentiality are universal and applicable in all aspects of healthcare. Similarly, the American Medical Association (AMA) Code of Ethics¹⁴⁴⁰ recognized the doctor's obligation to respect patient's rights and later recognized IC as a basic social policy necessary to enable patients to make their own choices even if the physician disagrees.

3.10.2 The rights of vulnerable population groups

The CIOMS guidelines describes vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes

¹⁴³⁶ WMA *Declaration of Lisbon on the rights of the patient* (WMA Oslo 2015).

¹⁴³⁷ UK "Patients charter of rights 1991" in Roberts G *Risk management in healthcare* 2nd ed (Whitterby London 2002) 36-40.

¹⁴³⁸ AHA *The patient's bill of rights* (American Hospital Association Chicago 1992).

¹⁴³⁹ HPCSA *Guidelines for good practice in the health care professions: National patients' right charter* (HPCSA Pretoria 2008).

¹⁴⁴⁰ AMA Council on Ethics and Judicial Affairs *Code of medical ethics: Current opinions with annotations* (AMA Chicago 2006-2007).

to protect their own interests.¹⁴⁴¹ In this context, the UNAIDS criteria for vulnerability refers to:

Limited economic development, inadequate protection of human rights and discrimination on the basis of health status, inadequate community and cultural experience with the understanding of scientific research, limited availability of healthcare and treatment options and limited ability of individuals in the community to provide informed consent.”¹⁴⁴²

Based on the previous reports, including a publication relating to the research study reported here, it may be argued that a majority of patients attending public hospitals in South Africa would satisfy these criteria for vulnerability and may be considered vulnerable.^{1443,1444} In general, vulnerable population groups include children, mentally incapacitated or incompetent adults, prisoners, populations of developing or resource poor countries, students, soldiers and others in dependent relationships and may include women in certain cultural environments.¹⁴⁴⁵ The central problem regarding the involvement of these population groups in research arises from the fact that their position in society may lead to an inequitable distribution of the benefits/burden of healthcare in such a way that they may be negatively impacted. Therefore, special care should be taken to protect the rights of such vulnerable populations groups in terms of distributive justice.¹⁴⁴⁶ It has been observed that failures of the IC process lead to serious inequities in healthcare and biomedical research, especially for the poor and the less educated who bear most of the research burden and are also more impacted by medical malpractice and clinical negligence.^{1447,1448}

¹⁴⁴¹ Council for International Organizations of Medical Sciences *International ethical guidelines for biomedical research involving human subjects* (CIOMS-WHO Geneva 2016) 57.

¹⁴⁴² Chima SC “Contemporary ethical issues and the regulation of biomedical research in African communities” in Mdluza T, Chima S and Nsimba C (eds) *A gateway to biomedical research in Africa* (Nova Science Publishers New York 2007)19-38.

¹⁴⁴³ Chima 2015 *Nig J Clin Pract* S46-S56.

¹⁴⁴⁴ Chima *A gateway to biomedical research in Africa* 19-38.

¹⁴⁴⁵ CIOMS *International ethical guidelines* 2016 [57-58].

¹⁴⁴⁶ Chima *A Primer on medical law* 169-181.

¹⁴⁴⁷ Ross L “Children as research subjects: A proposal to revise the current federal regulations using a moral framework” 1997 *Stan L & Policy Rev* 164.

¹⁴⁴⁸ Chima 2006 *BMJ* 848-51.

3.11 The concept of shared healthcare decision-making

It has been suggested that we may be living in an era where respect for patient's autonomy, which was considered untenable based on the Hippocratic tradition of medical paternalism, may have become an unquestionable moral imperative.¹⁴⁴⁹ Andrew Grubb¹⁴⁵⁰ states as follows with regard to medical paternalism:

Paternalism was more appropriate to a by-gone age when the population were presumed to be uneducated, and therefore incapable of playing an equal role in the doctor-patient relationship. Such a view has no foundation in our present society and consequently does not have any right to be reflected in our legal system.¹⁴⁵¹

However, it has been argued that in the current legal systems, IC for medical treatment may be nothing more than a risk-management strategy, whereby the doctor or HCP believes that if he or she discloses every possible risk to the patient, and if anything goes wrong, then the patient cannot sue. The view has been proposed that this does not meet the moral standard for IC, which is derived from respect for the patient's autonomy. Therefore the HCPs' goal should not be to minimize liability, rather it should be focused on how to help the patient make the best possible decision. These two goals are not mutually exclusive, but they often lead to a divergent opinion regarding what IC is; and different ideas about what information needs to be shared with patients.¹⁴⁵² Ironically, if IC becomes focused on a disclosure of the 'whole truth', then IC disclosure or documentation may become excessively voluminous and encyclopedic, thereby becoming meaningless because of an information overload to the patient. This would generally not meet the ethical standard for information disclosure and the moral standard of IC and shared healthcare decision-making because very few patients would be able to evaluate such data.^{1453,1454} As explained by Lord Diplock in the *Sidaway* case:

¹⁴⁴⁹ Lantos D "Informed consent- the whole truth for patients" 1993 *Cancer Suppl* 2811-2815.

¹⁴⁵⁰ Grubb A "A survey of medical malpractice law in England: Crisis? What crisis?" 1985 *J Contemp Health Law & Pol'y* 75-114.

¹⁴⁵¹ Grubb A 1985 *J Contemp Health Law & Pol'y* 114.

¹⁴⁵² Gordon 1997 *Fordham Urb L J* 1321-1362.

¹⁴⁵³ Lantos 1993 *Cancer Suppl* 2811-2815.

¹⁴⁵⁴ Beauchamp and Childress *Principles of biomedical ethics* [90-91].

[...] the only difference that a mention of risks can have on the patients mind, if it has any at all, can be in the direction of deterring the patient from undergoing the treatment which in the expert opinion of the doctor is in the patients interest to undergo. To decide what risks the existence of which a patient should be voluntarily warned and the terms in which such warning, if any, should be given, having regard to the effect the warning may have, is as much an exercise of professional skill and judgment as any other part of the doctors comprehensive duty of care to the individual patient.¹⁴⁵⁵

Therefore, determination of the doctor's duty to disclose generally requires consideration of two values, which are sometimes in conflict, namely the duty of the doctor to act in what he conceives to be the best interests of the patient; and the right of the patient to control his own life and have the information necessary to do so.¹⁴⁵⁶ For Lord Scarman in *Sidaway*, "the doctor's duty arises from the patient's rights".¹⁴⁵⁷ Further, the Canadian court in *Allan v Mount Sinai*¹⁴⁵⁸ described a patients' rights as follows:

Without consent, either written or oral, no surgery may be performed. This is not a mere formality; it is an important individual right to have control over one's own body, even where medical treatment is involved. It is the patient, not the doctor, who decides whether surgery will be performed, where it will be done, when it will be done and by whom it will be done.¹⁴⁵⁹

Unfortunately, this point of view is not generally accepted by the medical profession because traditional medical ethics and the Hippocratic tradition places emphasis on the patients welfare (*salus aegroti*) rather than his right of self-determination (*voluntas aegroti*),¹⁴⁶⁰ thereby creating a conflict in the doctor patient relationship. It has been argued that proper information disclosure is a *conditio sine qua non* of a legally acceptable consent.^{1461,1462} Further, consent is unitary in nature, an essential prerequisite for any

¹⁴⁵⁵ Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 1 All ER 643 [658].

¹⁴⁵⁶ F v R (1984) 33 SASR 189.

¹⁴⁵⁷ Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 1 All ER 643 [651].

¹⁴⁵⁸ Allan v New Mount Sinai Hospital (1980) 109 DLR (3d) 634.

¹⁴⁵⁹ Allan v New Mount Sinai Hospital (1980) 109 DLR (3d) 634 [363].

¹⁴⁶⁰ Giesen D "From paternalism to self-determination to shared decision-making in the field of medical law and ethics" in Westerhall L and Phillips C (eds) *Patient's rights-Informed consent access and inequality* (Nerenius & Santerus Publishers Stockholm 1994)19-38.

¹⁴⁶¹ Giesen *Patient's rights-Informed consent access and inequality* 19-38.

¹⁴⁶² Carstens and Pearmain *Foundational Principles* 883-894.

medical intervention, and for it to be valid, it must be given freely based on a sound understanding of what is at stake. Therefore, there is no room for a concept which leaves the HCP or the medical profession to decide how much information should be volunteered to the patient,^{1463,1464} because it is the patient who undergoes the risk of subjecting him or herself to a medical intervention and would-be any negative or positive consequences and therefore requires full information disclosure to make an informed decision.¹⁴⁶⁵ In recent times, most legal systems appear to prefer the patient's autonomy to medical paternalism, by recognizing the basic human right to self-determination which should not be denied to patients simply because they are sick and vulnerable. It has been suggested that the legal requirement of informed consent envisages a different type of doctor-patient relationship based on the equality of the patient and HCP and is built on a foundation of honesty, trust and mutual respect, thereby tending to support shared decision-making.¹⁴⁶⁶ Therefore, the issue is no longer about whether information should be disclosed by the HCP to the patient, but the standard and scope of such disclosure,¹⁴⁶⁷ while tackling the conflict between the patients right to self-determination and the doctor's beneficence.

Lord Scarman pointed out in *Sidaway* that the question whether a doctor is under a duty to disclose, or whether such a duty has been discharged, is ultimately a legal not a medical question.¹⁴⁶⁸ This approach has generally had the effect of reducing medical paternalism and preventing doctors from being the judge and jury in their own cases by determining the standard and scope of disclosure. Therefore a, patient-based standard of disclosure requires that a doctor or HCP should disclose information which the doctor or HCP knows or should know would enable the patient make his or her own decision based on the material risk standard.¹⁴⁶⁹ Therefore, according to Kirby J "The days of paternalistic medicine are numbered. The days of unquestioning trust of the patient also appear numbered [...] nowadays doctors, out of respect for themselves and for their patients; to

¹⁴⁶³ Carstens and Pearmain *Foundational Principles* 883-894.

¹⁴⁶⁴ *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11 [87].

¹⁴⁶⁵ *Canterbury v Spence* 464 F 2d 772 (DC Cir 1972).

¹⁴⁶⁶ Beauchamp and Childress *Principles of biomedical ethics* 81.

¹⁴⁶⁷ Giesen *Patient's rights-Informed consent access and inequality* 19-38.

¹⁴⁶⁸ *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643 [651].

¹⁴⁶⁹ Hartman M and Liang BA "Exceptions to informed consent in emergency medicine" 1999 *Hospital Physician* 53-59.

say nothing for deference to the law, must increasingly face the obligation of securing informed consent from the patient for the kind of therapeutic treatment proposed.”¹⁴⁷⁰ The President’s commission has urged that “most fundamentally, the law could emphasize the process of continuing communication and decision-making, rather than pro forma disclosure of particular risks” [...] suggesting that, “*ethically valid consent is a process of shared decision-making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments*”¹⁴⁷¹ In view of the above observations and discussion, it is clear that IC has become the legal and ethical ‘standard of care’ for medical practice since the late 20th century. More recently, others have argued for shared healthcare decision-making as recommended above, rather than informed decision-making, where informed decision-making has been described as “an individual’s overall process of gathering relevant information from both the clinician and other clinical and nonclinical sources with or without independent clarification of values.”¹⁴⁷² Shared decision-making, on the other hand, may be defined as a particular process of decision-making between the patient and clinician, in which the patient:

- i. Understands the risk or seriousness of the medical condition;
- ii. Understands the medical procedure including the risks, benefits, alternatives, and uncertainties;
- iii. Has weighed his or her personal values regarding the potential benefits and harms associated with the healthcare service;
- iv. Has engaged in decision-making at a level at which he or she feels comfortable, and finally
- v. Has come to a joint decision in association with the healthcare provider.¹⁴⁷³

¹⁴⁷⁰ Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 1 All ER 643 see also Editorial “Adequately informed consent” 1985 *J Med Ethics* 115-116.

¹⁴⁷¹ *Summaries of the reports from the President’s commission for the study of ethical problem in medicine and biomedical and behavioral research* Appendix 2 (US Government Printing Office Washington DC, 1982) 2-6.

¹⁴⁷² Kaplan 2004 *Am J Prev Med* 81.

¹⁴⁷³ Kaplan 2004 *Am J Prev Med* 81 see also King and Moulton 2006 *Am J Law Med* 429-501.

Advocates of shared decision-making argue that it promotes patient comprehension and autonomy, reduces unwanted medical procedures and malpractice claims, improves patient compliance, and decreases overall costs of healthcare service delivery.^{1474,1475,1476,1477}

3.12 Summary of chapter 3

Chapter three explored the doctrine of informed consent from a South African and comparative law perspective, by considering relevant laws and regulations, as well as case law, which have all contributed to the development of the doctrine of informed consent in South African law. The discussion has also turned to new developments in South African jurisprudence and some judgments by South African courts since the landmark judgment in *Castell v De Greef*,¹⁴⁷⁸ and the introduction of the National Health Act in 2003.¹⁴⁷⁹ In addition, some of the socio-cultural factors which may affect the practice of informed consent in South Africa were interrogated, as well as the interrelationship of multiculturalism, patients' rights and cultural belief systems, including economic and unique social factors. Finally, the historical practice of medicine in accordance with the Hippocratic tradition with its emphasis on benevolent paternalism and the obligation on physicians to conceal information from patients 'for their own good,' rather than information disclosure, has been examined. This was followed by a critical discussion of the evolution of the philosophical concept of autonomy from the perspectives of philosophers, such as Immanuel Kant and his ideas of principled autonomy, as well as the ethical theory of utilitarianism and liberty as espoused by John Stuart Mills. Also considered were other philosophers, such as Isaiah Berlin, who have explored individual autonomy, liberty and libertarian rights as the basis for autonomous decision making. The chapter concluded with a brief discussion on patients' rights during medical treatment, and

¹⁴⁷⁴ King and Moulton 2006 *Am J Law Med* 429-501.

¹⁴⁷⁵ Charles C, Gafni A and Whelan T "Shared decision-making in the medical encounter: What does it mean? (Or it takes at least two to tango)" 1997 *Soc Sci Med* 681-92.

¹⁴⁷⁶ Katz J *The silent world of doctor and patient* (Johns Hopkins University Press Baltimore 2002).

¹⁴⁷⁷ Chima 2015 *Niger J Clin Pract* 46.

¹⁴⁷⁸ *Castell v De Greef* 1994 (4) SA 408 (C).

¹⁴⁷⁹ National Health Act 61 of 2003.

the concept of shared healthcare decision-making which has evolved with the recession of medical paternalism and the dominance of the doctrine of informed consent and respect for autonomy in modern medical practice.

CHAPTER 4: RESEARCH DESIGN AND METHODOLOGY

4.1 Introduction

Chapter four of this thesis describes the research design and methods used to collect and analyse data in the empirical part of this study. This chapter will include a description of the methodological considerations and the underlying theoretical issues surrounding the empirical study. I will describe the study settings, such as hospitals included or excluded from the study, the study location, study population, sample size calculations, data collection methods and instruments used in collecting data. Methods used for storage and analysis of collected data, including statistical methods, and methods undertaken to ensure validity of data and ethical considerations including approvals from regulatory authorities, gate keepers and study participants will also be described..

4.2 Methodological considerations

Before I proceed with a full description of the research methods used in this study, it is necessary to provide a brief theoretical justification for using a particular research design approach, strategies, and techniques for sample collection and analysis of data applied in the empirical aspects of this research study consistent with the social science methods applied in 'empirical bioethics'. A broad and detailed overview of this theoretical considerations and justifications for using empirical methods to study bioethical issues is provided in chapters 1 and 2 of this thesis. A brief overview of research design and methods, including justifications, is included in the sections below.

4.3 Research design

Research can be described as the process of making claims, then refining or abandoning some of those claims for other claims more warranted based on empirical or objective

evidence or results derived from a particular study.¹⁴⁸⁰ A research design is a plan or procedure for a research study that spans decisions taken by the researcher, ranging from broad assumptions to detailed methods used in data collection and analysis. It involves and intersection of philosophy, strategies of inquiry and specific methods.¹⁴⁸¹ According to Schutt,¹⁴⁸² research design refers to how to measure empirical phenomena, identify causal relationships and generalize findings.¹⁴⁸³ Salazar¹⁴⁸⁴ also describes research design as the strategies an investigator chooses to answer a research question. Its ultimate goal is to guide data collection and analysis. Mouton¹⁴⁸⁵ further describes research design as the procedural plan or blueprint for conducting research in a particular setting. Therefore, one can conclude that a research design refers to the conceptual and procedural plans to conduct a research study, which emphasizes the importance of quality, validity and reliability of the design and methods used. ^{1486,1487}

Traditionally, there are three generally recognized styles and approaches of using different methods to collect and analyse data. However, none of these methods are considered superior to the other and are generally interlinked with a particular approach used in different situations, based on the theory or inferences that need to be drawn from the data.^{1488,1489} In recent times, researchers in the human and social sciences have used three generally recognized research design methods, which are the quantitative, qualitative or mixed methods research approaches. Quantitative research, which is

1480 Creswell JW *Research design- qualitative, quantitative and mixed methods approaches* 3rd ed (Sage Publications Thousand Oaks California 2009) 7.

1481 Creswell *Research design* 5.

1482 Schutt KR *Investigating the social world: The process and practice of research* (Sage Publications Thousand Oaks California 2001) 396.

1483 Schutt *Investigating the social world* 396.

1484 Salazar LF Crosby RA and Dicamente RJ *Research methods in health promotion* (Wiley San Francisco 2006) 75.

1485 Mouton J *How to succeed in your masters and doctoral studies: A South African sourcebook* 4th ed (Van Schaik Pretoria 2003) 24.

1486 Kumar R *Research methodology: A step-by-step guide for beginners* (Sage New Delhi 1999) 74.

1487 Mugisha E *Delivery and utilization of voluntary HIV counselling and testing services among fishing communities in Uganda* (D Litt et Phil thesis UNISA Pretoria 2008) 51.

1488 Creswell *Research design* [4-5].

1489 Marshall JE *Informed consent during the intrapartum period: An observational study of the interactions between health professionals and women in labour involving consent to procedures* (PhD Thesis University of Nottingham 2005) 51.

arguably one of the oldest methods of scientific enquiry, is a means of testing objective theories by examining the relationship amongst variables (dependent and independent variables).¹⁴⁹⁰ These variables are measured using various survey instruments e.g. survey questionnaires, so that numerical data can be derived, which are then analysed using statistical procedures.¹⁴⁹¹ In qualitative research on the other hand, the researcher tries to explore and understand the meaning individuals or groups ascribe to social and human problems or an individual's perceptions of the world. Using this method of inquiry, the researcher seeks insight rather than a statistical analysis of data and questions whether a scientific approach can be used when dealing with human beings.¹⁴⁹² In the case of mixed methods research, the researcher combines elements of both the quantitative and qualitative research methods in a single study.¹⁴⁹³ In this thesis, I have chosen to use a quantitative research design with data triangulation to study the process of IC in public hospitals as further described below.

4.3.1 Quantitative research

Generally, in quantitative research an investigator uses postpositivist claims for developing knowledge based on cause and effect thinking. These are then reduced to specific variables and hypotheses and questions, as well as use of measurement, observation, and the test of theories. This design method employs strategies of inquiry such as experiments and surveys, and collects data on predetermined instruments that yield statistical variables.¹⁴⁹⁴ Putting it another way, "quantitative researchers collect facts and study the relationship of one set of facts with another, which are then measured by using scientific techniques to produce objective, verifiable, quantifiable, and generalized conclusions."¹⁴⁹⁵ A survey design method provides a quantitative or numeric description

¹⁴⁹⁰ Creswell *Research design* 4.

¹⁴⁹¹ Creswell *Research design* [3-15].

¹⁴⁹² Creswell *Research design* 4.

¹⁴⁹³ Ivankova NV, Creswell JW and Stick SL "Using mixed-methods sequential explanatory design: From theory to practice" 2006 *Field Methods* 3-20.

¹⁴⁹⁴ Creswell *Research design* [145-171].

¹⁴⁹⁵ Marshall JE *Informed consent during the intrapartum period: An observational study of the interactions between health professionals and women in labour involving consent to procedures* (PhD Thesis University of Nottingham 2005) 51.

of trends, attitudes or opinions of a population by studying a sample of that population. Based on the results obtained, the researcher can then generalize or make claims about that particular population.¹⁴⁹⁶ Accordingly, Cargan¹⁴⁹⁷ describes quantitative research as a system of counting using standardized measuring instruments while Burns and Grove¹⁴⁹⁸ emphasize that quantitative research uses structured tools to generate numerical data, and then these are organized and analyzed using statistical methods. In this research study, I have used a quantitative research design, with structured instruments (questionnaires) to collect data which were stored and analyzed using a computer based statistical software package as further described below.

4.3.2 Cross-sectional studies and survey design

According to Creswell,¹⁴⁹⁹ survey design provides a quantitative or numeric description of trends opinions or attitudes of a particular population by studying a sample of that population. From the sample results, the researcher then draws conclusions, generalizes or makes claims about that particular population.¹⁵⁰⁰ In addition, cross-sectional studies are commonly used in social science research to measure a particular phenomenon at one point in time in that particular population, these are sometimes called one-shot studies.¹⁵⁰¹ Kumar has described a cross-sectional study as a study that defines a phenomenon by taking a section of it at any one time.¹⁵⁰² In this study, I have used a cross-sectional study methodology to survey the practice of IC (the phenomenon) in public hospitals in EThekweni metropolitan municipality, Kwazulu-Natal province (the population under study).

¹⁴⁹⁶ Creswell *Research design* [145-147].

¹⁴⁹⁷ Cargan L *Doing social research* (Rowman & Littlefield New York 2007) 47.

¹⁴⁹⁸ Burns N and Grove SK *The practice of nursing research: Conduct critique and utilization* 4th ed (Saunders Philadelphia 2001) 20.

¹⁴⁹⁹ Creswell *Research design* [145-149].

¹⁵⁰⁰ Creswell *Research design* 145.

¹⁵⁰¹ Hakim C *Research design: Successful designs for social and economic research* 2nd ed (Routledge London 2000)178.

¹⁵⁰² Kumar *Research methodology* 81.

4.3.3 Post positivist approach to research

A post positivist philosophical worldview, defined as a “basic set of beliefs that guide action,”¹⁵⁰³ is usually applicable in quantitative research design, and reflects the need to identify and assess the causes that influence outcomes. This approach is generally reductionist in nature, in that it tends to reduce general or big ideas into a small discreet set of ideas for testing, such as the dependent and independent variables that comprise the hypothesis and research questions. The knowledge that is derived through the post positivist method is based on a careful observation and measurement of the objective reality that exists in the world.¹⁵⁰⁴ Creswell¹⁵⁰⁵ argues that in using this method, general laws and theories can be tested and verified so that we can better understand the world. The postpositivist approach represents the traditional form of research and is sometimes called the *scientific method*. Using this method, post-positivist researchers begin with a theory or hypothesis, and then collect data, which either supports or refutes the theory or hypothesis in question. The researcher may then make necessary revisions before conducting additional tests or draw conclusions from the data generated.¹⁵⁰⁶ According to Walsh,¹⁵⁰⁷ when using the postpositivist approach, the researcher tends to maintain a distance between himself, the participants, and the research setting. Russell¹⁵⁰⁸ further suggests that the postpositivist approach helps the researcher maintain objectivity, and prevents him or her being influenced by the participants.

In this study, I adopted a postpositivist approach by constructing research instruments which were completed by the respondents/participants voluntarily and in their own time without any input from the researcher. Further, in the case of patients included in this study, the questionnaires and face-face interviews were conducted by research

¹⁵⁰³ Guba EG “The alternative paradigm dialog” in Guba EG (ed) *The paradigm dialog* (Sage New Bury Park 1990) 17-30.

¹⁵⁰⁴ Guba The alternative paradigm [17-30].

¹⁵⁰⁵ Creswell *Research design* [6-7].

¹⁵⁰⁶ Creswell *Research design* [6-7].

¹⁵⁰⁷ Walsh M *Research made real: A guide for students* (Nelson Thornes London 2001) 12.

¹⁵⁰⁸ Russell B *Social research methods: Qualitative and quantitative approaches* (Sage Publications Thousand Oaks 2000)15.

assistants. This approach assisted me as researcher to maintain objectivity and guarantee a measure of validity.

4.4 Triangulation

Triangulation refers to the use of multiple references to draw conclusions about what constitutes the truth. According to Denzin,¹⁵⁰⁹ triangulation refers to “the combination of methodologies in the study of the same phenomenon,” or it can be used metaphorically to refer to the use of multiple measures to converge on a single, discreet construct or point.¹⁵¹⁰ The original purpose of triangulation in research was to seek confirmation of apparent findings or consistency.¹⁵¹¹ More recently, triangulation has also been used for completeness purposes,¹⁵¹² for corroborating findings, and as a test of validity, although its use for these purposes is the subject of ongoing debate.^{1513,1514} Denzin¹⁵¹⁵ and Patton¹⁵¹⁶ have identified four generally accepted methods of triangulation; although a fifth method has been suggested by Kimchi,¹⁵¹⁷ called “analysis triangulation”.¹⁵¹⁸ Generally, the different types of triangulation are classified as follows:

- I. Data triangulation: This involves the use of multiple data sources in a study in order to get diverse views to aid in validating the conclusions.
 - a. Time triangulation may include collection of same data at different time periods;

¹⁵⁰⁹ Denzin NK (ed) *Sociological methods: A sourcebook* (Routledge New York 2017) 31.

¹⁵¹⁰ Denzin N *The research act: A theoretical introduction to sociological methods* to 3rd ed (McGraw-Hill New York 1989) 297.

¹⁵¹¹ Bekhet A and Zauszniewski J “Methodological triangulation: An approach to understanding data” 2012 *Nurse Res* 40-43.

¹⁵¹² Adami MF and Kiger A “The use of triangulation for completeness purposes” 2005 *Nurse Res* 19-29.

¹⁵¹³ Adami and Kiger 2005 *Nurse Res* 19-29.

¹⁵¹⁴ Robert Wood Johnson Foundation “Triangulation” Qualitative research guidelines project www.qualres.org/HomeTria-3692.html (Date of use: 7 November 2017).

¹⁵¹⁵ Denzin NK *Sociological methods* (McGraw-Hill New York 1978) see also Robert Wood Johnson Foundation “Triangulation” Qualitative research guidelines project www.qualres.org/HomeTria-3692.html (Date of use: 7 November 2017).

¹⁵¹⁶ Patton MQ “Enhancing the quality and credibility of qualitative analysis” 1999 *HSR* 1189-1208.

¹⁵¹⁷ Kimchi J, Polivka B and Stevenson JS “Triangulation: operational definitions” 1991 *Nurs Res* 364-366.

¹⁵¹⁸ Adami and Kiger 2005 *Nurse Res* 19-29.

- b. Space triangulation may involve collection of the same data from different locations, e.g. public versus private settings;
 - c. Person triangulation may involve collection of the same set of data from different persons or groups of persons.
- II. Investigator triangulation refers to the use of two or more trained researchers to analyze and interpret a set of data. This can provide a check on selective perception or bias and illuminate blind spots in interpretation.¹⁵¹⁹
 - III. Theory triangulation refers to the use of competing theories or hypotheses in the analysis and interpretation of a single set of data.
 - IV. Method triangulation involves the use of multiple methods in collecting data about the same phenomenon. For example, quantitative and qualitative data can be used in the same study to elucidate different aspects of the same phenomenon.
 - V. Analysis triangulation involves the use of two or more approaches to analyze the same set of data for the purpose of validation.

Therefore, triangulation can involve the use of different data collection tools with the same sample of participants; or, different qualitative methodologies to answer the same research question; as well as a combination of quantitative and qualitative research methodologies to answer the same research question; or the same data collection tools with different samples.

In the empirical research study included in this thesis, I have used what can be described as a form of '**multiple triangulation**', which is defined as the combination of two or more types of triangulation in the same study.^{1520,1521} Denzin describes the three basic types of data triangulation as time, space and person triangulations.¹⁵²² In this thesis, I have used both *space triangulation* (collecting data from different types of hospitals and clinical practice settings); and more specifically, *person triangulation*; whereby I have collected

¹⁵¹⁹ Robert Wood Johnson Foundation "Triangulation" Qualitative research guidelines project www.qualres.org/HomeTria-3692.html (Date of use: 7 November 2017).

¹⁵²⁰ Begley C "Using triangulation in nursing research" 1996 *J Adv Nurs* 122-128.

¹⁵²¹ Adami and Kiger 2005 *Nurse Res* 19-29.

¹⁵²² Denzin N *The research act* 297 see also Robert Wood Johnson Foundation "Triangulation" www.qualres.org/HomeTria-3692.html (Date of use: 7 November 2017).

data from medical doctors, nurses and patients, attending randomly selected public hospitals in eThekweni metropolitan municipality, Kwazulu-Natal province; in other test for consistency, validity and completeness of data with regards to questions raised about the process of obtaining IC during clinical practice in South African public hospitals.

4.5 The value of using empirical research methods to study informed consent

In recent times, applied ethicists have started to combine established social scientific methods of inquiry with normative ethical reflection and analysis.^{1523,1524} This is based on the criticism that philosophical bioethics is too abstract and insensitive to social realities and context. According to Emmanuel,¹⁵²⁵ “the two most common criticisms of bioethics is that it is divorced from reality and the actual issues that arise in medical practice, research, and health policy debates; and secondly that bioethicists are willing to layout arguments but skittish about actually deciding anything.”¹⁵²⁶ It has been suggested that one symbol of this divorce from reality is the lack of engagement of philosophical ethics with empirical data.¹⁵²⁷ Because of these observations, some authors have proposed a definition of ‘empirical ethics’ or ‘empirical bioethics’ as “normatively oriented medical ethical research that directly integrates empirical research”.¹⁵²⁸ Putting it another way, empirical ethics encompasses both empirical research with normative arguments and analysis, and tries to integrate both elements in such a way that new knowledge is produced, which might not have been possible without combining both methods.¹⁵²⁹ According to Emmanuel,¹⁵³⁰ the issue is not whether bioethics should focus on conceptual analysis or empirical research but that it must focus on both.

In terms of practical applications of empirical bioethics, it has been argued that empirical bioethics may serve three valuable purposes in healthcare or contemporary medical

¹⁵²³ Sulmasy and Sugarman *Methods of medical ethics* [3-18].

¹⁵²⁴ De Vries and Gordijn 2009 *Bioethics* 193-201.

¹⁵²⁵ Emanuel *The relevance of empirical research for bioethics* [99-110].

¹⁵²⁶ Emanuel *The relevance of empirical research for bioethics* 99.

¹⁵²⁷ Ives J 2008 *Health Care Ana* 1-6.

¹⁵²⁸ Mertz et al 2014 *BMC Med Ethics* 17.

¹⁵²⁹ Mertz et al 2014 *BMC Med Ethics* 17.

¹⁵³⁰ Emanuel *The relevance of empirical research for bioethics* 99.

practice and that it enriches the field of bioethics. In this context, empirical bioethics can assist with (1) debunking widely held but erroneous views; (2) assessing the importance of ethical concerns; and (3) facilitating the realization of certain ethical values.¹⁵³¹ This view was substantiated by citing contemporary empirical studies, which have been able to show that instead of the popular belief that pain is the most difficult or predominant issue in euthanasia and end-of-life care issues, empirical data was able to demonstrate that depression, hopelessness, and general psychological distress are consistently associated with interest in physician-assisted-suicide and euthanasia.¹⁵³² Other areas in which empirical bioethics and data analysis could play a role would include helping to resolve the conflict in IC regarding the comprehensiveness of information disclosure and understanding of information disclosed, as well as determining the methodological or the ethical concerns surrounding the storage and use of human biological specimens.

Empirical bioethics can also assist with the realization of ethical values such as respect for autonomy, and in some cases just allocation of scarce healthcare resources based on the ethical principle distributive justice.¹⁵³³ Other empirical studies have also shown that people generally have problems in understanding the risks and benefits of medical treatment and decision making, and this could impact on the actual application of existing laws.¹⁵³⁴ For example, a questionnaire based study by on Dutch nurses charged with taking care of nursing home residents while respecting the patient's autonomy and liberty, revealed that those nurses did not comply with the existing regulations on patient care in Dutch nursing homes.¹⁵³⁵ Others have advised that empirical ethics should be used to defend or criticize concrete moral principles or practices rather than make general claims about moral concepts.¹⁵³⁶ Therefore, De Vries and Gordijn¹⁵³⁷ have grouped some of these uses of empirical ethics into a five-fold typology of potential usage as described in detail in chapter one of this thesis.

¹⁵³¹ Emanuel *The relevance of empirical research for bioethics* [100-102].

¹⁵³² Emanuel *The relevance of empirical research for bioethics* 101.

¹⁵³³ Emanuel *The relevance of empirical research for bioethics* [104-105].

¹⁵³⁴ Musschenga *Reasoning in ethics* [183-204].

¹⁵³⁵ Van Thiel and Van Delden 1997 *Healthcare in Later Life* 177-186.

¹⁵³⁶ Sulmasy and Sugarman *Methods of medical ethics* [3-18].

¹⁵³⁷ De Vries and Gordijn 2009 *Bioethics* 193-201.

In many countries including South Africa, the current law requires that doctors and other HCPs must obtain IC from patients' before involving them in medical treatment or biomedical research as stipulated in the *National Health Act*.¹⁵³⁸ Consequently, in recent times, applied ethicists have shifted their focus towards combining empirical research studies, especially social scientific research with normative ethical analysis. Proponents of this approach, the latter termed 'empirical ethics', have argued that the study of people's actual moral beliefs, behaviour and reasoning should be the starting point of ethics. It has also been acknowledged that the methodologies of the social sciences, especially quantitative and qualitative research, using surveys, interviews and questionnaires is probably the best way to map the reality of peoples actual moral norms.¹⁵³⁹

In view of these pertinent observations, I decided to use the methodology of empirical bioethics and data analysis to study the contemporary practice of IC amongst doctors, nurses and patients using public hospitals in KZN province, South Africa.

4.6 Statement of the problem

From a review of the literature, recent evidence from empirical research, case law, medico-legal and bioethical analyses, suggest that many medical therapeutic procedures are often conducted in violation of the ethical principle of respect for autonomy and the legal requirements for valid IC in most parts of the world. This is most evident in developing countries such as South Africa, with its dual healthcare system,¹⁵⁴⁰ where the public hospitals have a patient overload, with about 80% of the population patronizing public hospitals. In this setting, the doctor to patient ratio is generally high¹⁵⁴¹ with long queues outside doctors' clinics and public hospitals.¹⁵⁴²

¹⁵³⁸ National Health Act 2003.

¹⁵³⁹ Borry et al 2004 *Med Health Care Philos* 1–3.

¹⁵⁴⁰ KZN Department of Health *KwaZulu-Natal Strategic Plan 2015-2019* (DOH KZN 2015) 20-21.

¹⁵⁴¹ Chima 2015 *Nig J Clin Pract* 49.

¹⁵⁴² Mhlongo and Mdingi 1997 *BMJ* 252.

This makes it difficult for doctors and other HCPs to spend enough time with patients in order to provide adequate information and ensure that all the other elements of IC are complied with. Further, low education standards, high illiteracy levels, poverty, language difficulties, and the power asymmetry that exists in the doctor-relationship, may also make it difficult for a large proportion of the South African patients, not only to comprehend the medical information disclosed, but also to insist on their right to IC.¹⁵⁴³ Further, consent forms and information sheets for treatment procedures are often written in a language that cannot be clearly understood by the majority of patients.¹⁵⁴⁴ In addition, verbal translation by informal interpreters may also not provide an accurate picture of what is at stake.¹⁵⁴⁵ Therefore, valid and voluntary IC may sometimes be problematic and difficult to obtain for vulnerable patients, since any offer of medical assistance or other assistance incidental thereto will be accepted because patients have limited choices, due to poverty and indigence of the local population which encourages undue influence, and sometimes therapeutic misconception.^{1546,1547} Finally, since the end of the apartheid era in South Africa, new laws have been introduced to safeguard the fundamental human rights of South Africans.¹⁵⁴⁸ One of such laws is the NHA,¹⁵⁴⁹ which codified the legal requirements for IC and outlined regulations for obtaining same. Other relevant laws include the Choice on termination of Pregnancy Act,¹⁵⁵⁰ which stipulates the age and conditions under which a woman can obtain a safe abortion; and the Children's Act,¹⁵⁵¹ which stipulates the age of consent to medical treatment for minors.

It is arguable whether all HCPS and healthcare users are fully aware of the current laws applicable with regards to IC and medical treatment in South Africa. In the light of the

1543 *Summaries of the reports from the President's commission for the study of ethical problems in medicine and biomedical and behavioral research* Appendix 2 (US Government Printing Office Washington DC 1982) 2-6.

1544 Krosin MT et al "Problems in comprehension of informed consent in rural and per-urban Mali, West Africa" 2006 *Clin Trials* 306-313.

1545 Schlemmer and Mash 2006 *SAMJ* 1084-1087.

1546 Sugarman J et al 2005 *Clinical Trials* 34-41.

1547 Beauchamp and Childress *Principles of biomedical ethics* [96-97].

1548 Truth and Reconciliation Commission Report. *Institutional hearings: The health sector* (CTP Book Printers Cape Town 1998)109-164.

1549 National Health Act 61 of 2003.

1550 Choice on Termination of Pregnancy Act 92 of 1996.

1551 Children's Act 38 of 2005.

foregoing, this study was designed to establish whether IC obtained from patients attending public hospitals in South Africa is fully informed, comprehensible, voluntary, and is obtained within the context of applicable local laws and regulations, when compared to the internationally acceptable standards of care.

4.6.1 Research questions

Based on a comprehensive review of literature, especially the ethical and legal and socio-cultural issues likely to impact on the IC process as described in chapters two and three above (background and literature review), the following research questions were generated for this study:

- I. Is sufficient and comprehensive information provided to patients involved in medical treatment by HCPs before consent is obtained from patients attending public hospitals in South Africa?
- II. Do patients understand the information provided including, diagnosis, medical procedures, treatments risks and benefits, treatment options, and right of refusal, before they give consent to treatment?
- III. Are patients undergoing medical procedures in South Africa generally competent to consent to medical treatment?
- IV. Do patients involved in medical procedures or treatment in South Africa give consent voluntarily, in the absence of coercion or undue influence?
- V. Overall, is the informed consent given by patients undergoing medical treatment in South Africa truly valid and consistent with applicable local laws and regulatory standards?

4.6.2 Aims, objectives, hypothesis and assumptions of the study

The general objective of this study was to establish whether informed consent is obtained from patients prior to involvement in medical treatment or procedures in South Africa. The specific study objectives as well as the hypothetical assumptions have been described in

detail in chapter one. For a detailed description please refer to sections 1.5.1 to 1.5.4 of this thesis.

4.7 Significance of anticipated outputs

The results of the study will assist in enhancing patients and HCPs education and awareness in the areas of medical law, ethics and human rights with particular reference to IC and communication between HCPs and patients, as well as improving all practices related to other areas of concern in the WMA Patients' Bill of Rights¹⁵⁵² and the South African Patients' Rights Charter.¹⁵⁵³ It will also be beneficial to lawmakers in the implementation and revision of current legislation, and drafting of new regulations to promote public health and healthcare practice in general. Finally, this study may also assist in the design of new consent documents and information sheets, used in obtaining valid IC from patients undergoing medical procedures in public hospitals, as well as highlighting new areas for training to improve the skills of HCPs and edification of patients. This study will also produce generalizable knowledge which will be disseminated by means of published academic papers, presentation of results at international conferences to further knowledge in the field of medical law and ethics of particular relevance to South Africa and other developing countries.

4.8 Validity and reliability of the study

4.8.1 Validity of the study

According to Creswell, validity in quantitative research refers to the fact that one can draw meaningful and useful inferences from scores in particular instruments, while in the case of qualitative research, it refers to use of procedures such as member checking and triangulating data sources to ensure readers of its accuracy.¹⁵⁵⁴ In this study, due to the

¹⁵⁵² WMA *Declaration of Lisbon on the Rights of the Patient* (World Medical Association Lisbon 1981).

¹⁵⁵³ HPCSA *National Patients' Rights Charter* (HPCSA Pretoria 2008).

¹⁵⁵⁴ Creswell *Research design* [162-165].

fact that research design methods are not mutually exclusive, I have also used methods of data triangulation such as person triangulation, as described above, by collecting data from doctors, nurses and patients to ensure consistency, accuracy, and validity of the data and study results.¹⁵⁵⁵ Further, I have ensured construct validity by using adequate definitions and measures of variables as shown in the next section, to enhance validity of data in this study. I have also minimized threats to internal validity by drawing from a wide variety of participants/respondents in different clinical departments and settings, such as randomizing the participating public hospitals; in order to be able to draw correct inferences and conclusions from the data generated, thereby minimizing participant bias or negative experiences. According to Pollitt and Beck, external validity refers to the “generalizability of the research findings to other settings.”¹⁵⁵⁶ Usually, studies are only generalizable if they are based on random sampling and conducted using quantitative methods.^{1557,1558}

In this study I have used stratified random sampling in the identification and selection of participating hospitals as described below. Moreover, the selection of participants/respondents were completely random in that any eligible participant whether, doctor, nurse or patient, at any of the randomly selected hospitals who was available and willing to participate was allowed to complete the questionnaire voluntarily and without coercion. This means that this study was based on random sampling and as such is generalizable, consistent with external validity.

4.8.2 Reliability of the study

Creswell describes reliability, as “whether scores ascribed to items on an instrument are internally consistent”.¹⁵⁵⁹ This raises questions whether the items’ responses are consistent across constructs and over time and whether there is consistency in test

¹⁵⁵⁵ Adami and Kiger 2005 *Nurse Res* 19-29.

¹⁵⁵⁶ Polit D and Beck C *Nursing research: Principles and methods* 7th ed (Lippincott Williams & Wilkins Philadelphia 2004) 217.

¹⁵⁵⁷ Creswell *Research design* [191-193].

¹⁵⁵⁸ Polit and Beck *Nursing research* 217.

¹⁵⁵⁹ Creswell *Research design* 233.

administration and scoring.¹⁵⁶⁰ In this study, the main study instruments were questionnaires. A single questionnaire with the same items was administered to all HCPs (doctors and nurses), at all locations within the same time period. This shows consistency in items and administration. Further, the questionnaire for patients was a different questionnaire further translated into the predominant local language, IsiZulu. Patients were free to respond in their chosen language and the interviews were administered with by same set of three research assistants over the research time period. This suggests that the study was reliable in accordance with the definition of reliability in research studies. According to Pollitt and Beck,¹⁵⁶¹ reliability refers to repeatability of one's study. Based on the study instruments used and methods of administration described further below, this study is reliable and repeatable.

4.9 Materials and Methods

4.9.1 Study rationale

The methodological considerations underpinning the chosen study design have been described in detail above and in preceding chapters of this thesis. Briefly, the empirical aspect of this thesis entails a descriptive cross-sectional study in contemporary clinical practice settings at public hospitals within an urban metropolitan municipality in KwaZulu-Natal province South Africa. The study was conducted in this setting using the methods further described below, because the time between procuring IC and treatment is very short and patients are normally in hospital for a limited time period. The descriptive approach allowed the participants/respondents including doctors, nurses and patients, to describe their experience with the IC process as it was happening, thereby bringing out the required information which is evaluated and reported in this empirical study.

¹⁵⁶⁰ Creswell *Research design* 233.

¹⁵⁶¹ Polit and Beck *Nursing research* 416.

4.9.2 Study variables

The independent variables in the study included age, sex, marital status, occupation, languages spoken, educational level, and income of participants. The dependent variables included decision-making capacity (DMC), information disclosure, comprehension and volition of the participants. Other variables included the extent of information disclosure, diagnosis, risks and benefits of treatment, treatment costs, rights of refusal of treatment, consequences of refusal, methods of obtaining consent (verbal, written or both). I also evaluated the methods employed in obtaining consent during emergency situations, as well as knowledge and practice of presumed or implied consent amongst HCPS, as well any evidence of coercion or undue pressure on patients giving informed consent during clinical encounters in public hospitals. Definition of the major variables studied are described in chapter one above. For a detailed description of these variables please refer to the '**definition of terms**' in chapter one, section 1.16 of this thesis.

4.9.3 Study location and setting

The study was carried out at selected public hospitals within eThekweni metropolitan municipality in KwaZulu-Natal Province of South Africa. EThekweni municipality comprises a major urban city (Durban) and semi-urban areas (townships). EThekweni municipality has a population of about 3.5 million people (2011 census).¹⁵⁶² According to statistics from KZN department of Health, there are 18 public hospitals ¹⁵⁶³ within this municipality ranging from tertiary, regional, district and specialized hospitals for chronic diseases. The list of public hospitals in EThekweni municipality which were stratified alphabetically and randomly sampled as shown in Appendix 4 of this thesis. The hospitals in EThekweni municipality are relatively well staffed since Durban is a major metropolitan city in South Africa. Also many hospitals within this district serve as teaching hospitals for the practical

¹⁴³³ Statistics South Africa http://www.statssa.gov.za/?page_id=1021&id=ethekweni-municipality (Date of use: 26 April 2016).

¹⁵⁶³ KZN Department of Health <http://www.kznhealth.gov.za/district1.htm> (Date of use: 26 April 2016).

training of doctors, nurses and allied health professionals up to specialist level. Therefore, all categories of HCPs are well represented in this population of healthcare workers (HCWs). In this study, all HCPs who were willing to participate in the study were eligible for inclusion.

In this setting which included the teaching and tertiary hospitals, it was hypothesized that the IC doctrine should not only be taught and known by the participants/respondents, but also be applied in the teaching and training of the various categories of HCPS. The study also sought to establish to what extent the ethical and legal doctrine of IC was practiced or applied, and the level of knowledge of the various categories of participants regarding IC, and the basic laws guiding the clinical practice of medicine at the randomly selected public hospitals within this metropolitan municipality, in KZN province, South Africa.

4.9.4 Target population groups

Patients, medical doctors and professional nurses at selected provincial hospitals within EThekweni municipality were randomly selected to participate in the study. Randomization occurred at the level of the health care facility, while the individual participants at the selected institutions had an equal chance to participate voluntarily in the study.

a) **Inclusion criteria:** Patients in the selected hospitals in the surgical, internal medicine, paediatric, obstetrics and gynaecology, wards and clinics had an equal chance of participating in the study if available and willing to participate during the site visits to the hospital. Similarly, all medical doctors, professional and enrolled nurses within the selected hospitals units were also equally eligible to participate in the study

b) **Exclusion criteria:** Patients with severe mental incapacity due to mental health or behavioural disorders such as unconsciousness, and those who are unable to provide valid IC, were excluded from the study. Similarly, minors below the legal age of consent whose guardians or parents were absent during the study to provide the necessary IC on their behalf, were excluded from the study. In the case of nurses, nursing staff in the categories of auxiliary nurse, nursing students, and nursing assistants, were all excluded from this study.

4.10 Sampling procedures

4.10.1 Selection of study site

It has been argued that based on logistic considerations it is usually difficult if not impossible to include every individual in a target study population. For this reason, a representative sample of the target population is usually selected for a particular study. Sampling may be defined as “a means used to draw a representative number of elements from a larger population”.¹⁵⁶⁴ Further, Kumar emphasizes that during sampling, it is essential to avoid bias in the selection of a sample, and also important to achieve maximum precision for a given outlay of resources.¹⁵⁶⁵ Thus, a small but representative number of units are usually scientifically selected to provide a fair and true reflection of the population under study. Therefore, the general rule is to use the largest sample size possible because it has been suggested that the larger the sample size, the more representative it is of the population and the more likely results will be acceptable.¹⁵⁶⁶ Nonetheless, it is usually advisable to make an extra effort to obtain a representative rather than a very large sample size, in this way; the eventual sample size chosen is usually a compromise between what is desirable and what is feasible. The main aspects considered in determining sample size from a population include the objectives of the study, the need for variations in the sample, and the ease of handling the data collected.¹⁵⁶⁷ According to Terre-Blanche and others,¹⁵⁶⁸ thirty percent (30%), of any population is generally adequate when conducting a cross-sectional descriptive study. Since this study was limited to public hospitals, out of the 18 public hospitals, six were randomly selected as study sites for this research study. Multi-stage stratified random sampling was used to select eligible hospital sites. The hospitals were first stratified by authority (provincial or private); and then selected using systematic random sampling. This was done by arranging the public hospitals alphabetically by name. Then every third

¹⁵⁶⁴ Cargan *Doing social research* 235.

¹⁵⁶⁵ Kumar *Research methodology* 19.

¹⁵⁶⁶ Cargan *Doing social research* 237.

¹⁵⁶⁷ Mugisha *Delivery and utilization of voluntary HIV counselling* 55.

¹⁵⁶⁸ Terre-Blanche et al *Research in practice* 50.

hospital from the list was selected. Probability sampling is used to ensure an unbiased sample population, whereby each individual in the population has an equal chance of being selected or included in the study population.^{1569,1570} Stratification of the available samples also helps to ensure that a representative sample is selected from each stratum. In this study, purposive sampling was also used to include the two major tertiary/teaching hospitals within EThekweni municipality, because they were most likely to yield the largest number of eligible study participants. That is, professional nurses and doctors at all levels of specialization, including newly qualified doctors serving their internship, as well as a variety of patients and HCPs in various clinical departments, to assist with a more robust sample population. It has been suggested that for non-probability sampling, participants' selection is based on specific predetermined criteria in order to cover a wider range of constituencies, in which case, selection of participants is considered purposive. Generally, purposive sampling targets and prescribes specific criteria for recruiting a sample. In this case recruitment of participants is therefore based on the characteristics they exhibit in relation to the research question.¹⁵⁷¹ In this study, purposive sampling was used to include the two major tertiary hospitals within the study setting, because they were most likely to yield the largest number of eligible study participants. The rest of the hospitals within the municipality district were randomly sampled as described above. Random selection of the public health institutions for the study ensured that patients from all socio-economic strata were covered and eligible for inclusion, further HCPs with different types of practice experience with regard to informed consent were also included in the study.

4.10.2 Sample size estimations

Preliminary sample size for each group of study participants was calculated using a web-based sample size calculator by Raosoft®,¹⁵⁷² based on this formula for sample size and 5% margin of error:

¹⁵⁶⁹ Babbie E *The basics of social research* 4th ed (Wadsworth Belmont California 2008) 238.

¹⁵⁷⁰ Russell *Social research methods* [144-147].

¹⁵⁷¹ Salazar et al *Research methods in health promotion* 303.

¹⁵⁷² Raosoft® <http://www.raosoft.com/samplesize.html> (Date of use: 26 April 2016).

$$x = Z(c/100)2r(100-r)$$

$$n = N x / ((N-1) E^2 + x)$$

$$E = \text{Sqrt} [(N - n) x / n (N-1)]$$

Where N is the population size,

r is the fraction of responses that we are interested in, and $Z(c/100)$ is the critical value for the confidence level c .

Based on results obtained from Raosoft™ via computerized application of the above sample size calculation equation, the estimated sample size for each category of participants to be recruited for the study was:

- A. **360** Medical Practitioners (all categories of medical doctors including consultant/specialists)
- B. **373** Nurses (professional and enrolled nurses)
- C. **385** Patients

The above figures gave an estimated total sample size for the study of **1118** study participants. This number served as a baseline for the number of participants to be recruited in each participant category for the entire study. Participant recruitment was then planned for a 3-month period from March to June 2012. Multiple visits were made to the selected hospitals/study sites during this time-period, after obtaining ethical approval from the various regulatory authorities and gatekeepers at each institution. The actual distribution of the questionnaires/ patient interviews was conducted by three trained research assistants who were at the minimum bilingual in (English/Zulu/Xhosa/Sotho). The research assistants distributed the questionnaires to willing participants (HCPs), and made arrangements to collect same at the respondents' convenience. Multiple visits were made to the various study sites to aid participant recruitment until the maximum number willing to participate was reached, in case of HCPs; and when the estimated sample size for patients was exceeded by 5% for patient respondents to compensate for incomplete forms or ineligibility.

4.11 Work Units

The wards and clinics in each selected hospital/ study site, were also randomly sampled; again the aim was to sample about 30% of the wards.¹⁵⁷³ Thereafter eligible HCPs and patients in the wards and outpatient clinics who were willing to participate in the study were all given a chance to participate in the study by completing the questionnaires. Generally, the outpatient departments (OPDs) and clinics were randomly targeted on the day of visit by the researcher and research assistants. Patients and HCPs were then approached by the research assistants, and those who were willing to participate were given the informed consent documents to read and sign. Then the study instrument (questionnaire) was handed over to the participant to complete in the case of HCPs. With regard to patient respondents, those who expressed a preference and were literate; were given the questionnaires to complete by themselves, after reading and signing the informed consent documents; while for those who wanted the questions to be read out, the research assistant would read out the questions and record the answers given by the patients *verbatim* onto the questionnaire for patients.

4.12 Research instruments

Data was collected using separate questionnaires (study instruments) for HCPS and patients. Two different semi-structured questionnaires with open and close-ended questions were applied to patients and healthcare professionals.¹⁵⁷⁴ The questionnaires were distributed manually to medical practitioners and professional nurses working in the selected hospitals under study. The questionnaires for patients was further translated into IsiZulu, the predominant language in KZN province. The translation from English to IsiZulu was done by qualified translators at the Department of IsiZulu Studies, University of KwaZulu-Natal, South Africa. Patients had the opportunity to respond using either in

¹⁵⁷³ Terre-Blanche et al *Research in practice* 50.

¹⁵⁷⁴ See Appendices 1-3.

IsiZulu or English based on their personal choice. The questionnaires for HCPs were in English language only.

4.12.1 Description of questionnaire for HCPs

The questionnaire for HCPs (doctors and nurses) was designed in 4 sections as shown in Appendix 1, but a brief description is provided here. The first section of the questionnaire was used to obtain information about respondent demographics or dependent variables, such as age, sex, job title, position, department in the hospital, years of professional experience, clinical speciality, amongst others. The second part of the questionnaire contained questions about informed consent practices such as: time spent on obtaining informed consent, patient workload, information disclosed to patients, language and methods used to obtain IC and communicate with patients; understanding of information by patients and challenges faced by HCPs when obtaining IC from patients. The third section of the questionnaire asked general knowledge questions about local healthcare laws such as 'age of consent to medical treatment' and 'age of consent for termination of pregnancy' and standards of information disclosure. The fourth section solicited questions about HCPs knowledge and practices regarding implied or presumed consent in clinical practice. The questionnaire for HCPs was first circulated for comment by a small sample of doctors and nurses, and then modified based on comments from potential participants prior to distribution to all eligible and agreeable participants. The questionnaires were distributed by hand at all selected sites by research assistants and retrieved by hand after completion by respondents at their own convenience. Participation in the study and completion of the questionnaire were entirely voluntary.

4.12.2 Description of questionnaire for patients

The study instrument for patients was a semi-structured questionnaire in English language, which was also translated into IsiZulu, the dominant language spoken by about

81% of the population of KZN.¹⁵⁷⁵ Questionnaires consisted of three sections. The first section collected sociodemographic data; including age, sex, marital status, employment status, educational level, income and living situation of patient participants. These were mostly dependent variables. The second part of the patient questionnaire was used to gather information on independent variables such as details of patient experiences of IC when interacting or when receiving treatment from HCPs. This section also contained questions about time spent on the clinical encounter, information disclosed by HCPs to patients before obtaining consent, methods and language used to communicate with patients, satisfaction level with information disclosure and completeness of information disclosure, understanding of information disclosed, and the absence of coercion or undue influence by healthcare providers during clinical encounters. The third part of the patient questionnaire asked questions about a patient's general knowledge, understanding, and opinions on IC, such as the legal age of consent to treatment, surrogate involvement in patients' healthcare decision-making or informed consent processes; as well open ended questions regarding patients level of satisfaction with their encounter and communication with local HCPs. Participants were interviewed by three trained bilingual research assistants. Those patients who were able to read and write and preferred to, were allowed to complete the questionnaire by themselves and return to research assistant at the same clinical site during the site visit. Patient respondents had the option of completing questionnaires either in English or IsiZulu based on their preferred language. The study was conducted at various hospital departments at selected sites as described previously and further below. Participation by patients was entirely voluntary, and questionnaires were completed by parents or guardians in the case of children or individuals not capable of giving informed consent.

4.12.3 Validity and reliability of the research instruments

Pre-testing of the research instrument (questionnaires), with regards to HCPs, this was done by distributing to a few doctors and nurses in a single hospital ward for comments

¹⁵⁷⁵ EThekwini Municipality *EThekwini language policy*
<http://www.Durban.gov.za.eThekwiniLanguagepolicy.pdf> (Date of use: 19 August 2014).

and validation, the comments and suggestions were then incorporated into the final questionnaire before distribution to all potential HCP participants. With regard to the patients' questionnaire after initial design and compilation in English based on the literature review, the questionnaire was then submitted to professional language experts in IsiZulu studies for translation into the local language. Questionnaires which were completed in the local language IsiZulu was back translated to English by native language speakers, before capturing of data in the research data base as described below. All of the above strategies were used to ensure validity and reliability of data collected. Further, the research instruments (questionnaires) were vetted and approved by a qualified biostatistician for reliability to collect the intended data suitable for analysis and drawing of valid conclusions. Validity of a research study may be defined as the "accuracy and trustworthiness of instruments, data, and findings in research".¹⁵⁷⁶ It has been argued that ensuring validity helps to make the researcher's evaluations more credible and provides defensible data, inferences and conclusions.¹⁵⁷⁷ In this study, validity was ensured by using several techniques such as multiple triangulation as discussed in section 4.3 of this thesis. In addition, there was extensive literature review prior to preparation of the study instruments. Furthermore, the study instruments were evaluated by a qualified biostatistician and pre-tested amongst a select sample of HCPs before use. Face validity refers to subjective judgments on whether the research instrument appears to measure what it ought to measure.¹⁵⁷⁸ In this study, face validity was maintained by constructing questions relevant to the study's aims and objectives as derived from an extensive review of relevant literature and case law. Content validity relates to knowing whether the entire interview items reflect the entire range of potential meanings in a study.¹⁵⁷⁹ In this study, the researcher (myself), tried as much as possible to ensure that all potentially relevant questions and items were included in the study instruments used; based on an extensive literature review prior to the construction of the study questionnaires.

¹⁵⁷⁶ Russell *Social research methods* [46-47].

¹⁵⁷⁷ Guion LA *Triangulation: establishing the validity of qualitative studies* (University of Florida IFAS 2002) 2.

¹⁵⁷⁸ Burns N and Grove SK *The practice of nursing research: conduct, critique and utilisation* 4th ed (Saunders Philadelphia 2007) 400 see also Cargan *Doing social research* 232.

¹⁵⁷⁹ Cargan *Doing social research* 232.

4.13 Data collection

Primary data was collected using questionnaires and interview schedules as described above. Further, relevant case law and statutory instruments were accessed from data available in the public domain, as well as applicable regulatory instruments based on a review of literature. In addition currently used standard consent documents or consent forms were collected where available from the various selected hospitals for comparative analysis.

4.13.1 Data storage and analysis

Data from the questionnaires which were completed manually were stored in a locked cabinet to maintain participant confidentiality and security. Then at the end of each collection date or site visit, the questionnaires were entered into a single laptop computer by one of the trained research assistants who also doubled up as a data capturer. The entered raw data was then evaluated for completeness and accuracy by the researcher (myself), and also cross-checked prior to analysis by a qualified biostatistician.

The software used for data capturing storage and analysis was the *Statistical Package for Social Sciences* (SPSS versions 18 to 22 IBM Corporation).¹⁵⁸⁰ It has been argued that that numbers and statistics by themselves are of little interest and are difficult to make any sense of. Thus, data analysis is a critical step during research.¹⁵⁸¹ Therefore, data analysis is “the search for patterns in the data and for ideas that help explain why those patterns maybe there in the first place”.¹⁵⁸²

4.14 Statistical methods

Descriptive statistics such as proportions, median, mode and interquartile range were used to summarize the data from this study. Bar charts, pie chart and graphs were used

¹⁵⁸⁰ IBM SPSS Statistics for Windows (IBM Corp Armonk NY 2012).

¹⁵⁸¹ Black TR *Understanding social sciences research* 2nd ed (Sage Publications London 2002) 21.

¹⁵⁸² Russell *Social research methods* 419.

to present the results, using Microsoft Excel.¹⁵⁸³ The scores for comprehension of informed consent were worked out from the responses. The Mann-Whitney U-test was used to examine the difference in scores between doctors and nurses and other applicable variables. The Kruskal-Wallis test was used to examine the relationship between (1) education level and the scores, (2) clinical department and scores and (3) profession and the scores, income level and scores etc., as will be further described in the findings in the following chapters of this thesis. Chi-squared tests or Fisher's exact test were used to test association between categorical variables in the study, as well as analysing and comparing the informed consent aggregate scores (ICAS); calculated between various cadres of HCPs, as will be described in detail below in the results section. Both descriptive and inferential statistics were calculated. Finally, the reliability of the questions used for ICAS was calculated using Cronbach's alpha. The data is displayed using graphs, tables and pie charts, with calculated proportions or percentages. Chi-square values were also calculated to obtain probability values (p-value) in order to evaluate the relationship between key variables, in accordance with suggestions by expert authorities.^{1584,1585}

4.14.1 Validity and reliability of statistical methods used

The study design and statistical methodology proposed used this study was reviewed and validated by a consultant biostatistician at College of Health Sciences, University of KwaZulu-Natal. Further, the statistical methodology of the study was further evaluated and approved by the Knowledge management and strategic services division of the KZN Department of Health, before approval of the proposed study and research proposal. Validity relates to the strength of the conclusions, inferences or propositions of a research study. Construct validity includes the definition of variables in line with existing literature and differentiates between respondents who possess the trait and those without the trait.¹⁵⁸⁶ Internal validity examines causal relationships,¹⁵⁸⁷ while external validity refers to

¹⁵⁸³ Microsoft Corporation *Microsoft Excel for Windows* ((Microsoft Office 2013).

¹⁵⁸⁴ Polit and Beck *Nursing research* [451-510] see also Wysocki DK *Readings in social research methods* (Wadsworth Belmont California 2001) 281.

¹⁵⁸⁵ Russell *Social research methods* 526 see also Schutt KR *Investigating the social world* 347.

¹⁵⁸⁶ Burns and Grove *The practice of nursing research* 232.

¹⁵⁸⁷ Polit and Beck *Nursing research* 214.

the “generalisability of the research findings to other setting or samples”,¹⁵⁸⁸ in other words, it tells us how well the results from one study, can be extrapolated to other similar or related settings. Generally, research findings can only be generalised to other populations if the sampling method was random. In the empirical study reported in this thesis, I employed random sampling techniques to select the sample sites and participants thereby enhancing external validity of this study. I also applied other measures to overcome threats to external validity, including sampling techniques used, such as cluster sampling or stratified random sampling which ensured random selection of the samples within each cluster as well as equal chances of each sample being included into the study cohort. Finally, reliability of a study refers to the consistency of one’s measurement, or the degree to which an instrument measures something the same way each time it is used under the same condition with the same subjects,¹⁵⁸⁹ otherwise known as the repeatability of one’s measurement. The strategies used to improve face, construct, and content validity in this study as described above, also helped reduce threats to reliability in this study.

4.15 Ethical considerations and approvals

Ethical approval was initially obtained from a subcommittee of UNISA Research Ethics Committee. In addition, ethical approval was obtained from the KZN Department of Health Knowledge and Strategic Management division (an accredited REC) as well as the EThekweni municipality department of health after review of the research proposal, including the biostatistical methodology. Further approvals were contained from each selected local hospital administration after evaluation of research proposals and ethical approvals. Finally, written informed consent was obtained from every participant in the research study, after full information disclosure and signing of the consent form prior to participation in the study. Sample informed consent documents used to obtain IC from participants are shown in appendices 4-6 of this thesis.¹⁵⁹⁰ Participant confidentiality was

¹⁵⁸⁸ Polit and Beck *Nursing research* 217.

¹⁵⁸⁹ Polit and Beck *Nursing Research* 416.

¹⁵⁹⁰ See Appendix 4-5 for copies of the informed consent documents used in this study.

maintained by safe storage and anonymization of data, and further, research results will also be reported anonymously.

4.16 Summary of chapter 4

This chapter describes the research methodology used to conduct the empirical research study, reported in part two of this thesis. In this chapter, I described the methodological considerations, including the post-positivist worldview, which underlies the scientific method of enquiry as well as the use of a cross-sectional quantitative research design in this study. Further, I have justified the importance of using empirical research methods to study social phenomena such as the doctrine of informed consent, as well as the use of data triangulation, in this case person and space triangulation to improve the reliability and consistency of the findings and results from this study. In addition, I have described the study location and populations under study, methods for calculating the sample size, as well as the research instruments which were used in this study. This involved the designing of two separate questionnaires for HCPs (doctors and nurses) and another for patients participating in the study. I have also described the methods used in the field studies and gathering of data, the selection of study sites using stratified random sampling and the calculation of sample size,¹⁵⁹¹ as well as the storage and analysis of data by means of a computer based software programme SPSS.¹⁵⁹² Finally, I have described the ethical considerations and permissions obtained, including mechanisms for obtaining statutory approval and informed consent from respondents and gatekeepers, as well as mechanisms for ensuring the validity and reliability of the statistical methods based on overview and input from a qualified biostatistician.

¹⁵⁹¹ Raosoft® <http://www.raosoft.com/samplesize.html> (Date of use: 26 April 2016).
¹⁵⁹² IBM SPSS Statistics for Windows (IBM Corp Armonk NY 2012).

PART TWO

RESULTS AND FINDINGS FROM THE EMPIRICAL RESEARCH STUDY AND THE IMPLICATIONS

Introduction

In part one of this thesis, I provided an introduction, background, literature review and research methodology applicable to this thesis. I reviewed and analysed the ethical, legal, and socio-cultural issues likely to impact on the practice of IC and respect for autonomy, with particular reference to the South African setting. In addition, I provided an analysis of the methodological considerations and justification for using empirical methods including a quantitative research methodology to study ethical and legal issues relating to IC in South African clinical practice.

In Part two of this thesis, I will present and discuss the results from the empirical study amongst doctors, professional nurses and patients working in, and utilizing public hospitals in EThekweni metropolitan municipality, KZN, in chapters five to seven. This will be followed by a synthesis and discussion of the implications of the findings from the empirical study and review of relevant South African case law and commentaries by legal authorities, as well as a comparative analysis of relevant foreign case law from other common law jurisdictions. I will then draw some inferences and conclusions and make some recommendations based on the overall findings from this thesis. Parts of the results from the empirical research study have already been published as three separate peer-reviewed research articles in accredited journals. These research articles are submitted as part of this thesis in the journal article format and appear in Annexures 1-3 of this thesis. Therefore, chapter five will present the results pertaining to the medical doctors,¹⁵⁹³ chapter six will present the results from professional nurses,¹⁵⁹⁴ while chapter seven will

¹⁵⁹³ Chima SC "Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study" 2013 (14 Suppl 1) *BMC Med Ethics* S3 1-17 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3878312/pdf/1472-6939-14-S1-S3.pdf> (Date of use: 23 April 2016).

¹⁵⁹⁴ Chima SC "Understanding and practice of informed consent by professional nurses in South Africa: An empirical study-brief report" The Asian Conference on Ethics, Religion &

provide patient perspectives,¹⁵⁹⁵ with regard to the practice of IC at selected public hospitals in EThekweni municipality, KZN, as found from this cross-sectional empirical study. This chapter will also present a summary of the findings from the empirical study as surmised from the empirical study. Finally, in chapters eight and nine, I will discuss the implications of the empirical research study in the context of the entire thesis and I will present the conclusions and recommendations arising from the study in the final chapter (nine). As I previously mentioned in the summary to chapter one, since we have applied the postpositivist scientific method in the empirical aspects of this thesis. I have also endeavoured to report the results using the IMRAD method, which is a scientific method for reporting studies in the biomedical sciences as opposed to the social sciences.¹⁵⁹⁶ The term IMRAD represents the first letters of the words Introduction, Materials and Methods, Results, and, Discussion. It indicates a pattern or format rather than a full listing of all sections of a research paper.¹⁵⁹⁷ The results of the empirical studies described in chapter five to seven of this thesis have been reported using the IMRAD method which may explain the possible duplication or repetition of theoretical arguments in each chapter. I crave your indulgence in applying this method of reporting, but as has already been noted, this is an interdisciplinary thesis necessitating the use of both biomedical and social sciences methods.

Philosophy 2017 March 22-27 Kobe Japan (ACERP Official Conference Proceedings 2017) 89-102.

¹⁵⁹⁵ Chima SC "Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa" 2015 *Nig J Clin Pract* S46-S56 http://www.njcponline.com/temp/NigerJClinPract18746-378318_103031.pdf (Date of use: 27 April 2016).

¹⁵⁹⁶ Sollaci LB and Pereira MG "The introduction, methods, results, and discussion (IMRAD) structure: a fifty-year survey" 2004 *J Med Libr Assoc* 364-371.

¹⁵⁹⁷ Nair PKR and Nair VD "Organization of a research paper: The IMRAD format" in *Scientific writing and communication in agriculture and the natural resources* (Springer International Publishing Switzerland 2014) <https://file:///C:/Users/user/Downloads/9783319031002-c2.pdf> (Date of use: 24 January 2017).

CHAPTER 5: FINDINGS ON QUALITY OF INFORMED CONSENT AS PRACTISED BY MEDICAL DOCTORS IN SOUTH AFRICA

5.1 INTRODUCTION

Informed consent is a legal and ethical doctrine derived from the principle of respect for autonomy. Generally two rights derived from autonomy are accorded legal protection, firstly the constitutional rights¹⁵⁹⁸ to bodily integrity and well-being protected by laws against trespass, assault and battery;¹⁵⁹⁹ and the rights against bodily well-being and privacy protected by professional negligence rules.¹⁶⁰⁰ Informed consent has been codified by the *National Health Act*,¹⁶⁰¹ requiring healthcare professionals (HCPs) to inform patients about diagnosis, treatment risks, benefits, options, and the right of refusal, while taking into consideration patients' language and literacy levels. Therefore, HCPs treating patients without valid informed consent may be guilty of infringing patients' rights to bodily integrity, privacy and well-being. However, many challenges are experienced by doctors trying to obtain valid informed consent among vulnerable population groups in resource poor settings globally. One can argue that complex multicultural societies like South Africa are most often challenged by problems of socio-cultural issues, multilingualism, poverty, education, unfamiliarity with libertarian rights based autonomy, and the power asymmetry between doctors and patients, all of which could influence the quality of informed consent obtained by medical doctors during clinical practice.

5.1.1 Aims and objectives of the study

The general objective of this aspect of the study was to evaluate the quality of informed consent obtained by doctors from patients attending public hospitals in South Africa. I specifically wished to establish whether sufficient information was provided to patients before consent is obtained. Further, I wanted to establish whether patients involved in

¹⁵⁹⁸ The Constitution s12 (2).

¹⁵⁹⁹ Jennings S "Medical Law and Individual Autonomy- Competing Perspectives" 2003 <http://www.nuigalway.ie/law/GSLR/2003/MedicalNegligence.pdf> (Date of use: 20 February 2008).

¹⁶⁰⁰ Schultz 1985 *Yale L J* 219-299.

¹⁶⁰¹ National Health Act 61 of 2003 [s6-9].

clinical procedures understand the information given to them, and also whether consent is obtained from patients voluntarily, and whether the informed consent provided by patients attending public hospitals in South Africa, is truly and legally valid.

5.2 RESEARCH DESIGN AND METHODOLOGY

This study was a descriptive cross-sectional study in contemporary clinical practice settings, aimed at obtaining data from practising medical doctors using a semi-structured questionnaire. Questionnaires were distributed to participants in hospital clinics and wards in real-time during clinic hours. The real-time approach within the hospital environment allowed doctors to describe their experience with the informed consent process as it is, thereby bringing out the required information. Three trained research assistants distributed and collected the questionnaires from healthcare professionals over a 3-month period from April to June 2012. To increase the response rate, repeated visits was sometimes necessary to collect completed questionnaires from doctors.

5.2.1 Research instrument

Data was collected using a self-administered semi-structured questionnaire. The questionnaire for healthcare professionals consisted of 4 sections. The first section collected information on participant demographics. The second section was used to gather information on informed consent practices, such as time spent on obtaining informed consent, patient workload, information disclosed to patients, language and methods used to communicate with patients, understanding of information by patients, and challenges faced by HCPs when obtaining informed consent. The third section dealt with generic questions on local laws and regulations on informed consent such as ‘the legal age of consent to treatment’ and standards of information disclosure. The fourth section dealt with understanding and use of implied and presumed consent by doctors and nurses.¹⁶⁰² Questionnaires were distributed and collected by hand to all participants.

¹⁶⁰² See Appendix 1 for sample questionnaire.

The study design and research instruments were evaluated and approved by a qualified biostatistician.

5.2.2 Study location and sampling procedures

The study was conducted in the outpatient clinics and wards at randomly selected public hospitals within EThekweni metropolitan municipality, KZN. EThekweni municipality comprises a major urban city (Durban), surrounded by semi-urban areas (townships). The population of this area is approximately 3.2 million (2010 estimate).¹⁶⁰³ According to information from KZN department of health, there are 18 public hospitals within this municipality ranging from tertiary to district hospitals.¹⁶⁰⁴ Multi-stage stratified random sampling was used to select participating hospitals. The 16 hospitals identified as eligible for inclusion were arranged alphabetically for stratified sampling, and every third hospital on the list was then selected.¹⁶⁰⁵ It has been statistically estimated that 30% of any population is adequate when conducting a descriptive study.¹⁶⁰⁶ Purposive sampling was also used to include the two tertiary teaching hospitals within the municipality because they contain the largest number of medical doctors, including specialists. The rest of the public hospitals within the municipality were randomly sampled. A total of five hospitals from Durban and one outlying hospital in nearby Pietermaritzburg with rotating surgical registrars from Durban were included in the study. Therefore a, total of six provincial public hospitals were included in this study.

5.2.3 Target population and inclusion criteria

Medical doctors at the selected public hospitals were randomly targeted to participate in this study. All medical doctors within the selected hospitals clinical units and departments

¹⁶⁰³ Statistics South Africa http://www.statssa.gov.za/?page_id=1021&id=ethekwini-municipality (Date of use: 26 April 2016).

¹⁶⁰⁴ KZN Department of Health <http://www.kznhealth.gov.za/district1.htm> (Date of use: 12 April 2016).

¹⁶⁰⁵ See Appendix 6.

¹⁶⁰⁶ Terre-Blanche et al *Research in practice* 50.

who were available duration the times when the study was conducted at the hospitals, and were willing to participate, were eligible for inclusion in the study.

5.2.4 Sample size

Preliminary sample size for each group of study participants was calculated using a web based freely accessible sample size calculator, Raosoft®.¹⁶⁰⁷ Based on the formula for sample size and 5% margin of error, the estimated sample size for this category of participants was for the recruitment of 360 medical practitioners. Available data on healthcare personnel statistics indicated that that there were about 5670 medical doctors registered in KZN in 2010, although there are disagreements on the total number of doctors practicing within South Africa and its provinces with high mobility and vacancy rates.^{1608,1609} Due to the fact that hospitals within the municipality serve as institutions for training of doctors and nurses, there is a constant rotation of medical personnel throughout the district and the province, and since the results were to be extrapolated to the practice of doctors generally in South Africa, I based my initial estimates on the total number of doctors and nurses practicing within KZN province as obtained from health personnel statistics.¹⁶¹⁰ Overall, because of the low numbers of health personnel, there was minimal difference in estimated sample size regardless of whether sample calculations were based on healthcare professionals within the municipality, practicing in the public sector, or within the province.¹⁶¹¹

5.2.5 Data analysis and statistical methods

Data from the questionnaires were captured directly into statistical package for social sciences (SPSS) by a research assistant. The captured data was then checked for

¹⁶⁰⁷ Raosoft® Sample size calculator <http://www.raosoft.com/samplesize.html> (Date of use: 19 August 2014).

¹⁶⁰⁸ KZN Department of Health: *KwaZulu-Natal Strategic Plan 2010-2014* (Department of Health KZN 2010).

¹⁶⁰⁹ Econex *Updated GP and specialist numbers for SA health reform note 7 2010* <http://www.econex.co.za> (Date of use: 14 September 2013).

¹⁶¹⁰ Health Systems Trust: Health Personnel 2013 <http://indicators.hst.org.za/healthstats/281/data> (Date of use: 14 September 2013).

¹⁶¹¹ Raosoft® Sample size calculator <http://www.raosoft.com/samplesize.html> (Date of use: 19 August 2014).

completeness and accuracy by the researcher (myself), and a consultant biostatistician. Data was later analysed using SPSS (version 21).¹⁶¹² Descriptive statistics such as proportions, median, mode and interquartile range were used to summarize the data. Scores for comprehension, understanding, information disclosure, voluntariness and informed consent aggregate scores were worked out from the responses. The Mann-Whitney test was used to examine the difference in scores between different categories of healthcare professionals in public hospitals. Kruskal-Wallis test was used to examine the relationship between area of specialization and scores, and occupational rank and scores. Chi-square or Fisher's exact tests were used to test for association between categorical variables in the study.

5.3 ETHICAL CONSIDERATIONS

Ethical approval was obtained from a sub-committee of University of South Africa (UNISA) Research Ethics Committee. The research protocol including the biostatistics methodology was also reviewed and approved by the health research and knowledge management sub-component (a local research ethics committee) of the KZN Department of Health. Approval was also obtained from the CEOs or medical managers at each of the randomly selected hospitals included in the study. Finally, written informed consent was obtained from each participant after full information disclosure prior to participation in the study.

¹⁶¹² IBM: SPSS Statistics for Windows Version 21.0 (IBM Corp Armonk NY 2012).

5.4 RESULTS: FINDINGS FROM THE DOCTORS' STUDY

5.4.1 Demographic characteristics of doctors

Demographic characteristics of participating doctors are as shown in Table 5.1. The response rate for this arm of the study was about 47% (46.66%) of the initial estimates with 168 doctors completing the questionnaires out of an initial estimate of 360. However, this low response rate is not unusual when compared to previous studies from doctors in South Africa.¹⁶¹³ There was a broad representation of all clinical specialties with participating doctors from all major clinical specialties as shown in Table 5.2. The occupational ranks of participating doctors is also shown in Figure 5.1. The cohort of participating doctors was then regrouped into 8 major clinical disciplines or specialties for further analysis as shown in Figure 5.2 below.

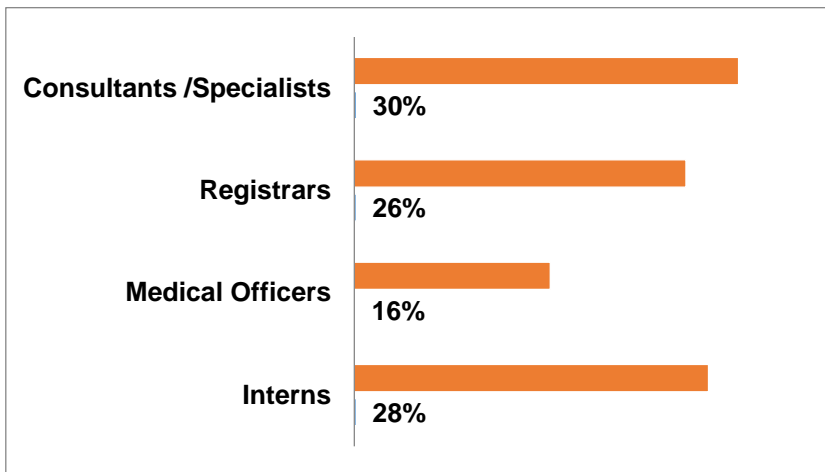


Figure 5.1: Participating doctors by occupational rank

¹⁶¹³ Henley L et al "Informed consent-a survey of doctors' practices in South Africa" 1995 *SAMJ* 1273-1278.

Table 5.1: Demographic characteristics of participating doctors

Doctor characteristics	Age	
	(years)	(%)
Age		
Median	30	
Range	22-77	
Gender		
Male	78	49.1
Female	81	50.1
Missing data	9	-
Occupational Ranks		
Interns	47	28
Registrars	44	26.2
Medical Officers (MO)	26	15.5
Consultant/Specialists	51	30.4
Total	168	100

Table 5.2: Clinical disciplines of medical doctors participating in the study

<u>Clinical disciplines/ sub-disciplines</u>	<u>No of Doctors</u>	<u>%</u>
Paediatrics	42	25
Obstetrics and Gynaecology	18	10.7
Internal Medicine	23	13.7
General Surgery	13	7.7
Urology	11	6.5
General Practice (GP)	11	6.5
Orthopaedic s	8	4.8
Dermatology	5	3
Radiology	5	3
Anaesthetics	4	2.4
Cardiology	2	1.2
Gastroenterology	2	1.2
HIV Medicine	1	0.6
Emergency Medicine	1	0.6
Maxillofacial Surgery	1	0.6
Neurology	1	0.6
Neonatology	1	0.6
Oncology	1	0.6
Medical management	1	0.6
<i>Practice location</i>		
Public	166	99.4
Private	1	0.6
Missing data	1	-
Total	168	100

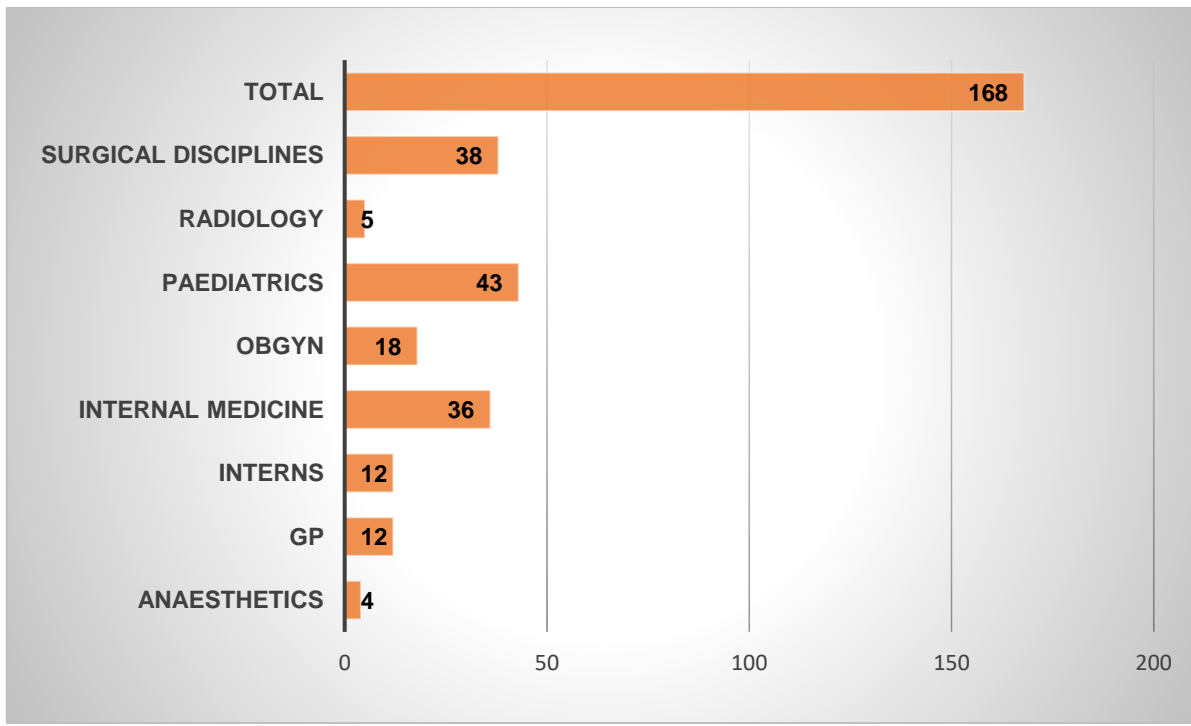


Figure 5.2: Participating doctors by clinical sub-discipline or specialty

5.4.2 Workload and time spent by doctors on a clinical encounter and informed consent

The average number of patients seen by doctors in this cohort ranged from 1 to 120 patients/day (median = 20 patients/day) as reported by medical practitioners. The majority of doctors spent about 5 to 10 minutes providing information to patients prior to treatment decision (Figure 5.3). When asked whether the amount of time was sufficient, 55.4% of doctors answered ‘yes’ (Table 5.3). Those who thought the time spent was inadequate gave various reasons including language barriers and uneducated patients requiring more time for explanations. Others complained of time constraints, administrative responsibilities, and large patient workloads as being factors militating against spending more time explaining procedures in order to obtain valid informed consent from patients. While others explained that, the time spent depends on the procedure. Some stated that the time spent was “*definitely inadequate*” with comments such as “*in an ideal world, patients [should be] counselled for at least 30 minutes with enough time for questions and clarifications*”.

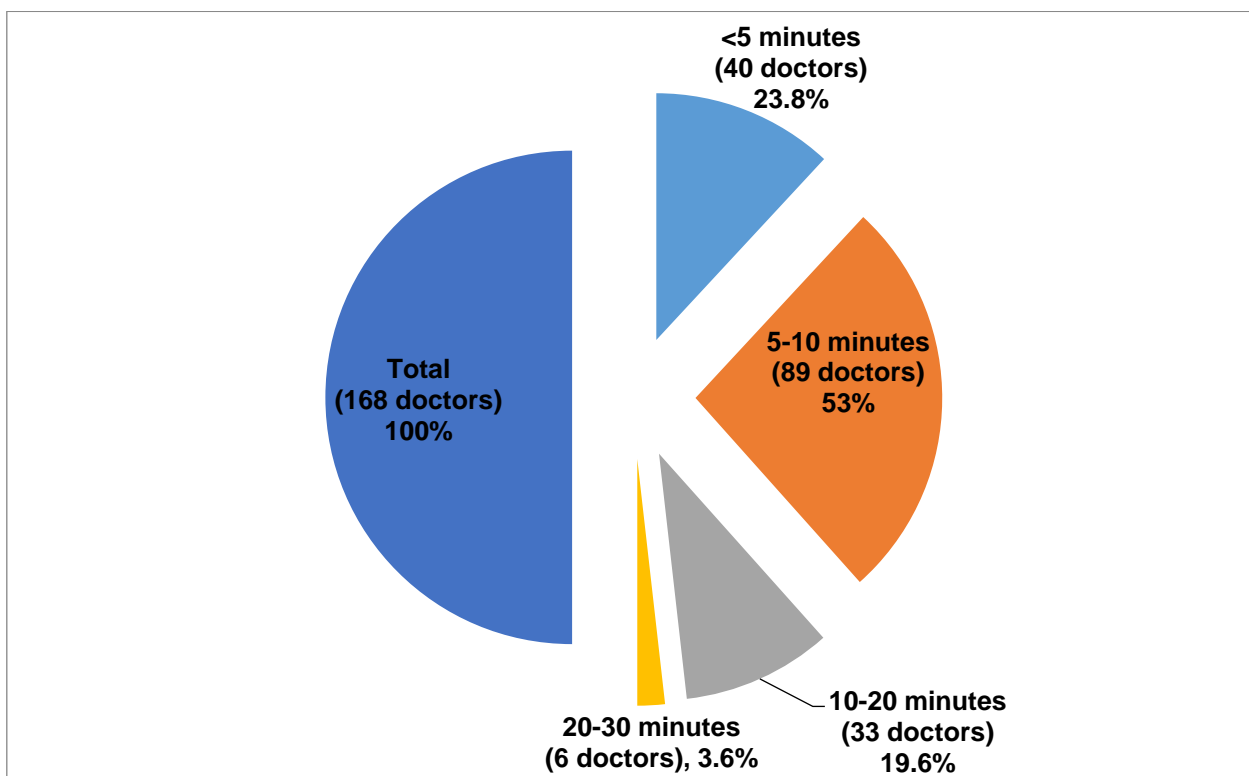


Figure 5.3: Time spent by doctors on IC and clinical encounter with patients

5.4.3 Information given to patients before obtaining consent

When asked about what types of information was generally disclosed to patients prior to obtaining consent. The majority of doctors said they provided information on '*diagnosis*' (96.4%); 89.3% provided information on the '*benefits of treatment*', 81% provided information on '*treatment options*', while 88.7% recommended a specific treatment. Another 83.3% gave information on '*risk of refusing treatment*', while 64.9% reported advising patients on '*the right of refusal*'. Only 11.9% of doctors said they gave information on the '*cost of treatment*' to patients because treatment at public hospitals in South Africa are provided free of charge. When asked specifically whether they explained the benefits of the procedure to a patient, 97% of doctors answered affirmatively, while 95% said they explained the risk of the procedure to patients. A summary of information provided to

patients prior to obtaining informed consent is shown in Table 5.3. When doctors were asked whether they thought the amount of information provided to patients was sufficient for valid informed consent, 72.5% answered affirmatively, 16.1% answered 'no'; while 11.4% answered that they 'don't know' (Table 5.3)

Table 5.3: Information given to patients by doctors prior to obtaining consent

Information disclosed to patients	Yes (%)	No (%)	Don't know (%)
Diagnosis	162 (96.4)	6 (3.6)	-
Treatment options	136 (81)	32 (19)	-
Recommended treatment	149 (88.7)	19 (11.3)	-
Risk of refusing recommended treatment	140 (88.3)	28 (16.7)	-
Cost of medical treatment	20 (11.9)	148 (88.1)	-
Information on general risks	147 (87.5)	21 (12.5)	-
Information on benefits	150 (89.3)	18 (10.7)	-
Information on right of refusal	109 (64.9)	59 (35.1)	-
<u>Probing Questions</u>			
Do you think the information you provide is sufficient?	121 (72)	27 (16.1)	19 (11.4)
Do you think this amount of time spent is sufficient?	93 (55.4)	66 (39.3)	9 (5.4)
Do you think the hospital consent form is adequate	105 (62.5)	51 (30.4)	12 (7.1)

5.4.4 Nature of risks disclosed to patients

Information about specific risks of each procedure was provided to patients by about 95% of doctors. When asked what *types of risks* were generally disclosed to patients, around 92% of doctors said they disclosed the '*most common risks*', 86% disclosed '*the most serious risks*', while only 21% disclosed '*all material risks*' to patients (Table 5.4). The nature of risks disclosed is important because disclosure of 'materials risks' is the current standard required based on the 'prudent-patient standard' of information disclosure as required by both South African and also expressed in international case law. This has been established in landmark court judgments such as the case of *Castell v De Greef*,^{1614,1615} the American case of *Canterbury v Spence*,¹⁶¹⁶ the Australian high court judgment in *Rogers v Whitaker*,¹⁶¹⁷ and the recent judgment of the UK Supreme Court, Scotland in *Montgomery v Lanarkshire*.¹⁶¹⁸

Chi-squared tests were used to test for statistical significance on the types and nature of information disclosed to patients across different clinical specialties. Information on disclosure of 'clinical diagnosis' was statistically significant ($p \leq 0.001$), with radiologists least likely to give patients information on diagnosis. Similarly there was statistical difference in disclosure of information on 'recommended treatment' ($p = 0.002$), with anaesthetists and radiologists least likely to recommend treatment to patients. Finally information disclosure on 'treatment options' was also statistically significant across different specialities ($p = 0.004$), with 60% of radiologists, 50% of anaesthetists, and 32.6% of paediatricians least likely to discuss treatment options with their patients. All other categories of information disclosed were not statistically significant across different clinical specialties. The specialties such as radiology, anaesthesiology and paediatrics which did not give information regarding 'clinical diagnosis', 'recommended treatment' and treatment options, is consistent with the fact that the first two specialties are generally

¹⁶¹⁴ Castell v De Greef (1993) 3 SA 501 [425-426].

¹⁶¹⁵ Van Oosten 1995 *De Jure* 164-179 [178].

¹⁶¹⁶ Canterbury v Spence [1972] 464 2d 772 (DC) [41-46].

¹⁶¹⁷ Rogers v Whitaker [1992] HCA 58 (1992) 175 CLR 479 [83].

¹⁶¹⁸ Montgomery v Lanarkshire Health Board Scotland [2015] UKSC 11[87].

ancillary specialists whose role is to support of the work of surgeons and physicians rather than rendering primary diagnosis. In the case of paediatrics, since most of the patients would be children below the age of consent to treatment, such information would be generally discussed with the consenting parents or guardians of such children, rather than the patients themselves.

Table 5.4: Nature of risks disclosed to patients

Types of risks disclosed to patients by doctors	Yes (%)	No (%)	Don't know (%)
Most serious risks	144 (85.7)	18 (10.7)	2 (1.2)
Most common risks	152 (92.1)	13 (7.9)	-
All material risks	35 (21.2)	117 (70.9)	13 (7.9)
Do you explain risks of the procedure to patients?	158 (94.6)	8 (4.8)	1 (0.6)
Do you explain benefits of the procedure to patients?	162 (97)	4 (2.4)	1 (0.6)

5.4.5 The current hospital consent forms

When asked whether the current consent form used to obtain informed consent from patients was satisfactory, 62.5% (105/168) doctors thought it was adequate, while 30.4% (51/168) doctors answered 'no' and 7.1% (12/168) answered 'don't know'. When asked to explain why the current universal consent forms used in public hospitals was inadequate, many doctors complained that the current form does not give opportunity to detail specific complications because different clinical conditions may require different mandatory disclosures. Some suggested that the consent forms should contain tick-boxes for more detailed information disclosure. Others complained that the current form does not take into account "privacy, language and cultural values". For example, one respondent stated that the form is "*done briefly in a language not the patients first language (sometimes cannot get an interpreter), so we take for granted the patients understands when he/she says yes to everything*". Other doctors complained that the form contains "*no binding space that consent was given or alternatives discussed*" while some said that it was "*not*

specific to minors; when guardian details must be recorded". Others suggested that the current form has, *"not kept up with current progress in medico-legal teaching"*.

5.4.6 Methods used to obtain consent from patients

When asked how patients would normally provide consent for clinical procedures, around 6.7% of doctors said 'verbally', another 50.9% answered 'written', while 34.5% said both verbally and written, while some 7.9% of doctors answered 'it depends'. Doctors who answered 'it depends' gave various reasons for obtaining consent using different formats. Most stated that it depends on the type of procedure. Others said it depends if there is an 'emergency' or if the patient is unconscious, or a minor. Some doctors said they would obtain telephonic consent when parent/guardian was not available, while others said sometimes the hospital superintendent would give the necessary consent in an emergency. Some doctors said it depends if law requires written consent. There was no statistical difference across specialities or occupational ranks in methods of obtaining informed consent ($p = 0.587$).

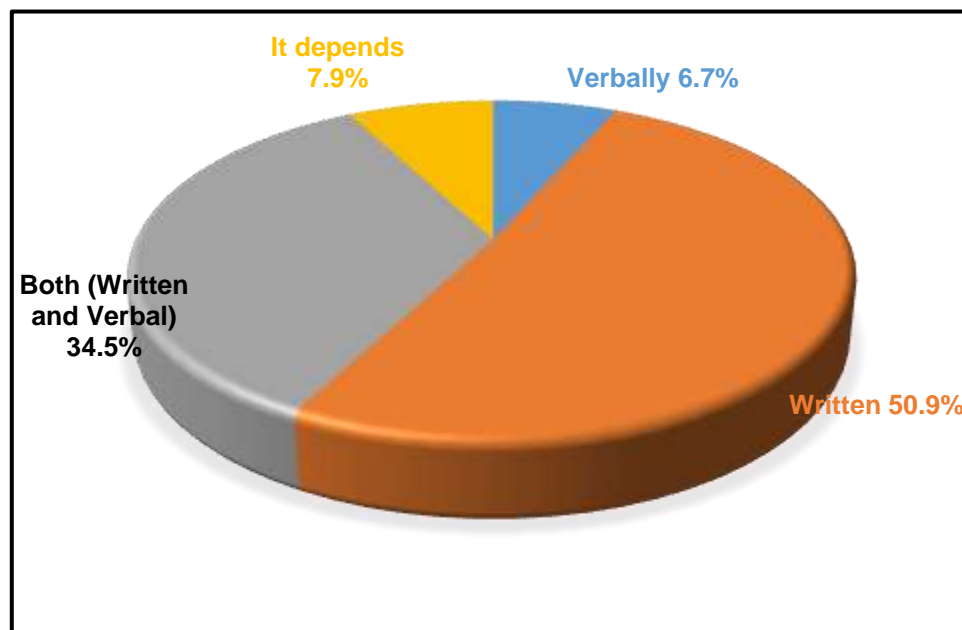


Figure 5.4: Methods used to obtain consent from patients by doctors

5.4.7 Methods used to enhance comprehension or understanding of information disclosed

To evaluate whether patients usually understand the information disclosed by doctors in the context of the language in which the information is provided, I asked questions about the language and methods used to obtain informed consent from patients. When communicating with patients, 64.3% (108/168) doctors said they used the '*English language*'. Another 44.6% (75/168) said they used the '*patients' local language*', while 69% (116/168) of doctors said they used '*both English and the patients' local language*'. To enhance or facilitate understanding of information disclosed to patients, 96.4% (162/168) doctors said they used '*words*' or communicated verbally. Another 20.2% (34/168) used '*pictures*'; 41.7% (70/168) used '*diagrams*', while 72% (121/168) used '*Interpreters*' to communicate with patients. When doctors were asked if they think patients understood the information given to them; 76.4% (126/168) answered affirmatively. Another 3.6% (6/168) answered 'no'; 12.7% (21/168) doctors answered 'don't know', while 7.3% (12) said they 'didn't think so'.

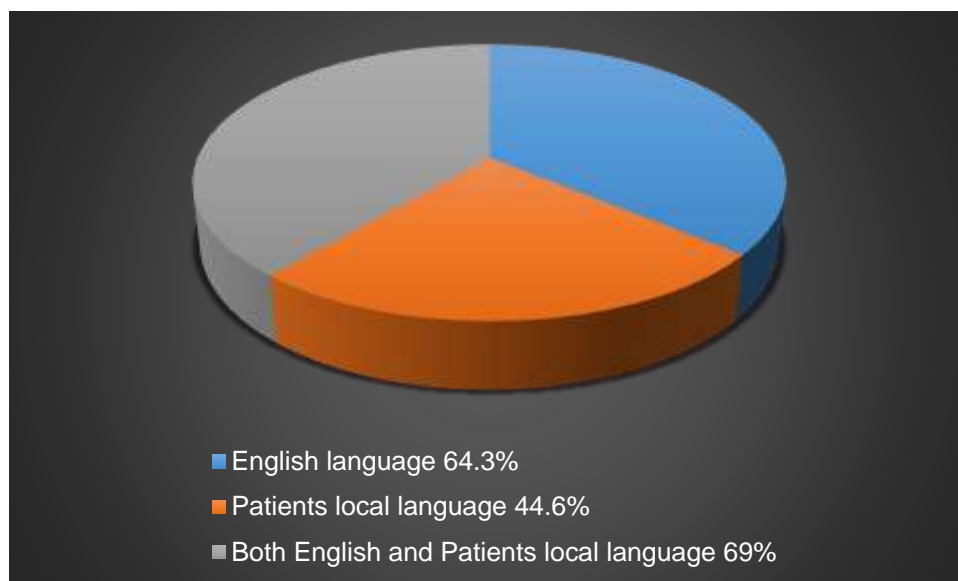


Figure 5.5: Language used by doctors to communicate with patients

5.4.8 Competence or capacity to give informed consent

When doctors were asked whether they generally presumed that patients had the capacity to consent to treatment; 67.3% (113/168) of doctors answered affirmatively. Another 31% (52/168) answered 'no', while 1.8% (3/168) answered 'don't know'. When asked whether they routinely assessed a patient's capacity to give consent to treatment, 58.9% (99/168) doctors answered 'yes', 37.5% (63/168) answered 'no'; while 3.6% (6/168) said they 'don't know'. When asked to rank the most important factors in assessing patients' decision making capacity (DMC), 73% (123/168) of doctors ranked '*level of consciousness*' first, 74% (125/168) ranked '*age*' second; 72.6% (122/168) ranked '*educational level*' third, 65.5% (110/168) ranked '*appearance*', fourth while 66.67% (112/168) ranked '*sex*' of the patient last in terms of importance. These rankings by doctors appeared somewhat consistent with the recommendations by the UK Mental Capacity Act 2005,¹⁶¹⁹ which suggested that "*a lack of capacity cannot be established merely by reference to a person's age, appearance, intelligence, level of education, or any condition or aspect of behaviour, which might lead others to make unjustified assumptions about capacity.*"^{1620,1621}

5.4.9 Methods used to assess capacity

When asked to rank methods used in assessing patients' capacity when confronted with difficult cases during clinical practice, 72.6% (122/168) of doctors ranked '*mental status examination*' first; 70.8% (119/168) ranked '*psychiatric consultation*' second; 66.1% (111/168) and 58.9% (99/168) doctors ranked '*ethics consultation*' and '*use of surrogates*' third. While '*court adjudication*' was ranked fourth by 62.5% (105/168) doctors. About 28.6% (48/168) of doctors said they would use '*none of the above*' methods. When asked to specify what method they routinely used in assessing patients mental capacity when

¹⁶¹⁹ UK Mental Capacity Act 2005.

¹⁶²⁰ Annandale et al "Mental capacity and best interests-Annual Review 2006"
www.bevanbrittan.com (Date of use: 27 March 2008).

¹⁶²¹ Chima 2009 *Trans J Coll Med S Afr* [42-43].

dealing with difficult cases during clinical practice, the majority of doctors said they used the mini-mental status exam (MMSE), followed by level of consciousness, or orientation in time place and person, and the Glasgow coma scale (GCS). Others said they would involve parents/guardians especially in paediatric cases, while some said they would use other surrogates such as a social worker/psychologist, family members or the hospital superintendent. There was no significant difference across clinical specialties in terms of 'presumption of capacity' ($p= 0.110$) or routine assessment of capacity ($p= 0.698$).

5.4.10 Consent in emergencies

When doctors were asked whether they usually obtained informed consent in emergency cases; 54.2% (90/168) of doctors answered affirmatively, while 19.9% (33/168) answered 'no'. Another 24.1% (40/168) doctors said 'it depends', while 1.8% (3/168) said they 'don't know'. Doctors who answered 'it depends' gave various reasons for not obtaining consent in emergency cases, including level of consciousness or mental status of the patient; availability of a parent or guardian to serve as surrogate decision maker. Other doctors said that if the patient was in a stable condition and able to comprehend, then they would obtain consent. Others said if patients were incapacitated, then proxy consent would be obtained from the consultant in charge, or medical superintendent of the hospital, consistent with current regulations as contained in the National Health Act 2003.¹⁶²² Other doctors indicated that it depends on the procedure and whether it was a life-threatening situation.

5.4.11 Voluntariness of consent during medical treatment

When doctors were asked whether they would 'allow patients to choose a medical procedure or treatment by themselves'; 53% (88/168) of doctors answered affirmatively. Another 44.6% (74/168) said 'no', while 2.4% (4/168) answered 'don't know'. To further explore whether doctors allowed their patients to exercise choice or act on their own free will during clinical encounters, doctors were asked about their understanding and use of

¹⁶²² National Health Act 61 of 2003 (s8).

implied and presumed consent in practice. Their responses to that question is reported below.

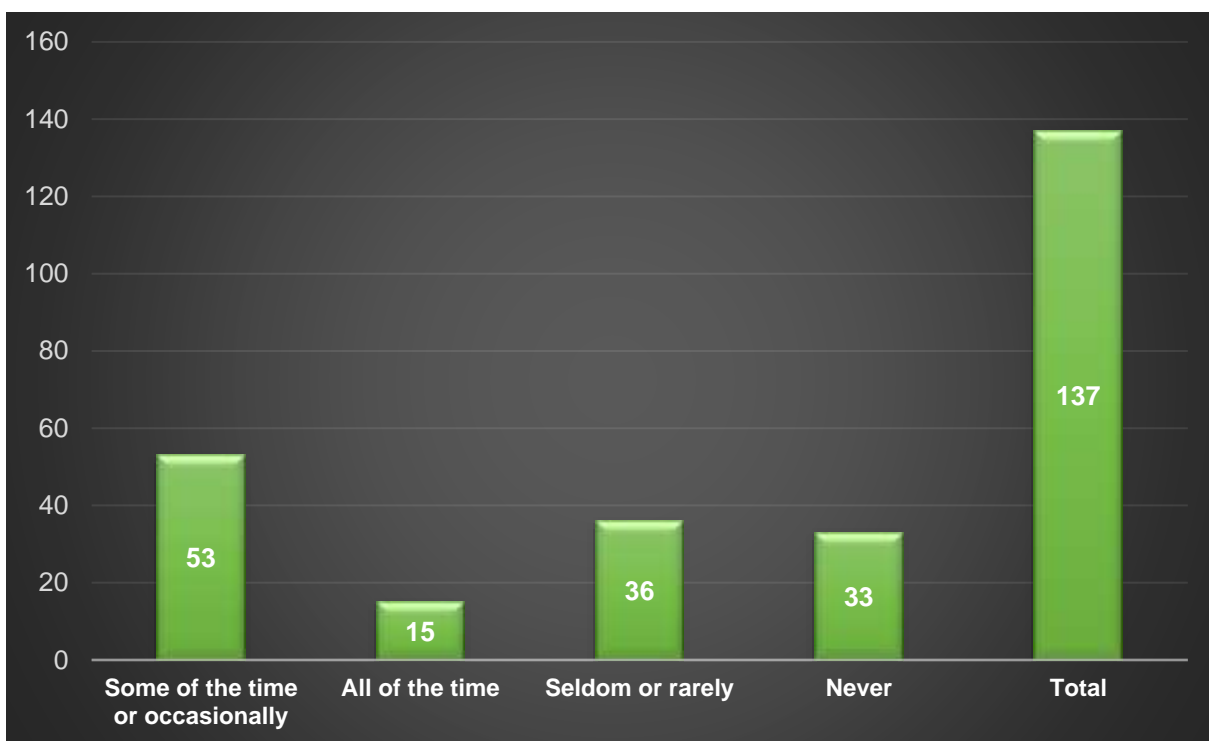


Figure 5.6: Use of implied or presumed consent by doctors

5.4.12 Understanding and use of implied/presumed consent by doctors

When doctors were asked whether they ever used implied or presumed consent when treating patients; 53% (80/168) of doctors answered affirmatively, while 47% (71/168) answered 'no'. More doctors said they used implied consent in an emergency rather than in the hospital wards or clinics (table 5.5). When asked how often they used implied or presumed consent in practice, about 39% of doctors said they used implied or presumed consent sometimes or occasionally, while 26% used it on rare occasions. Only about 11% said they used it all of the time, while another 24% said they never used it at all as shown in figure 5.6 below. Another 66% (95/168) of doctors also said they obtained specific consent for certain procedures, while 34% (49/168) said they did not (Table 5.5). Those doctors who said that they would obtain specific consent for certain procedures, generally indicated that they would obtain specific consent for minor and major surgical

procedures or blood transfusions. The issues surrounding voluntariness and consent to treatment will be evaluated further from the point of view of patients, when patients' data are analysed and discussed in Chapter 7 of this thesis.

5.4.13 Major challenges to obtaining informed consent

In this study, doctors were also required to rank a series of potential challenges experienced while obtaining informed consent in practice, on a seven point scale of 1-7, with 1 being most difficult and 7 as least difficult (Table 5.6). The major challenges identified by doctors in this setting included '*language difficulties*', ranked highest by 87.5% (147/168) of doctors, '*time constraints*' ranked second by 86.9% (146/168) doctors, followed by '*work load*' 85% (143/168) doctors. Then '*lack of education*' by 84.5% (142/168), '*lack of administrative support e.g. interpreters*' by 82% (138/168) of doctors. The least important constraints identified were '*cultural barriers*' generally, ranked by 79.8% (134/168) of doctors, while '*medical paternalism (doctor knows best)*' was ranked last by 78% (131/168) of doctors as shown in Figure 5.7. Cultural barriers identified by doctors included religious beliefs, such as Jehovah's witnesses, or traditional abhorrence of organ transplantation, amputations, and blood transfusions by some South African tribes. Other cultural factors noted by respondents include the need to obtain approval from husbands, other family members or elders prior to giving consent, preference for traditional healers, cultural taboos, and 'disempowered caregivers' according to one respondent. A test of statistical significance using the Kruskal-Wallis test for independent variables, showed that the '*lack of administrative support e.g. interpreters*' was statistically significant across all clinical specialities ($p = 0.013$) as shown in table 5.6.

Table 5.5: Use of implied or presumed consent in clinical practice

Implied/presumed consent	Yes (%)	No (%)	Don't know (%)
Do you ever use implied/presumed consent in practice?	80/168 (53)	71/168(47%)	
When do you use implied/presumed consent:			
1. When patients' present at the clinic?	49/168 (34)	95/168 (66)	1/168(1)
2. When patients are admitted to the ward?	45/168 (31)	98/168 (68)	1/168 (1)
3. In an emergency?	69/168 (48)	73/168 (50)	3/168 (2)
How often do you use implied/presumed consent?			
Some of the time or occasionally	53/168 (38.7)		
Seldom or rarely	36/168(26.3)		
All of the time	15/168(10.9)		
Never	33/168(24.1)		
Do you obtain consent for other specific procedures?	95/168 (66)	49/168 (34)	

Table 5.6: Major challenges to obtaining informed consent by doctors

Challenges	Median score	P-value
Lack of admin. support e.g. interpreters	4	0.013
Time constraints	2	0.226
Work load	3	0.110
Lack of education	4	0.915
Cultural barriers	5	0.551
Language barriers	2	0.453
Medical paternalism (doctor knows best)	7	0.300

Notes: (a) Challenges were ranked from 1-7, with 1 being most difficult and 7 being least difficult, median scores are reported here. (b) Tests of statistical significance across all clinical disciplines were done using Kruskal-Wallis test for independent samples, significance level is $P \leq 0.05$

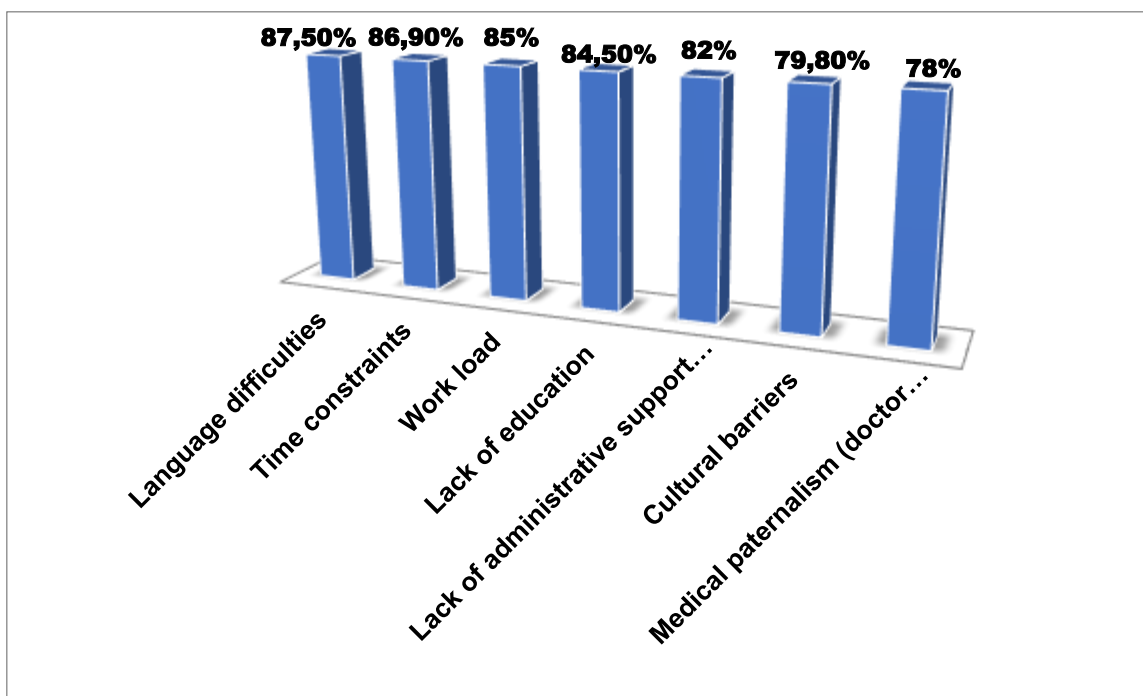


Figure 5.7: Challenges to obtaining informed consent reported by doctors

5.4.14 Understanding of standards for information disclosure

When doctors were asked whether the current standards for information disclosure was based on a 'reasonable doctor' or 'prudent patient standard', most doctors, 60.2% (97/168) answered that it was based on a '*reasonable doctor standard*', while 47.8% (76/168) correctly answered that it was based on a '*prudent patient standard*'. When asked whose duty it was to obtain consent from patients during routine clinical practice, 66.3% (110/168) of doctors correctly answered that it was responsibility of the '*doctor performing the procedure or treating the patient*'. About 6.1% (10/168) doctors answered that '*nurses*', were responsible. Another 44.6% (74/168) said that '*junior doctors*' were responsible, while 10.8% (18/168) doctors thought it was the responsibility of '*any available healthcare professional*', while 3.6% (6/168) doctors did not know who was responsible.

5.4.15 Responsibility for obtaining informed consent

When asked whose responsibility it was to assure that adequate information was provided before obtaining informed consent from patients, only 61.7% (100/168) of doctors thought that it was the '*doctor or healthcare professional's responsibility*'. About, 41% (66/168) of doctors answered that '*both the doctor and patient were jointly responsible*', while 5% (8/168) doctors thought it was '*the patient's responsibility*'.

5.4.16 General knowledge of basic local laws and regulations relating to informed consent

To test for basic knowledge of informed consent laws and regulations in South Africa, doctors were asked some specific questions. When asked to select the 'current age of consent' to routine treatment in South Africa, as recommended by the Children's Act¹⁶²³ only 70.7% of doctors were able to correctly select '12 years'. This question was answered incorrectly by many doctors with 10.8% choosing '15 years'; while 15.3% chose 18 years'; 1.9% of doctors selected '21 years', while another 1.3% of doctors did not know the correct

¹⁶²³ Children's Act 38 of 2005 as amended.

answer. Further, when asked to select the correct age when women can consent to termination of pregnancy (TOP) in accordance with the Choice on Termination of Pregnancy Act,¹⁶²⁴ only 29.6% of doctors correctly answered ‘any age’ as stipulated by law. Majority of doctors gave the wrong response with 50.9% of doctors choosing ‘12 years’; 13.2% chose ‘15 years’, 3.8% chose ‘18 years’, while about 2.5% did not know the correct age. Chi-squared tests were used to test for statistical significance in terms of general knowledge of informed consent laws and regulations across all specialities. There was no statistical significance detected in terms of age of consent, age for women to request for TOP, or standards of information disclosure.

5.4.17 Informed consent aggregate scores (ICAS)

To compare informed consent practices across occupational ranks of doctors and nurses, as well as between clinical specialties, I developed an aggregate score using a modified version of the method described by Sugarman and others.¹⁶²⁵ Previous authors used a series of seven questions derived from a brief informed consent evaluation protocol (BICEP) during research studies.¹⁶²⁶ I selected a series of questions from the questionnaire which relate to information disclosure, voluntariness, assessment of capacity and understanding or comprehension as shown in table 5.7. The questions included in calculating the ICAS were derived from the list of items included in the NHA¹⁶²⁷ and from a review of the relevant literature regarding information disclosure during informed consent. A total of twelve questions from the questionnaire for healthcare professionals¹⁶²⁸ were adjudged to satisfy these criteria. Each of the selected questions was given a rank score of one (1) and the aggregate score is the sum of the scores (12) as shown in table 5.7. ICAS aggregate scores for all doctors by occupational rank ranged from 1 to 12, with a median score of 10 (SD = 2.28). The lowest scores in this cohort were recorded by interns and registrars with a median score of 9; while medical officers and

¹⁶²⁴ Choice on Termination of Pregnancy Act 92 of 1996.

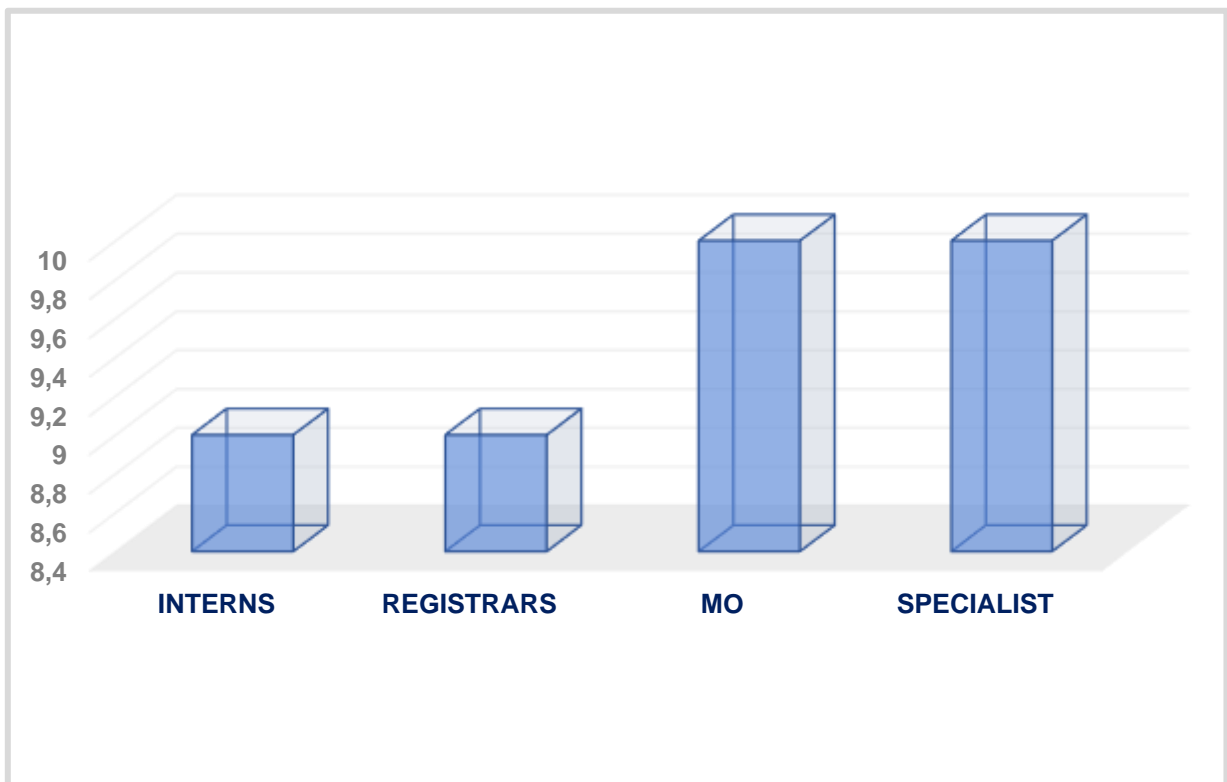
¹⁶²⁵ Sugarman J et al “Evaluating the quality of informed consent” 2005 *Clinical Trials* 34-41.

¹⁶²⁶ Sugarman et al 2005 *Clinical Trials* 35-37.

¹⁶²⁷ National Health Act (section 6).

¹⁶²⁸ See Appendix 1.

consultants/specialists recorded a median score of 10 respectively as shown figure 5.8. Tests of statistical significance for ICAS by occupational rank of doctors was not statistically significant ($p = 0.174$). However, comparison of ICAS scores by clinical speciality using the Kruskal-Wallis test was statistically significant ($p = 0.005$). In this case anaesthetists and radiologists had the lowest ICAS scores with a median score of 7 and 8, respectively, while the highest scores were obtained by OBGYN, Internal medicine and GP doctors with a median score of 10.50 as shown figure 5.9 below. Finally, when the ICAS scores of doctors were compared with that of professional nurses, scores by professional nurses was lower than that of doctors with a median score of 8, while the median score for doctors was 10. The difference in scores between doctors and nurses was highly statistically significant ($p \leq 0.001$), using the Mann-Whitney U test for independent samples at a significance level of 0.05. The comparative score of doctors versus nurses ICAS is further discussed in chapter six of this thesis.



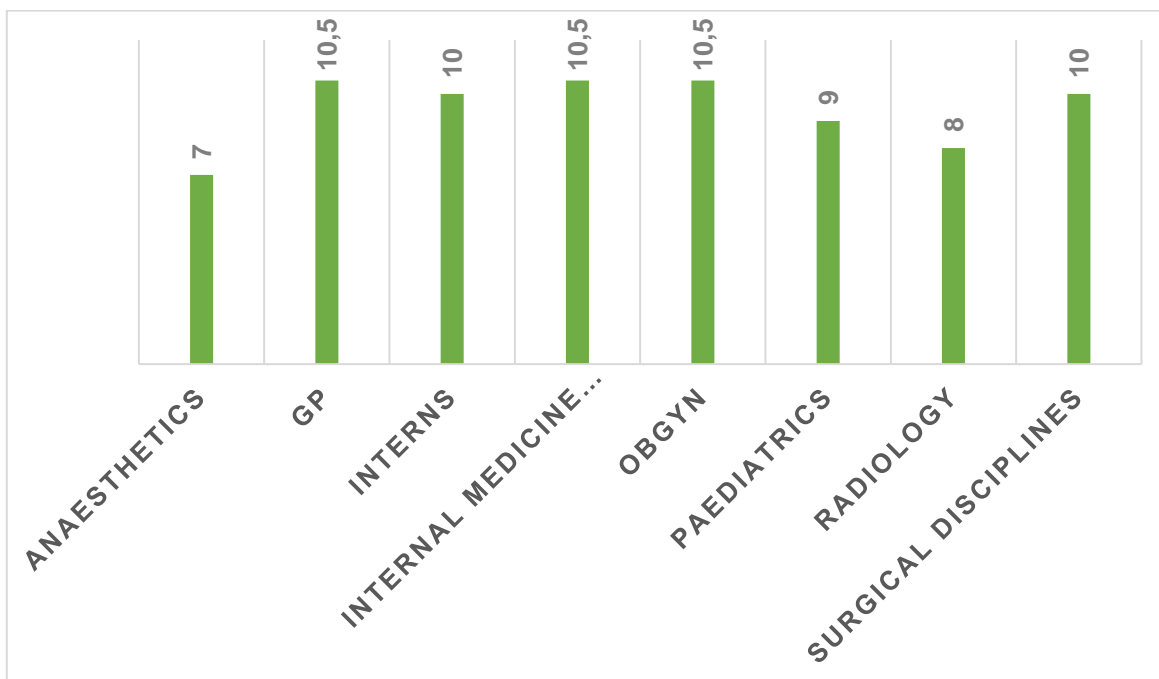
Note: MO = Medical Officers

Figure 5.8: Doctors ICAS by occupational rank

Table 5.7: Questions used to calculate ICAS

<i>A. Information disclosure:</i>	ICAS Score	
What information do you routinely provide to your patients?		
	Yes	No
Diagnosis	1	0
Treatment options	1	0
Recommended treatment	1	0
Risks of refusing recommended treatment	1	0
General risks	1	0
Benefits	1	0
Right of refusal	1	0
<i>B. Capacity/Competence</i>		
Do you routinely assess the competence of your patients to consent to treatment?	1	0
Do you generally presume that your patients have the capacity to consent to treatment?	1	0
<i>C. Voluntariness</i>		
Do you allow your patients to choose a procedure or particular treatment?	1	0
<i>D. Understanding</i>		
Do you think your patients understand the explanations given to them?	1	0
<i>E. Consent or agreement</i>		
Do you think the information you provide is sufficient to procure valid informed consent?	1	0
Total: Informed consent aggregate score (ICAS)	12	0

Note: The question about cost of medical treatment is excluded from this ICAS calculation in this cohort because the cost of healthcare services in SA public hospitals is generally free.



Note: GP = General Practitioners; OBGYN = Obstetricians and Gynaecologists

Figure 5.9: ICAS scores of doctors by clinical specialty

5.5 DISCUSSION

5.5.1 The quality of informed consent

Most studies which evaluated the quality of informed consent especially in developing countries have focused on informed consent practices in clinical research. These include previous studies from Nigeria,¹⁶²⁹ Uganda,¹⁶³⁰ South Africa,¹⁶³¹ and Mali.¹⁶³² Most of these

¹⁶²⁹ Taiwo O and Kass N "Post-consent assessment of dental subjects understanding of informed consent in oral health research in Nigeria" 2009 *BMC Med Ethics* 10 [11].

¹⁶³⁰ Kiguba K et al "Assessing the quality of informed consent in a resource-limited setting: A cross-sectional study" 2012 *BMC Med Ethics* 13 [21].

¹⁶³¹ Minnies D et al "Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting" 2008 *BMC Med Ethics* 9 [15].

¹⁶³² Krosin MT et al "Problems in comprehension of informed consent in rural and peri-urban Mali West Africa" 2006 *Clin Trials* 306-313.

studies reported problems with comprehension and understanding of the informed consent process by patients including the right of withdrawal. Other studies from developed countries have contended with problems of the human subject's therapeutic misconception, voluntariness and measurement of capacity to consent during biomedical research including clinical trials.^{1633,1634,1635} While many studies on informed consent have focused on clinical trials and biomedical research, very few studies have actually focused on the quality of informed consent in clinical practice, especially in Africa.^{1636,1637,1638} The paucity of studies in the area of clinical practice of IC is rather surprising, considering that patients or healthcare users are far more likely to seek treatment for routine medical treatment, than to participate in clinical trials or biomedical research. Nonetheless, most of the studies from developing country settings have highlighted the need for more education on medical ethics for biomedical researchers, HCPs, as well as patients or human subjects of biomedical research.^{1639,1640,1641,1642} Some studies have also identified the need to improve the quality of informed consent documents, including the need for simplified language to enhance participant understanding.¹⁶⁴³ Others have highlighted the different notions of informed consent such as the moral and legal dimensions of consent which have the potential to impact on the quality and practice of informed consent, including information disclosure, understanding and shared decision making.^{1644,1645}

1633 Sugarman et al 2005 *Clinical Trials* 34-41.

1634 Sturman ED "The capacity to consent to treatment and research: A review of standardized assessment tools" 2005 *Clin Psych Rev* 954-974.

1635 Appelbaum PS, Lidz CW and Klitzman R "Voluntariness of consent to research: A preliminary empirical investigation" 2009 *IRB: Ethics & Human Research* 10-14.

1636 Ezeome and Marshall 2009 *Dev World Bioeth* 138-148.

1637 Ogundiran and Adebamowo 2010 *J Med Ethics* 741-745.

1638 Henley et al 1995 *SAMJ* 1273-1278.

1639 Taiwo and Kass 2009 *BMC Med Ethics* 11.

1640 Kiguba K et al 2012 *BMC Med Ethics* 21.

1641 Minnies et al 2008 *BMC Med Ethics* 15.

1642 Krosin et al 2006 *Clin Trials* 2006 306-313.

1643 Jefford M and Moore R "Improvement of informed consent and the quality of consent documents" 2008 *The Lancet Oncology* 485-493.

1644 Lindegger and Richter 2000 *S Afr J Sci* 313-317.

1645 Mandava A et al "The quality of informed consent: mapping the landscape. A review of empirical data from developing and developed countries" 2012 *J Med Ethics* [361-363].

5.5.2 Standards of information disclosure

One of the more controversial areas of informed consent in practice surrounds the amount of information disclosure required before consent can be considered valid. On this consideration, there are two contesting schools of thought. On one hand is 'reasonable doctor standard' derived from the English common law judgment by McNair J in *Bolam v Friern HMC*¹⁶⁴⁶ commonly known as the *Bolam test*, which states that, "A doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of men skilled in that particular art...".¹⁶⁴⁷ It has been argued that English courts have opted for a paternalistic approach by following the reasonable doctor standard, which bases disclosure on the clinical judgement or accepted practice or substantial risk/normal/usual risk principles as established in *Bolam*.^{1648,1649} This judgment was later reaffirmed by the English House of Lords in the *Sidaway* case¹⁶⁵⁰ where Lord Templeman argued that:

At the end of the day, the doctor bearing in mind the best interests of the patient and bearing in mind the patients right to information which will enable the patient to make a balanced judgement, must decide what information should be given to the patient, and what terms that information should be couched.¹⁶⁵¹

However, Lord Scarman in the same case suggested the use of a 'prudent patient standard' of information disclosure, arguing that: "It was a strange conclusion if our courts should be led to conclude that our law...should permit doctors to determine in what circumstances...a duty arose to warn."¹⁶⁵² The courts in North America, have maintained in cases such as the American case of *Canterbury v Spence*¹⁶⁵³ and the Canadian case of *Reibl v Hughes*¹⁶⁵⁴ that a patient must be informed of all material risks, where those 'material risks' would consist of what a reasonable person, in such a patients position,

¹⁶⁴⁶ *Bolam v Friern Health Management Committee* [1957] 1 WLR 582.

¹⁶⁴⁷ *Bolam v Friern Health Management Committee* [1957] 1 WLR 582 [587].

¹⁶⁴⁸ *Van Oosten* 1991 [395-461].

¹⁶⁴⁹ *Carstens and Pearmain Foundational Principles* 679.

¹⁶⁵⁰ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643

¹⁶⁵¹ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643 [903].

¹⁶⁵² *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643 [932]

¹⁶⁵³ *Canterbury v Spence* [1972] 464 2d 772 (DC) [41-46].

¹⁶⁵⁴ *Reibl v Hughes* [1980] 114 DLR (3d) 15.

would be likely to attach significance to, in deciding whether to accept or forego a proposed treatment. Similarly, in the Australian case of *Rogers v Whitaker*¹⁶⁵⁵ the High Court of Australia reaffirmed the ‘material risk’ standard of information disclosure as the acceptable standard and this prudent patient standard of information disclosure was finally adopted into English law by a recent judgment of the UK Supreme court sitting in Scotland in the case of *Montgomery v Lanarkshire*.¹⁶⁵⁶ Comparatively, in South African case law, the issue of how much information should be disclosed to patients has been the subject of debate since the case of *Lymberg v Jeffries*¹⁶⁵⁷ where the Court was of the opinion that a “doctor is not obliged to disclose all the conceivable complications that may arise during a medical procedure.” However in the landmark South African case of *Castell v De Greef*¹⁶⁵⁸ the full bench of the High Court concluded, that a doctor is obliged to warn the patient of all the ‘material risks’ inherent in the proposed treatment, where material risks is based on a ‘prudent patient standard’.¹⁶⁵⁹ However in recent South African court judgments like the *Oldwage case*,¹⁶⁶⁰ the SCA seems to have abandoned, even if partially, the material risks standard as established in the *Castell case*¹⁶⁶¹ and reverted to the discredited ‘reasonable doctor’ standard as applied in the case of *Richter and Another v Estate Hamman*.¹⁶⁶² This recent judgment in the *Oldwage case* has been criticized by legal commentators and academic writers^{1663,1664} as being retrogressive and inconsistent with the regulations in the National Health Act.¹⁶⁶⁵ While the current requirements for information disclosure as codified in the NHA,¹⁶⁶⁶ are consistent with the prudent patient and material risks standards as practiced in North America and other common law jurisdictions, recent judgments by South African Courts in the *Oldwage case* and *Sibisi NO v Maitin*¹⁶⁶⁷ have brought this requirements into question since they are not being

¹⁶⁵⁵ *Rogers v Whitaker* [1992] HCA 58; (1992) 175 CLR 479 (Aust High Ct) [83].

¹⁶⁵⁶ *Montgomery v Lanarkshire Health Board (Scotland)* [2015] UKSC 11 [87].

¹⁶⁵⁷ *Lymberg v Jeffries* 1925 AD 236.

¹⁶⁵⁸ *Castell v De Greef* 1994 (4) SA 408 (C).

¹⁶⁵⁹ *Castell v De Greef* 1994 (4) SA 408 (C) [425-426].

¹⁶⁶⁰ *Louwrens v Oldwage* 2006 (2) SA 161 SCA [14]

¹⁶⁶¹ *Castell v De Greef* 1994 (4) SA 408 (C).

¹⁶⁶² *Richter and Another v Estate Hamman* 1976 (3) SA 226 (C) [232].

¹⁶⁶³ Thomas R 2007 *SALJ* 188-215 see also Britz and Roux-Kemp SAMJ 2012 [189-192].

¹⁶⁶⁴ Carstens and Pearmain *Foundational principles* [685-687].

¹⁶⁶⁵ National Health Act 61 of 2003.

¹⁶⁶⁶ National Health Act of 2003 (s6).

¹⁶⁶⁷ *Sibisi NO v Maitin* 2014 (6) SA 533 (SCA).

actively applied by South African law courts. In addition the courts have shown a reluctance to expand the common law based on comparative application of international legal jurisprudence as required by the Constitution.¹⁶⁶⁸

Section 6 of the NHA outlines the requirements for information during informed consent. One can argue that these requirements reaffirm the need for full disclosure of all material risks with few exceptions, as specified in Sections 7 and 8 of the Act.¹⁶⁶⁹

In the current study, the results show that while the majority of South African doctors complied substantially with the requirements of the NHA in terms of information disclosure as shown in Table 5.3, only about 21% of doctors complied with or understood the 'material risks' standard of risk disclosure as seen in Table 5.4. Further, a majority of doctors (60%) chose the 'reasonable doctor' rather than the 'prudent patient' standard as the required standard for information disclosure in clinical practice. Therefore, the current practice by doctors in terms of information disclosure is only partially compliant with ethical guidelines from the HPCSA¹⁶⁷⁰ or as codified in the National Health Act,¹⁶⁷¹ however, they may be supported by the inconsistent judgments of South African courts.¹⁶⁷²

5.5.3 Comprehension of information disclosed

It has been suggested that in developing countries such as South Africa, where education standards and literacy levels are low, knowledge and power asymmetry usually exist between patients and health care professionals.^{1673,1674} It is also important to recognize the historical backdrop of colonialism and racism, and ongoing challenges of poverty and inequality.^{1675,1676} In spite of such considerations however, it has been argued that doctors

¹⁶⁶⁸ The Constitution s39 (b) and (c).

¹⁶⁶⁹ National Health Act 2003 (sections 7 and 8).

¹⁶⁷⁰ HPCSA *Seeking patients informed consent* (HPCSA Pretoria 2008).

¹⁶⁷¹ National Health Act 61 of 2003 (S6-S9).

¹⁶⁷² Thomas R 2007 *SALJ* 188-215 see also Britz and Roux-Kemp *SAMJ* 2012 [189-192].

¹⁶⁷³ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

¹⁶⁷⁴ Ijsselmuiden and Faden 1992 *NEJM* 830-834.

¹⁶⁷⁵ Maphai 1989 [1-24] see also Mhlongo and Mdingi 1997 *BMJ* 252.

¹⁶⁷⁶ Annas and Grodin *Health and Human Rights* 1999 [373-380].

still have an obligation to adequately explain clinical procedures to patients without turning them or surrogates into students of medicine.¹⁶⁷⁷ It is therefore important that healthcare providers ensure that patients understand the proposed treatment or procedure prior to providing consent. Some authorities have suggested a verbal or written test to ascertain patient capacity, competence or understanding before considering informed consent valid.¹⁶⁷⁸ To further improve understanding and comprehension during the informed consent process in developing countries and traditional communities, the United States National Bioethics Advisory Commission (NBAC) has suggested that *community participation* is acceptable. This may include providing written information sheets for discussions with family members and holding community meetings, but cautions that family permission should not replace the requirement for individual informed consent.^{1679,1680}

5.5.4 Language as a barrier to informed consent

The ability to use written information is important to comprehension and understanding,¹⁶⁸¹ as such; barriers to communication arising from illiteracy and language differences may prevent a common understanding of medical procedures, thereby putting patients at risk of providing consent without comprehension.¹⁶⁸² In the current study, one of the major barriers towards obtaining valid consent by doctors was 'language difficulties', ranked highest by 88% of doctors in this cohort. This was supported by complaints about 'lack of education' (85%) and lack of administrative support such as interpreters by 82% of doctors (Figure 5.7). Therefore, it cannot be overemphasized that one of the major barriers to obtaining valid informed consent in this environment is the issue of language. It has been argued that language barriers can have a deleterious effect on healthcare service delivery, leading to such errors as misdiagnosis, failure of preventive therapy or

¹⁶⁷⁷ Lore 1993 *Medicus* 227-229.

¹⁶⁷⁸ Appelbaum 2007 *N Engl J Med* 1834-1840.

¹⁶⁷⁹ National Bioethics Advisory Commission *Presidential bioethics commission issues report on clinical trials research in developing countries* (Bethesda USA NBAC 2001).

¹⁶⁸⁰ Tindana et al 2006 *IRB* 1-6.

¹⁶⁸¹ Green et al 2003 *J Paediatric Child Health* 700-703.

¹⁶⁸² Richter L et al "Guidelines for the development of culturally sensitive approaches to obtaining informed consent for participation in HIV vaccine-related trials" (UNAIDS Geneva 1999).

non-adherence to prescribed medication, which could ultimately lead to charges of medical negligence and award of damages against doctors.¹⁶⁸³ The issues of language difficulties and the necessity for appropriately trained interpreters, is not limited to developing countries, but is also a barrier to proper healthcare service delivery in developed countries such as the USA or any multicultural/multilingual setting.^{1684,1685} Currently South Africa has eleven official languages; therefore language barriers, especially the absence of adequately trained interpreters to assist HCPs professionals in providing care to patients is a major problem. In another study at a South African district hospital, the authors concluded that language barriers in the hospital created significant problems for healthcare professionals and impacted negatively on patients' rights to confidentiality, informed consent and the quality of healthcare service delivery.¹⁶⁸⁶

5.5.5 Decision making capacity

In the common law, there is a presumption that every adult person has the capacity to consent or refuse medical treatment unless proven otherwise by acceptable evidence. A lack of capacity cannot be established merely by reference to a person's age, appearance, and intelligence, or level of education, or any condition or aspect of behavior, which might lead others to make unjustified assumptions about capacity.¹⁶⁸⁷ According to an opinion from an English court in the case of *Richmond v Richmond*:¹⁶⁸⁸

Capacity is ultimately a legal not a medical decision... it is for the court to decide the question of capacity, although the court must pay attention to the evidence of experts in the medical profession who can indicate the meaning of symptoms and give some idea of the mental deterioration which takes place in cases of this kind....

¹⁶⁸³ Flores 2006 *N Engl J Med* 229-331.
¹⁶⁸⁴ Schenker et al 2016 *J Gen Intern Med* 294-299.
¹⁶⁸⁵ Tate et al 2016 *Prehospital Emergency Care* 1-11.
¹⁶⁸⁶ Schlemmer and Mash 2006 *SAMJ* 1084-1087.
¹⁶⁸⁷ Chima 2009 *Trans J Coll Med S Afr* 42.
¹⁶⁸⁸ *Richmond v Richmond* [1914] 111 LT 273 2 [148].

Thorpe J summarized the common law test for capacity in *Re C*¹⁶⁸⁹ where he said that: the patient must be able to (a) comprehend and retain the information (b) believe it (c) weight it in the balance so as to arrive at a choice. However, the UK Mental Capacity Act¹⁶⁹⁰ further simplified this test, which now states that a person is deemed incapable of making a decision and exercising autonomy rights where that person is unable:

- a) To understand the information relevant to the decision,
- b) To retain that information
- c) To use or weigh that information as part of the process of making the decision, or
- d) To communicate his decision (whether by talking, using sign language or any other means).¹⁶⁹¹

In the study reported here, about 67% of doctors said that they would presume that patients have the capacity to consent to treatment, although this low percentage may have been influenced by the large number of pediatricians within our study cohort, who would normally assume that their patients could not provide the necessary consent based on their age. Similarly, only 59% of doctors in this cohort claimed that they routinely tested their patients for capacity to prior to treatment. On the other hand, the majority of doctors accurately ranked factors such as level of consciousness, age, educational level, appearance and sex, in descending order, as being factors used in the assessment of capacity. When assessing capacity in difficult cases, majority of doctors responding said they would use a MMSE, GCS or orientation in time place and person, to ascertain patient's capacity to give consent to treatment. This is contrary to previous studies on capacity assessment tools for medical treatment, which concluded that both the MMSE and GCS should be viewed as blunt instruments when determining patients' capacity.¹⁶⁹² Perhaps more sensitive capacity assessment tools, such as the MacArthur Competence Assessment Tool-Treatment (MacCAT-T) should be evaluated for use in this setting.^{1693,1694}

¹⁶⁸⁹ Re C: Adult Refusal of Medical Treatment [1994] 1 All ER 683.

¹⁶⁹⁰ UK Mental Capacity Act 2005.

¹⁶⁹¹ Chima 2009 *Trans J Coll Med S Afr* 43 see also Annandale et al www.bevanbrittan.com (Date of use: 27 March 2008).

¹⁶⁹² Sturman ED "The capacity to consent to treatment and research: A review of standardized assessment tools" 2005 *Clin Psych Rev* 954-974.

¹⁶⁹³ Sturman 2005 *Clin Psych Rev* 954-974.

¹⁶⁹⁴ Appelbaum PS 2007 *N Engl J Med* 1834-40.

5.5.6 Voluntariness and consent or agreement to treatment

Voluntariness of consent has been one of the more difficult areas to assess by empirical methods due to variations in patients' clinical condition and cultural norms associated with the concept of voluntariness.^{1695,1696} In traditional African societies the influence and respect for family, friends and elders is very important in accordance with cultural norms.¹⁶⁹⁷ Therefore, it is not unusual for individuals to seek the advice of family, friends and relatives before making important decisions regarding healthcare.^{1698,1699} While these types of interference may be considered undue influence in western cultures, with their history of libertarian autonomy and individual rights. African societies are more accepting of collective decision making, based on a different concept of autonomy derived from Ubuntu or "*sumus, ergo sum, (we are, therefore I am)*".^{1700,1701} It is generally recognized that voluntariness in informed consent means that the patients' consent must be given voluntarily, devoid of any undue influence or coercion either by fraudulent misrepresentation or trickery from the physician or family or friends.¹⁷⁰² According to Lord Donaldson in *Re T*:¹⁷⁰³

If...his will was overborne, the refusal will not have represented a true decision. In this context the relationship of the persuader to the patient—for example, spouse, parents or religious adviser—will be important, because some relationships more readily lend themselves to overbearing the patient's independent will than others.

In the current study, I have tried to study voluntariness by asking some indirect questions from doctors such as whether doctors would allow patients to choose a particular procedure or treatment, of which only 53% of doctors answered affirmatively. Similarly,

¹⁶⁹⁵ Nelson RM et al "The concept of voluntary consent" 2011 *AJOB* 6-16.

¹⁶⁹⁶ Appelbaum PS, Lidz CW and Klitzman R "Voluntariness of consent to research: A preliminary empirical investigation" 2009 *IRB: Ethics & Research* 10-14.

¹⁶⁹⁷ Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

¹⁶⁹⁸ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42 see also Ezeome and Marshall 2009 *Dev World Bioeth* 138-148.

¹⁶⁹⁹ Tindana et al 2006 *IRB* 1-6.

¹⁷⁰⁰ Cullinan T "Other societies have different concepts of autonomy" 1997 *BMJ* 248.

¹⁷⁰¹ Metz and Gaie 2010 *J Moral Educ* 273-9 see also Chima 2015 *Nig J Clin Pract* s1-S7 and Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

¹⁷⁰² Nelson et al 2011 *AJOB* 6-16 see also Beauchamp and Childress *Principles of biomedical ethics* 94-98.

¹⁷⁰³ *Re T (An adult): Consent to Medical Treatment* [1992] 2 *FLR* 458 [799].

when asked whether doctors ever used implied or presumed consent in practice, 53% answered affirmatively. When further asked how often they used implied or presumed consent in practice, 39% said they used it occasionally, 26% said rarely, while 11% said 'all of the time'. Only 24% of doctors said they 'never' used implied or presumed consent in practice (table 5.5). This suggests some forms of medical paternalism are still prevalent in clinical practice in this setting. It appears that many doctors resort to implied/presumed consent in lieu of obtaining legally valid consent, contrary to ethical guidelines from the HPCSA, which advises doctors not to simply presume that patients have given consent when they lay down on the examination table.¹⁷⁰⁴ The advice from the HPCSA is consistent with the injunction of a South African court in the case of *Stoffberg v Elliot*¹⁷⁰⁵ where the court said that:

A man by entering a hospital does not submit himself to such surgical operations as the doctors in attendance upon him might think necessary...he retains his rights of control and disposal of his own body; he still has the right to say what operation he will submit to, and unless consent to an operation is expressly obtained, any operation performed on him without his consent is an unlawful interference with his right of security and control of his own body...

Perhaps this unquestioned practice of using inferred consent could be explained by the power asymmetry that exists between doctors and patients in the African setting, or the special respect shown to doctors by patients in this environment as described by other studies from Nigeria.¹⁷⁰⁶ It may also be associated with the many challenges experienced by doctors practicing in this South Africa public hospitals who reported factors such as heavy workload and lack of administrative support as barriers to informed consent as shown in figure 5.7.

5.5.7 Comparative analysis of ICAS scores

Analysis of ICAS scores showed that interns and registrars scored lower than medical officers and consultant/specialists. This could be explained by the fact that interns and registrars are still trainees and it should be expected that their knowledge of informed

¹⁷⁰⁴ HPCSA *Seeking patients informed consent* (HPCSA 2008) 11.

¹⁷⁰⁵ *Stoffberg v Elliot* [1923] CPD 148 [150].

¹⁷⁰⁶ Ezeome and Marshall 2009 *Dev World Bioeth* 142.

requirements would be lower than that of their trainers and supervisors. Across the clinical subspecialties, radiologists and anaesthetists scored lower than internists, surgeons, and GPs. This is somewhat consistent with findings from another study in Croatia where anaesthetists scored lower than internists and surgeons on informed consent.¹⁷⁰⁷ A plausible explanation for this observation is that due to the fact that radiologists and anaesthesiologists are ancillary subspecialties, they may not be required to provide information to patients such as diagnosis and treatment options etc., and may also depend on primary care physicians to obtain prior informed consent, before referral for supplementary services in terms of scope of practice.¹⁷⁰⁸ In the case of comparison between nurses and doctors, it should be expected that doctors are more knowledgeable about informed consent regulations, because doctors are generally better trained in the areas of medical law and ethics and are required to make final decisions regarding patient care, therefore the requisite knowledge about regulations and practice maybe more rigorously enforced by the regulatory authorities. However it must be noted that the NHA stipulates that ‘every healthcare provider’¹⁷⁰⁹ must obtain informed consent from healthcare users’ (patients), before any medical procedure. This clearly requires professional nurses and other HCPs to be equally knowledgeable about IC when compared to medical doctors.

5.6 CONCLUSIONS

Previous studies on informed consent during clinical practice in African hospitals have shown that while doctors are generally knowledgeable about the ethical doctrine of informed consent, the application and adherence to the standard ethical requirements of informed consent is usually lacking in practice. Analysis of data from this study confirm these observations by showing that doctors practicing in public hospitals in South Africa are relatively knowledgeable about the ethical requirements of informed consent, such as

¹⁷⁰⁷ Jukic M et al “Knowledge and practices of obtaining informed consent for medical procedures among specialist physicians: Questionnaire study in 6 Croatian hospitals” 2009 *Croat Med J* 567-574.

¹⁷⁰⁸ HPCSA *Seeking patients informed consent: the ethical considerations* 2nd ed (HPCSA Pretoria 2007).

¹⁷⁰⁹ National Health Act of 2003 (s6).

information disclosure, and decision making capacity. However not all doctors in this cohort adhered to the critical elements of IC as specified in the National Health Act 2003, or the requirements based on international standards of care or local ethical guidelines. The major challenges militating against the proper practice of informed consent as identified in this study were related to issues of language barriers, lack of administrative support in the form of interpreters to assist with communicating with patients. Other factors identified include large patient numbers with associated time constraints and heavy workload. These results show that while the majority of doctors spent an average of 5-10 minutes on obtaining informed consent, this amount of time was considered inadequate by other doctors. Knowledge of essential local laws such as the age of consent to routine medical treatment or age of consent for TOP in South Africa was not universally known by doctors. Similarly, the majority of doctors still believed in the paternalistic concept of a 'reasonable doctor standard' rather than more currently accepted 'prudent patient' and 'material risks' standards of information disclosure. This study suggests that doctors were statistically more knowledgeable about informed consent than professional nurses, however it remains to be seen whether this translates directly into clinical practice. Finally, there was evidence of overuse of implied and presumed consent or inferred consent by doctors with poor implications for medical paternalism, respect for autonomy and lack of patient volition to provide valid informed consent. Some limitations of this study include the fact that this study was limited to public hospitals in an urban setting and the study period was restricted to 3 months. It is possible that other studies in private hospitals or in a more rural setting in South Africa may yield some different results. Based on the findings in this study, one can recommend the recruitment and training of a 'corps' of interpreters as part of the medical team in South African public hospitals, to assist in improving the quality of doctor-patient communications, informed consent, patient confidentiality and healthcare service delivery in public hospitals. It would also be useful to modify the current universal hospital consent form to better reflect current teaching in medico-legal practice, by including translations in local languages, or options for specific consent for certain procedures or mandatory disclosures as required by law. It would also be useful for patient information leaflets to be produced in local languages to enhance patient education, information disclosure, and understanding by patients, prior to providing

consent. Finally, continuing education for doctors and other healthcare professionals in ethics and medical law will go a long way towards improving the overall quality of healthcare service delivery in South African hospitals.

5.7 Summary of chapter 5

This chapter reports the findings from doctors who participated in the cross-sectional empirical research study conducted at randomly selected public hospitals in EThekweni metropolitan municipality (Durban), KZN province, South Africa. One hundred and sixty-eight (168) doctors, ranging from interns to specialist consultants completed the questionnaire-based study. Almost all major clinical disciplines were represented in the study. The major findings from this aspect of the thesis is that doctors practising in this setting are fairly knowledgeable regarding the IC regulations in South Africa and international ethical guidelines, however implementation in practice was deficient. Doctors generally disclosed many of the items as stipulated in the *National Health Act 2003*, prior to obtaining IC from patients. However, doctors knowledge of basic local laws pertaining to IC and medical treatment was deficient with only 70% of doctors able to identify the correct age of consent to treatment as '12' years of age. Further, only 30% of doctors were able to correctly identify the age of consent to termination of pregnancy as stipulated in the Choice on Termination of Pregnancy Act 1996. To compare knowledge about IC between different categories of doctors and nurses, a 12-item informed consent aggregate score (ICAS) was designed. Using the ICAS, I was able to show that practising medical officers (MOs) and consultant/specialists were more knowledgeable regarding IC regulations when compared to interns and registrars in training. ICAS aggregate scores for all doctors by occupational rank ranged from 1 to 12, with a median score of 10 (SD = 2.28). The lowest scores were recorded by interns and registrars with a median score of 9, while medical officers and consultants/specialists recorded a median score of 10 out of 12. Tests of statistical significance for ICAS by occupational rank of doctors was not significant ($p \leq 0.174$). However, comparison of ICAS by clinical speciality using the Kruskal-Wallis test was statistically significant ($p \leq 0.005$). In this case, anaesthetists and radiologists had the lowest ICAS scores with a median score of 7 and 8, respectively,

while the highest scores were obtained by Obstetricians and Gynaecologists, Internists and General Practitioners with a median score of 10.50 out of 12. Finally, when the ICAS scores of doctors was compared with that of professional nurses; nurses scored significantly lower than doctors with a median score of 8, while the median score for doctors was 10. The difference in scores between doctors and professional nurses was statistically significant ($p \leq 0.001$), using the Mann-Whitney U test for independent samples at a significance level of $p \leq 0.05$. The findings for nurses from this study are further elaborated in chapter 6 below. The major barriers to IC identified by doctors were 'language barriers' followed by 'time constraints,' 'workload', and lack of education by patients' as well as 'lack of administrative support e.g. interpreters'. Based on the findings in this part of the study, I am able to conclude that doctors would benefit from continuing professional education in the area of medical law and ethics. Further, due the language barriers, workload and lack of interpreters, it may be prudent public health policy to introduce a corps of trained interpreters to assist HCPs in their work especially in the public hospital setting. This will generally improve the process of the IC and the overall quality of healthcare service delivery in public hospitals in South Africa. Finally, this aspect of the empirical research study forming part of this doctoral thesis has been published as a peer-reviewed research article in an international biomedical journal.

A hard copy of the published journal article is shown in annexure one of this thesis.

CHAPTER 6: FINDINGS ON THE KNOWLEDGE AND PRACTICE OF INFORMED CONSENT BY PROFESSIONAL NURSES IN SOUTH AFRICA

6.1 INTRODUCTION

Informed consent (IC) is a legal and ethical doctrine derived from the principle of respect for autonomy. The rights to bodily and psychological integrity and the right to security in and control of their own body are constitutionally protected rights in South Africa.¹⁷¹⁰ It has been argued that a South African court decision in the *Castell* case¹⁷¹¹ led to a shift in South African medical jurisprudence from the 'reasonable doctor' to the 'prudent patient' standard of information disclosure.¹⁷¹² The National Health Act codified the requirements for informed consent in South African law and medical practice by stipulating that healthcare professionals (HCPs) must inform healthcare users (patients) about; diagnosis, risks, benefits, treatment options, and the right of refusal, in a language that patients understand.¹⁷¹³ However, it must be noted that complex multicultural societies like South Africa, may be inherently challenged by problems of poverty, education, language, and the power asymmetry that exists between doctors and patients. All of which could impact on the practice of IC in this setting.^{1714, 1715, 1716}

This chapter reports on the findings of an empirical study designed to evaluate the knowledge and practice of IC by professional nurses in South African public hospitals.

¹⁷¹⁰ The Constitution s12 (2) (a-c).

¹⁷¹¹ *Castell v De Greef* [1993] (3) SA 501.

¹⁷¹² Van Oosten 1995 *De Jure* 171-175.

¹⁷¹³ National Health Act 61 of 2003 (s6 and s7).

¹⁷¹⁴ Ezeome and Marshall 2009 *Dev World Bioeth* 142 see also Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

¹⁷¹⁵ Gordon E 1997 *Fordham Urb L J* 1321-1362.

¹⁷¹⁶ Richter et al *Guidelines for the development of culturally sensitive approaches to obtaining informed consent for participation in HIV vaccine-related trials* (UNAIDS Geneva 1999).

6.2 Knowledge of ethics, human rights and medical law among South African nurses

Despite the adoption of the international Code of Nursing Ethics,¹⁷¹⁷ and the Code of Ethics for nursing practice in South Africa;¹⁷¹⁸ both of which emphasize the importance of IC and human rights, professionalism, and advocacy for healthcare users, in the practice of nursing. Recent studies from South Africa have shown that nurses are not fully aware or well indoctrinated on the ethical practice of nursing or knowledgeable about the basic ethical principles and legal doctrines applicable in modern healthcare practice.^{1719,1720,1721} It has been suggested that overcoming this deficiency may require better training in medical law, ethics, human rights.¹⁷²² In addition, training on the cross-cultural issues underlying nursing practice and contemporary healthcare service delivery is also required.^{1723,1724} One area where there is an identifiable gap in knowledge of professional nurses, especially in resource-poor settings and developing countries, may be with regards to ethical and legal rules surrounding IC and nursing care.^{1725,1726,1727} Other areas where there is a knowledge gap or deficiency amongst South African nurses, as reported by a recent study include; “inadequate social skills, lack of initiative, inability to apply theoretical knowledge to patient care, lack of basic nursing skills, and lack of understanding of professional practice”.¹⁷²⁸ However, this knowledge gap amongst nurses

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- ¹⁷¹⁷ International Council of Nurses *ICN Code of Ethics for Nurses* (ICN Geneva 2012).
¹⁷¹⁸ South African Nursing Council Code of ethics for nursing practitioners in South Africa (SANC Pretoria 2013).
¹⁷¹⁹ White J, Phakoe M and Rispel LC “Practice what you preach: Nurses’ perspectives on the code of ethics and service pledge in five South African hospitals” 2015 *Glob Health Action* <http://dx.doi.org/10.3402/gha.v8.26341> (Date of use: 28 July 2017).
¹⁷²⁰ Stellenberg EL and Dorse AJ “Ethical issues that confront nurses in private hospitals in the Western Cape metropolitan area” 2014 *Curationis* <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 28 July 2017).
¹⁷²¹ London L and Baldwin-Ragaven L “Human rights and health: Challenges for training nurses in South Africa” 2008 *Curationis* 5-18.
¹⁷²² London and Baldwin-Ragaven 2008 *Curationis* 5-18.
¹⁷²³ Barnes DM, Davis AJ and Moran T et al “Informed consent in multicultural cancer patient population: Implications for nursing practice 1998 *Nurs Ethics* 412-423.
¹⁷²⁴ Shaibu 2007 *Nurs Ethics* 503-509.
¹⁷²⁵ Stellenberg and Dorse 2014 *Curationis* <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 28 July 2017).
¹⁷²⁶ Rosse PA and Krebs LU “The nurse’s role in the informed consent process” 1999 *Semin Oncol Nurs* 116-123.
¹⁷²⁷ Bristol ST and Hicks RW “Protecting boundaries of consent in clinical research: implications for improvement” 2014 *Nurs Ethics* 16-27.
¹⁷²⁸ Armstrong SJ and Rispel LC “Social accountability and nursing education in South Africa” 2015 *Glob Health Action* <http://dx.doi.org/10.3402/gha.v8.27879> (Date of use: 28 July 2017).

is not limited to South Africa or only developing countries.¹⁷²⁹ It is equally evident in nurses trained in other parts of the world, including developed countries due to cross-cultural issues and other ethical and moral conflicts as reported in studies from Indonesia,¹⁷³⁰ Iran,¹⁷³¹ Korea,¹⁷³² Japan,¹⁷³³ and Greece.¹⁷³⁴

6.3 The doctrine of Informed consent and respect for autonomy

The ethical and legal doctrine of IC is derived from the principle of respect for autonomy. Although there are many theories regarding the concept of autonomy, there is no universally accepted definition,¹⁷³⁵ leading to a situation where there are various interpretations of this concept by nurses, including diverse interpretations such as “self-governance, liberty, rights, privacy, individual choice, freedom of will, governing one’s behaviour and being one’s own person”.¹⁷³⁶ Based on this lack of clarity on the meaning of respect for autonomy, some have suggested alternative interpretations of autonomy such as:

- (a) A liberal view based on an individual’s freedom of choice and self-determination;
- (b) The Kantian idea of moral autonomy, which emphasizes self-determination as well rationality of choice;

¹⁷²⁹ Butts JB, “Ethics in professional nursing practice” in *Nursing ethics: Across the curriculum and into practice* Butts JB and Rich KL (eds) (Jones and Bartlett Publishers Burlington MA 2008) 71-122.

¹⁷³⁰ Susilo AP et al “Nurses role in informed consent in a hierarchical and communal context” 2013 *Nurs Ethics* 413-425.

¹⁷³¹ Rouhangiz M and Rutledge DN “Perceptions of informed consent for care practices: Hospitalized patients and nurses” 2011 *Applied Nurs Res* 276-280.

¹⁷³² Lee S et al “Nurses perceptions of informed consent and their related roles in Korea: An exploratory study” 2009 *Int J Nursing Stud* 1580-1584

¹⁷³³ Masaki S, Ishimoto H and Asai A “Contemporary issues concerning informed consent in Japan based on a review of court decisions and characteristics of Japanese culture” 2014 *BMC Med Ethics* 8.

¹⁷³⁴ Lemonidou C et al “A comparison of surgical patients’ and nurses perceptions of patients’ autonomy, privacy and informed consent in nursing interventions” 2003 *Clin Eff Nurs* 73-83.

¹⁷³⁵ Aveyard H “The requirements for informed consent prior to nursing care procedures” 2002 *J Adv Nurs* 243-249 [244].

¹⁷³⁶ Lemonidou et al 2003 *Clin Eff Nurs* 74 see also Hertz JE Conceptualization of perceived enactment of autonomy in the elderly 1996 *Issues Ment Health Nurs* 261–273.

(c) A narrative interpretation which emphasizes an individual's life plan based on their own historical and cultural context; and

(d) Respect for autonomy is an ethic of care, which emphasizes a caring attitude towards others.¹⁷³⁷

The above interpretations appear not to have provided the necessary clarity because the authors concluded that caregivers seemed to value different notions of autonomy based on the circumstance, therefore a multidimensional interpretation of the ethical principle of respect for autonomy would best fit nursing home care.¹⁷³⁸ This misunderstanding of the concept of autonomy and IC may have led to incomplete or wrong definitions by some professional nurses, such as “autonomy within ethics means that individuals have the right to information, and, on the basis of this, the right to agree or refuse to participate in research” as suggested by one author.¹⁷³⁹ Such an incomplete definition leaves out important aspects of the IC doctrine, including capacity, comprehension of information disclosed, and voluntariness of action in agreeing or refusing recommended treatment. Further, valid IC decisions must occur in the absence of coercion and undue influence.¹⁷⁴⁰ Misconceptions about respect for autonomy and the key elements of IC may also lead to misapplication of this doctrine during nursing care and clinical practice. In medical law and ethics, respect for autonomy could be simply defined as “the right to self-determination or freedom of choice”.¹⁷⁴¹ The ethical doctrine of IC as derived from the principle of respect for autonomy was illustrated by Faden and Beauchamp,¹⁷⁴² as follows:

X is an informed consent by person P to intervention I if and only if:

- i. P receives a thorough disclosure regarding I
- ii. P comprehends the disclosure
- iii. P acts voluntarily in performing X

¹⁷³⁷ Van Theil GJM and Van Delden JJM “The principle of respect for autonomy in the care of nursing home residents” 2001 *Nurs Ethics* 419-431.

¹⁷³⁸ Van Theil and Van Delden 2001 *Nurs Ethics* 419.

¹⁷³⁹ Shaibu S 2007 *Nurs Ethics* 504.

¹⁷⁴⁰ Beauchamp and Childress *Principles of biomedical ethics* 94-98.

¹⁷⁴¹ Chima 2009 *Trans J Coll Med S Afr* 38.

¹⁷⁴² Faden and Beauchamp *The history and theory of informed consent* 275.

- iv. P is competent to perform X
- v. P consents to I

It has been argued that the principle of respect for autonomy has never been considered a legally enforceable right in law; rather two rights derived from this principle have been generally accorded legal protection.¹⁷⁴³ These are the rights to bodily integrity protected by the legal rules against assault and battery, and the right to bodily welfare protected under professional negligence rules.^{1744,1745} The legal doctrine of IC during medical treatment was famously summarized by Cardozo J in the *Schloendorff case*¹⁷⁴⁶ where the judge opined that, “every human being of adult years and sound mind has a right to determine what shall be done with his own body [...]” This legal opinion has been reaffirmed in other legal cases including the US Supreme Court in the *Cruzan case*¹⁷⁴⁷ where the Court stated that “[n]o right is held more sacred or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of another.”¹⁷⁴⁸ Therefore, any HCP who treats any patient without IC or exceeds the consent given by a patient, maybe guilty of infringing the patients’ right to bodily integrity and bodily well-being as shown in the South African case of *Minister of Safety and Security v Xaba*.¹⁷⁴⁹ This observation was succinctly summarized by Lord Donaldson in the case of *Re F*¹⁷⁵⁰ when he held that “prima facie, therefore, in the absence of consent all, or almost all, medical treatment and all surgical treatment of an adult is unlawful, however beneficial such treatment might be. This is incontestable.”¹⁷⁵¹

¹⁷⁴³ Shultz 1985 *Yale LJ* 219-299.

¹⁷⁴⁴ Jennings <http://www.nuigalway.ie/law/GSLR/2003/MedicalNegligence.pdf> (Date of use: 20 February 2008).

¹⁷⁴⁵ Shultz 1985 *Yale LJ* 219-299.

¹⁷⁴⁶ *Schloendorff v Society of New York Hospital* (1914) 211 NY 105 NE 92.

¹⁷⁴⁷ *Cruzan v Director Missouri Department of Health* (1990) Supreme Court of the United States 497 US 261 see also *Union Pacific Railway Co v Botsford* 141 US 250 (1891) [251].

¹⁷⁴⁸ *Union Pacific Railway Co v Botsford* 141 US 250 (1891).

¹⁷⁴⁹ *Minister of Safety and Security v Xaba* 2003 (2) SA 703 (D) see also Carstens and Pearmain *Foundational Principles* [543-544].

¹⁷⁵⁰ *Re F* (1992) AC 1 [12D] see also Hocton *Law of consent to medical treatment* 18.

¹⁷⁵¹ *Re F* (1992) AC 1 [12D].

6.4 The legal doctrine of IC in South Africa and other common law jurisdictions

Informed consent is an established principle in South African medical jurisprudence.¹⁷⁵²

This was demonstrated in cases such as *Stoffberg v Elliot* 1923,¹⁷⁵³ and the *Esterhuizen* case.¹⁷⁵⁴ In the former case, Watermeyer J argued that:

In the eyes of the law, every person has certain absolute rights, which the law protects. They are not dependent upon a statute or upon a contract, but they are rights to be respected, and one of those rights is the right of absolute security of the person....Any bodily interference with or restraint of a man's person which is not justified in law or excused by law, or consented to, is a wrong, and for that wrong the person whose body has been interfered with has a right to claim such damages as he can prove he has suffered owing to that interference.¹⁷⁵⁵

In more recent South African cases, such as *Minister of Security v Xaba*¹⁷⁵⁶ and the *Castell* case,¹⁷⁵⁷ local courts have defended the patients fundamental right to bodily integrity and privacy, as shown in the *Xaba* case where a high court judge rejected police request to conduct a surgical procedure on a patient in order to retrieve a bullet which was to be used as evidence in criminal proceedings against the accused. It was held that this would be an infringement on the accused person's constitutionally guaranteed rights to bodily integrity and privacy.¹⁷⁵⁸ By contrast, in the case of *Minister of Safety and Security v Gaqa*,¹⁷⁵⁹ another high court judge allowed such a request by the Police based on regulations within the Criminal Procedure Act,¹⁷⁶⁰ public necessity, and statutory authority.¹⁷⁶¹ It has been suggested that the court in the *Castell* case¹⁷⁶² appears to have adopted the principle of respect for autonomy based on a 'prudent patient' and 'material risks' standards, whereby the level of information disclosure required for IC should be

¹⁷⁵² Van Oosten *The doctrine of informed consent in medical law* (LLD Thesis UNISA1989).

¹⁷⁵³ *Stoffberg v Elliot* 1923 CPD 148-150.

¹⁷⁵⁴ *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T).

¹⁷⁵⁵ *Stoffberg v Elliot* 1923 CPD 148.

¹⁷⁵⁶ *Minister of Safety and Security v Xaba* 2003 (2) SA 703 (D)

¹⁷⁵⁷ *Castell v De Greef* 1993 (3) SA 501.

¹⁷⁵⁸ *Minister of Safety and Security v Xaba* 2003 (2) SA 703 (D) see also Carstens and Pearmain *Foundational Principles* [543-544].

¹⁷⁵⁹ *Minister of Safety and Security v Gaqa* 2002 (1) SACR 654.

¹⁷⁶⁰ Criminal Procedures Act 51 of 1977 section 37(2).

¹⁷⁶¹ Carstens and Pearmain *Foundational Principles* [907, 917].

¹⁷⁶² *Castell v De Greef* 1993 (3) SA 501.

based on what a reasonable patient would consider important before making a healthcare decision.¹⁷⁶³ This is consistent with the practice in North America as shown in the Canadian case of *Reibl v Hughes*¹⁷⁶⁴ and the landmark judgment of an American court in *Canterbury v Spence*¹⁷⁶⁵ where the District of Columbia Appeals Court held that: “[...] a risk is material when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy”.¹⁷⁶⁶ Similarly, Australian High Court decisions have generally adopted the ‘prudent patient standard’ since the judgments in *F v R*,¹⁷⁶⁷ and *Rogers v Whitaker*.¹⁷⁶⁸ It has been argued that the court in the *Castell* case appears to have adopted the subjective ‘prudent patient standard’ into South African jurisprudence,¹⁷⁶⁹ while rejecting the professional practice or ‘reasonable doctor’ standard of IC previously accepted and practised in common law jurisdictions since the judgment of Ackerman J in *Bolam v Friern HMC*.¹⁷⁷⁰ It has been further suggested that the court in *Castell* also seems to have moved South African medical jurisprudence from paternalism to patient autonomy, by placing patients’ informed consent within the framework of *volenti non fit injuria* or voluntary assumption of risk rather than delict.^{1771,1772}

The current situation in English law is that the ‘prudent patients standard’ is becoming more acceptable as shown in *Pearce v United Bristol*,¹⁷⁷³ where Lord Woolf urged doctors to inform patients of any significant risks which would affect the judgement of a reasonable person. Further, in *Bolitho v City and Hackney*¹⁷⁷⁴ the English House of Lords held that the opinion of any expert witnesses ought to be assessed by the courts for its logicity

¹⁷⁶³ Van Oosten 1995 *De Jure* 164-179.

¹⁷⁶⁴ *Reibl v Hughes* [1980] 114 DLR (3d) 1.

¹⁷⁶⁵ *Canterbury v. Spence* [1972] 464 2d 772 (DC).

¹⁷⁶⁶ *Canterbury v Spence* [1972] 464 2d 772 (DC) [41-46].

¹⁷⁶⁷ *F v R* [1983] (39) 33 SASR.

¹⁷⁶⁸ *Rogers v Whitaker* [1992] HCA 58; 175 CLR 479 [489-490].

¹⁷⁶⁹ Van Oosten FFW1995 *De Jure* 178.

¹⁷⁷⁰ *Bolam v Friern Health Management Committee* (1957) 1 WLR 582.

¹⁷⁷¹ Van Oosten FFW1995 *De Jure* 164-179.

¹⁷⁷² Carstens and Pearmain *Foundational principles* [875].

¹⁷⁷³ *Pearce v United Bristol NHS Healthcare Trust* (1998) 48 BMLR 18 [21].

¹⁷⁷⁴ *Bolitho v City and Hackney Health Authority* (1998) AC 232[HL] see also *Bolitho* (1993) 4 Med LR 381 [386].

and reasonableness. More recently in the case of *Chester v Afshar*¹⁷⁷⁵ the English CA held that it could be considered negligent if omission to disclose risks fell below the required professional standard, thereby finding a doctor negligent for failing to disclose a 1-2% risk of nerve damage even when enquires were made by the patient. One can therefore conclude that the 'prudent patient standard' is becoming the accepted professional standard of care in most common law jurisdictions with regard to information disclosure and IC, reminiscent of the dissenting judgment of Lord Scarman in the *Sidaway* case.¹⁷⁷⁶ This dissenting opinion of Lord Scarman and the recent judgments regarding informed consent, information disclosure and the reasonable doctor standard were recently re-examined by a UK Supreme Court (Scotland), in the case of *Montgomery v Lanarkshire HA*,¹⁷⁷⁷ resulting in an unanimous judgment by the UK Supreme Court, that the expected standard of care based on all current considerations including the introduction of the human rights regime into European and international medical law jurisprudence should be based on the 'prudent patients' standard'.¹⁷⁷⁸ The Court further held that this standard of information disclosure would extend *mutatis mutandis* to all categories of healthcare professionals.¹⁷⁷⁹

6.5 IC regulations in South Africa since enactment of the National Health Act

As previously discussed, the NHA¹⁷⁸⁰ codified the legal requirements for IC in medical practice in South Africa. Section 7 of this act specifies that healthcare services cannot be provided to patients, without the patients' IC, unless the patient is unable to provide IC, and such consent is given by another person, mandated by the patient in writing to grant consent on their behalf; or another person authorized to give such consent in terms of any law or court order; or where the patient is unable to give IC and no person is mandated or authorized to give such consent.¹⁷⁸¹ The law further requires that every health care

¹⁷⁷⁵ *Chester v Afshar* (2002) EWCA Civ 724 [5].

¹⁷⁷⁶ *Sidaway v Board of Governors of Royal Bethlem Hospital and Wisbech AHA* (1985) 1 All ER 643 [889-890].

¹⁷⁷⁷ *Montgomery v Lanarkshire Health Board* (2015) UKSC 11 [87].

¹⁷⁷⁸ *Montgomery v Lanarkshire Health Board* (2015) UKSC 11 [76].

¹⁷⁷⁹ *Montgomery v Lanarkshire Health Board* (2015) UKSC 11 [75].

¹⁷⁸⁰ National Health Act 61 of 2003.

¹⁷⁸¹ National Health Act 61 of 2003 (s7).

provider must inform the healthcare user or patient of his or her health status except in circumstances where there is substantial evidence that the disclosure of such information would be contrary to the best interests of the patient, thereby making provision for the exception of therapeutic privilege.¹⁷⁸² More specifically, section 6 of the NHA summarizes the requirements for information disclosure during IC to include:

- (a) The range of diagnostic procedures and treatment options generally available to the user.
- (b) The benefits, risks, and consequences generally associated with each option; and
- (c) The user's right to refuse health services and explain the implications, risks, and obligations of such refusal.¹⁷⁸³

The NHA also requires that the health care providers must inform the patient 'in a language that the patient understands while taking into account the patient's literacy level'.¹⁷⁸⁴ One can argue that in general terms, the NHA appears to encompass most of the key elements of IC as described by most international ethical guidelines and authoritative texts.^{1785,1786} Albeit, while also allowing for the controversial doctrine of therapeutic privilege,^{1787,1788} where the law states that "every health care provider must inform the patient of his or her health status except in circumstances where there is substantial evidence that the disclosure of such information would be contrary to the best interests of the healthcare user".¹⁷⁸⁹ IC has been defined as an autonomous authorization by individuals of a medical intervention, whereby in order to give a binding authorization, the patient must be fully informed, have the capacity to comprehend the information, then voluntarily consent or agree to the procedure.^{1790,1791} Others have proposed that IC involves more than a mere signing of a consent form; describing it as "process of mutual

¹⁷⁸² National Health Act (s8) (2).

¹⁷⁸³ National Health Act s6 (1).

¹⁷⁸⁴ National Health Act s6 (2).

¹⁷⁸⁵ Van Oosten *The doctrine of informed consent in medical law* (LLD thesis UNISA 1989) see also Carstens and Pearmain *Foundational Principles* [871-941].

¹⁷⁸⁶ Beauchamp and Childress *Principles of biomedical ethics* [57-112].

¹⁷⁸⁷ Chima 2009 *Trans J Coll Med S Afr* 42.

¹⁷⁸⁸ Van Oosten 1991 *Med Law* 31-41.

¹⁷⁸⁹ National Health Act 61 of 2003 s8 (2).

¹⁷⁹⁰ Chima 2013 *BMC Med Ethics* S3.

¹⁷⁹¹ Faden and Beauchamp *History and theory of informed consent* [277-280] see also Beauchamp and Childress *Principles of biomedical ethics* [57-112].

exchange of information, understanding, trust, voluntariness, competence, willingness, a lack of coercion, and consent between the patient and the staff".¹⁷⁹² IC has also been described as a conversation that follows specific rules In which case such conversations should ideally be initiated by the HCP, and should involve transparency, engagement by both parties, and continues throughout the period of medical intervention. This conversation may require evidence of its occurrence such as an eyewitness, a co-signed document or annotation in the patients' clinical notes.¹⁷⁹³

As a general rule, medical treatment should not proceed unless the HCP has first obtained the patient's consent which may be express or implied, written or verbal.^{1794,1795} The consent given by a patient may be withdrawn at any time during the clinical encounter, and could be vitiated by any change in circumstances which are not communicated to, or approved by the patient.^{1796,1797} Some authorities have indicated that IC documentation, especially in biomedical research, should not include any exculpatory language which would *prima facie* absolve the person obtaining the consent from any accusations of negligence or malpractice.¹⁷⁹⁸ Therefore, for IC to be considered true or valid in clinical practice, there must be evidence that five key elements have been adhered to; vis-à-vis information disclosure, capacity, comprehension, voluntariness followed by consent or agreement to the medical procedure or research intervention. Otherwise, such consent maybe considered invalid.¹⁷⁹⁹

¹⁷⁹² Lemonidou et al 2003 *Clin Eff Nurs* 74.

¹⁷⁹³ McCormick <http://depts.washington.edu/bioethx/> (Date of Use: 31 August 2013).

¹⁷⁹⁴ Aveyard 2002 *J Adv Nurs* 245.

¹⁷⁹⁵ Chima *A primer on medical law* 68-104.

¹⁷⁹⁶ *Ciarlariello v Schactr* (1993) 100 DLR (4th) 609 SCC.

¹⁷⁹⁷ Chima *A primer on medical law* 68-104.

¹⁷⁹⁸ US Code of Federal Regulations (CFR 46.116).

¹⁷⁹⁹ Beauchamp and Childress *Principles of biomedical ethics* [57-112] see also Chima *A primer on medical law* [56-104].

6.6 Socio-cultural factors potentially influencing nursing practice in South Africa

South Africa is a complex multicultural society with a recent history of racial segregation, healthcare and human rights challenges.^{1800,1801} Currently, there is a high unemployment rate of around 25%,^{1802,1803} with a reportedly low labour participation rate.¹⁸⁰⁴ Further, the healthcare system is dichotomous with privately funded healthcare services used by about 20% of the population who can afford private healthcare insurance, compared with public health services patronized by the majority of indigent citizens.^{1805,1806} Furthermore, South Africa has 11 official languages,¹⁸⁰⁷ which impacts on the ability of HCPs to effectively communicate with patients, leading to reported deficiencies in the quality of healthcare service delivery.¹⁸⁰⁸ Previous studies amongst doctors practising in local hospitals in South Africa have identified language barriers as one of the challenges faced by HCPs working in setting.^{1809,1810} Under such circumstances it has been suggested that nurses practicing in this environment have sometimes become involved in the process of ‘cultural brokerage’, defined as “the act of bridging, linking or mediating between groups or persons for the purpose of reducing conflict or producing change”.^{1811,1812}

The problem of language difficulties may require nurses to undertake the additional role of acting as interpreters as a form of cultural brokerage to enhance patients’

¹⁸⁰⁰ London and Baldwin-Ragaven 2008 *Curationis* 5-18.

¹⁸⁰¹ Benatar SR “Health care reform and the crisis of HIV and AIDS in South Africa” 2004 *N Engl J Med* 81-92 see also Mhlongo and Mdingi 1997 *BMJ* 252.

¹⁸⁰² Trading Economics *South Africa unemployment rate 2017*
<https://www.tradingeconomics.com/south-africa/unemployment-rate> (Date of use: 27 June 2017).

¹⁸⁰³ Chima 2015 *Niger J Clin Pract* S46-S56.

¹⁸⁰⁴ Vollgraaff R “Little hope of hitting job-creation target” 2011-02-20 *Sunday Times* South Africa.

¹⁸⁰⁵ Zelnick J and O'Donnell M “The impact of the HIV/AIDS epidemic in KwaZulu-Natal, South Africa: Nurses perspectives and implications for health policy” 2005 *J Public Health Policy* 163-185.

¹⁸⁰⁶ *KwaZulu-Natal Strategic Plan 2010-2014* (KZN DOH 2010) see also Chima 2015 *Niger J Clin Pract* S46-S56.

¹⁸⁰⁷ EThekwini language policy <http://www.Durban.gov.za.eThekwiniLanguagepolicy.pdf> (Date of use: 19 August 2014).

¹⁸⁰⁸ Schlemmer and Mash 2006 *SAMJ* 1084-1087.

¹⁸⁰⁹ Chima 2013 *BMC Med Ethics* S3.

¹⁸¹⁰ Schlemmer and Mash 2006 *SAMJ* 1084-1087.

¹⁸¹¹ Shaibu 2007 *Nurs Ethics* 507 see also Degazon EC “Cultural diversity and community-oriented nursing practice” in Stanhope M and Lancaster J (eds) *Community and public health nursing: promoting health of aggregates, families and Individuals* 5th ed (Mosby St Louis 2000) 138-156.

¹⁸¹² Jezewski 1990 *West J Nurs Res* 497-513.

understanding of the IC process during healthcare service delivery.^{1813,1814} Unfortunately, this additional role imposed on nurses may impact on workload, leading to inefficiencies in the IC process,¹⁸¹⁵ with the potential to lead to other ethical and moral dilemmas,¹⁸¹⁶ which could negatively impact on nurse-patient relationships, and the overall quality of healthcare services.^{1817,1818} This increased workload occasioned by cultural brokerage, and requirements to work in unfamiliar roles or outside of the job description for nurses, coupled with the moral distress and healthcare burden associated with the impact of HIV/AIDS pandemic in South Africa, may equally be associated with poor job satisfaction and job attrition frequency reported amongst nurses working in South Africa.^{1819,1820,1821,1822} Other factors which may impact on IC process in this setting include the power asymmetry between HCPs and patients, hierarchical cultural system, and the practice of communality, such as the involvement of family members and elders in healthcare decision-making.^{1823,1824,1825,1826} African culture is communal in nature as exemplified by the Ubuntu philosophy prevalent in South Africa.^{1827,1828,1829} Similar to some Asian communities where families and elders also have an important role in life

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- 1813 Shaibu 2007 *Nurs Ethics* 507.
- 1814 Schlemmer and Mash 2006 *SAMJ* 1085-1087 see also Chima 2013 *BMC Med Ethics* S3.
- 1815 Schlemmer and Mash 2006 *SAMJ* 1084.
- 1816 Stellenberg and Dorse 2014 *Curationis* <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use 28 July 2017).
- 1817 Schlemmer and Mash 2006 *SAMJ* 1085-1087 see also Chima 2015 *Niger J Clin Pract* S46-S56.
- 1818 Stellenberg and Dorse 2014 *Curationis* Art 38.
- 1819 Zelnick and O'Donnell 2005 *J Public Health Policy* 163-185.
- 1820 Mmamma ML, Mothiba TM and Nancy MR "Turnover of professional nurses at Mokopane hospital in the Limpopo province, South Africa: Experiences of nursing unit managers" 2015 *Curationis* 38(2) <http://dx.doi.org/10.4102/curationis.v38i2.1566> (Date of use: 28 July 2017).
- 1821 Khunou SH and Davhana- Maselesele M "Level of job satisfaction amongst nurses in the North-West Province, South Africa: Post occupational specific dispensation" 2016 *Curationis* <http://dx.doi.org/10.4102/curationis.v39i1.1438> (Date of use: 28 July 2017).
- 1822 Pillay R "Work satisfaction of professional nurses in South Africa: A comparative analysis of the public and private sectors" 2009 *Hum Resour Health* 7-15.
- 1823 Shaibu 2007 *Nurs Ethics* 505-506.
- 1824 Tindana et al 2006 *IRB* 1-6.
- 1825 Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.
- 1826 Matthew DB "Race religion and informed consent-lessons from social science" 2008 *J Law Med Ethics* 149-173.
- 1827 Chima 2015 *Niger J Clin Pract* S1-S7.
- 1828 Metz and Gaie 2010 *J Moral Educ* 273-90.
- 1829 Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

events and healthcare decision-making.^{1830,1831} Previous studies from South Africa,¹⁸³² and other reports and analysis have shown the impact of lack of education, illiteracy, poverty, religious beliefs as confounding factors when obtaining IC in African and other complex multicultural societies.^{1833,1834,1835,1836}

6.7 RESEARCH DESIGN AND METHODOLOGY

6.7.1 Aims and of this study

This aspect of the empirical study was designed to evaluate the quality of IC as practised by professional nurses at South African public hospitals. This was a cross-sectional questionnaire based quantitative study amongst nurses practicing in public hospitals within EThekweni municipality, KwaZulu-Natal province (KZN). The objective here was to establish whether nurses are actually complying with the current regulations guiding IC in clinical practice as required by the NHA,¹⁸³⁷ relevant case law, other healthcare regulations and ethical guidelines. This chapter reports observations amongst nurses at public hospitals in Durban, KZN, South Africa.

6.7.2 Study objectives

The general objectives of this study was to establish whether valid IC is obtained from patients prior to involvement in medical treatment at public hospitals in South Africa. Specific aims were, with regards to professional nurses were:

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- ¹⁸³⁰ Susilo AP et al "Nurses role in informed consent in a hierarchical and communal context" 2013 *Nurs Ethics* 413-425.
- ¹⁸³¹ Lee et 2009 *Int J Nursing Stud* 1580-1584 see also Masaki et al 2014 *BMC Med Ethics* 15 [8].
- ¹⁸³² Schlemmer and Mash 2006 *SAMJ* 1084-1087 see also Chima 2015 *Niger J Clin Pract* S46-S56.
- ¹⁸³³ Barnes DM et al "Informed consent in multicultural cancer patient population: Implications for nursing practice" 1998 *Nurs Ethics* 412-423 see also Shaibu 2007 *Nurs Ethics* 503-509.
- ¹⁸³⁴ Lee et al 2009 *Int J Nursing Stud* 1580-1584 See also Masaki et al 2014 *BMC Med Ethics* 15.
- ¹⁸³⁵ Chima 2015 *Niger J Clin Pract* S1-S7 see also Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.
- ¹⁸³⁶ Matthew 2008 *J Law Med Ethics* 149-173 see also Tindana et al 2006 *IRB* 1-6.
- ¹⁸³⁷ National Health Act 61 of 2003.

- a. To find out whether sufficient information was provided to patients before IC.
- b. To establish whether patients involved in medical treatment actually understand the information provided.
- c. To establish whether IC is voluntarily obtained from patient without coercion or undue influence.
- d. To establish whether IC provided by patients during medical practice in is truly valid
- e. The study also sought to establish to what extent the ethical and legal doctrines of IC were actually being applied in practice, and the level of knowledge of various categories of nurses regarding IC and some basic laws guiding medical practice in South Africa.

6.7.3 Research design

This study was a quantitative study using semi-structured, self-administered questionnaires to collect quantitative and qualitative data, in contemporary clinical practice settings. The descriptive approach allowed all participants to describe their experience with the IC process as it happened, thereby bringing out the required information. Further, the techniques of person and data triangulation were used^{1838,1839} to compare the findings from the nurses with other HCPs (doctors), as well patients simultaneously surveyed during this study. The technique of multiple triangulation was also used to ensure consistency and reliability of the study.¹⁸⁴⁰

6.7.4 Study location and setting

The study was carried out at selected public hospitals within eThekweni metropolitan municipality, located on the east coast of South Africa in KZN province. The municipality

¹⁸³⁸ Denzin NK *Sociological methods* (McGraw-Hill New York 1978) see also Denzin N *The research act* 297 and Robert Wood Johnson Foundation “Triangulation” Qualitative research guidelines project www.qualres.org/HomeTria-3692.html (Date of use: 7 November 2017).

¹⁸³⁹ Kimchi J, Polivka B and Stevenson JS “Triangulation: operational definitions” 1991 *Nurs Res* 364-366.

¹⁷⁷¹ Begley C “Using triangulation in nursing research” 1996 *J Adv Nurs* 122-128 see also Adami and Kiger 2005 *Nurse Res* 19-29.

comprises a major urban city (Durban), and semi-urban areas (townships), with an estimated population of 3.5 million people (2011 census).¹⁸⁴¹ The area consists of a diverse population of about 80% black Africans, with various social, economic, environmental, and governance challenges.¹⁸⁴² According to statistics from KZN department of health, there are 18 public hospitals within this municipality ranging from tertiary, regional, district and specialized hospitals for chronic diseases such as tuberculosis (TB) and psychiatry.¹⁸⁴³ The hospitals within EThekweni municipality are relatively well staffed, since many hospitals within the municipality serve as teaching hospitals for medical students, postgraduate doctors, nurses and allied health professionals up to specialist level.¹⁸⁴⁴

6.7.5 Target population

All professional and enrolled (staff) nurses at the selected public hospitals were eligible for participation in the study. Randomization occurred at the health care facility level, while the individual participants at the selected institutions had an equal chance to participate voluntarily in the study. See sampling procedure below and as previously described.¹⁸⁴⁵

6.7.6 Inclusion criteria

According to the South African Nursing Council (SANC)¹⁸⁴⁶ and other sources, there are three categories of registered nurses in South Africa, professional nurses, staff nurses, and nursing auxiliaries.^{1847,1848} A professional nurse, sometimes called a nursing sister, is

¹⁸⁴¹ Statistics South Africa http://www.statssa.gov.za/?page_id=1021&id=ethekwini-municipality (Date of use: 26 April 2016).

¹⁸⁴² Statistics South Africa http://www.statssa.gov.za/?page_id=1021&id=ethekwini-municipality (Date of use: 12 April 2016).

¹⁸⁴³ KZN Department of Health <http://www.kznhealth.gov.za/district1.htm> (Date of use: 12 April 2016).

¹⁸⁴⁴ Chima 2013 *BMC Med Ethics* S3.

¹⁸⁴⁵ Chima 2013 *BMC Med Ethics* S3 [6-7].

¹⁸⁴⁶ South African Nursing Council *Strategic plan for nurse education, training and practice 2012/13 – 2016/17* (SANC Pretoria 2012).

¹⁸⁴⁷ KZN Department of Health *KwaZulu -Natal Strategic Plan 2010-2014*.

¹⁷⁷⁹ Rispel LC “Transforming nursing policy, practice and management in South Africa” 2015 *Glob Health Action* <http://dx.doi.org/10.3402/gha.v8.2800> (Date of use: 28 July 2017).

an individual who has completed a minimum 4-year programme at university or tertiary institution such as nursing college, and is certified competent to practice comprehensive nursing and midwifery.¹⁸⁴⁹ An enrolled or staff nurse is a registered nurse with a minimum of 2-years tertiary nursing education,¹⁸⁵⁰ while an auxiliary nurse has one year of nursing education.¹⁸⁵¹ In this study, only nurses in the categories of professional nurse and enrolled/staff nurse were included. Nurses working in the surgical, internal medicine, paediatric, obstetrics and gynaecology, wards and clinics that were available and willing to participate during the site visit and study period, were given an equal opportunity to participate in the study.

6.7.7 Exclusion criteria

Apart from the three categories of registered nurses in South Africa, there are also nursing assistants and student nurses.¹⁸⁵² All other categories of nurses, including student nurses studying for bachelor degrees, were excluded from this study. The objective was to ascertain the level of knowledge of practising professional nurses within the field.

6.7.8 Sampling procedures

According to Terre-Blanche and others, 30% of any population is generally adequate when conducting a cross-sectional descriptive study.¹⁸⁵³ Since this study was limited to public hospitals, out of the 18 public hospitals in EThekweni municipality, six were randomly selected as study sites. Multi-stage stratified random sampling was used to select eligible hospitals (see list of hospitals in appendix 6). The hospitals were first stratified by authority (provincial or private), then selected using random sampling. In this

¹⁸⁴⁹ SANC Bachelor's degree in nursing and midwifery qualification framework- Purpose and rationale of the qualification www.sanc.co.za (Date of use: 22 November 2017).

¹⁸⁵⁰ SANC Diploma in nursing: Staff nurse qualification framework- Purpose and rationale of the qualification www.sanc.co.za (Date of use: 22 November 2017).

¹⁸⁵¹ SANC Higher certificate: Auxiliary nursing qualification framework- Purpose and rationale of the qualification www.sanc.co.za (Date of use: 22 November 2017).

¹⁸⁵² Stellenberg and Dorse 2014 *Curationis* <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 28 July 2017) See also SANC *Strategic plan for nurse education, training and practice 2012/13-2016/17* (SANC Pretoria 2012).

¹⁸⁵³ Terre-Blanche et al *Research in practice* 50.

case, public hospitals were listed alphabetically; then every third hospital on the list was chosen. Purposive sampling was also used to include the two tertiary teaching hospitals within this municipality because they were likely to yield the largest number of study participants, i.e. professional nurses at all levels of specialization to assist with a more robust sample population. In this way, HCPs with different types of practice experience with regard to IC were included in the study, similar to a previously reported study amongst doctors.¹⁸⁵⁴

6.7.9 Work units

The wards and clinics at each participating hospital were also randomly sampled; again, the aim was to sample about 30% of the wards and clinics. Thereafter, eligible professional nurses working in the wards and outpatient clinics (OPDs) who were willing to participate in the study, were given an equal chance to participate by completing the study instrument (questionnaires). OPDs and wards were randomly selected on the day of site visit by the researcher and research assistants. Nurses were generally approached by three trained research assistants, and those who were willing participants were given the IC documents to read and sign. The study questionnaires were then handed over to the participant for completion. Occasionally, in order not to disrupt the work environment, the matron-in-charge of the ward or clinics was approached for permission, the study was explained to her and then the matron undertook to collect and distribute the questionnaires and IC documents, to nurses during a convenient time. Research assistants were then informed when questionnaires were ready for collection. Repeated visits were sometimes made to study sites during the study period to increase the number of respondents. All participants who completed questionnaires were also required to provide written informed consent. The study was conducted during a 3-month period from March to June 2012. Manual distribution and retrieval of questionnaires was done by three trained research assistants who were also bilingual in (English/Zulu/Xhosa/Sotho).

¹⁸⁵⁴ Chima 2013 *BMC Med Ethics* S3.

6.7.10 Sample size calculations

Preliminary sample size for this study was calculated using a web-based sample size calculator by Raosoft®.¹⁸⁵⁵ Based on the formula for sample size calculations from this computer programme, the number of nurses required using a 95% confidence limit and 5% margin of error, was estimated at 373 nurses (as shown in chapter four, section 4.10.2). This served as a baseline for the number of nurses to be recruited.

6.7.11 Research instruments

Data was collected using the same questionnaire for all HCPs (doctors and professional nurses). The questionnaire for HCPs was divided into 4 sections, as previously reported,¹⁸⁵⁶ and described (see chapter five, section 5.2.1). The first section was designed to obtain demographic information about respondents including dependent variables, such as age, sex, job title, department in the hospital, years of professional experience, clinical specialization. The second part of the questionnaire contained questions about IC practices such as; time spent on obtaining IC, patient workload, information disclosed to patients, language and methods used to communicate with patients; and challenges faced by nurses when obtaining IC from patients. The third section asked general knowledge questions about local healthcare laws such as age of consent to medical treatment and age of consent to termination of pregnancy and standards of information disclosure. The fourth section solicited questions about nurses' knowledge and practices regarding implied or presumed consent in clinical practice. The questionnaire for HCPs was first circulated for comment by a small sample of doctors and nurses in a single hospital ward. It was then modified, based on comments from potential participants prior to distribution to all eligible participants. Participation in the study and completion of the questionnaire was voluntary. A sample questionnaire is attached to this thesis in Appendix 1.

¹⁸⁵⁵ Raosoft *Sample size calculator* <http://www.raosoft.com/samplesize.html> (Date of Use: 12 February 2016).

¹⁸⁵⁶ Chima 2013 *BMC Med Ethics* S3.

6.7.12 Statistical methods

Descriptive statistics such as proportions, median, mode and interquartile range were used to summarize the data. Bar charts, pie chart and graphs are used to present the results, using Microsoft Excel.¹⁸⁵⁷ The scores for comprehension of informed consent were worked out from the responses. The Mann-Whitney U test was used to examine the difference in scores between doctors and nurses and other applicable variables. Kruskal-Wallis test was used to examine the relationship between (1) education level and the scores, (2) clinical department and scores and (3) professional category and the scores. Chi-squared tests or Fisher's exact test were used to test association between any categorical variables, as well as analysing and comparing the informed consent aggregate scores (ICAS) scores between various cadres of HCPs. Cronbach's alpha was used to evaluate the internal consistency and reliability of the questions used to calculate ICAS.

6.7.13 Data storage and analysis

The computer software used for data storage and analysis was the Statistical Package for Social Sciences (SPSS) versions 18-22.¹⁸⁵⁸ Primary data was collected using questionnaires. I also collected information on local laws, statutes and regulations, from information available in the public domain via literature review. Standard consent forms were also collected from the selected hospitals for comparative analysis. Questionnaires were filled out manually by respondents, then collected and stored in a locked cabinet to maintain security and confidentiality. At the end of each site visit, data from questionnaires was entered into a single laptop computer by a trained research assistant/data capturer. The raw data was evaluated for completeness by the principal investigator (myself) and also cross-checked for completeness and accuracy by a qualified biostatistician.

¹⁸⁵⁷ Microsoft Excel (Part of Microsoft Office Professional Edition) (Microsoft Corp Seattle WA 2003).
¹⁸⁵⁸ IBM *SPSS Statistics for Windows* (IBM Corp Armonk NY 2012).

6.7.14 Validity and reliability of statistical methods

The study design and statistical methodology for this was reviewed and validated by a consultant biostatistician at College of Health Sciences, University of KwaZulu-Natal, South Africa. The statistical methodology was further evaluated by the knowledge management and strategic services division of the KZN Department of Health (a local research ethics committee), before approval of the study proposal. According to Creswell, “validity in quantitative research refers to whether one can draw meaningful and useful inferences from scores on particular instruments”.¹⁸⁵⁹ Methods used to ensure internal and external validity as well as construct validity and reliability have been described in detail above in Chapter four of this thesis.

6.8 ETHICAL CONSIDERATIONS

Ethical approval was obtained from a subcommittee of University of South Africa (UNISA) Research Ethics Committee. Local approvals were obtained from the KZN department of health knowledge and strategic management ethics committee, as well as the EThekweni municipality department of health, after review of the research protocol. Further approvals were obtained from each participating hospital administration after evaluation of research proposals and other ethical approvals. Finally, written IC was obtained from every participant in the study after full information disclosure. Participant confidentiality was maintained by safe storage and anonymization of data, research results are also being reported anonymously.

¹⁸⁵⁹ Creswell *Research design* 235.

6.9 RESULTS

6.9.1 General demographic characteristics of nurses

The overall response rate for nurses who participated in this study was 95% (355/373) of initial estimates. Majority of participating nurses were female (92%) with a median age of 39 years, and range of 22-62 years. The age distribution of the participating nurses showed a normal distribution using the one-sample Kolmogorov-Smirnoff test (mean = 39.25; SD= 9.912). Majority of participants were professional nurses representing 85% (330/355) of participants, while 15% (54/355) were enrolled or staff nurses as shown in figure 6.1. Nurse respondents had from 1 to 41 years of professional experience (median = 9 years) as shown in figure 6.2. In addition, almost all participating nurses worked in the public hospitals (99.7%) as shown in Table 6.1. All major nursing domains were represented in this study including internal medicine, surgery, obstetrics and gynaecology and paediatrics. There were also nurses with specialized training practising in units such as trauma/casualty, theatre/perioperative care, burns/critical care, as well as neonatal intensive care as shown in Table 6.2 and figure 6.3. General demographic characteristics of participating nurses are shown in Table 6.1.

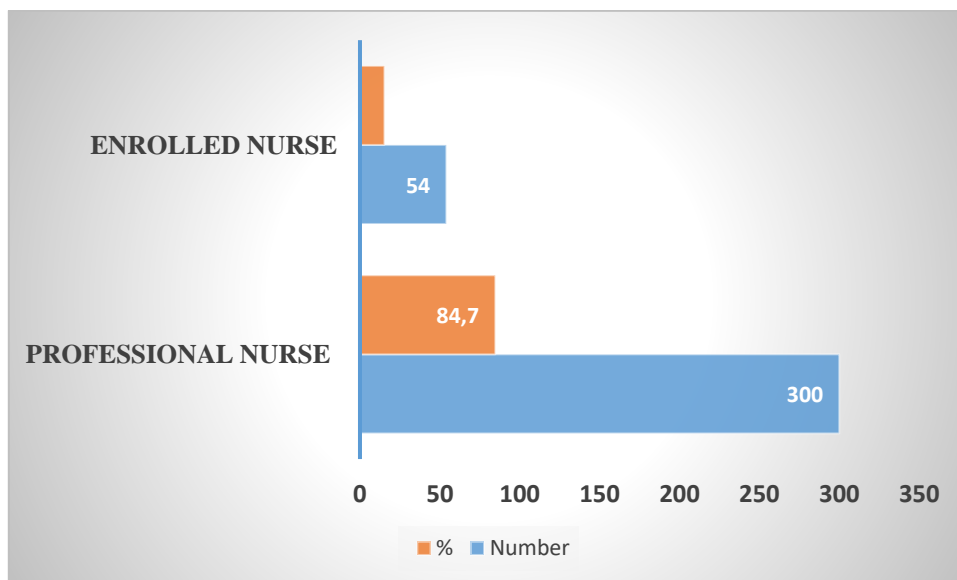


Figure 6.1: Nurses by occupational category

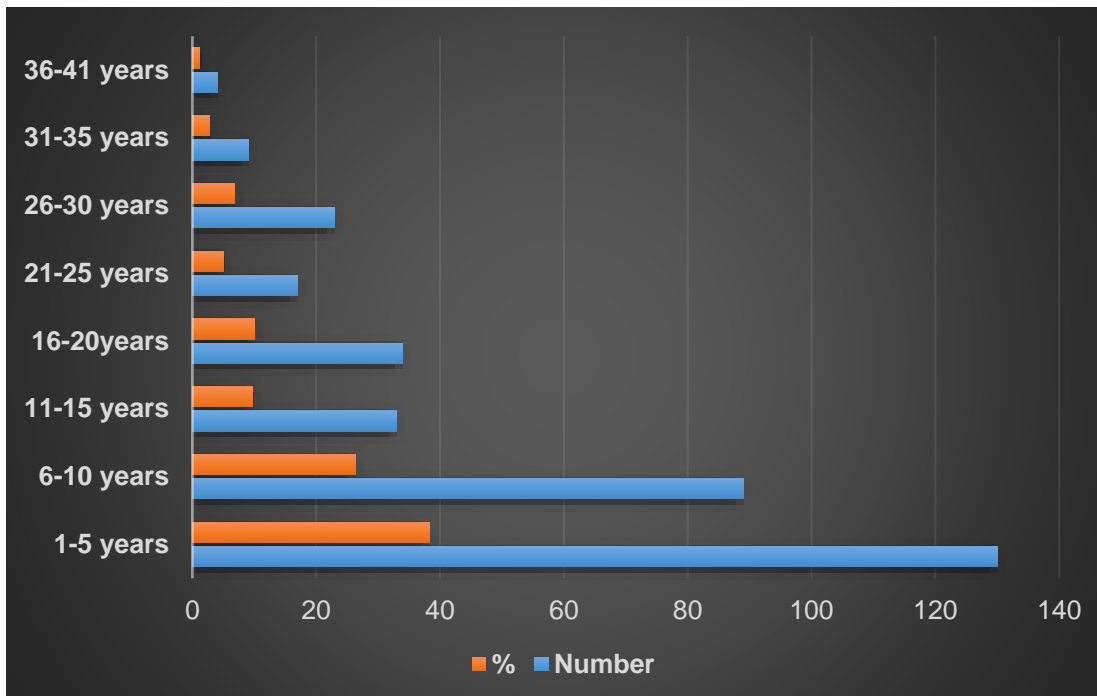


Figure 6.2: Nurses categorized by years of professional experience

6.9.2 Information disclosure by nurses

Information given to patients by nurses during medical treatment included; diagnosis as reported by 77% (265/346) of nurses. Treatment options were disclosed by 68% (233/345) nurses. Recommended treatment was disclosed by 65% (223/346) of nurses according to nurse respondents. Risks of refusing recommended treatment was disclosed by 80% (277/346) nurses. Benefits of treatment were disclosed by 71% (246/346) of nurses, and patients' right to refuse recommended treatment was disclosed by 67% (232/346) of nurses. Risks of treatment were reportedly disclosed by 69% (238/346) nurses, while 23% (81/346) nurses said they also disclosed the cost of treatment. Overall 78.9 % of nurses felt that the amount of information disclosed to patients was adequate, while 85% of nurses felt that patients understood the information disclosed. Details of information disclosure by nurses are shown in Table 6.3 below.

Table 6.1: Demographic characteristics of participating nurses

Item	Number	Valid Percent (%)
Gender		
Male	26	8.4
Female	283	91.6
Missing data	46	
Professional category		
Professional nurse (Nursing sister)§	300	84.7
Enrolled nurse (Staff nurse)*	54	15.3
Missing data	1	
Age of respondents (years)		
Minimum	22	
Maximum	62	
Mean	39.25	
Standard deviation	9.912	
Professional experience (years)		
Minimum	1	
Maximum	41	
Median	9	
Area of Practice (Public or private hospital)		
Public hospitals	354	99.7
Private hospital	1	0.3

Note: §Professional nurse (minimum 4-year Nursing diploma or Degree); *Enrolled nurse (minimum 2-year nursing diploma)

Table 6.2: Hospital departments and nursing domains involved in the study

Clinical domain	Hospital units	Number of nurses	%
Surgical Domain	Surgery; including, surgical outpatients (SOPD), Male and female surgical wards, Plastic & reconstructive Surgery, Urology	83	23.4
Medical Domain	Medicine; including Neurology, medical outpatients (MOPD), male and female medical wards, TB/infectious diseases, psychiatry, dermatology, GI & respiratory clinic, endocrine &diabetes clinic	123	34.6
Obstetrics & Gynaecology (OBGYN) domain	OBGYN; including Maternity and labour wards, antenatal and postnatal clinics and matrons office	36	10.1
Paediatrics and child nursing domain	Paediatrics clinics and wards including (neonatal intensive care (NICU), and mother and child clinics	39	11
Theatre and Perioperative nursing domain	Theatre including critical care, peri-operative and peri-anaesthetic nursing	18	5.1
Trauma, Casualty Emergency Nursing domain	Trauma, casualty, Acute Medical Unit, Resuscitation and Emergency Nursing	16	4.5
Orthopaedic nursing	Orthopaedics clinics and wards	17	4.8
Surgical Burns nursing domain	Burns including adult paediatric burns units and wards	19	5.4
Unknown	not specified	4	1.1
TOTAL		355	100

6.9.3 Time spent on informed consent

Most nurses reported spending about 5-10 minutes on the IC process. This amount of time was reported by 41% (144/350) of nurses, while 24% (85/350) reported spending about 10-20 minutes. Another 16% (57/350) of nurses reported spending less than 5 minutes, while 11% (39/350) of nurses reported spending 20-30 minutes, and 7% (23/350) said they spent over 30 minutes on IC. Responses of nurses regarding time spent on informed consent are shown in figure 6.4. When asked if this amount of time was sufficient, majority of nurses 52% (185/353) answered 'yes', while 41% said 'no'. Those

who said the time was insufficient gave various reasons for the negative response including; time constraints, large patient workload and language barriers.

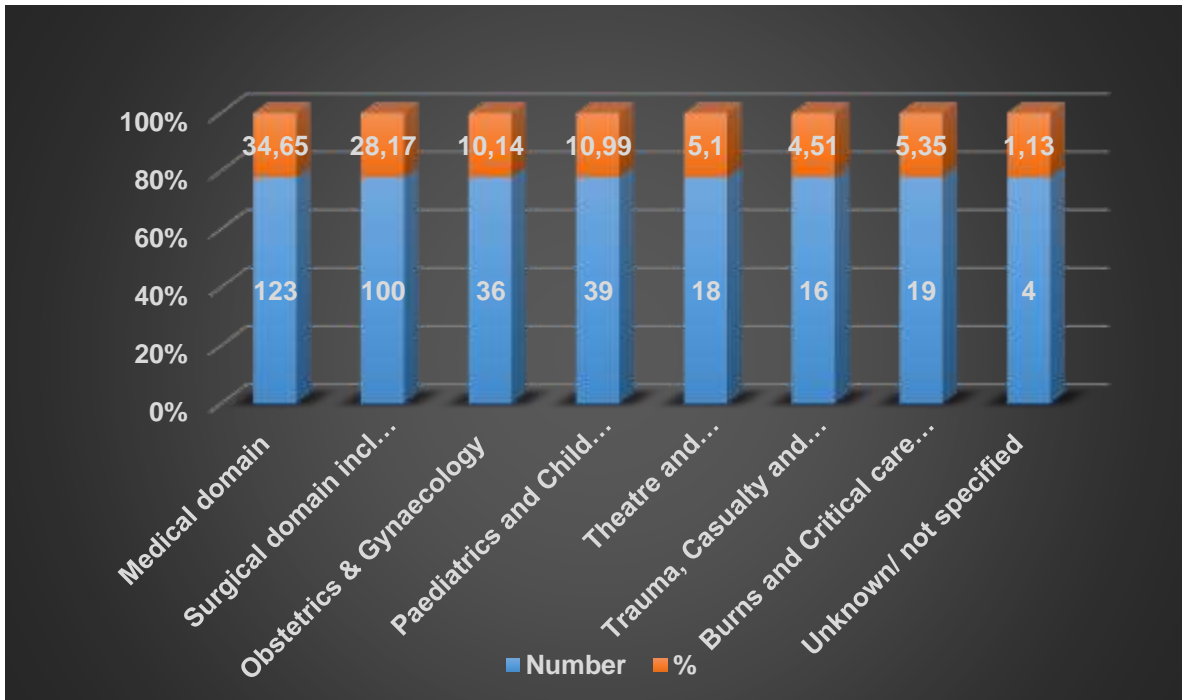


Figure 6.3: Nursing domains/hospital departments where this study was conducted

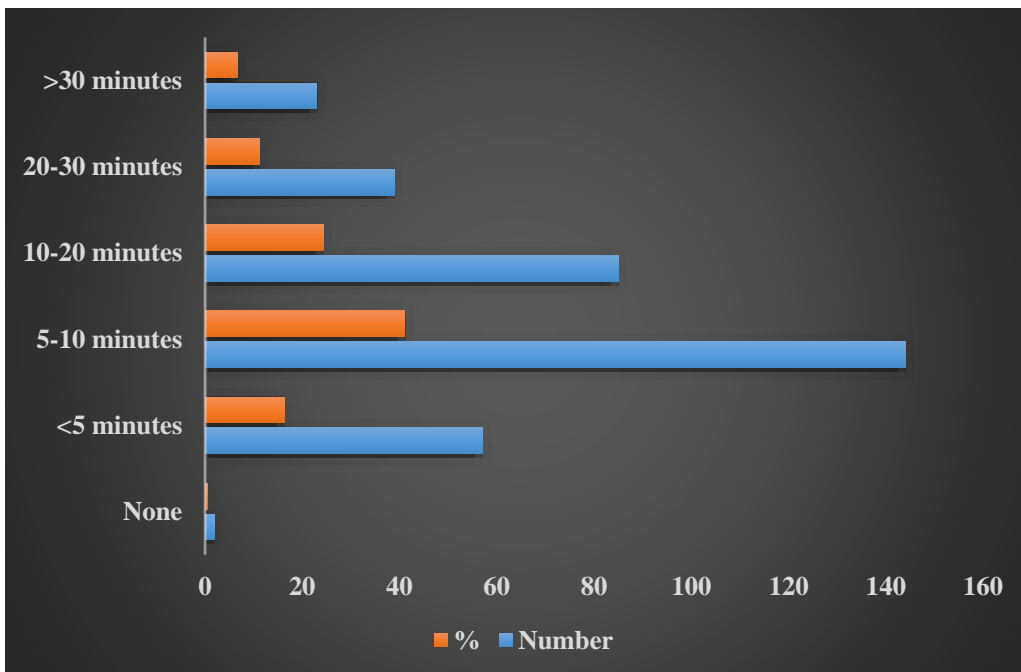


Fig 6.4: Time spent on informed consent by nurses

Table 6.3: Information provided to patients by nurses prior to obtaining consent

Information disclosed to patients	Nurses (No.)		Valid%
	Yes	No	(%)
Diagnosis	265	81	76.6
Treatment options	233	112	67.5
Recommended treatment	223	123	64.5
Risk of refusing recommended treatment	277	69	80.1
Costs of medical treatment **	81	265	23.4
Information on risks of treatment	238	108	68.8
Information on benefits of treatment	246	100	71.1
Information on right of refusal	232	114	67.1
<u>Probing Questions</u>			
Do you think the information you provide is sufficient?	270	46	78.9
Do you think patients understand the information given?	294	8	85
Do you presume that patients have the capacity to consent?	183	119	54.8

Note: ** Costs of treatment in public hospitals in South Africa are generally free

6.9.4 Nature of risks disclosed by nurses

The majority of nurses in this study reported disclosing the most common and serious risks to patients; with 80% (256/320) of nurses disclosing the 'most common risks', while 42% (134/319) of nurses said they disclosed the 'most serious risks'. However, only 36% (114/318) nurses reported disclosing 'all material risks' to patients. When compared to preference of patients regarding risk disclosure, the majority of patients preferred disclosure of 'all-risks' according to 304/391(77.4%) of patients.¹⁸⁶⁰ A minority of patients 22/391 (5.63%) preferred only 'some risks' being disclosed; while 5.63% (22/391) wanted 'none' of the risks disclosed.¹⁸⁶¹ The nature of risks disclosure by nurses when compared to preferences by patients is shown in Table 6.4 below.

Table 6.4: Nature of risks disclosed by nurses compared to preferred disclosure by patients

Risks Disclosed	Nurses		Patients		
	No.	(Yes) %	Preferred Risk Disclosure	No.	(Yes) %
Most common Risks	256/320	80	All of the risks	304	78
Most Serious Risks	134/319	42	Some of the risks	22	6
All Material Risks	114/318	36	None of the risks	22	6
			Don't know	43	11

6.9.5 Methods used to obtain informed consent from patients

The majority of nurses reported obtaining 'written' IC from patients 49% (167/343) of nurses, while 8% (26/343) nurses reported obtaining 'verbal' consent. Another 39% (135/343) of nurses said they used both methods 'verbal' and 'written' to obtain IC from patients, while 5% (17/343) of nurses answered 'it depends'. On the other hand, patients from another aspect of this study reported that HCPs obtained consent verbally in most

¹⁸⁶⁰ Chima 2015 *Niger J Clin Pract* S46-S56.

¹⁸⁶¹ Chima 2015 *Niger J Clin Pract* S51.

cases as reported by 73% (274/374) patients, while written consent was only obtained in 19% (71/374) cases, with both methods being reported by 5% (19/374) patients. This observation will be further discussed in chapter 7 of this thesis.

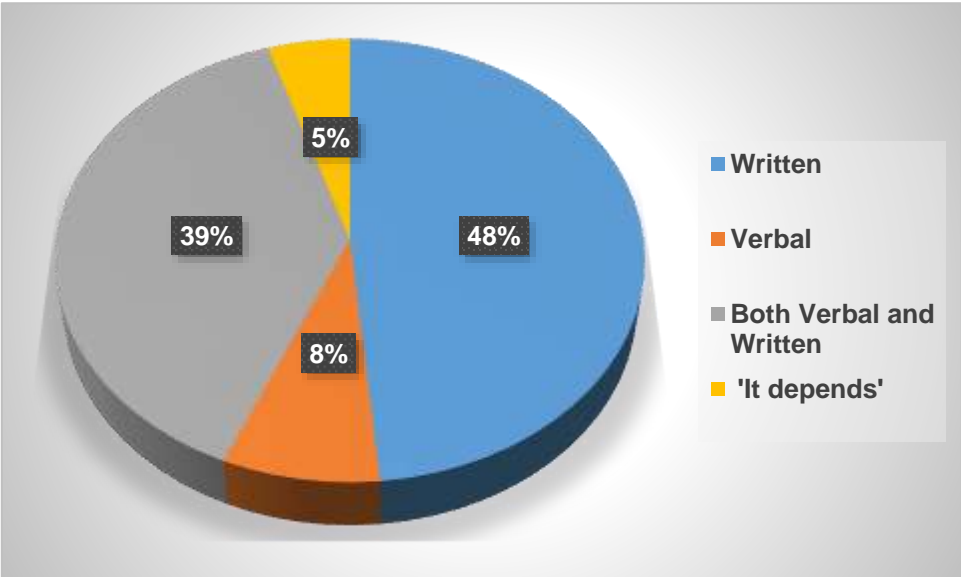


Figure 6.5: Methods used to obtain informed consent from patients by nurses

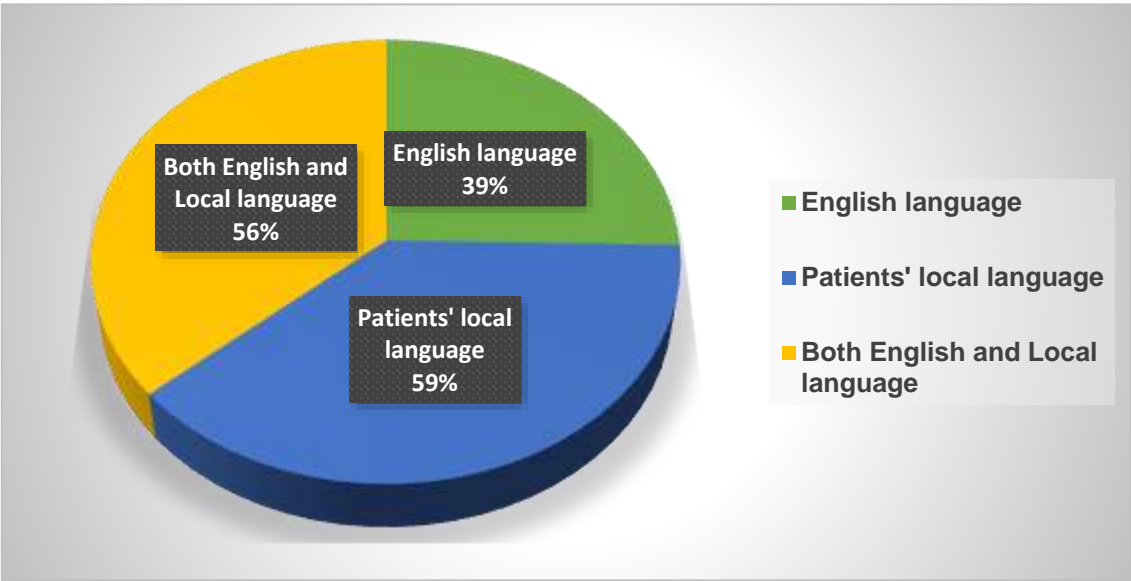


Figure 6.6: Language used to facilitate communication with patients by nurses

6.9.6 Methods of communicating with patients

Most nurses reported communicating with patients verbally using their local language as reported by 59% (206/350) of nurses. Another 39% (135/350) of nurses said they used English language, while 56% (195/350) of nurses reported using both English and the local language. Other methods used to enhance patient communication include use of diagrams and pictures as reported by 20% (69/349) of nurses. The use of interpreters was reported by 56% (197/349) of nurses; but was only corroborated by 3.5% (14/404) of patients. The implications of this finding will be discussed further below in chapter seven of this thesis.

6.9.7 Capacity of patients to provide consent to treatment

With regard to presumption of capacity, 55% (183/334) of nurses said they would generally presume that patients have the capacity to consent to treatment, whilst 36% (119/334) said they would not. Another 9.6% (32/334) of nurses said they did not know. In addition, a majority of nurses 76% (257/337) said they would routinely assess the patient capacity to consent to treatment, 19% (64/337) said they would not, while 4.7% (16/337) said they did not know. When asked to rank a series of 5 items consisting of age, sex, educational level, appearance, and level of consciousness; in terms of importance in assessing capacity, most nurses correctly ranked 'level of consciousness' first, followed by age, and educational level, in order of importance. Sex and appearance were correctly ranked as least important when determining a patient's decision-making capacity (DMC). When asked to rank 5 criteria consisting of mental status examination, psychiatric consult, ethics consult, court adjudication, surrogates, plus 'none of the above', by virtue of importance in difficult cases. Most nurses correctly ranked 'mental status examination' and 'psychiatric consult' as being most important in assessing mental capacity in difficult cases. When asked to specify which methods they would use to assess capacity in difficult cases, most nurses listed the Glasgow coma scale (GCS), mini-mental status exam (MMSE), orientation in time place and person, and level of consciousness. When deciding about difficult cases, a few nurses stated they would obtain "Superintendent's consent" when confronted with difficult cases. This refers to the legal requirement which requires

that when HCPs are unable to obtain consent from a patient in emergency situations, or when the appropriate guardian or next-of-kin is unavailable to give consent, then such consent can be provided by the Minister of Health, represented by the hospital superintendent for such emergency treatment or overriding of the requirement healthcare users informed consent.¹⁸⁶²

Table 6.5: Barriers to obtaining IC reported by different categories of nurses

Occupational rank		Time constraint	Work load	Language difficulties	Lack of administrative support e.g. interpreters	Cultural barriers	Lack of education	Medical paternalism
Prof nurse	N	194	190	228	181	186	197	163
	Median	3.00	2.00	1.00	3.00	3.00	3.00	6.00
	Minimum	1	1	1	1	1	1	1
	Maxim'm	7	7	7	7	7	7	7
Enrolled nurse	N	22	26	31	22	21	23	20
	Median	4.00	1.50	1.00	2.00	3.00	2.00	4.50
	Minim'm	1	1	1	1	1	1	1
	Maxim'm	7	7	7	7	6	7	7
Total	N	216	216	259	203	207	220	183
	Median	3.00	2.00	1.00	3.00	3.00	3.00	6.00
	Minimum	1	1	1	1	1	1	1
	Maxim'm	7	7	7	7	7	7	7

Note: Results from the top column represents responses from 'professional nurses', the middle column represents responses from 'enrolled nurses', while the lower column represents the combined responses from both categories of nurses. There was no statistically significant difference between 'professional' and 'enrolled/staff' nurses.

6.9.8 Barriers to informed consent identified by nurses

Nurses were asked to rank a series of potential barriers to IC on a 7 point scale , where 1 was considered the most difficult challenge, while 7 was the least difficult. The major challenges identified by nurses are illustrated in figure 6.7 below. Overall, majority of

¹⁸⁶² National Health Act 61 of 2003 s7 (1) (e).

nurses ranked 'language difficulties' as being their most challenge. This was followed by lack of education, work load and time constraints. Further followed by cultural barriers and lack of administrative support e.g. interpreters. The least difficult challenge experienced by nurses was due to medical paternalism. The results are also shown in tabular form above in table 6.5 above, which categorizes responses from professional and enrolled nurses separately. There was no statistically significant difference in barriers identified between 'professional' and 'enrolled/staff' nurses. However language difficulties, cultural barriers, lack of education and medical paternalism showed statistically significant differences when compared between doctors and nurses, with a range of $p \leq 0.001$ to $p = 0.002$.

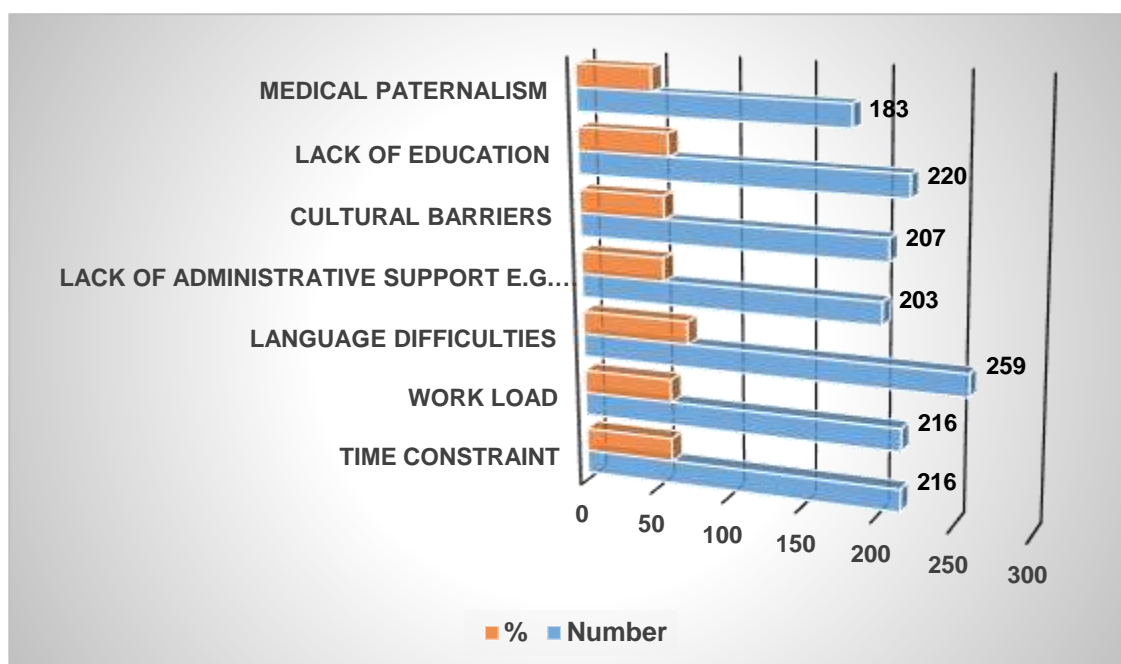


Fig 6.7: Barriers to informed consent reported by nurses.

6.9.9 The understanding and use of implied or presumed consent by nurses

With regard to the understanding and use of implied or presumed consent in clinical practice by nurses, around 20% (44/218) of nurses said they 'sometimes or occasionally' used implied or presumed consent; while 23% (51/218) of nurses said they 'seldom or

rarely' used it. Another 40% (88/218) of nurses said they 'never' used implied or presumed consent during clinical practice, while 16% (35/218) of nurses said they used it 'all of the time' as shown in figure 6.8 and table 6.6 below. However, when asked to define or describe what they understood by "implied or presumed consent", the majority of nurses did not appear to fully comprehend the meaning of implied or presumed consent. Many nurses indicated that when patients showed up at a clinic or healthcare facility to seek help or treatment, this automatically implies that such a person or patient had consented to receive medical treatment. Verbatim responses from nurses when asked to explain what they understood by 'implied or presumed consent' included statements such as: *"By routine of the patient coming to the healthcare facility- he is consenting to treatment."* Or *"by virtue of the fact that you have sought my help"* and *"patient presents themselves requesting treatment."* In terms of when they actually or were most likely to use implied/presumed consent during medical treatment; 26% (73/280) of nurses said they used it 'when patients present at the clinic'. Another 31% (87/281) of nurses said they would use it 'when patients are admitted to the ward', while most nurses, 41% (117/284) said they used implied or presumed consent during 'emergencies'. A further 57% (142/248) of nurses said they usually obtained specific consent for certain clinical procedures. Examples of procedures enumerated by nurses where specific consent was required included blood transfusions, lumbar punctures, surgical operations e.g. tubal ligation, bone marrow aspiration. Others were HIV testing, CT scans and 'anything invasive' according to some nurse respondents.

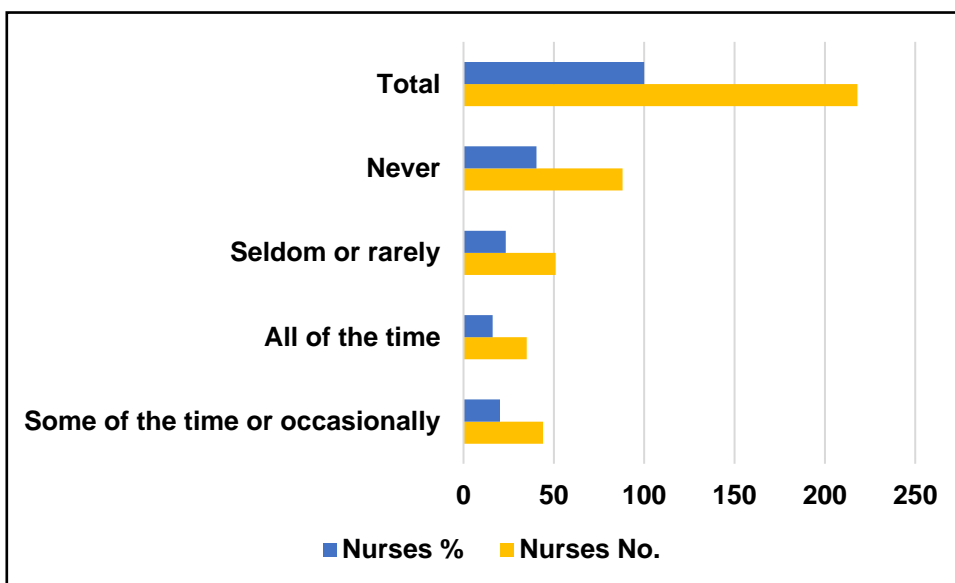


Fig 6.8: Use of implied and presumed consent by nurses

Table 6.6: Use of implied/ presumed consent by nurses in practice

Implied/presumed consent	Nurses No.	Nurses Yes (%)
<u>When do you use implied/presumed consent:</u>		
1. When patients' present at the clinic?	73/280	26.1
2. When patients are admitted to the ward?		
3. In an emergency?	87/281	31
	117/284	41.2
<u>How often do you use implied or presumed consent in practice?</u>		
Some of the time or occasionally	44/218	20.2
Seldom or rarely	51/218	23.4
All of the time	35/218	16.1
Never	88/218	40.4

6.9.10 Nurses' general knowledge regarding the IC doctrine

When nurses were asked who should normally obtain IC from patients, the majority of nurses 79% (270/342), correctly answered that the HCP performing a medical procedure should ideally obtain consent from the patient. When asked what standard should be used for information disclosure, 56% (165/295) of nurses chose the 'reasonable doctor standard', while 47% (138/291) chose the 'prudent patient standard'. When asked whose responsibility it was to ensure that adequate information was disclosed during IC, most nurses, 60% (196/325), said that that it was the responsibility of HCPs. Another 37% (121/325) of nurses felt that HCPs and patients were jointly responsible; while 12% (40/326) of nurses felt that it was the responsibility of patients. When asked whether the amount of time spent on information disclosure is adequate; 52% (185/353) of nurses answered 'yes'. Similarly when asked if the current consent form used in public hospitals was adequate, 81% (281/345) of nurses felt it was adequate. Nurses who felt that the current consent form was inadequate complained about lack of space to detail complications for patients since different clinical conditions may require different mandatory disclosures. With regards to voluntariness, when asked if they would allow patients to choose a particular procedure or treatment by themselves; 40% (137/337) of nurses answered 'yes', while 50% (170/337) said 'no'.

6.9.11 Knowledge of local healthcare laws by nurses

To test the general knowledge of HCPs with regards to local laws pertaining to IC; two sets of general knowledge questions were included on the questionnaire. On the first question relating to 'age of consent' to routine medical treatment in South Africa, only 30% (99/331) nurses chose '12 years' as the correct answer. Another 10% of nurses chose '15years', 55% (183/331) selected '18 years'; 3.6% chose '21 years', while 1.2% nurses did not know the correct answer. Concerning age of consent for termination of pregnancy in South Africa in terms of the Choice on Termination of Pregnancy Act,¹⁸⁶³ the majority

¹⁸⁶³ Choice on termination of pregnancy Act 92 of 1996.

of nurses 58% (190/327) chose '12 years' as the correct answer, while only 8% (25/327) nurses correctly chose 'any age'. The difference in knowledge of the age of consent for medical treatment and for TOP when compared between doctors and nurses showed statistical significance ($p \leq 0.001$).

6.9.12 Comparison of IC aggregate scores (ICAS) between nurses and other HCPs

To compare knowledge and practice of IC across occupational and professional ranks of doctors and nurses, I developed an aggregate score using a modified version of the criteria described by Sugarman et al,¹⁸⁶⁴ which was previously used to evaluate the quality of informed consent and therapeutic misconception among patients involved in clinical trials. To this end, I selected a series of 12 questions from the questionnaire for HCPs as previously described.¹⁸⁶⁵ The questions included for this scoring represent selected questions, which reflect the key elements of informed consent as recognized by independent legal and academic authorities.^{1866,1867} The questions selected for the ICAS calculation are also consistent with the elements of information disclosure as stipulated in the NHA.¹⁸⁶⁸ Each of the selected questions was given a score of 1 (one) and the aggregate score represents the overall ICAS score. The questions used for the ICAS was evaluated for reliability by calculating the Cronbach's alpha, described as a test of internal consistency which shows how closely related a set of items are as a group.¹⁸⁶⁹ Comparison of the ICAS scores between 'professional nurses' and 'enrolled nurses' showed that professional nurses scored 9 on average, while enrolled nurses scored 7. However this difference was not statically significant $p = 0.090$. Further analysis showed that there was no significant differences between nurses working in different nursing domains, even though nurses working in trauma and casualty departments had the

¹⁸⁶⁴ Sugarman et al 2005 *Clinical Trials* 36-37.

¹⁸⁶⁵ Chima 2013 *BMC Med Ethics* S3:1-17

¹⁸⁶⁶ Beauchamp and Childress *Principles of biomedical ethics* 80.

¹⁸⁶⁷ Carstens and Pearmain *Foundational Principles* 883-918.

¹⁸⁶⁸ National Health Act 61 of 2003 (section 6).

¹⁸⁰⁰ Statistical Consulting Group UCLA "Introduction to SAS"

[www.https://stats.idre.ucla.edu/sas/modules/sas-learning-module-introduction-to-the-features-of-sas](https://stats.idre.ucla.edu/sas/modules/sas-learning-module-introduction-to-the-features-of-sas) (Date of use: 13 February 2018).

highest ICAS score of 10. The difference in scores between nursing domains was also not statistically significant when compared using the Kruskal-Wallis test ($p = 0.293$). On the other hand, comparison of ICAS scores between doctors and nurses was significantly different with doctors having an aggregate score of 10, compared to nurses with an aggregate score of 8. The difference between doctors and nurses was statistically significant when compared using the Mann-Whitney U test ($p \leq 0.001$). The Cronbach's alpha score for the 12 items included in the ICAS was calculated as 0.646. Although the interpretation of alpha is somewhat controversial, this score is within the magnitude of reliability scale of 'high' with regards to Cronbach's alpha, where a high score for Cronbach's alpha is classified as scores of between 0.61-0.80.¹⁸⁷⁰ This score suggests that the items used for calculating ICAS have internal consistency and are at least moderately closely related.¹⁸⁷¹

6.10 DISCUSSION

6.10.1 Overview of findings from nurses in relation to other studies on IC practice

This aspect of the empirical study discussed in this chapter focuses on practising professional nurses at public hospitals in South Africa. The overall objective for this study was to establish whether HCPs are actually knowledgeable and practising within the regulatory framework for IC as codified in the NHA,¹⁸⁷² and other national and international ethical codes for nursing,¹⁸⁷³ ethical guidelines for HCPs,¹⁸⁷⁴ and other relevant South African legislation.^{1875,1876} I also wanted to establish whether the quality of IC practised by HCPs in South Africa is consistent with international ethical guidelines and standards of

¹⁸⁷⁰ Flores JWC https://www.researchgate.net/post/How_do_i_interpret_my_Alpha_value (Date of use: 30 January 2018).

¹⁸⁷¹ Tavakol M and Dennick R "Making sense of Cronbach's alpha" 2011 *IJME* 53-55.

¹⁸⁷² National Health Act 61 of 2003

¹⁸⁷³ International Council of Nurses *ICN Code of Ethics for Nurses* (ICN Geneva 2012) see also *SANC Code of ethics for nursing practitioners in South Africa* (SANC Pretoria 2013).

¹⁸⁷⁴ HPCSA *Guidelines for good practice in the healthcare professions* (HPCSA Pretoria 2008).

¹⁸⁷⁵ Children's Act 38 of 2005 as amended.

¹⁸⁷⁶ Choice on Termination of Pregnancy Act 92 of 1996.

care.^{1877, 1878} The quality of informed consent may be described as completeness of information disclosure, comprehension of the information disclosed, and voluntary agreement or disagreement with the proposed treatment in the absence of coercion or undue influence.^{1879,1880,1881} In this case, IC would be considered true or valid consent, if consisting of the five key elements of IC as stipulated by law, international ethical guidelines and academic and legal authorities.^{1882,1883,1884} As previously reported by other authors and discussed in chapter 5 of this thesis, medical doctors practising in South Africa are generally knowledgeable about IC regulations, but not consistent or effective in actual implementation of IC guidelines as stipulated by local laws and professional ethical codes.^{1885,1886} This observation was also supported by analysis of responses from the patients who were simultaneously evaluated during this study,¹⁸⁸⁷ and will be discussed in chapter 7 below. Not many empirical studies have previously evaluated the knowledge and practice of IC by HCPs in Africa.¹⁸⁸⁸ There are also few studies which have evaluated nurses' understanding of IC in clinical practice in an African setting. The few reported studies from other African countries have generally focused on the performance of doctors with some nurse participation.^{1889,1890,1891} Previous reports from African countries have generally highlighted deficiencies in the clinical implementation of IC by doctors, especially in the context of surgical practice, a clinical area where many of these studies were

¹⁸⁷⁷ ICN *Code of Ethics for Nurses* (ICN Geneva 2012).

¹⁸⁷⁸ US Code of Federal Regulations 45 CFR 46.116 *General requirements for informed consent* <http://www.law.cornell.edu/cfr> (Date of use: 29 June 2017).

¹⁸⁷⁹ Chima 2013 *BMC Med Ethics* [12] see also Minnies et al 2008 *BMC Med Ethics* 15 [2].

¹⁸⁸⁰ Sugarman J et al 2005 *Clinical Trials* 35.

¹⁸⁸¹ Kiguba et al 2012 *BMC Med Ethics* 13 [6-7].

¹⁸⁸² Beauchamp and Childress *Principles of biomedical ethics* [80] see also Carstens and Pearmain *Foundational Principles* 875-941.

¹⁸⁸³ Van Oosten LLD thesis 1989.

¹⁸⁸⁴ Beauchamp TL and Faden RR "Informed consent: Meaning and elements of informed consent" in *Encyclopaedia of Bioethics* Reich WT (ed) (Simon & Schuster Macmillan New York 1995) 1240- 1245.

¹⁸⁸⁵ Chima 2013 *BMC Med Ethics* Suppl1 S3 [1-17].

¹⁸⁸⁶ Henley et al 1995 *SAMJ* [1273 &1277].

¹⁸⁸⁷ Chima 2015 *Niger J Clin Pract* S46-S56.

¹⁸⁸⁸ Henley et al 1995 *SAMJ* 1273-1278.

¹⁸⁸⁹ Dairo MD, Oyetunde MO and Olaitan PB "Informed consent in a tertiary hospital in Nigeria: how involved is the nurse?" 2007 *Niger Postgrad Med J* 209-212.

¹⁸⁹⁰ Kajja I, Bimenya GS and Sibinga CTS "Informed consent in blood transfusion: Knowledge and administrative issues in Uganda hospitals" 2011 *Transfus Apher Sci* 33-39.

¹⁸⁹¹ Sippel D et al "Clinical ethics in Gabon: The spectrum of clinical ethical issues based on findings from in-depth interviews at three public hospitals" 2015 *PLoS One* 10.

conducted.^{1892,1893} With regard to knowledge and practice of IC by nurses during nursing care, even fewer empirical studies have been conducted and most of these have either been in association with doctors,^{1894,1895} or usually in the context of biomedical research.^{1896,1897} In previously reported studies from Africa, nurses have generally played a secondary or passive role, both in their knowledge and application of IC in clinical practice.^{1898,1899} However, recent studies on the knowledge of ethics and ethical dilemmas confronting nurses in South Africa appear to focus on issues such as nurses' appreciation of the nurses pledge,^{1900,1901} which suggests a superficial understanding of medical ethics by nurses. In these studies, the most frequent ethical dilemmas in nursing practice were limited to patient abuse, job satisfaction, and the unprofessional attitudes of caregivers who are not registered nurses. These studies also emphasise that the general knowledge of professional ethics and healthcare law amongst different categories of nurses in South Africa may be somewhat deficient, with nurses in the auxiliary and junior cadres complaining and implying that ethical nursing care practice appeared to be limited to or valued only by professional and enrolled nurses with college or university education.^{1902,1903} These reported deficiencies in nurses' education and knowledge of ethical issues in healthcare still appear consistent with a twenty-year-old report by the Democratic Nurses of South Africa (DENOSA) to the Truth and Reconciliation Commission (TRC) in 1996, which stated that:

¹⁸⁹² Ogundiran and Adebamowo 2010 *J Med Ethics* 741-745.

¹⁸⁹³ Ochieng J et al 2014 *BMC Med Ethics* 15.

¹⁸⁹⁴ Kajja et al 2011 *Transfus Apher Sci* 33-39.

¹⁸⁹⁵ Dairo et al 2007 *Niger Postgrad Med J* 209-212

¹⁸⁹⁶ Taiwo and Kass 2009 *BMC Med Ethics* 10: 11

¹⁸⁹⁷ Minnies et al 2008 *BMC Med Ethics* 9.

¹⁸⁹⁸ Dairo et al 2007 *Niger Postgrad Med J* 209-212

¹⁸⁹⁹ Sippel et al 2015 *PLoS One* 10.

¹⁹⁰⁰ White J, Phakoe M and Rispel LC "Practice what you preach: Nurses' perspectives on the code of ethics and service pledge in five South African hospitals" 2015 *Glob Health Action* 8 <http://dx.doi.org/10.3402/gha.v8.26341> (Date of use: 28 July 2017).

¹⁹⁰¹ Stellenberg and Dorse 2014 *Curationis* 38: <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 28 July 2017).

¹⁹⁰² White J et al 2015 *Glob Health Action* 8: 2634 <http://dx.doi.org/10.3402/gha.v8.26341> (Date of use: 28 July 2017).

¹⁹⁰³ Stellenberg and Dorse *Curationis* 38: <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 28 July 2017).

Ethics content has always been included in nursing curricula. However, it seems that educators largely did not succeed in teaching this subject so that it had everyday application. While provision is made for the teaching of ethics in the curriculum, nurses do not seem to identify it as significant to their professional role. In one particular study, it was found that 87% of the research sample indicated that they did not regard the subject Ethos as necessary to their work as registered nurses. It also appeared from interviews that, in teaching the subject, more attention was given to the history of nursing and etiquette than to ethics and professional conduct, and that students perceived the subject as a list of 'do's and don'ts'.^{1904,1905}

Therefore, reports from the present and previous studies suggest that training in the area of medical law and ethics needs to be enhanced amongst all categories of nurses in South Africa. The study reported here was limited to professional and enrolled nurses with nursing college diplomas and some with university education. This report shows that while many of these nurses are somewhat knowledgeable about some theoretical aspects of IC, majority of nurses were generally deficient in their specific knowledge of legal requirements of IC as stipulated by current laws and regulations, especially the NHA.¹⁹⁰⁶ Secondly, with regard to the age of consent for medical treatment in South Africa, only about 28% of responding nurses could correctly identify the current age of consent for minors as 12 years as specified in the Children's Act.¹⁹⁰⁷ This observation is important because the 'age of consent' plays an important role in determining the capacity of individuals to consent to treatment. Furthermore, in the specific case of South Africa, the age of consent to treatment was reduced from 14 years to 12 years in recent times, due to the large number of self-sustaining AIDS orphans whose parents or guardians previously died due to the AIDS epidemic in South Africa, leaving in essence a large number of child-headed households in South Africa. Failure to recognize this special category could lead to discrimination and stigmatization¹⁹⁰⁸ of such children, including the potential for denial of rights to consent to treatment for themselves or to obtain testing and

¹⁹⁰⁴ London and Baldwin-Ragaven 2008 *Curationis* 5-18 [6].

¹⁹⁰⁵ Truth and Reconciliation Commission Report *Institutional hearings: The health sector* (CTP Book Printers Cape Town 1998)109-164 [110].

¹⁹⁰⁶ National Health Act 61 of 2003.

¹⁹⁰⁷ Children's Act 38 of 2005 as amended (s129-142).

¹⁹⁰⁸ Famoroti TO, Fernandes L and Chima SC "Stigmatization of people living with HIV/AIDS by healthcare workers at a tertiary hospital in KwaZulu-Natal, South Africa: A cross-sectional descriptive study" 2013 *BMC Med Ethics* S6.

treatment for HIV/AIDS in the absence of a surrogate parent or guardian.¹⁹⁰⁹ Similarly, on the question regarding the age of consent for termination of pregnancy as stipulated in the Choice Act,¹⁹¹⁰ only 8% of nurses could identify the correct response as ‘any woman of any age’. This knowledge is important for HCPs, including nurses, to be able to correctly advice women including children on their rights to information regarding contraception and TOP, because this Act was designed to mitigate the issue of illegal abortions, and poor access to contraception which was prevalent under the former discredited Abortion and Sterilization Act,¹⁹¹¹ used during the apartheid era. The new law was designed to enhance “reproductive rights and extend freedom of choice by affording ‘any woman of any age’ the right to choose whether to have an early safe and legal termination of pregnancy according to her individual beliefs”.¹⁹¹² The lack of knowledge by nurses regarding this legal requirement was quite surprising, considering that over 90% nurses who participated in this study were female, and in the geopolitical context of South Africa, nurses should be expected to provide accurate health advice and information to their local communities, considering that nurses represent major category of HCPs practising in sub-Saharan African countries, including South Africa.^{1913,1914,1915} Further, such ‘information giving’ roles could also be considered part of the nurses’ role of ‘cultural brokerage’ in resource-poor settings.^{1916,1917} Studies amongst nurses in other medium income developing countries similar South Africa like Indonesia,¹⁹¹⁸ have suggested that nurses may have up to four separate roles to play in the IC process in communities with strong communality, such as the Ubuntu philosophy as practiced in some African

¹⁹⁰⁹ Brand South Africa “Government explains new Children’s Act” 03 July 2007 <https://brandsouthafrica.com/governance/services/government-explains-newchildrens-act> 03 July 2007 (Date of use: 13 October 2017) see also Children’s Act 2005 s130.

¹⁹¹⁰ Choice on Termination of Pregnancy Act 92 of 1996.

¹⁹¹¹ Abortion and Sterilization Act 2 of 1975.

¹⁹¹² Choice on Termination of Pregnancy Act 92 of 1996 [para1].

¹⁹¹³ Crisp N and Chen L “Global supply of health professionals” 2014 *N Engl J Med* 2014 950-957.

¹⁹¹⁴ Anyangwe SCE and Mtonga C “Inequities in the global health workforce: The greatest impediment to health in Sub-Saharan Africa” 2007 *Int J Enviro Res Public Health* 93-100.

¹⁹¹⁵ World Health Organisation *Strategic directions for strengthening nursing and midwifery services 2011-2015* (WHO Geneva 2011) www.who.int/hrh/resources/nmsd/en/index.html (Date of use: 28 July 2017).

¹⁹¹⁶ Shaibu 2007 *Nurs Ethics* 503-509.

¹⁹¹⁷ Jezewski 1990 *West J Nurs Res* 497-513.

¹⁹¹⁸ Susilo et al 2013 *Nurs Ethics* 413-425.

communities.^{1919,1920} This is similar to the familial and hierarchical structure prevalent in Asian cultures.^{1921,1922,1923} According to the study reported by Susilo and others, the nurses' role in the IC process may include:¹⁹²⁴

- (a) *Manager* - in this role nurses ensure that the IC is conducted properly including taking responsibility for preparing consent forms, making sure that both doctors and patients accurately sign the forms, and ensuring that the completed forms are placed in patients' records.
- (b) *Witness* - this role requires nurses to attend meetings between patients, doctors and family members or surrogates, witness the IC conversation between doctor and patient, and should sign the IC document as witness.
- (c) *Patient advocate*-in this role nurses can mediate between different parties in the IC process, such as encouraging patients to ask questions or express any wish to the doctors and other HCPs, thereby enhancing the IC process and patient understanding. This is similar to the 'cultural brokerage' role sometimes played by nurses in other settings.¹⁹²⁵
- (d) *Information giver* - in this role nurses could expand on the brief information provided by doctors, assist with patient understanding and compliance with instructions for clinical procedures e.g. fasting before anaesthesia, or the proper way to take medications, etc.

Based on the study reported here, the deficiency of knowledge regarding IC regulations by nurses was no different between professional and enrolled nurses. Neither did the observed deficiency in knowledge differ based on the years of professional experience. Further, there was a statistically significant difference between the levels of knowledge of doctors generally, when compared to nurses in this study using ICAS comparison.¹⁹²⁶ This

¹⁹¹⁹ Chima 2015 *Niger J Clin Pract* S1-S7.

¹⁹²⁰ Metz and Gaie 2010 *J Moral Educ* 273-90

¹⁹²¹ Barnes et al 1998 *Nurs Ethics* 412-423.

¹⁹²² Lee 2009 *Int J Nursing Stud* 1580-1584

¹⁹²³ Masaki et al 2014 *BMC Med Ethics* 15:8

¹⁹²⁴ Susilo et al 2013 *Nurs Ethics* 413-425.

¹⁹²⁵ Jezewski MA 1990 *West J Nurs Res* 497-513 see also Shaibu 2007 *Nurs Ethics* 507.

¹⁹²⁶ Chima 2013 *BMC Med Ethics* S3.

observation indicates that training in the area of medical law and ethics and professional practice readiness may not be properly catered for in local nursing schools. This finding is also consistent by studies of newly graduated nurses from a local nursing college, where their competence to practice at graduation was found to be unsatisfactory.¹⁹²⁷ One may argue that nurses are not generally required to obtain IC from patients; therefore they need not bother about specific details of the IC regulations. However, the current law as specified by the NHA¹⁹²⁸ requires that ‘users must have full knowledge’ prior to involvement in medical procedures. Section 6 of the Act also states that: “[e]very health care provider must inform a user of –

- 1) 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;
- 2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user’s level of literacy.¹⁹²⁹

Section 7 of the Act states further that “subject to section 8, a health service may not be provided to a user without the user’s informed consent”, unless with defined exceptions.¹⁹³⁰ These injunctions ultimately include all registered HCPs, including nurses. These requirements also indicate that knowledge of IC regulations by nurses is not expected to be lower than that of any other HCPs, including doctors. The above observation is further supported by the recent judgment of the UK Supreme court in the case of *Montgomery v Lanarkshire*,¹⁹³¹ where the Court held that:

In addition, a wider range of healthcare professionals now provide treatment and advice of one kind or another to members of the public, either as individuals, or as members of a team

¹⁹²⁷ Morolong BG and Chabeli MM “Competence of newly qualified registered nurses from a nursing college” 2005 *Curationis* 38.

¹⁹²⁸ National Health Act 61 of 2003.

¹⁹²⁹ National Health Act (s6).

¹⁹³⁰ National Health Act 2003 (s7).

¹⁹³¹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

drawn from different professional backgrounds (with the consequence that, although this judgment is concerned particularly with doctors, it is also relevant, **mutatis mutandis**, to other healthcare providers)".¹⁹³²

On the other hand, one can argue that such criticism of nurses' factual knowledge should not be limited to South African nurses, because studies from other developing countries such as Iran, Indonesia, and some East African countries, seem to indicate a deficiency in knowledge and implementation of IC by practicing nurses, either due to inadequate knowledge or other socio-cultural factors.^{1933,1934,1935,1936,1937} Similarly, studies regarding nurse performance in developed countries such as Netherlands, Greece, Korea, Japan and elsewhere have also indicated that nurses do not generally implement all the elements of IC in clinical practice, either due to a confusion about the role of nurses in the IC process or incomplete appreciation of the ethical principle of respect for autonomy and the doctrine of IC in nursing care practice.^{1938,1939, 1940,1941,1942} It has been suggested that nurses' role in the IC process may also be multidimensional because of the current emphasis on the respect for autonomy over professional beneficence in healthcare, and the evolution of consumer, human and cultural rights in modern society, coupled with

¹⁹³² Montgomery v Lanarkshire Health Board [2015] UKSC 11 [75].

¹⁹³³ Barnes et al 1998 *Nurs Ethics* 412-423.

¹⁹³⁴ Shariff N and Potgeiter E "Extent of East-African nurse leaders' participation in health policy development" 2012 *Nurs Res and Pract* doi:10.1155/2012/504697.

¹⁹³⁵ Susilo P et al 2014 *Nurs Ethics* 684-694 [685].

¹⁹³⁶ Rouhangiz and Rutledge 2011 *Applied Nurs Res* 276-280

¹⁹³⁷ Dairo et al 2007 *Niger Postgrad Med J* 209-212.

¹⁹³⁸ Rosse and Krebs 1999 *Semin Oncol Nurs* 116-123.

¹⁸⁷⁰ Bristol ST and Hicks RW "Protecting boundaries of consent in clinical research: implications for improvement" 2014 *Nurs Ethics* 16-27.

¹⁹⁴⁰ Lee et al 2009 *Int J Nursing Stud* 1580-1584 see also Masaki et al 2014 *BMC Med Ethics* 15.

¹⁹⁴¹ Aveyard 2003 *Int J Nurs Stud* 697-705

¹⁹⁴² Lemonidou et al 2003 *Clin Eff Nurs* 73-83 see also Van Theil and Van Delden 2001 *Nurs Ethics* 419-431.

greater awareness of patients generally regarding human dignity and consumer rights.^{1943,1944,1945,1946,1947}

6.10.2 Barriers and challenges to IC identified by nurses

In the current study, the primary barrier identified by nurses against the practice of IC in this setting was the issue of 'language barriers', which was identified by 73% of professional nurses in this study, as well as 88% of doctors as previously reported.¹⁹⁴⁸ Other barriers identified by nurses include the issues of 'lack of education', 'workload', 'time constraints', and 'lack of administrative support in the form of interpreters'. The three combined barriers of language, lack of interpreters, and poor education of patients, point to the importance of language in the understanding and practice of IC in a multilingual and multicultural country like South Africa. It has been suggested previously that problems of language may have a deleterious impact on healthcare practice, leading to such unforeseen outcomes like misdiagnosis, failure of preventive advice, or non-compliance with prescribed medications by patients, which could ultimately result on charges of medical negligence and misconduct against HCPs.^{1949,1950,1951} The issue of language barriers to IC and clinical practice is not limited to South Africa;¹⁹⁵² it has also been reported amongst multicultural communities in developed countries such as the USA.^{1953,1954,1955} According to another study by Schenker and others, "language barriers

¹⁹⁴³ Montgomery v Lanarkshire Health Board [2015] UKSC 11 [para 75].

¹⁹⁴⁴ Chima *A primer on medical law* 18-20.

¹⁹⁴⁵ Davis AJ "Global influence of American nursing: some ethical issues" 1999 *Nurs Ethics* 118-125

¹⁹⁴⁶ Leino-Kilpi H et al "Patients autonomy, privacy and informed consent in legal norms and professional codes" in *Patients autonomy privacy and informed consent* (IOS Press Amsterdam 2000) 5-9.

¹⁹⁴⁷ Truth and Reconciliation Commission Report *vol 4 The health sector* (Truth and Reconciliation Commission 1998) 108-159.

¹⁹⁴⁸ Chima 2013 *BMC Med Ethics* S3 [8-10].

¹⁹⁴⁹ Flores 2006 *N Engl J Med* 229-331

¹⁹⁵⁰ Schenker et al 2007 *J Gen Intern Med* 294-299.

¹⁹⁵¹ Clark et al 2011 *J Surg Educ* 143-147.

¹⁹⁵² Schlemmer and Mash 2006 *SAMJ* 1084-1087 See also Chima 2013 *BMC Med Ethics* S3 [8-10].

¹⁹⁵³ Flores 2006 *Engl J Med* 229-331 see also Schenker et al 2007 *J Gen Intern Med* 294-299.

¹⁹⁵⁴ Tate et al 2016 *Prehosp Emerg Care* 1-11.

¹⁹⁵⁵ Schenker et al 2008 *Ann Intern Med* 264-269.

have been found to complicate many aspects of patient care, including receipt of medical services, patient satisfaction, interpersonal processes of care, comprehension, adherence to prescribed medication regimens, and length of hospital stay”.¹⁹⁵⁶ In this study, it was reported that even where interpreter services are readily available; such availability did not prevent failure to document IC in patients’ clinical notes among patients with low English proficiency. Further, in another international comparative study between USA and South Africa, in a prehospital ambulatory care setting, emergency medical services (EMS) telecommunicators identified telephonic interpreter services as the single most effective strategy for overcoming language barriers.¹⁹⁵⁷ However, it was also reported that while interpreter services did improve the efficiency of patient-provider communication, other unorthodox methods were used to enhance communication between patients and HCPs due to frustration with the interpreter services.¹⁹⁵⁸

Another study from a South African district hospital found evidence that language barriers impacted negatively on patients’ rights to confidentiality, IC and the overall quality of healthcare services.¹⁹⁵⁹ Therefore, the impact of language barriers on the IC process and potential impact on healthcare service delivery cannot be overemphasized. One may further suggest that the problem of lack of trained interpreters in local hospitals not only detracts from clinical practice, but also increases the workload of nurses who are usually called upon to act as interpreters in this setting, in the practice of cultural brokerage.¹⁹⁶⁰ The inappropriate use of interpreter services by doctors has also been identified as contributing to language barriers during IC in the hospital setting. In this study, the authors suggested four factors that should inform the decision to call an interpreter or not. That is, “the clinical situation, degree of language gap, available resources, and patients’ preference.”¹⁹⁶¹ One may conclude that the incidences of work overload occasioned by the use of nurses in lieu of trained interpreters in the study reported here, may also

¹⁹⁵⁶ Schenker et al 2007 *J Gen Intern Med* 295

¹⁹⁵⁷ Tate et al 2016 *Prehosp Emerg Care* 1-11 [1]

¹⁹⁵⁸ Tate et al 2016 *Prehospital Emerg Care* 1.

¹⁹⁵⁹ Schlemmer and Mash 2006 *SAMJ* 1085-1086 see also Levin ME “Language as a barrier to care for Xhosa-speaking patients at a South African teaching hospital 2006 *SAMJ* 1076-1079.

¹⁹⁶⁰ Jezewski MA 1990 *West J Nurs Res* 497 see also Shaibu 2007 *Nurs Ethics* 507.

¹⁹⁶¹ Schenker et al 2008 *Ann Intern Med* 264.

contribute to the increased patient workload reported by nurses, which may be associated with the high turnover of nurses due job attrition and lack of job satisfaction reported in South African hospitals.^{1962,1963,1964}

6.10.3 Similarities and inconsistencies between professional nurses, doctors and patients

The overall knowledge of legal aspects relating to IC was higher amongst doctors than nurses when compared using ICAS as previously reported,¹⁹⁶⁵ and discussed in chapter 5 of this thesis. Furthermore, doctors were more knowledgeable concerning basic local laws such as age of consent treatment, which was correctly identified by 70% of doctors but only 30% of nurses, as discussed above. There was no significant difference in knowledge and practice of IC between professional nurses with 4-years or more of university or nursing college education, compared to enrolled/staff nurses with a minimum of 2 years nursing college diploma. Both doctors and nurses were equally deficient in their interpretation of implied and presumed consent and its usage in clinical practice. There were some inconsistencies between nurses' understanding, when compared to patients, with fewer nurses disclosing elements of IC such as 'recommended treatment,' 'risks of refusing recommended treatment' and 'right of refusal', whereby nurses claimed comparatively higher percentages of disclosure when compared to patients as previously reported.¹⁹⁶⁶ With regard to the method of obtaining informed consent from patients, while most nurses (48%) claimed that they obtained written informed consent from patients rather than by verbal means as shown in figure 6.5 above, the majority of patients otherwise reported that informed consent was obtained verbally by HCPs in most cases,

¹⁹⁶² Mmamma ML, Mothiba TM and Nancy MR "Turnover of professional nurses at Mokopane hospital in the Limpopo province, South Africa: Experiences of nursing unit managers" 2015 *Curationis* Art. #1566 <http://dx.doi.org/10.4102/curationis.v38i2.1566> (Date of use: 28 July 2017.)

¹⁹⁶³ Khunou and Davhana- Maselesele 2016 *Curationis* Art. #1438 <http://dx.doi.org/10.4102/curationis.v39i1.1438> (Date of use: 28 July 2017).

¹⁹⁶⁴ Pillay R 2009 *Hum Resour Health* 7:15.

¹⁹⁶⁵ Chima 2013 *BMC Med Ethics* Suppl1 S3 [15].

¹⁹⁶⁶ Chima 2015 *Niger J Clin Pract* 54.

with only 19% of patients reporting that written informed consent was obtained by nurses and doctors respectively.¹⁹⁶⁷

6.11 LIMITATIONS OF THIS STUDY

Potential limitations of this study may include the fact that the study was carried out in selected public hospitals in an urban setting. It is possible that a similar study in a more rural setting in KZN province or elsewhere in South Africa could yield a different set of results based on the impact of socio-cultural factors prevalent in the rural setting. Further, similar studies carried out in private, for-profit hospitals, may yield a different set result, gleaned from IC studies in private hospitals in Greece, which indicate that doctors are generally more compliant with IC disclosures in such settings.¹⁹⁶⁸ However, another study from the Western Cape Province, South Africa, on ethical issues in nursing practice conducted in private hospitals, suggested there were similar deficiencies in nurses' knowledge regarding IC.¹⁹⁶⁹ It is therefore unlikely that nurses practicing in private practice settings in South Africa are more knowledgeable than those practising in public hospitals because nurses are generally trained using the same curricula in South African nursing colleges. However, there may be stricter compliance by private practitioners because of the added fear of negligence litigation, lower patient workloads, better remuneration of HCPs, and more educated and knowledgeable patients. It is hence recommended that future studies should endeavour to compare IC as practised in public hospitals with that in private practice settings in South Africa.

Finally, the data discussed in this study is based on the self-reporting of IC practises by nurses. I have therefore assumed that nurse respondents have provided an accurate report of their understanding of IC and current practice. However, if data reported on the research instruments are not an accurate reflection of the IC in practice, this could also

¹⁹⁶⁷ Chima 2015 *Niger J Clin Pract* 52.

¹⁹⁶⁸ Falagas ME, Akrivos PD and Alexiou VG *et al* "Patients' perception of quality of pre-operative informed consent in Athens Greece: A pilot study" 2009 *PLoS One* 4:e8073.

¹⁹⁶⁹ Stellenberg and Dorse 2014 *Curationis* Art. #38 <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 28 July 2017).

be an additional limitation to the interpretation of results from this study. However, since the report comprises results from a large sample of over 300 nurses from randomly selected public hospitals with variable experience, it is unlikely that this limitation would have contributed significantly to any bias, because the large sample size, variety of participant nurses, and application of multiple triangulation, have contributed towards minimizing bias and improving the reliability of this study.

6.12 CONCLUSIONS

The findings from this study with regard to knowledge of IC regulations by professional nurses in South Africa suggest the need for increased training of all categories of nurses in medical law, ethics and human rights, with particular focus on knowledge of basic local laws and healthcare regulations, especially as specified in the National Health Act.¹⁹⁷⁰ Despite specific laws which require that all HCPs must provide the key elements of IC to patients prior to medical treatment, this study has revealed that many nurses are not fully conversant with the basic requirements of IC as stipulated by the law. Further, the process of IC requires improved communication skills by nurses who may be hampered by multiple demands on their time, coupled with the excessive workload, in the public hospital setting. This study also demonstrated that the major barriers to IC practice in this setting include language difficulties, poorly educated patients, heavy workload and time constraints, as well as lack of administrative support in the form of interpreters. Therefore, it may be prudent public health policy for government as an employer to develop a 'corps' of trained interpreters to assist nurses in their work. This would ultimately result in better job satisfaction and less job attrition by professional nurses, leading to retention of nurses in public healthcare services. Moreover, training of nurses at nursing colleges and universities in South Africa may require modification of the nursing curricula to better reflect the job role of nurses which may include 'cultural brokerage' and also reflect the need for nurses to be proficient in the four roles identified for nurses in the IC process, i.e., *manager, patient advocate, witness and information giver*.¹⁹⁷¹ For patients who do not

¹⁹⁷⁰ National Health Act 61 of 2003.

¹⁹⁷¹ Susilo et al 2013 *Nurs Ethics* 413-425 [413].

speak English, additional time and effort may be required by nurses to provide the necessary information in the individual patient's language of choice, as well obtaining IC using the patient's chosen language, in order to ensure adequate understanding of information disclosed.

Low educational level identified as a barrier to IC by nurses is common amongst users of public hospitals in South Africa, as previously reported¹⁹⁷² and further discussed in chapter 7 below. It is important that nurses and other HCPs understand that they have a moral and legal obligation to obtain valid IC from all patients, regardless of how onerous the process maybe. Whereas it may present more challenges, IC among vulnerable patient groups is critical to ensure patient safety and the protection of human rights and dignity of patients compatible with a patient-centred healthcare services, and constitutional requirements.

6.13 Summary of chapter 6

This chapter summarises the findings from a cohort of professional nurses from EThekweni metropolitan municipality KZN who participated in the empirical part of this study. This was a cross-sectional quantitative descriptive study using semi-structured questionnaires for nurses, conducted simultaneously with the study by doctors, using the same questionnaire previously administered to doctors as described in chapter 5.

In this case only registered nurses with minimum 4 years university or nursing college education (professional nurses); or those with a minimum of 2 years nursing college diploma (enrolled/ staff nurses), were included in this study. Overall, 355 registered nurses completed the study, of which 85% were categorized as professional nurses, while 15% were enrolled nurses. The majority of participants were female (92%), with a median age of 39-years, and 1-41 years of professional experience. Information reportedly disclosed by nurses included diagnosis (77%); treatment options (68%); recommended treatment (65%); treatment benefits (71%) and risks (69%).

¹⁹⁷² Chima 2015 *Niger J Clin Pract* [51].

Data triangulation revealed some inconsistencies between nurses and patients with 25-41% of patients reporting non-disclosure regarding the 'right of refusal', 'treatment options' and 'risks of refusing recommended treatment' as required by the *National Health Act*. Nurses who completed this study appeared unfamiliar with basic legal provisions relating to the current age of consent to treatment, with only 30% nurses responded accurately. Similarly, with regard to the 'age of consent for termination of pregnancy' as stipulated by the *Choice on Termination of Pregnancy Act*, only 8% of nurses accurately selecting the correct response of 'any age'. Comparison of results obtained from nurses with those from doctors using an informed consent aggregate scores (ICAS) showed that nurses were significantly less knowledgeable about IC regulations, when compared to doctors and this difference was statistically significant ($p < 0.001$). However, there was no significant difference in knowledge between professional and enrolled nurses. Barriers or challenges to IC identified by nurses were 'language barriers', 'lack of education', 'workload', and 'time constraints', followed by 'lack of administrative support in the form of interpreters'.

From this study, one may conclude that professional nurses in South Africa may require continuing professional education in the areas of medical law, ethics human rights, and communication skills. Furthermore, nursing curricula at nursing colleges and universities may require revision to re-emphasize training on medico-legal issues in healthcare and communication skills. Provision of trained interpreters in public hospitals will help minimise language barriers, lighten nurses' workload, improve job satisfaction, minimize job attrition among nurses, and improve the overall quality of healthcare service delivery in South African public hospitals.

CHAPTER 7: PATIENTS' PERCEPTIONS ON INFORMED CONSENT PRACTICES BY HEALTHCARE PROFESSIONALS IN SOUTH AFRICA

7.1 A BRIEF OVERVIEW OF THIS STUDY

As discussed in previous chapters of this thesis, informed consent (IC) is a legally enforceable right in South Africa, based on constitutionally protected rights to bodily integrity and well-being. In terms of the law, specifically the National health Act,¹⁹⁷³ patients cannot be involved in medical treatment or research without IC. Healthcare providers must inform healthcare users or patients about diagnosis, risks, benefits, treatment options, and right of refusal in a language patients understand, based their literacy level.

This chapter of the thesis reports an empirical study on patients' perceptions of IC as practiced by doctors and nurses in South Africa. A cross-sectional descriptive study, using a semi-structured questionnaire was conducted among patients attending randomly selected public hospitals in EThekweni metropolitan municipality (Durban), KwaZulu-Natal province (KZN). Competent patients or legal surrogates were eligible for inclusion. IC was obtained from all participants. Four-hundred and four (404) participants completed questionnaires of which 68% were female. The median age of participants was 35 years (range 11-91 years). Most respondents spoke IsiZulu (55%), were single (56%), unemployed (66%), with secondary school education (69%). Patients were generally informed about diagnosis (81%), risks (57%), and benefits of treatment (61%). Few were informed about treatment options (41%), recommended treatment (28%), and right of refusal (25%). IC was obtained verbally in 73% of cases. Patients favoured disclosure of all material risks (78%) and few consulted surrogates before decision-making (76%). There was association between participant's age and knowledge of the age of consent to routine medical treatment ($p = 0.005$). Most patients were satisfied with information disclosed (91%), and did not feel coerced. Some were afraid to ask questions for fear of losing free treatment benefits (8%). This study revealed that patients using public hospitals are aware of the right to IC. However, many were vulnerable due to indigence.

¹⁹⁷³ National Health Act 61 of 2003.

Barriers to IC include poverty, language, and low educational level. South African patients prefer disclosure of all material risks, better communication skills by HCPs, and a shift towards informed or shared healthcare decision-making.

7.2 INTRODUCTION

7.2.1 The doctrine of informed consent in South Africa

Informed consent before medical treatment is a constitutionally protected right in South Africa.¹⁹⁷⁴ Section 12(2)(b) of the Constitution provides that “[e]veryone has the right to bodily and psychological integrity, which includes the right (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent”. Further, section 12(1)(c) of the Constitution states that “[e]veryone has the right to freedom and security of the person which includes-the right to be free from all forms of violence from public or private sources”.¹⁹⁷⁵ These constitutional rights to bodily integrity and security have been demonstrated in landmark judgments by South African courts prior to the enactment of the final Constitution, in cases such as *Stoffberg v Elliot*,¹⁹⁷⁶ *Esterhuizen v Administrator Transvaal*,¹⁹⁷⁷ and more recently in *Minister of Safety and Security v Xaba*,¹⁹⁷⁸ and *Castell v De Greef*.¹⁹⁷⁹

In most of these cases, South African courts have defended the patients’ right to bodily integrity and the need for information disclosure prior involvement in any medical treatment or surgical procedures. However, in some recent judgments in cases such *Minister of Safety and Security v Gaqa*,¹⁹⁸⁰ (hereinafter the *Gaqa* case), and the *Oldwage* case;¹⁹⁸¹ there have been some contradictory or conflicting judgments by some local courts. For example, in the *Gaqa* case, a South African High Court judge allowed a police

¹⁹⁷⁴ Constitution of the Republic of South Africa 1996.

¹⁹⁷⁵ The Constitution s12.

¹⁹⁷⁶ *Stoffberg v Elliot* [1923] CPD 148.

¹⁹⁷⁷ *Esterhuizen v Administrator Transvaal* [1957] (3) SA 710 (T).

¹⁹⁷⁸ *Minister of Safety and Security v Xaba* [2003] (2) SA 703 (D).

¹⁹⁷⁹ *Castell v De Greef* [1993] (3) SA 501.

¹⁹⁸⁰ *Minister of Safety and Security v Gaqa* 2002 (2) SACR 654 (C).

¹⁹⁸¹ *Louwrens v Oldwage* 2006 (2) SA 161 (SCA).

request to remove a bullet or bullets from the body of a suspected criminal, which was to be used in evidence against the accused. The judge based his judgment on sections of the Criminal Procedure Act,¹⁹⁸² as well section 36 of the Constitution, which provides for the limitation of rights.¹⁹⁸³ In the *Oldwage* case, the SCA overturned a High Court judgment by applying the questionable ‘reasonable doctor standard’ of information disclosure as established in the case of *Richter and another v Estate Hamman*,¹⁹⁸⁴ rather than the more recent ‘prudent patient standard’ based on the judgment of a full bench of the High Court in the *Castell* case.¹⁹⁸⁵ Following the High Court judgment in the *Castell* case,¹⁹⁸⁶ it has been suggested that South African jurisprudence appears to have shifted from a ‘reasonable doctor standard’ to the ‘prudent patient standard’ of information disclosure.^{1987,1988} Further, it has been argued that there was a shift in risk disclosure to the objective ‘material risks’ standard which is based on what a reasonable patient would attach importance to, in arriving at a decision whether to accept or refuse a recommended treatment.^{1989,1990,1991} The *National Health Act*¹⁹⁹² codified the requirements for IC before treatment by requiring in section 6 that every healthcare provider before treating a patient must amongst other requirements disclose the following:

- (a) The range of diagnostic procedures and treatment options generally available to the user.
- (b) The benefits, risks, and consequences generally associated with each option;
- (c) The user’s right to refuse health services and explain the implications, risks, obligations of such refusal.

1982 Criminal Procedure Act 1978.
 1983 The Constitution s36.
 1984 Richter and another v Estate Hamman 1976 (3) SA 226 (C).
 1985 Castell v De Greef [1993] (3) SA 501.
 1986 Castell v De Greef [1993] (3) SA 501.
 1987 Van Oosten 1995 *De Jure* 164-179.
 1988 Carstens and Pearmain *Foundational Principles* 673-694.
 1989 King and Moulton 2006 *A J Law Med* 429-501.
 1990 Chima 2013 *BMC Med Ethics* S3 [3-4].
 1991 Van Oosten 1995 *De Jure* 174-176.
 1992 National Health 61 of 2003.

(d) The health care providers must give the user this information in a language that the user understands and in a manner which takes into account the user's level of literacy.¹⁹⁹³

According to Van Oosten¹⁹⁹⁴ for consent to be used as a defence, the consenting individual must be fully aware of the following:

- a. what is consented to must be recognized by law, i.e. it must not be *contra bono mores*;¹⁹⁹⁵
- b. it must be given by a person capable in law of consenting i.e. by someone who is capable of forming an intention or of understanding what he consents to;
- c. it must be free or voluntary i.e. not induced by fear or force or fraud;
- d. the consenting party must have had knowledge and been aware of the nature and extent of the harm or the risk;
- e. the consenting party must have appreciated and understood the nature of the harm or risk;
- f. the consenting party must have consented to the harm or assumed the risk
- g. it must be comprehensive i.e. extend to the entire transaction inclusive of its consequences;
- h. it must be clear and unequivocal;
- i. it must precede the conduct in question;
- j. it must be manifested externally to qualify as a legal act;
- k. it must as a rule be granted by the plaintiff or claimant himself;
- l. the conduct in question must fall within the limits of the consent given i.e. it must not exceed the bounds of the consent given.^{1996,1997}

¹⁹⁹³ National Health 61 of 2003 S(6)

¹⁹⁹⁴ Van Oosten LLD Thesis 1989 [448-449] see also Carstens and Pearmain *Foundational Principles* [883-890].

¹⁹⁹⁵ Slabbert MN "South Africa" in *International encyclopedia of laws* 2014 [113-115] see also Carstens v Pearmain *Foundational Principles* 937.

¹⁹⁹⁶ Van Oosten LLD Thesis 1989 See also Carstens and Pearmain *Foundational Principles* [883-890].

¹⁹⁹⁷ Barit *The doctrine of informed consent in South African medical law* (LLM dissertation University of Pretoria 2016) 8.

Failure to follow these guidelines may result in offending HCPs being found guilty of assault, battery or negligence.^{1998,1999,2000}

7.2.2 Socio-cultural factors that may impact on informed consent in South Africa

Other factors which may impact on the practice of IC in South Africa and other African communities include socio-cultural issues such as language, education and literacy level, modern technology, economic factors and religion.^{2001,2002, 2003,2004,2005} South Africa is a multicultural middle-income country, with a population of around 54 million people,²⁰⁰⁶ with a high unemployment rate, and eleven official languages.^{2007,2008} The country has historical socio-cultural inequities resulting from an apartheid policy which left a section of the local population marginalized,²⁰⁰⁹ with a high unemployment rate currently estimated at around 27%.²⁰¹⁰ Because of these historical inequities, there is an apparent dichotomy in the provision of healthcare services with the majority indigent population, of about 88% uninsured in KwaZulu-Natal province, using publicly funded healthcare services, while the minority affluent populace use privately funded healthcare services.²⁰¹¹ This has created a situation of work overload, whereby doctors and other HCPs may be unable to comply

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- 1998 Stoffberg v Elliot [1923] CPD 148-150 see also Esterhuizen v Administrator Transvaal [1957] (3) SA 710 (T).
- 1999 Minister of Safety and Security v Xaba [2003] (2) SA 703 (D) see also Castell v De Greef [1993] (3) SA 501.
- 2000 Slabbert *International encyclopaedia of laws* 109-155.
- 2001 Ezeome and Marshall 2009 *Dev World Bioeth* 138–148.
- 2002 Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.
- 2003 Molyneux et al 2005 *Soc Sci Med* 443-454
- 2004 Jack C et al “Language, cultural brokerage and informed consent-will technological terms impede telemedicine use?” 2014 *S Afr J B L* 14-18.
- 2005 Chima 2015 *Niger J Clin Pract* S1-S7.
- 2006 Statistics South Africa *Mid-year population estimate 2014* <http://beta2.statssa.gov.za/> (Date of use: 20 July 2014).
- 2007 Schlemmer and Mash 2006 *SAMJ* 1084-1087.
- 2008 EThekweni Municipality *EThekweni language policy* <http://www.Durban.gov.za.eThekweniLanguagepolicy.pdf> (Date of use: 19 August 2014).
- 2009 Maphai VT “Affirmative action in South Africa -a genuine option?” 1989 *Social Dynamics* 1-24.
- 2010 Trading Economics *South Africa unemployment rate 2017* <https://www.tradingeconomics.com/south-africa/unemployment-rate> (Date of use: 27 June 2017).
- 2011 KZN Department of Health *KwaZulu-Natal Strategic plan 2010-2014* (Department of Health, KZN 2010) www.kznhealth.gov.za/stratplan2010-2014.pdf (Date of use: 29 June 2017).

with the legal requirements of IC, especially in public hospitals.^{2012,2013,2014} It has been suggested that there may be geographic and cultural barriers to the practice of IC even in developed countries such as the USA.^{2015,2016,2017} This has led most international ethical guidelines to recommend that cultural factors and language must be taken into consideration when obtaining IC from patients especially those in developing countries during biomedical research or treatment.^{2018, 2019, 2020, 2021}

7.2.3 Informed consent and current medical practice

The World Medical Association (WMA) aptly points out the dilemma that HCPs face in current times:²⁰²²

Until recently, physicians generally considered themselves accountable only to themselves, to their colleagues in the medical profession and for religious believers, to God. Nowadays they have additional accountabilities to their patients, to third parties such as hospitals and managed healthcare organizations, to medical licensing and regulatory authorities, and often to courts of law. These different accountabilities can conflict with one another.²⁰²³

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- 2012 Chima 2013 *BMC Med Ethics* Suppl1 S3.
2013 Schlemmer and Mash 2006 *SAMJ* 1084-1087.
2014 Chima *Understanding and practice of informed consent by professional nurses in South Africa* [89-102].
2015 Wennberg J and Gittelsohn A "Small variations in healthcare delivery-A population-based health information system can guide planning and regulatory decision-making"1973 *Science* 1102-1108.
2016 King and Moulton 2006 *A J Law Med* 430.
2017 Clark et al 2011 *J of Surg Educ* 143.
2018 United Nations Educational Scientific and Cultural Organization *Universal Declaration on Bioethics and Human Rights* (UNESCO Paris 2005).
2019 National Bioethics Advisory Commission *Presidential bioethics commission issues report on clinical trials research in developing countries* (NBAC Bethesda USA 2001).
2020 CIOMS *International ethical guidelines for biomedical research involving human subjects* (CIOMS-WHO Geneva 2016).
2021 International Bioethics Committee *Report of the International Bioethics Committee of UNESCO on Consent* (Social and Human Sciences Sector Bioethics Section UNESCO Paris 2008).
2022 World Medical Association *Medical Ethics Manual* 3rd ed (WMA Ferney-Voltaire Cedex France 2015).
2023 WMA *Medical ethics manual* 2015 [23].

Due to recent controversies surrounding the ethics of healthcare decision-making, a central dilemma has arisen in modern medical practice, which can be summarized as ‘*whether the principle of respect for autonomy should have priority over professional beneficence?*’²⁰²⁴ It has been argued by some scholars in bioethics that persistence with professional beneficence by doctors and other HCPs creates a culture of medical paternalism, which does not fully respect patients’ autonomy.²⁰²⁵ In these types of situation, the ethical principle of beneficence may come into conflict with the principle of respect for autonomy, thereby creating a tension in the doctor-patient relationship.²⁰²⁶ To promote patients’ autonomy it has been advocated by common law cases such as *Canterbury v Spence*²⁰²⁷ that:

The patients’ right to self-determination can be effectively exercised only if the patient possesses enough information to enable an intelligent choice...True consent to what happens to one’s self is the informed exercise of choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each...from these axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by the physician to the patient to make such a decision possible.²⁰²⁸

In view of the above, adequate information disclosure prior to IC has become the legal and ethical ‘standard of care’ for medical practice since late 20th century, demonstrated in the American cases of *Salgo v Leland Stanford University*,²⁰²⁹ where the term ‘informed consent’ was first applied in a case of trespass or assault, and *Natanson v Kline*,²⁰³⁰ where the charge of ‘negligence’ rather than assault was first applied to a case of lack of informed consent. Similarly the standard of information disclosure prior to consent have been debated in common law court cases such as the English case of *Bolam v Friern HMC*,²⁰³¹ where the *Bolam principle* or the ‘reasonable doctor standard’ was first applied in English

2024 Chima *A primer on medical law* 19.

2025 Chima 2009 *Trans J Coll Med S Afr* 43.

2026 Beauchamp and Childress *Principles of biomedical ethics* [176-194].

2027 *Canterbury v Spence* (1972) 464 F 2d 772 (DC Circuit).

2028 *Canterbury v Spence* (1972) 464 F 2d 772 [29-32].

2029 *Salgo v Leland Stanford Junior University Board of Trustees* 317 P 2d 170 CA (1957).

2030 *Natanson v Kline* 186 Kan. 393 (1960) 350 P2d 1093.

2031 *Bolam v Friern Barnet Health Management Committee* [1957] 2 All ER 118.

law, and the South African case of *Stoffberg v Elliot*.²⁰³² More recently, some bioethicists have argued for ‘shared decision-making’ in healthcare rather than ‘informed decision making’. These authorities have distinguished *informed decision-making* as “an individual’s overall process of gathering relevant information from both the clinician and other clinical and non-clinical sources with or without independent clarification of values.”²⁰³³ Shared decision-making, on the other hand, may be defined as a particular process of decision making by the patient and clinician during which the patient:

- (i) understands the risk or seriousness of the medical condition;
- (ii) understands the medical procedure including the risks, benefits, alternatives, and uncertainties;
- (iii) has weighed his or her personal values regarding the potential benefits and harms associated with the healthcare service;
- (iv) has engaged in decision-making at a level at which he or she feels comfortable; and finally
- (v) has come to a joint decision in association with the healthcare provider.

Advocates of shared healthcare decision-making argue that it promotes patient comprehension and autonomy, reduces unwanted medical procedures and malpractice claims, improves patient compliance, and decreases overall costs of healthcare service delivery.^{2034,2035,2036}

7.2.4 Elements of informed consent to medical treatment

In its ideal legal and ethical contexts, IC requires five key elements to establish validity. These key elements must include (i) competence, (ii) voluntariness (iii) information disclosure (iv) understanding of information disclosed, and (v) authorization or consent to

²⁰³² Stoffberg v Elliot 1923 CPD 148-150.

²⁰³³ Kaplan RM “Shared medical decision making: A new tool for preventive medicine” 2004 *Am J Prev Med* 81-83.

²⁰³⁴ King and Moulton 2006 *A J Law Med* 468-473.

²⁰³⁵ Charles C, Gafni A and Whelan T 1997 *Soc Sci Med* 681-692.

²⁰³⁶ Katz J *The silent world of doctor and patient* (Johns Hopkins University Press Baltimore 2002) ix-xxxiv.

the medical procedure or treatment.^{2037,2038} In medical practice, IC should ideally involve a conversation between a doctor or other HCP and the patient, initiated by the healthcare professional. This conversation must involve complete transparency, engagement by both parties, continuity, and may require evidence that it occurred, such as an eyewitness, documentation in the clinical notes, or a signed consent form.^{2039,2040} Informed consent could be withdrawn at any time by the patient as demonstrated in the case of *Ciarlariello v Schactr* (1993)²⁰⁴¹ where the Canadian Supreme Court held that “an individual’s right to determine what medical procedures will be accepted must include the right to stop a procedure”.²⁰⁴² Furthermore, a patient’s consent may be vitiated by any changes in material facts not previously communicated to, or approved by the patient.²⁰⁴³ Further, in accordance with some state laws, any exculpatory statements intended to deny any claims rights of the individual giving consent in order to protect responsible parties are expressly prohibited and may nullify consent.²⁰⁴⁴ Furthermore, valid consent in accordance with certain state regulations and case law requires the absence of coercion, undue influence or deception, as demonstrated in the English case of *Re T*.^{2045,2046} In this case, a patient refused blood transfusion because of coercion and undue influence by the mother, who was a Jehovah’s Witness. The court held that her refusal was not freely given because her will was overborne by undue influence from her mother. Therefore, her refusal did not represent an independent choice. The court therefore overruled her refusal and authorized blood transfusion in the patient’s best interests.²⁰⁴⁷

²⁰³⁷ Chima SC *Consent and patients’ rights* 34-36.

²⁰³⁸ Beauchamp and Childress *Principles of biomedical ethics* [89-90].

²⁰³⁹ Chima 2009 *Trans J Coll Med S Afr* 38-44.

²⁰⁴⁰ McCormick <http://depts.washington.edu/bioethx/> (Date of use: 31 August 2013)

²⁰⁴¹ *Ciarlariello v Schactr* (1993) 100 DLR (4th) 609 (SCC).

²⁰⁴² Hocton *Law of consent to medical treatment* 14.

²⁰⁴³ US Federal regulations on research in human subjects 45 CFR 46.116 (Federal Register 56 No.117 1991) *General requirements for informed consent* www.law.cornell.edu/cfr (Date of use: 29 June 2017).

²⁰⁴⁴ US Code of Federal Regulations 45 CFR 46.116-*General requirements for informed consent* www.law.cornell.edu/cfr (Date of use: 29 June 2017).

²⁰⁴⁵ UK Department of Health *Good practice in consent implementation Guide: Consent to examination or treatment* (HMSO London 2001) 3.

²⁰⁴⁶ *Re T (An Adult): Consent to Medical Treatment* [1992] 2 FLR 458 [799].

²⁰⁴⁷ Hocton *Law of consent to medical treatment* 7.

It is noticeable that US courts have become increasingly reluctant to dismiss personal injury claims on the ground that the victims consented to the injury causing risks. Therefore, these courts have disfavoured consent-based defences such as assumption of risk, and product warning, as a form of defence against negligence or battery.²⁰⁴⁸

7.2.5 Informed consent and patients' rights

Patients' rights may be defined as a combination of claims, liberties, powers and immunities that ensure the protection of the patient's dignity and moral autonomy.²⁰⁴⁹ This definition forms the core claims which patients may have against clinicians and defines the duties of clinicians to patients. Patient rights ensure access to data and information, protection from most kinds of unconsented activities. It suggests that patients may do no wrong by choosing to accept or refuse any recommended medical intervention.²⁰⁵⁰ Wear and others have described patient's rights and IC as enabling and empowering a patient population that has traditionally been largely powerless and mute in the face of medical expertise and authority.²⁰⁵¹ In this way, patients' rights while remaining based on the legal autonomy model, also extend beyond the confines of any particular legal system.²⁰⁵² Patients' rights during medical treatment and research have risen to prominence in the later part of the twentieth century, especially after the reported abuses of human subjects of biomedical research in the scientific literature,^{2053,2054,2055} and the moral conflicts between respect for autonomy and professional beneficence.²⁰⁵⁶ Further, recent advances in biomedical technology have also led to a constant rethinking of the rights of

²⁰⁴⁸ Schuck 1994 *Yale L J* 899-959 [908-911].

²⁰⁴⁹ Chima *Consent and patients' rights* 53.

²⁰⁵⁰ Chima *Consent and patients' rights* 53.

²⁰⁵¹ Wear A Geyer-Kordesch J and French R (eds) *Doctors and ethics: The historical setting of professional ethics* (Rodopi Amsterdam 2003).

²⁰⁵² Schuck 1994 *Yale L J* 899-959.

²⁰⁵³ Papworth MH *Human guinea pigs: Experimentation in man* (Beacon Press Boston 1967).

²⁰⁵⁴ Katz J *Experimentation with human beings* (Russell Sage Foundation New York 1972).

²⁰⁵⁵ Chima 2006 *BMJ* 848-851.

²⁰⁵⁶ WMA *Medical ethics manual* [37-41] see also Chima *A primer on medical law* 18-19.

individuals utilizing the beneficial aspects of modern science.^{2057,2058} Prior to these recent evolutions in bioethics and medical practice, with subsequent challenges to the *status quo*, the rights of patients have previously been based on medical paternalism.²⁰⁵⁹ Patients' rights were solely dependent on the goodwill of doctors and the presumption that doctors would act in the best interests of the patients.²⁰⁶⁰ With revelations of physician/researcher abuses however, and ongoing unethical research, ethicists and legal scholars began to question whether it was still appropriate for a patient to rely entirely on the judgment of doctors, and if not, how patients should be involved in the healthcare decision-making process.²⁰⁶¹ Further, as medical practice has become more industrialized and sophisticated, patients have become consumers of healthcare services rather than involuntary participants in the healthcare decision-making process, raising the questions about consumer rights.^{2062,2063} One aspect of the recognition of the moral autonomy of the patient has been the recognition of the need for adequate information disclosure, which would enable the patient to accept, reject or choose between different medical therapies, as first recognized in cases such as *Canterbury v Spence*²⁰⁶⁴ or as debated by the English House of Lords in the case of *Sidaway*.²⁰⁶⁵ Another aspect of this debate has been whether to persist with the 'reasonable doctor standard' as established in the case of *Bolam v Friern HMC*²⁰⁶⁶ or to follow the "prudent patient standard" as suggested by Lord Scarman in the *Sidaway* case,²⁰⁶⁷ and adjudicated in the South African case of *Castell v De Greef*,²⁰⁶⁸ and also recently confirmed as the accepted standard of care in most

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- 2057 Chima SC "The importance of ethics and human rights to Africa in the 21st century" 2014 *Arab Health Magazine* 3 http://arabhealthmagazine.com/the-importance-of-ethics-and-human-rights-to-africa-in-the-21st-century/ (Date of use: 25 September 2014).
- 2058 International Bioethics Committee *Report of the International Bioethics Committee of UNESCO on Consent* (Social and Human Sciences Sector Bioethics Section UNESCO Paris 2008).
- 2059 Beauchamp and Childress *Principles of biomedical ethics* [176-194] see also Chima 2009 *Trans J Coll Med S Afr* 43.
- 2060 WMA *Medical ethics manual* [23] see also Chima *A primer on medical law* 18-19.
- 2061 McLean SAM "A patient's right to know: Information disclosure the doctor and the law (Dartmouth Aldershot 1989).
- 2062 Schuck 1994 *Yale L J* 899-959.
- 2063 WMA *Medical ethics manual* [22-23] see also Chima *A primer on medical law* 18-19.
- 2064 *Canterbury v Spence* (1972) 464 F 2d 772 (DC Circuit).
- 2065 *Sidaway v Bethlem Royal Hospital Governors and Others* [1985] 1 All ER 643.
- 2066 *Bolam v Friern Health management Committee* [1957] 1 WLR 582.
- 2067 *Sidaway v Bethlem Royal Hospital Governors and Others* [1985] 1 All ER 643 see also Hocton *Law of consent to treatment* 35-37.
- 2068 *Castell v De Greef* [1993] (3) SA 501.

common law jurisdictions by the UK Supreme Court sitting in Scotland in the case of *Montgomery v Lanarkshire*.²⁰⁶⁹

Information disclosure is an important aspect of enhancing the patient's moral autonomy and ability to choose.²⁰⁷⁰ As suggested by Mclean, its potential invasiveness and its social and political potential make it an area ripe for rights discourse.²⁰⁷¹ Debates in this area have therefore focused on several issues including whether the doctors' duty to disclose based on the patients' right to receive information can be tested independently of patient understanding.²⁰⁷² However, if the patient is unable to understand, what is the point of disclosure? Is there hence a duty imposed on clinicians to ensure patient understanding prior to providing informed consent? There may also be concerns regarding the rationality of patient's decision-making, specifically with regard to the competence of incapacitated patients, minors, and other vulnerable members of society.^{2073,2074}

In light of the above, questions about competence, information disclosure, understanding, and the rights of vulnerable population groups have dominated contemporary debate on patients' rights, respect for autonomy, and the informed consent doctrine.^{2075,2076,2077} Some have questioned whether providing information about risks, benefits and alternatives actually improve patients' decision-making.²⁰⁷⁸ Schuck identified two obligations imposed on the doctors by these requirements. First, the fiduciary duty of care i.e. the duty imposed on doctors to put patients' interests above their own. Secondly, the problems associated with cost and resource allocation since the obligation on full information disclosure, which may actually increase the burden on healthcare

²⁰⁶⁹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

²⁰⁷⁰ Chima *Consent and patients' rights* 54 see also Beauchamp and Childress *Principles of biomedical ethics* 81-86.

²⁰⁷¹ McLean SAM *A patient's right to know: Information disclosure, the doctor and the law* (Dartmouth Aldershot 1989) see also Bal BS and Choma TJ "What to disclose? Revisiting informed consent" 2012 *Clin Orthop Relat Res* 1346-1356.

²⁰⁷² Chima *Consent and patients' rights* 51-56.

²⁰⁷³ Chima 2009 *Trans J Coll Med S Afr* 42-43.

²⁰⁷⁴ Chima *A gateway to biomedical research in Africa* 19-38.

²⁰⁷⁵ Katz *Experimentation with human beings* 1972.

²⁰⁷⁶ Chima 2006 *BMJ* 848-851 see also Chima *Consent and patients' rights* 51-56.

²⁰⁷⁷ McLean *A patients' right to know: Information disclosure, the doctor and the law* 1989.

²⁰⁷⁸ Schuck 1994 *Yale L J* 913-915.

resources.²⁰⁷⁹ Others have argued that shared healthcare decision-making may actually decrease healthcare costs for well-informed patients.^{2080,2081,2082,2083} Such observations seem to suggest IC should also be viewed in terms of cost-effectiveness.²⁰⁸⁴ Therefore, there may be need to re-conceptualize IC to suit the particular geographical or socio-cultural environment involved.²⁰⁸⁵ For example, it has been suggested that there may be need to reduce consent procedures in ‘minimal risk’ research or treatment while providing more information in ‘high-risk’ situations.²⁰⁸⁶ Further, not all patients require the same level of information disclosure, either due to personal choice or cultural belief systems. For example, it has been reported that among certain South Asian populations, the disclosure of negative information may be considered harmful,²⁰⁸⁷ while some Nigerian- African population groups are reportedly averse to negative information disclosure due to religious beliefs.²⁰⁸⁸ Consequently, one may argue that IC needs to be viewed as a normative variable, not an empirical constant, due to its cultural plasticity as suggested by Schuck.²⁰⁸⁹ Therefore effective implementation of IC should allow for different cultural belief systems and differences in regional or geographical medical practice.^{2090,2091,2092} However, the protections enshrined in the UNESCO Convention on Bioethics,²⁰⁹³ the Nuremberg code²⁰⁹⁴ and the ICCPR, amongst other instruments, are emphatic about the

2079 Schuck 1994 *Yale L J* 916-917.

2080 Kaplan 2004 *Am J Prev Med* 82.

2081 King and Moulton 2006 *A J Law Med* 468-473.

2082 Charles et al 1997 *Soc Sci Med* 681-689.

2083 Katz J *The silent world of doctor and patient* (Johns Hopkins University Press Baltimore 2002) ix-xxxiv.

2084 Schuck 1994 *Yale L J* 908-909.

2085 King and Moulton *A J Law Med* 478-480

2086 King and Moulton *A J Law Med* 481-486.

2087 Dein and Thomas 2002 *Europ J Pal Care* 5.

2088 Irabor and Omonzejele 2009 *Dev World Bioethics* 37.

2089 Schuck 1994 *Yale L J* 899-959 see also Chima *Consent and patients' rights* 54.

2021 Wennberg J and Gittelsohn A “Small variations in healthcare delivery-A population-based health information system can guide planning and regulatory decision-making” 1973 *Science* 1102-1108.

2022 Irabor and Omonzejele 2009 *Dev World Bioeth* 36-40 see also Ezeome and Marshall 2009 *Dev World Bioeth* 138–42.

2092 Dein and Thomas 2002 *Europ J Pal Care* 5.

2093 United Nations Educational Scientific and Cultural Organization *Universal Declaration on Bioethics and Human Rights* (UNESCO Paris 2005).

2094 Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (2) (US Government Printing Office Washington DC 1949)181-182.

implementation of an acceptable informed consent regimen in biomedical research and healthcare.²⁰⁹⁵

7.2.6 Rationale for the study

From the foregoing introduction it is obvious that there may be geographic and cultural barriers to the practice of IC, even in very developed but multicultural countries such as the USA.^{2096,2097} This has led most international ethical guidelines to recommend that cultural factors such as language and belief systems must be taken into consideration when obtaining IC from patients especially those in developing countries during biomedical research or treatment.^{2098,2099,2100} In chapters 5 and 6 of this thesis, I reported on the understanding and practice of informed consent by medical doctors²¹⁰¹ and professional nurses²¹⁰² in South African public hospitals.

In this chapter, I report on patient's actual experiences, perceptions and evaluation of the IC process at local public hospitals in EThekweni metropolitan municipality (Durban), KZN province, South Africa. This study was conducted concurrently with the study on doctors and professional nurses practicing in KZN provincial hospitals as reported in chapters 5 and 6.

²⁰⁹⁵ United Nations *International Convention on Civil and Political Rights (ICCPR)* (United Nations 1966) Article 7.

²⁰⁹⁶ Wennberg and Gittelsohn 1973 *Science* 1102-1108.

²⁰⁹⁷ Flores 2006 *N Engl J Med* 229-31 see also Clark et al 2011 *J Surg Educ* 143-47.

²⁰⁹⁸ National Bioethics Advisory Commission *Presidential bioethics commission issues report on clinical trials research in developing countries* (NBAC Bethesda USA 2001).

²⁰⁹⁹ Council for International Organizations of Medical Sciences *International ethical guidelines for biomedical research involving human subjects* (CIOMS-WHO Geneva 2016).

²¹⁰⁰ United Nations Educational Scientific and Cultural Organization *Universal Declaration on Bioethics and Human Rights* (UNESCO Paris 2005).

²¹⁰¹ Chima 2013 *BMC Med Ethics* S3.

²¹⁰² Chima *Understanding and practice of informed consent by professional nurses in South Africa* [89-102].

7.2.7 Aims and objectives of the study

The general objective of this study was to establish whether IC is obtained from patients prior to medical treatment in South African public hospitals. Specific objectives were to establish whether sufficient information was provided to patients; whether patients understand the information provided to them; whether patients providing IC to treatment are generally competent to consent to such treatment, and whether IC is obtained from patients voluntarily. Finally, the question asked was whether the IC provided by patients in this setting is truly valid, and consistent with the requirements of the National Health Act 2003²¹⁰³ and other pertinent local laws and regulations.

7.3 MATERIALS AND METHODS

7.3.1 Study population and location

The study location and stratified random sampling methodology used to select public hospitals and patient populations were previously described in detail in chapter 4 of this thesis. Briefly, this study was conducted at the outpatient clinics (OPD) and inpatient wards of selected public hospitals in EThekweni metropolitan municipality (Durban). Inclusion criteria were such that any adult and competent patient attending the selected hospitals during the period of study (March to June 2012), who were willing to participate voluntarily, was eligible for inclusion in the study. Exclusion criteria were mental incapacity and absence of parent or guardian to provide consent for children below the age of consent (12 years) in South Africa as stipulated by the Children's Act.²¹⁰⁴

7.3.2 Study instrument

The main study instrument was a semi-structured questionnaire in the English language, which was also translated into the IsiZulu language, the dominant language spoken by

²¹⁰³ National Health Act 61 of 2003.

²¹⁰⁴ Children's Act 38 of 2005.

about 81% of the population of KZN province.²¹⁰⁵ Professional translation of the questionnaire from English language to IsiZulu was done by the department of IsiZulu studies, University of KwaZulu-Natal. The questionnaire used for this study consisted of three sections. The first section collected socio-demographic data on the participants; the second part was designed to collect information on patient experiences of IC practices by healthcare providers during clinical encounters. The third section of the questionnaire asked questions about patient's general knowledge about healthcare, understanding and opinions on IC generally. Participants were interviewed by three trained bilingual research assistants or alternatively those patients who preferred were allowed to complete the questionnaire by themselves. Respondents had the option of completing questionnaires either in English or IsiZulu according to their wishes. The study was conducted in various hospital departments as illustrated in Figure 7.1 below.

7.3.3 Study design and statistical analysis

The preliminary sample size for this study was calculated using a web based sample size calculator, Raosoft®.²¹⁰⁶ Based on the formula for sample size and margin of error from Raosoft, a representative sample size of 385±20 patients was calculated (95% CI; P = 0.05). Data from questionnaires was transcribed directly into a computer software named statistical package for social sciences (SPSS)²¹⁰⁷ and analysed. The captured data was first checked for completeness and accuracy by both the PI (myself) and a qualified biostatistician. Descriptive statistics such as percentages, proportions, median, mode, and interquartile range were used to summarize the data. Scores for comprehension, understanding, information disclosure, voluntariness were worked out from the responses. Fisher's exact test was used to test for association between categorical variables and groups of patients. Pearson's chi-squared test was used to test for differences in responses between patients and HCPs (doctors and nurses). One sample Kolmogorov-Smirnoff test was used to test for the normality of patients' age distribution.

²¹⁰⁵ EThekwini municipality *EThekwini language policy*
www.Durban.gov.za.eThekwiniLanguagepolicy.pdf (Date of use: 19 August 2014).

²¹⁰⁶ Raosoft® <http://www.raosoft.com/samplesize.html> (Date of use: 12 June 2012).

²¹⁰⁷ IBM *SPSS Statistics for Windows version 21.0* (IBM Corp Armonk NY 2012).

7.3.4 Ethical considerations

Initial ethical approval for this study was obtained from a subcommittee of the research ethics committee at the University of South Africa (UNISA). The study protocol and biostatistical methodology was also reviewed and approved by the health research and knowledge management research ethics committee of the KZN Department of Health, and the EThekweni municipality health department. Ethical approvals were also obtained from the management of each of the hospitals included in the study. Finally, written IC was obtained from each respondent after full information disclosure prior to participation in the study.

7.4 RESULTS

7.4.1 Demographic characteristics of patient participants

Four-hundred and four (404) valid questionnaires were completed by patient respondents with few missing data. The clinical disciplines and hospital departments from which patient participants were recruited is shown in figure 7.1 below. The socio-demographic characteristics of the participants are summarized in tables 7.1 and 7.2 below. The majority of the questionnaires were completed by the patients themselves (88.2%, 351/398), while the remainder were completed by surrogates including parents or guardians (8.2%, 33/398). The majority of the participants in this study were female 68.2% (272/399); while 56% (225/403) were single and 37% (149/403) were married. The age of patient participants showed a normal distribution ($p < 0.001$, median = 35.5 years), with a range of 11-91 years. Most of the participants were bilingual, with 55% (222/403) IsiZulu speakers, about 49% also spoke the English language (195/403), 8% spoke IsiXhosa (32/403), and 2% (9/403) were Afrikaans speakers. Other minority languages spoken by this cohort of patients included Hindi, Tamil, Tswana and Sesotho. The majority of the patients reported having secondary school education (69%, 278/401); about 16% also had some tertiary education (65/401); 12% had primary education (49/401), whilst 2%

(9/401) reported having no formal education. The majority of the participants were unemployed 66% (262/398), while 27% (106/398) were employed. The majority of the participants also reported having no monthly income 65% (262/404). The detailed earnings of participants are shown in figure7.2 below.

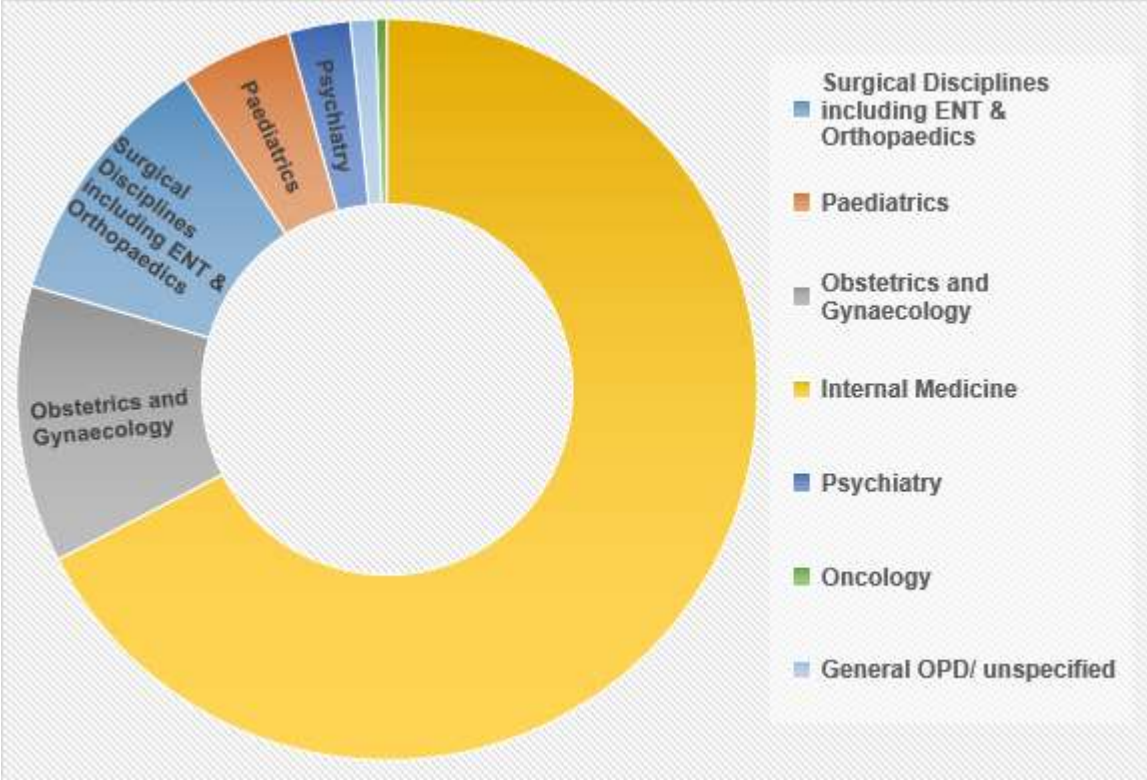


Figure 7.1: Percentage of patient participants by clinical departments

Table 7.1: Demographic characteristics of patient respondents

Characteristic	Number	%
Gender		
Male	127	31.4
Female	272	67.3
Missing	5	1.2
Age (years)		
Range	11-91	
Mean	38.093	
Median	35.50	
Standard deviation	15.84	
Age group (categorized in years)		
1-20	42	11.5
21-40	192	52.5
41-60	90	24.6
>61	42	11.5
Missing	38	9.4
Marital status		
Married	149	36.9
Single	225	55.8
Divorced	8	2
Widowed	21	5.2
Separated	0	0
Missing	1	

Status of minors (<18years)		
Orphaned	12	6.5
Living with parents	75	40.8
Living on my own	97	52.7
Total	184	100
Languages spoken		
English	195	48.3
IsiZulu	222	55.08
IsiXhosa	32	7.9
Afrikaans	9	2.2
Other (Hindi, Tamil, Sesotho, Tswana)	8	2
Educational Level		
Primary	49	12.2
Secondary	278	69.3
Tertiary	65	16.2
None	9	2.2
Missing	3	0.7

Table 7.2: Secondary demographic and social stratification data of patients

Characteristic	Number	%
Occupation		
Unemployed	262	65.8
Employed	106	26.6
Self-employed	15	3.8
Other (housewife, student, pensioner)	15	3.8
Missing	6	1.5
Monthly Earnings (Rands)		
No earnings	227	56.2
<1000	18	4.5
1001-3000	46	11.4
3001-5000	42	10.4
5000-10000	13	3.2
>10000	3	0.7
Don't know/refuse to disclose	55	13.6
Educational Level		
Primary	49	12.2
Secondary	278	69.3
Tertiary	65	16.2
None	9	2.2
Missing data	3	0.7

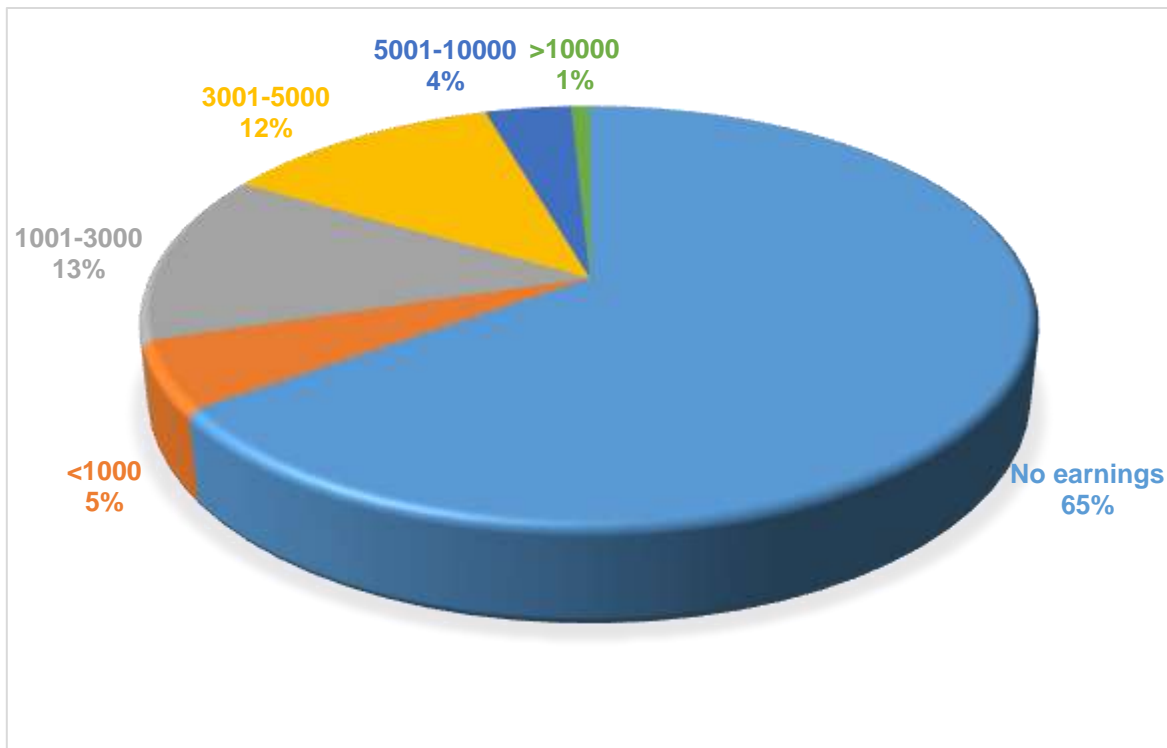


Figure 7.2: Monthly earnings of participants

Note: Salaries are shown in South African Rands (ZAR); 1\$ (USD) ≥ 13.5 ZAR (2015 rates).

7.4.2 Information disclosure

The majority of the respondents reported that a HCPs (doctors or nurses) explained the treatment or medical procedure to them 88% (355/403). Information provided to the patients included diagnosis as reported by 81% (326/403) of the patients; treatment risks reported by 57% (229/403) patients, and treatment benefits reported by 61% (245/403) patients. Less than half of the respondents were informed about treatment options as reported by 41% (165/403) patients; recommended treatment by 28% (113/403), and risks of refusing recommended treatment by 25% (99/403) of patients. Only 28% of

patients (113/403) reported that they were given information about their right of refusal. Detailed information regarding information disclosure is shown in table 7.4 below.

7.4.3 Patients preference on risk disclosure

The majority of patients reported that they would prefer to receive information on “all the risks” associated with a treatment or medical procedures as reported by 78% (304/391) of patients. Another 6% (22/391) of patients said they preferred to be informed about “some of the risks”, while 6% (22/391) of patients preferred to know “none of the risks”. Around 11% (43/391) of patients responded “don’t know” to this question. Patients’ preference regarding risk disclosure when compared to risks disclosed by HCPs is shown in table 7.3. Some reasons given by patients for requesting full disclosure of all material risks are reported verbatim in table 7.6 below. For example, some patients wanted to know about the side-effects of the drugs, because they were allergic to some medications. Others were more concerned about the impact of prescribed medications on their children, or on their pregnancy, or current health status. Those who preferred partial or none-disclosure of risks gave varying reasons for their choices. Some patients preferred not knowing about risks to prevent excessive worrying, while others stated that some of the information was irrelevant, as summarized in table 7.6.

Table 7.3: Nature of risks disclosed by doctors and nurses vs. preferred disclosure by patients

Risks Disclosed	Doctors Yes (%)	No (%)	Nurses Yes (%)	No (%)	P-value Pearson χ^2
Most common Risks	15/165(92)	13/165 (8)	256/320(80)	59/320 (18)	$\rho = 0.002$
Most Serious Risks	144/164(88)	18/164 (11)	134/319(42)	177/319(56)	$\rho = 0.000$
All Material Risks	35/165 (21)	117/165(71)	114/318(36)	183/318(58)	$\rho = 0.004$

Patients	
Preferred disclosure	risk Yes (%)
All of the risks	304 (78)
Some of the risks	22 (6)
None of the Risks	22 (6)
Don't Know	43 (11)

7.4.4 Time spent on information disclosure

Time spent by patients with doctors or other nurses during a clinical encounter, including obtaining IC ranged from less than 5 minutes as reported by 15% (58/399) of patients. Another 29% (115/399) of patients reported 5-10 minutes; while 10-20 minutes was reported by 23% (91/399) of patients; 20-30 minutes was reported by 13% (51/399) of patients, and more than 30 minutes reported by 15% (59/399) of patients. A breakdown of times spent on clinical encounters between HCPs and patients is shown in figure 7.3. However, it is unclear whether the amount of time reported here refers to the time spent on obtaining IC from patients or the entire clinical encounter. However, because most patients would not be able to distinguish between IC procedures and the entire clinical encounter between HCP and patient, one can assume that the time intervals reported by

patients' most likely correlate with the entire clinical encounter for each visit between a HCP and the patient.

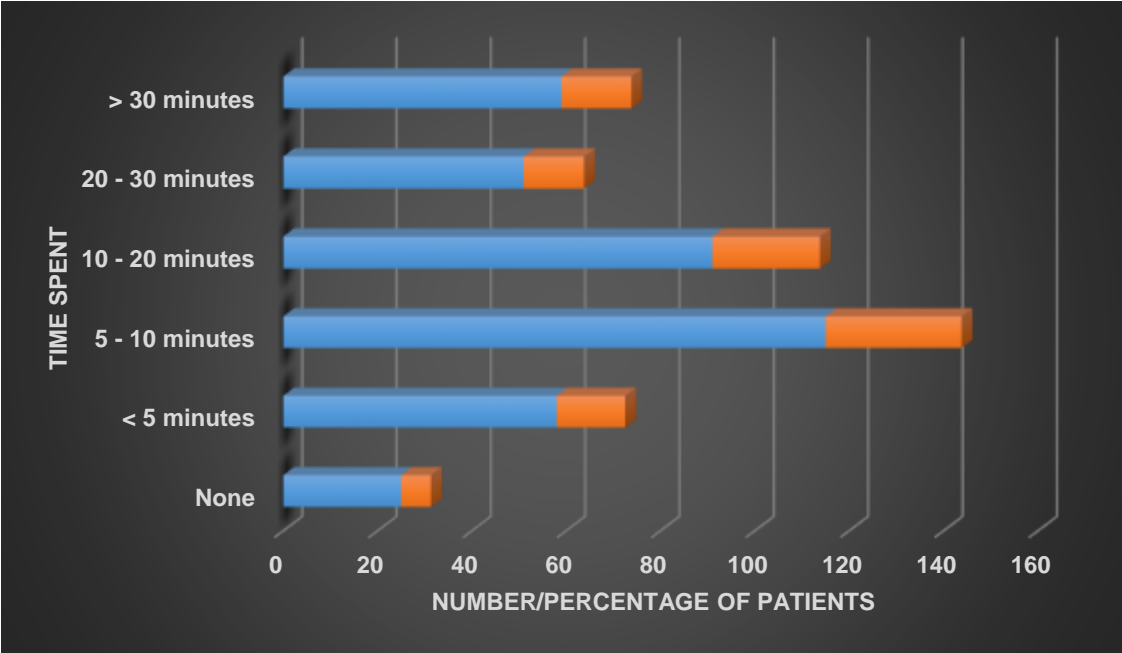


Figure 7.3: Time spent on IC/ clinical encounter by HCPs as reported by patients.

Table 7.4: Information disclosed by healthcare professionals to patient during IC

Information disclosed to patients	Yes (%)	No (%)	Don't know/ remember
Did the doctor/nurse explain treatment or procedure?	355 (88.1)	48 (11.9)	
Information provided:			
Diagnosis	326 (80.9)	77 (19.1)	
Treatment options	165 (40.9)	238 (59.1)	
Recommended treatment	113 (28)	290 (72)	
Risk of refusing recommended treatment	99 (24.6)	304 (75.4)	
Information on general risks	229 (56.8)	174 (43.2)	
Information on benefits	245 (60.8)	158 (39.2)	
Information on right of refusal	113 (28)	290(72)	
<i>Probing questions</i>			
In what language was information provided?			
English	257 (63.6)		
IsiZulu	131 (32.4)		
English and a local language	13 (3.2)		
Methods used to explain treatment?			
Words (verbally)	358 (89.3)	43 (10.7)	
Pictures/photographs	32 (8)	369 (92)	
Diagram	21 (5.2)	380 (94.8)	
Interpreter	14 (3.5)	387 (96.5)	
Did you understand the information provided?	355 (90.6)	31 (7.9)	6 (1.5)
Did you ask any questions about the treatment?	275 (70.3)	113 (28.9)	3(0.8)

7.4.5 Methods used to obtain informed consent and enhance information disclosure

The majority of patients in this cohort reported that informed consent was obtained 'verbally' by HCPs as reported by 73% (274/374) of patients. Another 19% (71/374) of patients reported that IC was obtained in a 'written' format; while 5% (19/374) of patients said both methods were used. Information disclosure and communication with patients were rendered using 'words' in the majority of cases as reported by 89% (358/401) of

patients. Further, the English language was used while discussing with patients as reported by 66% (255/384) of patients, while the predominant local language IsiZulu was the language of communication reported by 32% (124/384) of patients. Methods used to enhance information disclosure included pictures as reported by 8% (32/401) patients; diagrams as reported by 5% (21/401), and use of 'interpreters' as reported by 3.5% (14/401) of patients. The methods used to enhance communication or facilitate information disclosure to patients are summarized in tables 7.4 above, and 7.5 below.

Table 7.5: Methods used to communicate and enhance patient understanding

Methods used in obtaining enhancing disclosure or IC	Doctors Yes (%)	Nurses Yes (%)	Patients Yes (%)	P-value Pearson χ^2
Written	84/165 (50.9)	167/343 (48.7)	19/374 (19.0)	$\rho = 0.000$
Verbal	11/165 (6.7)	26/343 (7.6)	274/374 (73.3)	
Both	57/165 (34.5)	135/343 (39.4)	19/374 (5)	
It depends	13/165 (7.9)	15/343 (4.4)	(2.7)	
Methods used To explain to patients				
Words (verbal)	162/168 (96.4)		358/404 (89.3)	
Pictures/photos	34/168 (20.2)		32/404 (8)	
Diagrams	70/168 (41.7)		21/404 (5.2)	
Interpreters	121/168 (72)		14/404 (3.5)	

7.4.6 Understanding of information disclosed

The majority of patient respondents said they understood the information provided by HCPs as reported by 91% (355/392) of participants; while about 8% (31/392) answered "no" to this question. When asked if they were able ask any questions about their treatment, about 70% (275/391) of patients answered 'yes', while 29% (113/391) answered 'no'. When asked about reasons for not asking questions about treatment,

responses by patients included statements such as “doctor knows best”, or “I didn’t know what to ask”. Others said they were already familiar with their medical diagnosis and treatment regimen. Some complained that they did not have time to ask questions because doctors were in a hurry or too busy. *“The doctor was too fast he didn’t give me time to ask, he didn’t have time at all.”*

7.4.7 Voluntariness during informed consent

When patients were asked if the amount of information provided by HCPs was enough, about 74% (290/391) answered ‘yes’, while 24% (92/391) said “no”. When asked whether they made decisions regarding their treatment of their own free will, without input from others; about 95% (348/366) of patient respondents answered affirmatively. However, some respondents said they usually only followed orders from the doctor, with one stating: *“The doctors tell you what needs to be done and you do it.”* When asked if they could change their minds if they did not like the recommended treatment by HCPs, about 87% (309/356) of respondents answered ‘yes’ while 12% (41/356) of patients answered ‘no’. Several patients who stated that they could not change their mind regarding their treatment and explained it was because they had no choice or could not afford any alternative treatments as summarized in table 7.6 below. Statistical analysis using chi-squared tests showed that there was no significant association between patients’ age and knowledge of the right of refusal ($p = 0.334$); educational level and the right of refusal ($p = 0.404$); or income level and right of refusal ($p = 0.480$).

7.4.8 Potential impact of undue influence or coercion on patients’ informed consent

When patients were asked whether they were advised that they could accept or reject any recommended treatment or procedure, only 42% (153/370) answered ‘yes’. When asked if they felt threatened or were afraid to say ‘no’ during the clinical encounter, 8% (30/379) of patients answered ‘yes’ while the majority of patients, 91% (343/379) answered “no”. Patients’, who said they were afraid to say ‘no’, gave various reasons as detailed in table 7.6 below. Reasons given by patients include those who complained that they were afraid

because the doctor or HCP was simply too rude or aggressive or that they would be asked why they were refusing help. When patients were asked if they were given any perverse incentive or persuaded to accept any particular treatment; 9 patients or 2.4% (9/377) answered 'yes' while the majority of patients 97% (365/377) answered 'no'. Some of the patients who responded affirmatively said they were given some pills and money for bus fare. *"They gave me money and they said it was bus fare."* Another said; *"There are pills that they say we must take for them to see if they are working and they gave us R120."* Another was persuaded by being told it would benefit her in the end.

7.4.9 Involvement of surrogates by patients in healthcare decision-making

When patients were asked whether they sought assistance from any other person before deciding to accept or reject the treatment recommended by HCPs, the majority of patients 76% (274/363) answered 'no', while 24% (86/363) answered 'yes'. Regarding those who reportedly sought help from surrogates, about 11% (42/370) sought input from 'parents' while 6% (21/369) sought inputs from another family member. These included assistance or input from a husband reported by 3% (11/369) patients; about 2.4% (9/369) sought input from a 'friend'; another 1% (4/369) of patients received input from a wife, and less than 1% obtained input from a 'child'. A few patients also reported seeking input or assistance from a HCP (doctor or nurses). Others looked for information from the internet or in a few cases from another patient. Most of those seeking assistance or input from parents reported doing so because they were 'minors' currently dependent on their parents/guardians. Those seeking assistance from doctors or nurses felt that HCPs knew better about treatment options or they were seeking a second opinion from another HCP.

7.4.10 Specific comments by patients regarding informed consent and clinical encounters with HCPs.

Selected comments regarding various aspects of IC and the clinical encounter with HCPS are summarized in table 7.6 below.

Table 7.6: Selected verbatim responses from patient to questions on IC

<p>Patients choice on full risk disclosure</p>	<p><i>“Because I want to be informed. To be part of the decision making”</i></p> <p><i>“Because I want to know what the options are, and weigh them myself”.</i></p> <p><i>“Because i want to know what is going to happen or why; I also look up info on the internet”.</i></p> <p><i>“I have a right to know about everything because I’m the one who is going to be taking medication”</i></p> <p><i>“People are not the same, so I have to know about my medication because I have asthma so I am allergic to some medication.”</i></p>
<p>Patients choice on non-disclosure or reduced disclosure of risks</p>	<p><i>“Because I worry unnecessarily”</i></p> <p><i>“I don’t want to know irrelevant information”;</i></p> <p><i>It’s scary to know sometimes”</i></p> <p><i>“I think it’s a waste of time”.</i></p> <p><i>“Will knowing really make a difference?”</i></p>
<p>Voluntariness of consent: Patients who were afraid to say ‘no’</p>	<p><i>“If we say no to the treatment, we will be rejected and told to leave (victimization)”</i></p> <p><i>“Sometimes we face difficult situation where we need to say yes to everything”.</i></p> <p><i>“If I say no I will get in trouble but if I listen to whatever the nurse or doctor say I’m going to get help”.</i></p> <p><i>“When you desperate for help you do whatever they say, because if you don’t they just leave you.”</i></p>
<p>Patients who feel they have no choice or cannot refuse any recommended treatment because of poverty</p>	<p><i>“Because I’m not working i cannot afford to purchase medication by myself”</i></p> <p><i>“If I’m poor I can’t change my mind i have to accept because I don’t have money to go expensive hospital”</i></p> <p><i>“If I leave whatever medication provided to me it will be like committing suicide”</i></p>

7.4.11 General knowledge of relevant local laws by patients

When asked about the 'age of consent' to treatment by children in South Africa, most patient respondents answered wrongly, with 26% (96/373) choosing, "15 years". Another 33% (122/373) of patients chose '18 years'; while 11% (40/373) chose "21 years", and 6% (21/373) did not know the correct response. Only about 25% (94/373) of patients correctly answered "12 years". There was a statistically significant association between participants' age and knowledge of the 'age of consent' to treatment in South Africa ($p \leq 0.005$). Older patient age groups were more likely to respond correctly. There was no significant association between patients' educational level, or income level and knowledge of age of consent to treatment. Tests of statistical significance based on these criteria using chi-squared tests returned scores of ($p = 0.080$) for educational level, and ($p = 0.334$) for income level respectively.

7.5 DISCUSSION

This study was designed to evaluate patients' understanding and perceptions on the quality of IC as practiced by HCPs (doctors and nurses) in an urban public hospitals in South Africa. Patients reported being generally satisfied with the level of information disclosure during medical treatment with about 74% expressing satisfaction with information disclosed by HCPs. Patients also confirmed that doctors provided most of the information headings required by the National Health Act,²¹⁰⁸ which included diagnosis, general risks and benefits of treatment. This was consistent with a previous study on doctors practicing in the same clinical setting as previously reported,²¹⁰⁹ and discussed in chapter 5 of this thesis.

However, about 25-41% of patients reported that they were not given information on the right of refusal, treatment options, recommended treatment, and risks of refusing recommended treatment as stipulated by section 6 of the National Health Act.²¹¹⁰

²¹⁰⁸ National Health Act 61 of 2003.

²¹⁰⁹ Chima 2013 *BMC Med Ethics* S3.

²¹¹⁰ National Health Act 61 of 2003 (s6).

Concerning understanding of information disclosed, over 90% of patients stated that they understood the information provided by HCPs, and about 70% said they were able to ask questions about their treatment. However, about 30% of patients said that they were afraid to ask questions about their treatment for fear of losing the free treatment benefits provided in public hospitals. This was due to the fact that they were indigent and did not have any alternative means of obtaining healthcare services. This observation is consistent with a similar study in Kenya, where it was reported that patients appeared too timid or afraid to ask questions due to the fear of losing the benefits of free treatment provided during clinical trials or research.^{2111,2112} In terms of voluntariness of consent, the majority of patients in this study reported making healthcare decisions of their own free will, while those who sought assistance from surrogates reported involvement of mostly family members, friends and occasionally other healthcare workers (HCWs).

Most patients in this cohort also reported that there was absence of coercion or undue influence during the clinical encounter, with over 90% reporting that they were not afraid to say 'no' if they felt uncomfortable with the recommended treatment. This is somewhat unusual for developing country especially in Africa, where cultural and family influences are thought to play a major role in healthcare decision-making, as reported from studies in Nigeria²¹¹³ and Kenya.²¹¹⁴ This observation may indirectly indicate that South African patients are more aware of patients' rights and more sophisticated in terms of their understanding of IC when compared to patients from other developing countries in Africa. This may be a compliment to the passage and wide publication of the National Health Act,²¹¹⁵ and the patients' rights charter,²¹¹⁶ both of which required to be displayed by law in all public hospitals in South Africa. This observation may provide a good example to

²¹¹¹ Molyneux CS et al 2005 *Soc Sci Med* 443-454.

²¹¹² Molyneux C.S, Peshu N and Marsh K "Understanding informed consent in a low-income setting: three case studies from the Kenyan coast" 2004 *Soc Sci Med* 2547-2559.

²¹¹³ Ezeome and Marshall 2009 *Dev World Bioethics* 138-148 see also Irabor and Omonzejele 2009 *Dev World Bioethics* 34-42.

²¹¹⁴ Molyneux CS et al 2005 *Soc Sci Med* 443-454 see also Molyneux et al 2004 *Soc Sci Med* 2547-2559.

²¹¹⁵ National Health Act 61 of 2003.

²¹¹⁶ HPCSA *National patients' right charter* (HPCSA Pretoria 2008).

other countries in Africa, such as Nigeria, who are yet to legally enforce healthcare laws in their own jurisdictions.²¹¹⁷

Most patients in this cohort also reported that there was no perverse influence on their healthcare decision-making such as financial inducement or threats, except few who reported being given money for 'bus fare'. The latter were probably patients involved in ongoing clinical trials that were financially compensated for participation, although the amount of 120 ZAR reported here by these patients was less than the nationally recommended rate of 150 ZAR per day according the South African National Health Research Ethics Committee.²¹¹⁸ The majority of patients in this study reported that the amount of time spent on the IC process and clinical encounters between HCPs and patients was within the range of 5 to 20 minutes, consistent with the timeframe previously reported by doctors as discussed in chapter 5 of this thesis. However, it is unclear from the patients' account whether time spent with patients refers to time specifically spent on obtaining IC, or also includes the time spent on the entire clinical encounter with HCPs. One can assume that it is probably the latter, since most doctors in the public hospitals are very busy with a large caseload, thereby militating on time spent on IC as previously observed.²¹¹⁹ On the other hand, this timeframe of less than 20 minutes is consistent with the time spent on the entire clinical encounter during outpatient hospital visits as reported from other jurisdictions like USA, where the estimated duration of an average primary care visit is reported to be 15 minutes.²¹²⁰ Some cultural factors impacting on IC in this population under study includes unemployment and poverty, with over 65% of patients in this cohort reportedly unemployed and another 56% reporting no monthly income whatsoever. Other cultural issues identified from this study include language difficulties, with majority of patients speaking IsiZulu or other African languages, while communication with HCPs on IC was predominantly in the English language. Language as a barrier to IC

²¹¹⁷ Akinloye A "Nigeria's National Health Bill: Delayed, disputed and desperately needed" www.Thinkafricapress.com (Date of use: 13 September 2014).

²¹¹⁸ National Health Research Ethics Committee "Payment of trial participants in South Africa: Ethical considerations for research ethics committees South Africa" (NHREC Pretoria 2012).

²¹¹⁹ Chima 2013 *BMC Med Ethics* S3 [7-8].

²¹²⁰ Kaplan 2004 *Am J Prev Med* 81.

was previously reported in other studies from South Africa,^{2121,2122} and the USA.^{2123,2124} Language as a barrier to IC was also reported by doctors and professional nurses in this setting as previously discussed in chapters 5 and 6 of this thesis. However, this barrier or constraint did not seem to affect understanding of information in this cohort of patients, with over 90% of respondents claiming they understood the information provided by HCPs. Nonetheless, there were some inconsistencies with previous reports where doctors claimed that IC was obtained in writing in 51% of cases as reported in chapter 5 of this thesis, compared with patients in this study who reported that IC was obtained verbally in over 75% of cases. In addition, doctors reported giving patients information on right of refusal in 65% of cases, while patients reported only 28% disclosure. Further, doctors reported using interpreters in 72% of cases when obtaining IC as reported previously,²¹²⁵ and discussed in chapter 5 of this thesis. On the other hand, patients in this cohort reported that interpreters were involved in only 3.5% of clinical encounters. This inconsistency cannot be readily explained, although it could be due to the practice of “cultural brokerage”, whereby nurses may be used to “translate, mediate and negotiate on behalf of patients”.²¹²⁶ In the clinical setting, patients may not readily recognize or relate the use of interpreters during clinical encounters, while a doctor or nurse may report otherwise, due to the fact that they are more aware that using nurses or other healthcare workers (HCW) as an ‘interpreter’ during a clinical practice, is not part of their job description, but rather an informal arrangement employed in the absence of suitable alternatives.

Finally, patients showed a poor knowledge of the legal age for consent in South Africa, with only 25% identifying the current age of consent to routine treatment. Overall patients in this study were satisfied with their encounter with HCPs, although they preferred being involved in the healthcare decision-making process via informed or shared healthcare

²¹²¹ Schlemmer and Mash 2006 *SAMJ* 1084-1087.

²¹²² Jack et al 2014 *S Afr J B L* 14-18.

²¹²³ Flores 2006 *N Engl J Med* 229-231.

²¹²⁴ Clark et al 2011 *J of Surg Educ* 143-147.

²¹²⁵ Chima 2013 *BMC Med Ethics* S3 [7].

²¹²⁶ Jezewski 1990 *West J Nurs Res* 497-513 see also Shaibu 2007 *Nurs Ethics* 507.

decision-making.^{2127;2128} The findings from this study appear consistent with reports from other parts of Africa such as Nigeria²¹²⁹ and Kenya,²¹³⁰ as well as from Greece.²¹³¹ In these cases, patients felt that while IC was important, they also wanted to be involved in decisions affecting their healthcare. It has been suggested by some American researchers that informed and shared decision-making represent important aspects of preventive medicine and public health.^{2132,2133}

Recommendations by patients in this study regarding improvement IC practices in this setting include improved communication skills by HCPs, with many patients complaining that doctors were too busy, rude or aggressive. Patients' responses to this question included comments such as:

"Bit more time spent with each patient will help," and "communicate better with patients". Others said, *"Doctors need to give all the important information without patients asking."* Another patient commented, *"I think nurses must try to spend more time explaining the treatment because sometimes they just right (write) in your card and you can hardly see what is written."* And another, *"I think they must be more careful with our documents and they must also learn how to speak to patients."* Finally, *"I think they need to manage their time better."*

²¹²⁷ Kaplan 2004 *Am J Prev Med* 81 see also "Rethinking informed consent: The case for shared medical decision-making" 2006 King and Moulton 2006 *A J Law Med* 429-501 and Whitney SN et al A "Typology of shared decision making informed consent and simple consent" 2003 *Ann Intern Med* 54-59 [55-56].

²¹²⁸ Charles et al 1997 *Soc Sci Med* 681-692.

²¹²⁹ Adeleye OA and Tobin EA "Hospitalized patients in a Nigerian community consider informed consent necessary?" 2013 *AJOB Prim Res* 51-56.

²¹³⁰ Molyneux CS et al 2005 *Soc Sci Med* 443-454 see also Molyneux et al 2004 *Soc Sci Med* 2547-2559 and Gikonyo C et al "Taking social relationships seriously: Lessons learned from the informed consent practices of a vaccine trial on the Kenyan coast" 2008 *Soc Sci Med* 708-720 [718-719].

²¹³¹ Falagas ME et al "Patients' perception of quality of pre-operative informed consent in Athens Greece: A pilot study" 2009 *PLoS ONE* 4-e8073.

²¹³² Sheridan et al and Shared-decision making workgroup of the US preventive services task force. "Shared decision making about screening and chemoprevention: A suggested approach from the U.S. preventive services task force" 2004 *Am J Prev Med* 56-66.

²¹³³ Bris P et al "Promoting informed decisions about cancer screening in communities and healthcare systems" 2004 *Am J Prev Med* 67-80 see also Kaplan 2004 *Am J Prev Med* 82.

7.6 LIMITATIONS OF THIS STUDY

Potential limitations to this study include the fact that it was carried out in an urban metropolitan municipality in South Africa (Durban), with an arguably better-educated and more knowledgeable population of patients by African standards. It is possible that a similar study in a rural location in KZN province or other rural parts of Africa may yield a different result. Further, it is also unclear whether a study in a more cosmopolitan South African city such as Cape Town or Johannesburg with different population demographics may or may not produce a different result. It is possible that similar studies on patients utilizing private healthcare services may also produce a different result, because it has been suggested that doctors in private healthcare setting in Greece are more likely to provide detailed information to patients.²¹³⁴

7.7 CONCLUSIONS

This study confirms that majority of patients utilizing South African public hospitals are vulnerable because of their indigence and lack of alternative means of obtaining healthcare. This study also shows that despite their evident vulnerability, most patients in this setting are generally aware of their right to information disclosure, human rights and dignity in healthcare. Patients want to be informed and to participate in informed or shared healthcare decision-making. This study partly supports previous reports by doctors and nurses regarding the IC practices in South Africa as discussed in chapters 5 and 6 of this thesis, although there were some areas of inconsistency in actual practice, with patients and HCPs differing on certain items of information disclosure, such as right of refusal; and the methodology of information disclosure, such as use of interpreters. The major cultural factors militating against IC in this cohort include poverty and poor communication skills by HCPs. One can therefore conclude that there is need to further educate patients and HCPs on patients' rights and the legal requirements of IC, with continuous professional training of HCPs in ethics, medical law and communication skills. This will improve the doctor or HCP-patient relationship, and enhance patient's rights and human dignity.

²¹³⁴ Falagas et al 2009 *PLoS ONE* 4-e8073 [5].

Future research should focus on details of informed and shared healthcare decision-making, as well as comparative studies of IC in public and private healthcare facilities, in order to improve the overall quality of curative and preventive healthcare services in South Africa.

7.8 Summary of chapter 7

This chapter summarizes the findings from patients who participated in this empirical study. It provides patients perspectives on the practice of IC by HCPs at provincial hospitals in KZN province. To summarize the findings from this aspect of the study: Four-hundred and four (404) patients completed the patients questionnaire of which majority were female (67%) and 56% were unmarried. Most of the patient participants completed the study questionnaires on their own behalf (88%), while about 9% were surrogate parents or guardians completing on behalf of minors or others. The majority of participants in this study were IsiZulu speakers (55%). The major findings in this part of the study was that majority of patients attending public hospitals were indigent, with 66% being unemployed and 56% having no monthly earnings whatsoever. In terms of IC and information disclosure, majority of respondents said they were informed about their diagnosis (81%); risks of treatment (57%) and benefits of treatment (61%). Fewer patients were informed about recommended treatment (28%); risks of refusing recommended treatment (25%) and the right of refusal (28%). Most patients said HCPs communicated with them verbally using the English language. Patients also said they were satisfied with the amount of information disclosed (74%), but most would prefer disclosure of “all risks” during IC. However, some patients only wanted ‘some risks’ disclosed, while a few did not want any information regarding risks of treatment. In terms of voluntariness, most patients said they made decisions regarding their treatment choices by themselves, voluntarily, and without any form of coercion, although a small number of respondents did ask for input from surrogates including family members or HCPs. When asked if they were afraid to ask questions about their treatment from HCPs, majority of respondents said ‘no’; however a few participants said they were afraid to ask questions because they could not afford to lose the free treatment benefits provided in public hospitals. Most patients wanted

to be involved in their healthcare decision-making process, and urged HCPs to improve their communication skills and time management. Based on comparisons between doctors, nurses and patients, one was able to identify some inconsistencies between the responses by HCPs when compared to patients. For example, while doctors and nurses claimed that IC was obtained in writing in most cases, patients reported that they gave IC verbally (73%), compared to 51% of doctors and 49% of professional nurses who reported that they usually obtained IC in writing. Further, while between 24 to 28% patients said they were not informed regarding recommended treatment, risks of refusing recommended treatment, and right of refusal; most doctors and nurses (65-88%) claimed that they disclosed such information to patients.

From this study, I was able to conclude that majority of patients attending public hospitals in KZN are vulnerable due to poverty and indigence, consistent with the criteria for vulnerability, which includes, poverty, low education and lack of alternative means for obtaining healthcare.^{2135,2136} Although patients from this study were poor and indigent, they were still aware of their rights to IC, since the majority of patient respondents preferred full information disclosure and wanted shared decision-making with regard to their own healthcare. Some parts of this study have been published as a peer-reviewed journal article in an accredited biomedical journal.²¹³⁷ A hard copy of the published journal article is attached in Annexure 3 of this thesis.

²¹³⁵ Chima *A gateway to biomedical research in Africa* 19-38 see also Chima *A primer on medical law* 169.

²⁰⁶⁷ CWG “Summary of discussions on vulnerability criteria and targeting” (Cash working Group Jordan 2013) www.CWG-schematics/vulnerabilitycriteriaandtargeting-June2013.pdf (Date of use: 27 November 2017).

²¹³⁷ Chima 2015 *Niger J Clin Pract* S46-S56.

CHAPTER 8: SYNTHESIS AND DISCUSSION

8.1 INTRODUCTION

In first part of this chapter, I will analyse the legal, ethical, and socio-legal findings pertaining to IC and its implications. While in the second segment I will summarize the justifications and findings from the empirical research studies conducted among HCPs and patients attending public hospitals in within EThekweni metropolitan municipality, KZN. Finally I will summarize the implications of the findings from both the literature review and empirical studies for the practice of informed consent in South Africa.

8.2 Recent developments in South African jurisprudence on informed consent since enactment of the National Health Act 2003

8.2.1 Impact of constitutional provisions on the informed consent doctrine

Informed consent has been defined as a person's "knowing choice" about a medical treatment or procedure made after a physician or other HCP discloses whatever information a reasonably prudent provider in the medical community would give to a patient regarding the risks involved in the medical treatment or procedure.²¹³⁸ IC has also been defined as "an autonomous authorization by individuals of a medical intervention or participation in research based on full information disclosure and complete understanding of all the consequences."²¹³⁹ Informed consent is an established doctrine in South African law based on court judgments in cases such as *Stoffberg v Elliot 1923*²¹⁴⁰ and *Esterhuizen v Administrator Transvaal 1957*²¹⁴¹ and the *Castell case*.²¹⁴² Informed consent in South African law operates under the doctrine of *volenti non fit injuria*, that is, to a willing person; no harm can be done; as argued by authoritative South African legal scholars.²¹⁴³

²¹³⁸ Garner BA (ed) *Black's law dictionary* 10th ed (West Publishing Minnesota 2017) 346.

²¹³⁹ Chima *Consent and patients' rights* 35 see also McCormick "Informed consent its basis problems uncertainties" <http://depts.washington.edu/bioethx/> (Date of Use: August 2013).

²¹⁴⁰ *Stoffberg v Elliot 1923 CPD 148-150*.

²¹⁴¹ *Esterhuizen v Administrator Transvaal 1957 (3) SA 710 (T)*.

²¹⁴² *Castell v De Greef 1994 (4) 408*.

²¹⁴³ Van Oosten LLD Thesis 1989 see also Carstens and Pearmain *Foundational Principles* 875-876.

However, in recent times, the foundational basis for IC practice is derived from the Constitution.²¹⁴⁴

Section 12(2) (b) of the Constitution states that:

Everyone has a right to bodily and psychological integrity, which includes the right –

(b)To security in and control over their body”

(c)*Not to be subjected to medical or scientific experiments without their informed consent.*

(emphasis added)

Section 12(1) of the Constitution further states that:

Everyone has the right to freedom and security of the person, which includes the right-

(b)To be free from all forms of violence from either public or private sources.

It has been argued that the Constitution provides clear provisions with regard to an individuals’ physical integrity, whereby such integrity can only be interfered with, based on the doctrine of *volenti non fit injuria*.²¹⁴⁵ In the case of *Christian Lawyers Association v Minister of Health*,²¹⁴⁶ the court stated as follows:

The concept of [informed consent] is not alien to our common law, it forms basis of the doctrine of *volenti non fit injuria* conduct that would otherwise have constituted a delict or crime if it took place without the victim’s informed consent. More particularly, day to day invasive medical treatment, which would otherwise have constituted an invasion of a patient’s privacy and personal integrity, is justified and is lawful only because, as a requirement of the law, it is performed with the patient’s informed consent.

Some authorities have suggested that the statements of “security in” and “control over” their own body as stated in section (12) (2) (b) of the Constitution refer separately to the right to bodily integrity against intrusion from “either public or private sources”; while the

²¹⁴⁴ Constitution of the Republic of South Africa 1996.

²¹⁴⁵ Barit A *The doctrine of Informed Consent in South African Medical Law* 9.

²¹⁴⁶ *Christian Lawyers Association v Minister of Health (Reproductive health Alliance as Amicus Curiae)* 2005 (1) SA 509 (T) see also *Carstens v Pearmain Foundational Principles* 983.

term “control of” would refer to the right to be left alone to live life as one chooses.²¹⁴⁷ This is also related to privacy rights as stipulated in section 14 of the Constitution.²¹⁴⁸ It is important to understand that the constitutional protections for bodily integrity and privacy are not unfettered, in that some trivial or other forms of interference to bodily integrity could be allowed based on the constitutional provision relating to the limitation of rights.²¹⁴⁹ Section 36 of the Constitution on the limitation of rights states:

(1)The rights in the Bill of Rights maybe limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors including-

- (a) the nature of the right;
- (b) the importance and purpose of the limitation
- (c) the nature and extent of the limitation
- (d) the relation between the limitation and its purpose; and
- (e) less restrictive means to achieve the purpose

Such limitations have been used in South African courts to limit the rights to bodily integrity and privacy, as was applied by a high court judge the case of *Minister of Safety and Security v Gaqa*.²¹⁵⁰ In this case, the court allowed a police request for extraction of bullets from the body of an accused criminal, which was to be used as evidence in his criminal trial. The judge justified this decision by referring to the constitutional provisions on the limitation of rights, based on public interests, as well as provisions in the Criminal Procedure Act,²¹⁵¹ which allowed police to examine individuals against their will or by force in section 27,²¹⁵² or in order to obtain identifying marks and features e.g. fingerprints as stipulated in section (37) (1) (c) of the same Act.²¹⁵³ By contrast, the High Court in the

²¹⁴⁷ Currie I and De Waal J *The bill of rights handbook* (Juta & Company Ltd Cape Town 2014) 287 see also MDCN v Okonkwo (2002) AHLR 159 (NgSC 2001) and Chima A *primer on medical law* 74.

²¹⁴⁸ The Constitution (s14).

²¹⁴⁹ Barit *The doctrine of informed consent in South African medical law* 10.

²¹⁵⁰ Minister of Safety and Security v Gaqa 2002 (2) SACR 654 (C).

²¹⁵¹ Criminal Procedure Act 51 of 1977.

²¹⁵² Criminal Procedure Act 1977 (s27).

²¹⁵³ Criminal Procedure Act (s37) (1) (c).

case *Minister of Safety and Security v Xaba*,²¹⁵⁴ denied a similar police request for the removal of bullets from the body of an accused criminal, to be used in his criminal trial. The judge in this case stated that granting such a request would contravene the individual's constitutionally protected rights to bodily integrity and privacy, and that sections stated by the former judge with regard to sections 27 and 37 of the *Criminal Procedure Act*²¹⁵⁵ did not permit forceful removal of an object from the body of a person. The judgment in the former case has been duly criticized by some legal scholars on basis that it was grounded on a misapplication of the limitation of rights clause in the Constitution, as well as a misinterpretation of Criminal Procedure Act.²¹⁵⁶ It must be said that such contradictory and inconsistent judgments by South African courts regarding the constitutionally protected right to bodily integrity may send mixed messages to the legal fraternity and society in South Africa pertaining to the doctrine of informed consent and individual autonomy. In conclusion, the Bill of Rights has richly contributed to the current demands for the individual rights to bodily integrity, self-determination, privacy, equality, dignity, full information disclosure, administrative and social justice, subject to the limitations imposed by section 36 of the Constitution.²¹⁵⁷

8.2.2 Impact of the National Health Act on the informed consent doctrine

The National Health Act,²¹⁵⁸ which was assented to by the President of the Republic of South Africa and gazetted in 2004,²¹⁵⁹ codified the requirements for informed consent by giving effect and providing details to the principles established in the Constitution.²¹⁶⁰ The act stipulates in section 7(1) that:

Subject to section 8, a health service may not be provided to a user without the user's informed consent,

²¹⁵⁴ *Minister of Safety and Security v Xaba* 2003 (2) SA 703 (D).

²¹⁵⁵ Criminal Procedures Act 51 of 1977 (S 27 and 37).

²¹⁵⁶ Carstens and Pearmain *Foundational Principles* [924-926].

²¹⁵⁷ The Constitution (chapter 2) see also Carstens and Pearmain *Foundational Principles* 875.

²¹⁵⁸ National Health Act 61 of 2003.

²¹⁵⁹ National Health Act 61 of 2003 Government Gazette Vol 469 No 26595 Cape Town 23 July 2004.

²¹⁶⁰ Constitution of the Republic of South Africa 1996.

Further, section 7(2) of the same Act states that:

A health care provider must take all reasonable steps to obtain the user's informed consent.

In section 7(3), the Act defines informed consent as follows:

For the purposes of this section "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.

Furthermore, section 8(1) the Act requires that healthcare users must be able to participate in healthcare decision-making where it states that:

A user has the right to participate in any decision affecting his or her personal health and treatment.

From the foregoing, it becomes apparent, that lawful informed consent before medical treatment is a requirement of South African law. Section 6 of the Act further stipulates that healthcare "users to have full knowledge" by specifying the elements of such full knowledge to include:

6. (1) 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 and explain the implications, risks, obligations of such refusal.

(2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

Sections 7 and 8 of the Act further detail conditions under which treatment may be provided without the users informed consent, or where the healthcare user does not have

the capacity to provide consent. A detailed analysis of the elements and subsections in section 6 of the Act will show what information a HCP is obliged to give to a patient or healthcare user prior to obtaining informed consent. Section (6) (2) further provides that HCPs must take into consideration the healthcare users' language and literacy level; which shows that a HCP must assess each patient to determine not only the language they will understand, but also the extent of their literacy in order to provide this information in such a way that the healthcare user will comprehend and appreciate it enough to give the required consent or refusal. It has also been argued that the requirement for only 'knowledge' and the absence of the requirement for 'appreciation' is a deficiency which may need to be remedied in the National Health Act, since it provides a legal *lacuna* which requires a somewhat superficial and incomplete IC process only and which could be exploited by HCPs.²¹⁶¹

According to Van Oosten, 'knowledge' during informed consent must also include 'appreciation' whereby "information as a *sine qua non* for informed consent must include both knowledge and appreciation".²¹⁶² Finally, it has also been submitted that the use of the phrase 'where possible' with regard to the requirement for language creates another *lacuna*, in that the absence of a translator during the IC process, where required, patients affected by this absence may not be able to fully exercise their constitutionally guaranteed rights to full information disclosure prior to consenting to treatment.

However, provisions in the Constitution related to the progressive and gradual realisation of socio-economic rights (e.g. health care specifically, as found in sections 27(1), 24(a) and 35 of the Constitution), may provide a valid justification due the unavailability of resources, to provide an interpreter in all cases. Chapters five to seven of this thesis, report on recent empirical studies, which were designed to evaluate quantitatively and qualitatively whether the key elements of the National Health Act, especially the detailed criteria for information disclosure prior to obtaining informed consent as stipulated in sections 6 to 9, were actually understood and being adhered to by HCPs practising in

²¹⁶¹ Barit *The doctrine of informed consent in South African medical law* [16-17].

²¹⁶² Van Oosten *LLD Thesis* 1989 [20].

South African public hospitals. The purpose of the empirical study, reported in chapter 7, was to evaluate whether healthcare users or patients, actually understood or 'had knowledge' of the information disclosed to them. That is, in terms of meeting the criteria for valid consent, whether patients actually had knowledge and appreciation of the information provided by HCPs prior to providing IC. Some of the findings have already been discussed in chapters' five to seven of this thesis, but will be further summarized and discussed below in this chapter of the thesis.

8.2.3 Impact of South African case law

A landmark judgment in the case of *Castell v De Greef*²¹⁶³ arguably introduced the subjective prudent patient and material risks standards of IC into South African medical jurisprudence.²¹⁶⁴ Since the landmark judgment in the *Castell* case by the full bench of the Cape High Court, other judgments regarding informed consent in South Africa law have tried to live up to the exalted standards established in this case. The full details of this first-mentioned judgment were discussed above in chapters 2 and 3 of this thesis. The facts of the case are briefly as follows: a patient presented to surgeon for cosmetic breast surgery. After the surgery, the female patient developed complications in the operated breasts and eventually brought a suit against the surgeon for failure to obtain valid informed consent, based on incomplete disclosure. The patient further argued that if she had been adequately, or fully informed regarding the potential complications of the breast surgery, she might not have consented to the procedure. In arriving at a judgment in this case, Ackerman J opined that "in the South African context, the doctor's duty to disclose a material risk must be seen in the contractual setting of an unimpeachable consent to the operation and its setting".²¹⁶⁵ The Court held that for consent to serve as a defence during medical procedure, the following criteria must be fulfilled:

- i. The consenting party must have had knowledge and been aware of the extent of the harm or the risk

²¹⁶³ *Castell v De Greef* 1994 (4) SA 408 (C).

²¹⁶⁴ *Van Oosten* 1995 *De Jure* 171-175.

²¹⁶⁵ *Castell v De Greef* 1994 (4) SA 408 (C) [79].

- ii. The consenting party must have appreciated and understood the extent of the harm or the risk
- iii. The consenting party must have consented to the harm or assumed the risk
- iv. The consent must be comprehensive, that is extend to the entire transaction inclusive of its consequences.²¹⁶⁶

These criteria suggest that the consenting party must have both knowledge and appreciation of all the consequences of the medical procedure, including all the benefits, harms or risks before providing consent.²¹⁶⁷ Further, the consent provided must encompass the entire transaction including any future complications. In other words, by contrast to the National Health Act, simply having knowledge of the medical procedure or treatment, without realizing or appreciating all its consequences, including complications, may not make for true or valid consent.²¹⁶⁸ With regards to risk disclosure, the Court asked what the extent of risks that a HCP must be expected to disclose in order to discharge this onus, are. In answering this question, the Court referred to and quoted from the judgment of the Australian court in *Rogers v Whitaker*,²¹⁶⁹ where the court stated that:

The law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment [...]

And that

a risk is material if, in the circumstances of a particular case, a reasonable person in the patients position, if warned of the risk, would be likely to attach significance to it, or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. This duty is subject to therapeutic privilege.

²¹⁶⁶ Castell v De Greef 1994 (4) SA 408 (C) [425] see also Carstens and Pearmain *Foundational Principles* 684.

²¹⁶⁷ Strauss SA *Doctor, patient and the law: A selection of practical issues* (Van Schaik Publishers Pretoria 2004) 8 see also Carstens and Pearmain *Foundational Principles* 690.

²¹⁶⁸ Khan et al *Clinical Negligence* 2nd ed (Cavendish Publishing Limited London 2002) 44.

²¹⁶⁹ Rogers v Whitaker [1992] HCA 58 (1993) 4 Med LR 79 see also Khan et al *Clinical Negligence* 185.

The judge then defines the material risks standard in the South African context by specifying that:

A risk being material in the circumstances of the particular case where:

- a) A reasonable person in the patients position, if warned of the risk, would be likely to attach significance to it; or
- b) The particular medical practitioner is, or should reasonably be aware, that the particular patient, if warned of the risk, would be likely to attach significance to it.²¹⁷⁰

Similarly, Lord Scarman in the English case of *Sidaway*²¹⁷¹ stated as follows:

The critical limitation is that the duty to warn patients of risks inherent in treatment, is confined to material risk. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would likely attach significance to the risk.²¹⁷²

Therefore, from the above judgments, it becomes obvious that the expected standard of information disclosure is the subjective material risk standard, in terms of which a reasonable person in the patient's situation, if warned of the risk, would be likely to attach significance to it, or if the HCP is reasonably aware that a particular patient, if warned of the risk, will likely attach significance to it.

Despite the judgment and rules laid down in the *Castell* case,²¹⁷³ in more recent South African court judgments such as the *Oldwage* case²¹⁷⁴ and *McDonald v Wroe*,²¹⁷⁵ South African courts have made some controversial and contradictory judgments, such as in the *Oldwage* case, discussed previously in chapter three of this thesis. Briefly, a patient presented to his general practitioner (GP) with complaints of severe pain in the leg. Having made a preliminary diagnosis of vascular insufficiency, the GP referred the patient to a

²¹⁷⁰ *Castell v De Greef* 1994 (4) SA 408 (C) [426].

²¹⁷¹ *Sidaway v Bethlem Royal Hospital* (1985) 1 AC 871.

²¹⁷² *Sidaway v Bethlem Royal Hospital* (1985) 1 AC 871 [889] see also Khan et al *Clinical Negligence* 44.

²¹⁷³ *Castell v De Greef* 1994 (4) SA 408 (C).

²¹⁷⁴ *Louwrens v Oldwage* (2006) 1 SA 197 (SCA).

²¹⁷⁵ *McDonald v Wroe* [2006] 3 All SA 565 (C).

specialist vascular surgeon for further treatment. The surgeon performed an investigation in the form of a contrast aided radiological test (angiogram) which revealed substantive blockage in some of the patients' lower limb arteries. The surgeon concluded that the patient was suffering from severe ischaemic disease, which was the cause of the pain and recommended an urgent bypass surgery. The surgery performed was a cheaper "femoro-femoro" or ilio-femoral bypass rather than a more expensive "aorto-bifemoral bypass", which the patient could not afford. However, after the vascular surgery the patient still felt severe pain and discomfort, requiring him to consult a neurosurgeon who then diagnosed a degenerative lumbar disc, which required further surgery in the form of a laminectomy. After the laminectomy, the patient's pain and discomfort then disappeared and he felt much better, but not fully recovered. The plaintiff, Mr Oldwage then turned around to sue the vascular surgeon Dr Louwrens for misdiagnosis, and failure to obtain valid informed consent due to the fact that he did not disclose the issue of a "steal syndrome" as a possible complication of the ilio-femoral bypass surgery. In the High Court, the case hinged on the question whether the surgeon was negligent in not making a full disclosure regarding this potential complication, and whether the surgeon had missed the diagnosis of the degenerated lumbar disc which could be classified that the patient had a dual pathology, namely two disorders occurring at the same time, at the time of his initial presentation or diagnosis. In the High Court judgment, Yekiso J accepted the opinion of the expert witnesses for the plaintiff as being more logically acceptable as established in the English case of *Bolitho v City and Hackney HA*.²¹⁷⁶ The judge further referred in detail to the judgment of the full bench of the Cape High Court in the *Castell* case with regard to the material risks standard of information disclosure.²¹⁷⁷ He further resolved the dispute of facts based on the rules laid down in *SFW Group and Another v Martin et Cie*.²¹⁷⁸ In this case, the SCA held that resolving a dispute of facts should be based on credibility of expert witnesses, amongst other issues. In the *Oldwage* case, the judge preferred the opinion of the expert witnesses for the plaintiff, who had produced statistics that a known complication of the ilio-femoral bypass was a "steal syndrome" which could occur in about 4% of cases, rather than the opinion of the expert witnesses

²¹⁷⁶ *Bolitho v City and Hackney Health Authority* (1998) AC 232(HL) [241-243].

²¹⁷⁷ *Castell v De Greef* 1994 (4) SA 408 (C) [425-426].

²¹⁷⁸ *SFW Group and Another v Martin et cie & Others* 2003 1 SA 11 (SCA)

for the defendant who claimed that based on more recent literature, this complication only occurred in 2% of cases.²¹⁷⁹ In arriving at his decision, the High Court judge referred to the South African case of *Mitchell v Dixon*,²¹⁸⁰ which held that the mere fact that the accident occurred, was not itself *prima facie* proof of negligence.”²¹⁸¹ The judge further referred to the English case of *Whitehouse v Jordan*²¹⁸² where the English CA held that “a mere error of judgment” on the part of a medical practitioner did not necessarily constitute negligence. However, based on logical reasoning as outlined in *Michael and Another v Linksfield Park Clinic*,²¹⁸³ he accepted the opinion of the plaintiff’s witnesses as being more reasonable and defensible.²¹⁸⁴ On the issue of consent, the judge contented that for consent to be considered valid, it must be “informed”, citing a quotation from which it is said:

A consent to treatment will only be “informed” if it is based on substantial knowledge concerning the nature and the effect of the act consented to. Thus a medical practitioner is obliged to warn a patient of the material risks and consequences which may ensue during and consequent to the proposed treatment.²¹⁸⁵

In arriving at his decision, the judge further referred to the *dictum* established by Ackerman J in the *Castell* case²¹⁸⁶ regarding to the defence of consent. He also referred to the judgment of the English CA in *Chester v Afshar*²¹⁸⁷ where it was held that:

There is a duty on the medical practitioner properly to inform the patient of the risks attendant on his or her treatment and its dangers. The object is to enable the patient to decide whether or not to run the risk of consenting to the treatment or procedure proposed.²¹⁸⁸

²¹⁷⁹ Louwrens v Oldwage (2004) 1 All SA 532 (C) [55-60].

²¹⁸⁰ Mitchell v Dixon 1914 AD 519.

²¹⁸¹ Mitchell v Dixon 1914 AD 519 [525].

²¹⁸² Whitehouse v Jordan and another (1981) 1 All ER 267(HL) [281].

²¹⁸³ Michael & Another v Linksfield Park Clinic (Pty) Ltd 2001(3) SA1188 (SCA).

²¹⁸⁴ Louwrens v Oldwage [2004] 1 All SA 532 (C) [60-61].

²¹⁸⁵ Claasen NJB and Verschoor T *Medical negligence in South Africa* (Butterworth Publishers Pty Ltd South Africa 1992) 62.

²¹⁸⁶ Castell v De Greef 1994 (4) SA 408 (C) [425].

²¹⁸⁷ Chester v Afshar (2002) 3 All ER 552 [572].

²¹⁸⁸ Louwrens v Oldwage [2004] 1 All SA 532 (C) [89].

He then considered the judgment of the South African court in the case of *Richter and Another v Estate Hamman*,²¹⁸⁹ where the court said that:

In reaching a conclusion (as regards the disclosure of a risk by the doctor) a court should be guided by medical opinion as to what a reasonable doctor, having regard to all, the circumstances of the particular case, should or should not do. The court must, of course, make up its own mind, but it will be assisted in doing so by medical evidence.²¹⁹⁰

In contrast to the *Richter* case, where the court based its decision on the ‘reasonable doctor’ standard of information disclosure, the full bench of the Cape High Court had considered this option in the *Castell* case, but rejected it. Yekiso J therefore held in the *Oldwage* case that he was bound by this decision. In the final analysis, the judge found, based on a balance of probabilities that the vascular surgeon, Dr. Louwrens, was negligent due to misrepresentation of facts, lack of full information disclosure, and therefore was guilty of failure to obtain valid informed consent.²¹⁹¹ The surgeon appealed this ruling to the SCA, asking it to determine *inter alia* what standard of disclosure should be used in cases of informed consent. The SCA, in its judgment, overruled the High Court by applying the discredited ‘reasonable doctor standard’²¹⁹² rather than the more recent judgment of the Cape High Court in the *Castell* case, which had accepted the ‘prudent patient and material risks standards’ of information disclosure as the accepted standards for informed consent’ in South African jurisprudence.²¹⁹³ The judgment in the *Oldwage* case has been criticized by legal scholars, such as Carstens and Pearmain²¹⁹⁴ and others.²¹⁹⁵ Despite ongoing criticism and controversy surrounding the judgment in the *Oldwage* case, this misguided judgment has been carried forward in more recent cases. For example, in the case of *McDonald v Wroe*,²¹⁹⁶ a Cape High Court judge found a dentist negligent for failure to obtain valid informed consent due to failure to disclose a risk of nerve damage and

²¹⁸⁹ Richter and Another v Estate Hamman 1976(3) SA 226(C)
²¹⁹⁰ Richter and Another v Estate Hamman 1976(3) SA 226(C) [232].
²¹⁹¹ Louwrens v Oldwage [2004] 1 All SA 532 (C) [115-118].
²¹⁹² Louwrens v Oldwage (2006) 1 SA 197 (SCA).
²¹⁹³ Castell v De Greef 1994 (4) SA 408 (C).
²¹⁹⁴ Carstens and Pearmain *Foundational Principles* [683]
²¹⁹⁵ Britz and Roux-Kemp 2012 *S Afr Med J* 746-748.
²¹⁹⁶ McDonald v Wroe [2006] 3 All SA 565 (C)

facial paralysis following extraction of wisdom teeth. Expert opinion was that there was about 1% risk of this complication occurring, especially where such surgery is not performed by a specialist maxillo-facial surgeon. This decision was recently overturned by a full bench of the Cape High Court, based on the question of causation.²¹⁹⁷

Facts of the McDonald case: In this case, the patient and plaintiff had developed repeated bouts of pericoronitis (inflammation) around her wisdom teeth, and the dentist correctly advised her that it was necessary for her wisdom teeth to be surgically extracted under general anaesthesia. The surgery was performed by the dentist. However, post-operatively, the patient experienced numbness on the left side of her face. This numbness was the result of damage to her inferior alveolar nerve, which appeared to be permanent in nature. The risk of permanent nerve damage to the inferior alveolar nerve was a known risk and complication arising due to surgery in that area of the jaw. Expert witnesses were of the opinion that this complication could occur in about 1% of cases. However, other experts suggested that this complication was less likely to arise if the procedure was performed by a maxillo-facial surgeon, rather than by a general dentist. The patient brought a claim against the defendant dentist, based on the fact that he had failed to warn her of this risk/ complication, and further that the dentist had not offered her the option of having the procedure performed by a specialist, while obtaining consent for the surgical procedure. Expert witnesses also testified that only about 10% of such procedures were performed by general dentists in the Cape area.

Judgment: In the High Court judgment, the judge cited the rules for material risks and informed disclosure as established in the *Castell* case.²¹⁹⁸ He further established that though the dentist performed the procedure effectively, there was a proximate nexus or foreseeability between the procedure and the patient's subsequent facial paralysis and nerve damage. Therefore, the dentist had not obtained valid informed consent due to lack of full disclosure of all the material risks. He further outlined the onus of proof required in South African law as:

²¹⁹⁷ Esterhuysen S "Medical Negligence" www.bowmanslaw.com/insights/tax/medical-negligence (Date of use: 25th October 2017).

²¹⁹⁸ *Castell v De Greef* 1994 (4) SA 408 (C) [425-426].

If a medical practitioner through his/her wrongful and negligent conduct causes damage to a patient, the practitioner will be delictually liable to the patient if there was a causal nexus between the conduct of the practitioner and the damage suffered by the patient. The medical practitioner cannot be liable if his/her conduct has not caused any damage.²¹⁹⁹

Further:

The *conditio sine qua non* theory, also known as the “but-for” test, requires proof on a balance of probabilities that the relevant act of commission or omission was a necessary condition of the harmful event. Legal causation is present in the event that there is a close enough relationship between the wrongdoers conduct and its consequence for such consequence to be imputed to the wrongdoer in view of policy considerations based on reasonableness, fairness and justice.²²⁰⁰

In arriving at his judgment, Fourie J also partly relied on the judgment of the English House of Lords in *Chester v Afshar*²²⁰¹ where the Court noted that:

Standing back from the detailed arguments, I have come to the conclusion that, as a result of the surgeon’s failure to warn the patient, she cannot be said to have given informed consent to the surgery in the full legal sense. Her right to autonomy and dignity can and ought to be vindicated by a narrow and modest departure from traditional causation principles.... On a broader basis I am glad to have arrived at the conclusion that the claimant is entitled in law to succeed. This is in accordance with one of the most basic aspirations of the law, namely to right wrongs. Moreover, the decision announced by the House today reflects the reasonable expectations of the public in contemporary society.

Therefore using a broader consideration of causation and justifiable public interests, the judge found the defendant dentist negligent, due to failure to obtain appropriate informed consent based on non-disclosure of all material risks, and also applying the principles of

²¹⁹⁹ McDonald v Wroe [2006] 3 All SA 565 (C) [568].

²²⁰⁰ Neethling J, Potgieter JM and Visser PJ *Law of Delict* 7th ed (LexisNexis Durban 2015) 186-195.

²²⁰¹ Chester v Afshar [2004] 4 All ER 587 [596].

reasonableness, fairness and justice based on the constitutional rights to bodily integrity and self-determination.²²⁰²

The dentist appealed this decision of the judge to a full bench of the Cape High Court based on the question of causation. In its judgment, the full bench of the High Court argued that:

The defendant's wrongful and negligent failure to warn the Plaintiff of the risk involved resulted in the plaintiff consenting to defendant performing the surgery. He performed the surgery correctly without negligence. The experts were unable to fault the manner in which he performed the surgery in any way. The harm, which the plaintiff suffered, is due to a risk which is inherent in the surgical procedure in question and which can ensue without negligence on the part of the practitioner, be it a general practitioner or a specialist, who performs the procedure. The harm which the plaintiff suffered, is harm she might equally probably have suffered in any event if the surgery had been performed by a specialist surgeon. There is, therefore, no direct causal link between the defendant's negligence (in failing to warn the plaintiff of the risk) and occurrence of the harm, unless it is shown that the plaintiff, upon being warned of risk, would not have undergone the procedure at all. That is not the plaintiff's case.²²⁰³

Based on the above considerations, the full bench of the Cape High Court overturned the judgment of Fourie J by reaffirming causation as an element deeply entrenched in the South African law of delict. Based on this judgment, a patient who intends relying on the argument of lack of informed consent bears the onus to prove on a balance of probabilities that (1) the healthcare professional was negligent in so far as he or she failed to warn the patient of the particular risk or complication; and (2), the healthcare professional's negligent omission as such caused the damages suffered by the patient.^{2204,2205}

As demonstrated by the cases above, recent judgments on informed consent rendered by South African courts have led to controversial rulings which mean that further clarifications

²²⁰² The Constitution (s12).

²²⁰³ Nicola McDonald v Dr Graham Wroe (2006) 3 All SA 565 (C) [para 34].

²²⁰⁴ Esterhuysen S "Medical Negligence" April 13 2007
www.bowmanslaw.com/insights/tax/medical-negligence (Date of use: 25th October 2017).

²²⁰⁵ Baron M *McDonald v Wroe* [2006] 3 All SA (C) Denys Reitz General Case Law Update March 2007 [http:// www.denysreitz.co.za/directors/monique_baron.html](http://www.denysreitz.co.za/directors/monique_baron.html) (Date of use: 25 October 2017).

are required, and that in addition to clarification, there is a need to further develop the legal position relating to IC as espoused in NHA²²⁰⁶ and regulations, and affirmed in the Constitution.²²⁰⁷ This need is illustrated by the judgments in two recent cases, namely that of *Sibisi NO v Maitin*²²⁰⁸ and *Pane v MEC Free State*.²²⁰⁹ These cases were discussed in detail in chapter 3 of this thesis.

However, for the sake of continuity and comprehensiveness, the cases are briefly summarized here, as they may be perceived to have introduced new requirements, such as that of a “dual burden of proof”²²¹⁰ regarding the doctrine of informed into South African jurisprudence. Specifically noteworthy is the judgment of the SCA in the *Sibisi case*,²²¹¹ where it was held that the plaintiff in a case of informed consent must prove both negligence and wrongfulness to discharge the onus of proof in informed consent cases.²²¹² According to the court, the “plaintiff did not discharge the onus of proving negligence on the part of the doctor” and that informed consent cannot be considered an issue once negligence is not established.²²¹³ This case was referred on appeal from the KwaZulu-Natal High Court. The facts of this case are related to issues arising from the delivery of a large (macrosomic) baby by a specialist obstetrician, which resulted in permanent injury to the baby after delivery. The plaintiff in this matter instituted a claim on behalf of her minor daughter, who had suffered bodily injuries following natural birth.

These injuries and *sequelae* included damage to the infant’s brachial plexus as a result of alleged excessive traction during childbirth; resulting in a medical condition called Erb’s palsy. In addition, there was injury to the child’s left eye, which required ongoing treatment and permanent damage to the child’s vision, upper eye and facial features. The plaintiff’s claim was based on medical negligence, and the absence of informed consent in the

2206 National Health Act 61 of 2003 (s6-9).

2207 The Constitution.

2208 *Sibisi NO v Maitin* 2014 (6) SA 533 (SCA).

2209 *Pane v MEC Free State Department of Health* [2016] ZAFSHC 99.

2210 Zwartz L “Sibisi NO v Maitin: A dual burden of proof?” June 2015 *De Rebus* 33.
www.derebus.org.za/sibisi-no-v-maitin-a-dual-burden-of-proof/ (Date of use: 28 October 2017).

2211 *Sibisi NO v Maitin* 2014 (6) SA 533 (SCA).

2212 Hogan Lovells “The doctor’s duty to inform” 2014 www.hoganlovells.com/publications/the-doctors-duty-to-inform (Date of use: 28 October 2017).

2213 *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156 1 October 2014 [1].

alternative.²²¹⁴ The plaintiff also asked the court to develop the common law on informed consent in line with the constitutional rights to bodily integrity and autonomy by establishing that the test for whether a doctor has obtained a patient's informed consent is whether, a patient in the position of the plaintiff would have elected not to undergo the procedure and instead elect another one, if the patient was fully informed of the available options by the defendant.²²¹⁵ The facts of the case include the fact that Dr. Maitin did not inform the pregnant woman that she was pregnant with a baby weighing over 4kg, and that such a large baby might likely lead to shoulder dystocia and a difficult vaginal delivery. This condition materialized during labour and the doctor was forced to use an emergency manoeuvre (McRoberts manoeuvre) to deliver the baby. During delivery, the excessive traction associated with the manoeuvre and the size of the big baby caused the child's postpartum injuries.

At court, the doctor admitted that he used his own discretion or expertise in deciding on what information to disclose the pregnant woman (akin to the reasonable doctor standard). Expert witnesses agreed that one could not readily predict the occurrence of shoulder dystocia based simply on the size or weight of a baby. It was further agreed by that necessary force was required in performing the McRoberts manoeuvre to deliver a baby in an emergency. On the other hand, the plaintiff argued that she should have been informed regarding the potential impact of the large baby and the option of delivery by caesarean section (C/S). She therefore alleged that failure to inform her amounted to lack of informed consent against the obstetrician. However, the plaintiff did assert that she depended on the doctor to make the right decision on her behalf, and may not have chosen the option of a C/S even if she were advised of this option beforehand.²²¹⁶ The High Court found the doctor not to have been negligent. On appeal, the SCA also found that Dr. Maitin was not negligent. The SCA held that Mrs Sibisi, as the plaintiff, bore the onus of showing that the obstetrician with the reasonable skill and diligence possessed

²²¹⁴ Zwartz L "Sibisi NO v Maitin: A dual burden of proof?" June 2015 De Rebus 33. www.derebus.org.za/sibisi-no-v-maitin-a-dual-burden-of-proof/ (Date of use: 28 October 2017).

²²¹⁵ Hogan Lovells "The doctor's duty to inform" December 2014 www.hoganlovells.com/publications/the-doctors-duty-to-inform (Date of use: 28 October 2017).

²²¹⁶ Sibisi NO v Maitin (311/13) [2014] ZASCA 156 [52].

by that branch of the medical profession, would have foreseen the possibility of shoulder dystocia and taken steps to mitigate the risk, as established the case of *Van Wyk v Lewis*.²²¹⁷ The Court found that the plaintiff did not discharge that onus of negligence because there was no mismanagement of the pregnancy, labour and delivery on the part of Dr Maitin, hence he was not negligent. The Court held that any reasonable obstetrician in Dr Maitin's position would not have foreseen the possibility of shoulder dystocia in this case, and would have proceeded on the same basis that Dr Maitin did.²²¹⁸

The Court also reasoned that once the plaintiff has failed to establish medical negligence, the question of informed consent and of wrongfulness automatically became moot. The Court held that the plaintiff '...would still have to establish negligence on the part of the defendant to succeed in the action [...].'²²¹⁹ Therefore, the defendant was absolved from liability on both grounds. In arriving at its decision, the SCA again referred to the reasonable doctor standard as established in *Richter and Another v Estate Hamman*²²²⁰ where the court said:

A doctor whose advice is sought about an operation to which certain dangers are attached-and there are dangers attached to most operations-is in a dilemma. If he fails to disclose the risks, he may render himself liable to an action for assault, whereas if he discloses them he might well frighten the patient into not having the operation when the doctor knows full well that it would be in the patient's interests to have it.²²²¹

The SCA however asserted that in keeping with the rights to autonomy and bodily protection, now entrenched in the Constitution,²²²² the test should rather be whether the reasonable patient, in her position, if warned of the risk, would attach significance to it. On the issue of negligence and informed consent, the SCA referred to the judgment in the *Castell* case where the court held :

²²¹⁷ Van Wyk v Lewis 1924 AD 438 [444].

²²¹⁸ Sibisi NO v Maitin (311/13) [2014] ZASCA 156 [39].

²²¹⁹ Sibisi NO v Maitin (311/13) [2014] ZASCA 156 [22].

²²²⁰ Richter & Another v Estate Hamman 1976 (3) SA 226 (C)

²²²¹ Richter & Another v Estate Hamman 1976 (3) SA 226 (C) [232].

²²²² The Constitution (s12).

[...] that, in our law, for a patient's consent to constitute a justification that excludes the wrongfulness of medical treatment and its consequences, the doctor is obliged to warn a patient so consenting of a material risk inherent in the proposed treatment; a risk being material if, in the circumstances of the particular case:

(a) A reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or

(b) The medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.²²²³

The SCA in the *Sibisi* case held that:

This passage makes it clear, however, that the question of informed consent goes to the wrongfulness element of the Aquilian action. Negligent conduct on the part of the doctor will be wrongful if the patient has not given informed consent. Where there is no negligence proved, however, the test for wrongfulness does not even arise.²²²⁴

The SCA concluded that since Mrs Sibisi had not proved negligence on the part of Dr. Maitin, there was no need to establish which standard of information disclosure should be applicable in informed consent cases, thereby failing to extend the South African common law and jurisprudence on informed consent as required by the Constitution on the interpretation of the Bill of Rights.²²²⁵ The principle of the 'dual burden of proof' derived from the judgment of the SCA in the *Sibisi* case has since been applied at the high court level in a judgment in the case of *Pane v MEC Free state*,²²²⁶ where the court held that in the absence of a proof of negligence, the defendant could not establish lack of informed consent, or that the argument regarding lack of informed consent by HCPs could not be further pursued against an offending doctor or other HCP.²²²⁷

²²²³ Castell v De Greef 1994 (4) SA 408 (C) [426].

²²²⁴ Sibisi NO v Maitin (311/13) [2014] ZASCA 156 [50].

²²²⁵ The Constitution (s39).

²²²⁶ Pane v MEC Free State Department of Health [2016] ZAFSHC 99.

²²²⁷ Pane v MEC Free State Department of Health [2016] ZAFSHC 99 [41-50]

8.2.4 Further implications of the SCA judgment in the Sibisi case on extension of the common law on informed consent in South Africa

The evidence placed before the Court in the *Sibisi case*²²²⁸ was that shoulder dystocia, while a risk of vaginal delivery, could not be reasonably foreseen based on the weight or size of a foetus. This was based on the evidence by two expert witnesses invited to assist the Court in this case. In addition, the Court relied on a guideline issued by the Royal College of Obstetricians and Gynaecologists (RCOG), on the foreseeability of shoulder dystocia, which advised that while there is a relationship between foetal size and shoulder dystocia, “it is not a good predictor. The large majority of infants with a birth weight of [more than] 4500g do not develop shoulder dystocia and, equally importantly, 48% of incidences of shoulder dystocia occur in infants with a birth weight less than 4000 g”.²²²⁹ The guideline also pointed out that clinical foetal weight estimation is unreliable, and even ultrasound scans have a ten per cent margin of error. The guideline further advised that “elective caesarean section is not recommended for suspected fetal macrosomia (estimated fetal weight over 4.5 kg) without diabetes. Estimation of fetal weight is unreliable and the large majority of macrosomic infants do not experience shoulder dystocia. In the USA, a decision analysis model estimated that an additional 2345 caesarean deliveries would be required, at a cost of US\$4.9 million, to prevent one permanent injury from shoulder dystocia.”²²³⁰ The expert witness for Mrs Sibisi contended that if the doctor had shown up earlier during labour, a C-section could have been performed. He also suggested that application of the McRoberts manoeuvre in the wrong position was negligent. He conceded, however, that the weight of the foetus was not a good correlate of shoulder dystocia and that failure to estimate the weight accurately by Dr. Maitin was not negligent.

²²²⁸ Sibisi NO v Maitin (311/13) [2014] ZASCA 156.

²²²⁹ RCOG *Shoulder dystocia-Green-top guideline No. 42 2nd ed updated February 2017* (RCOG London 2012) [https:// www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg/42/](https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg/42/) (Date of use: 28 November 2017).

²²³⁰ RCOG *Shoulder dystocia Green-top guideline No. 42 2nd ed* (RCOG London 2012) as updated February 2017 www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg/42/ (Date of use: 28 November 2017).

The SCA made the point that informed consent goes to the wrongfulness of a medical practitioner's negligent conduct.²²³¹ In arriving at its decision, Lewis J referred to the judgments in the case of *Van Wyk v Lewis*²²³² arguing that Mrs Sibisi, as the plaintiff, bore the onus of showing that an obstetrician with the reasonable skill and diligence possessed by that branch of the profession would have foreseen the possibility of shoulder dystocia and taken steps to mitigate the risk. The judge held that she did not discharge that onus, thereby basing part of its judgment on the 'reasonable doctor' standard of information disclosure. Further, the Court referred to the controversial judgment in *Richter v Estate Hamman*²²³³ stating that "[o]ur courts have in the past held that in order to determine whether a doctor is under a duty to disclose the risks of a procedure we must determine whether a reasonable doctor, in the position of the defendant, would have disclosed risks however remote", quoting Watermeyer J as saying:

... It may well be that in certain circumstances a doctor is negligent if he fails to warn a patient, and, if that is so, it seems to me in principle that his conduct should be tested by the standard of the reasonable doctor faced with the particular problem. In reaching a conclusion a Court should be guided by medical opinion as to what a reasonable doctor, having regard to all the circumstances of the particular case, should or should not do. The Court must, of course, make up its own mind, but it will be assisted in doing so by medical evidence."²²³⁴

The Court suggested that Mrs Sibisi's argument implied that by applying the reasonable doctor standard, "[...] this approach leaves the determination of a legal duty to the judgment of doctors appointed in their own cause."²²³⁵ Further, the Court cited the judgment in *Castell v De Greef*²²³⁶ and the international cases referred to in that judgment, which stated that "in keeping with the rights to autonomy and bodily protection, now entrenched in the Constitution, the test should rather be whether the reasonable patient, in her position, if warned of the risk, would attach significance to it."²²³⁷ The Court opined

²²³¹ Hogan Lovells <http://www.hoganlovells.com/en/publications/the-doctors-duty-to-inform> (Date of use: 28 September 2017) see also *Sibisi NO v Maitin* [2014] ZASCA 156 [50].

²²³² *Van Wyk v Lewis* 1924 AD 438 [444].

²²³³ *Richter & another v Estate Hamman* 1976 (3) SA 226 (C).

²²³⁴ *Richter & another v Estate Hamman* 1976 (3) SA 226 (C) [232G-H].

²²³⁵ *Sibisi NO v Maitin* 311/13 [2014] 156 [47].

²²³⁶ *Castell v De Greef* 1994 (4) SA 408 (C).

²²³⁷ *Sibisi NO v Maitin* 311/13 [2014] 156 [47].

that the test established in *Castell v De Greef*²²³⁸ by a full bench of the Cape High court accepted that this ought to be the test. The *Sibisi* Court quoted Ackermann J as saying that South African courts ought to follow the approach of an Australian decision in *Rogers v Whitaker*,²²³⁹ which also took into account English and Canadian decisions that previously adopted a similar approach “suitably adapted to the needs of South African jurisprudence”.²²⁴⁰ Lewis J quoted Ackerman in *Castell v De Greef* as follows:

It is in accord with the fundamental right of individual autonomy and self-determination to which South African law is moving. This formulation also sets its face against paternalism, from many other species whereof South Africa is now turning away. It is in accord with developments in common law countries like Canada, the United States of America and Australia, as well as judicial views on the continent of Europe [...] I therefore conclude that, in our law, *for a patient's consent to constitute a justification that excludes the wrongfulness of medical treatment and its consequences*, the doctor is obliged to warn a patient so consenting of a material risk inherent in the proposed treatment; a risk being material if, in the circumstances of the particular case [...]²²⁴¹

The judge concluded that the above passage makes it clear that the question of informed consent goes to the wrongfulness element of the Aquilian action. Negligent conduct on the part of the doctor will be wrongful if the patient has not given informed consent. However, negligence is still a requirement, as affirmed in the *Castell* case.²²⁴² Where there is no negligence proved, however, the test for wrongfulness does not even arise.²²⁴³

It has been argued elsewhere in this thesis that courts have now conclusively demonstrated that informed consent falls within the element of wrongfulness relating to a claim based on delict. In order to found this element of wrongfulness on a doctors' or other HCPs conduct, the conduct must be negligent. You cannot have one without the other, as then there would be no claim in delict. Although Mrs Sibisi was not successful in her claim against Dr Maitin, this case highlighted the importance of HCPs gaining their patient's

²²³⁸ *Castell v De Greef* 1994 (4) SA 408 (C)
²²³⁹ *Rogers v Whitaker* (1993) 67 ALJR 47
²²⁴⁰ *Castell v De Greef* 1994 (4) SA 408 (C) [426].
²²⁴¹ *Sibisi NO v Maitin* 311/13 [2014] 156 [49].
²²⁴² *Castell v De Greef* 1994 (4) SA 408 (C).
²²⁴³ *Sibisi NO v Maitin* 311/13 [2014] 156 [49-50]

informed consent. Furthermore, it has also shown that, even in circumstances where a HCP has done everything within his or her skill set to assist a patient, a medical malpractice claim can still arise in any litigious society. Doctors or other HCPs are required to assess the circumstances and determine what their patients need to know when coming to a decision whether or not to undergo a procedure, and the courts currently leave that in their hands. Further, it has been suggested by some legal authorities that informed consent may prove valuable in defending medical malpractice claims and should not be dismissed as a mere formality by HCPs.²²⁴⁴

8.2.5 Comparative law

Section 39(1) of the South African constitution²²⁴⁵ stipulates that “when interpreting the Bill of Rights, a court, tribunal or forum-

- a) Must consider international law; and
- b) May consider foreign law”²²⁴⁶

Judge McNair J in the English case of *Bolam v Friern HMC*,²²⁴⁷ where the reasonable doctor standard or ‘Bolam principle’ or doctrine was established as the expected standard of care in negligence cases made the following observation:

I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. I do not think there is much difference in sense. It is just a different way of expressing the same thought. Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view [...].²²⁴⁸

However, in the case of *Hills v Porter* Hirst J opined that:

²²⁴⁴ Hogan Lovells <http://www.hoganlovells.com/en/publications/the-doctors-duty-to-inform> (Date of use: 28 September 2017).

²²⁴⁵ The Constitution of the Republic of South Africa 1996

²²⁴⁶ The Constitution (s39).

²²⁴⁷ *Bolam v Friern Barnet Health Management Committee* [1957] 1 WLR 582.

²²⁴⁸ *Bolam v Friern Barnet Health Management Committee* [1957] 1 WLR 582 [587].

I do not accept that...by adopting the Bolam principle, the court in effect abdicates its power of decision to the doctors. In every case the Court must be satisfied that the standard contended for on their behalf accords with that upheld by a substantial body of medical opinion, and that this body of medical opinion is both respectable and responsible, and experienced in this particular field of medicine.²²⁴⁹

The *Bolam* principle²²⁵⁰ has been the major doctrine or ‘reasonable doctor standard’ applied in English common law cases regarding negligence and informed consent since the late 1950s, despite dissenting opinions in landmark cases such as the *Sidaway*²²⁵¹ case where Lord Scarman advocated for the adoption of the informed consent doctrine as applied by north American courts.²²⁵² In the *Sidaway* case, the majority of the bench at the English House of Lords (HL) adopted a broad standard of information disclosure as established in *Chatterton v Gerson*,²²⁵³ where it was held that the patient needs to be only informed in broad terms, as determined by an accepted body of medical practitioners in that particular field as established in *Bolam*.²²⁵⁴ According to Bristow J in the *Chatterton* case, “[...] once the plaintiff is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of action...is negligence, not trespass [...]”.²²⁵⁵

North American common law jurisdictions in the USA and Canada, in contrast, have long adopted as the basis of informed consent, the material risks standard of information disclosure, as established in the landmark judgments of *Canterbury v Spence*²²⁵⁶ and *Riebl v Hughes*.²²⁵⁷ In the *Canterbury* case it was held that “[a] risk is... material when a reasonable person in that the physician knows or should know to be the patient’s position, would likely attach significance to the risk or cluster of risks in determining whether or not

2249 Hills v Porter [1984] 1 WLR 641 [653].

2250 Bolam v Friern Barnet Health Management Committee [1957] 1 WLR 582.

2251 Sidaway v Bethlem Royal Hospital (1985) 1 AC 871.

2252 Khan et al 2nd *Clinical Negligence* 44.

2253 Chatterton v Gerson [1981] 1 All ER 257.

2254 Bolam v Friern Barnet Health Management Committee [1957] 2 All ER 118.

2255 Chatterton v Gerson [1981] 1 All ER 257[265].

2256 Canterbury v Spence (1972) 464 F (2d) 772.

2257 Riebl v Hughes (1980) 114 DLR (3d) 1.

to forego the proposed therapy.²²⁵⁸ In the Canadian case of *Reibl v Hughes*,²²⁵⁹ a physician failed to disclose a 10% risk of a stroke resulting from surgery, which was regarded as remote and as one that might not have affected the plaintiff or patients decision, except that he was nearing retirement and would have been eligible for a full pension. The risk of a disabling stroke was, however, very significant to this particular patient, because he would not have wanted to risk his pension by undergoing the surgery.²²⁶⁰ Consequently, the court in *Reibl* ruled with regard to the material risk standard that: “[...] the test is based on the decision that a reasonable person in the patients position would have made. I should make it clear that the patient’s particular concerns must also be reasonably based [...].”²²⁶¹

The material risks standard of information disclosure has also been adopted by Australian courts in landmark judgments and cases such as *Rogers v Whittaker*²²⁶² and *F v R*.²²⁶³ In the case of *Rogers*, a woman, partially blind in one eye, developed a severe infection in her second eye which needed a surgical procedure. The woman was very concerned about losing sight in her ‘good eye’ and made enquiries regarding complications arising from the surgery. Despite these enquiries, the surgeon did not inform her that there was a 1 in 14000 chance of sympathetic ophthalmoplegia. Unfortunately, this risk did materialize and the patient became almost completely blind in her previously partially ‘good eye’. She sued the surgeon for negligence. The Australian High Court found on the plaintiff’s behalf against the defendant surgeon, stating:

[...] that standard is not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion in the relevant profession or sphere...further...in the field of non-disclosure of risk and the provision of advice and information, the Bolam principle has been discarded and instead, the courts have adopted the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what

2258 *Canterbury v Spence* (1972) 464 F (2d) 772 [787].

2259 *Riebl v Hughes* (1980) 114 DLR (3d) 1

2260 *Khan et al 2nd Clinical Negligence* [210-211].

2261 *Riebl v Hughes* (1980) 114 DLR (3d) 1 see also *Khan et al 2nd Clinical Negligence* [210-211].

2262 *Rogers v Whittaker* [1993] 4 Med LR 79.

2263 *F v R* (1993) 33 SASR 189.

is the appropriate standard of care giving weight to the paramount consideration that a person is entitled to make his own decisions about his life.²²⁶⁴

The full bench of the Cape High Court also examined the material risks standard of information disclosure in the *Castell case*,²²⁶⁵ and adopted it as the accepted standard of care in South African jurisprudence.²²⁶⁶ This standard was further re-examined by the SCA in the cases of *Broude v McIntosh*²²⁶⁷ and *Louwrens v Oldwage*²²⁶⁸ where the SCA did not overrule these judgments. However, in recent judgments such as *McDonald v Wroe*²²⁶⁹ and *Sibisi No v Maitin*,²²⁷⁰ the SCA seems to have contradicted itself by reverting to the reasonable doctor standard as established in *Richter and Another v Estate Hamman*.²²⁷¹ Further, the SCA and other South African High Courts seem to have introduced a dual burden of proof in informed consent cases, as shown the *Sibisi case*²²⁷² and that of *Pane v MEC Free State*,²²⁷³ by requiring that a claimant must prove not only negligence, but also lack of informed consent, and once there was no proof of negligence, consideration of failure to obtain valid informed consent automatically falls away.²²⁷⁴

This state of affairs requires further reconsideration by the SCA by reference to recent judgments in foreign case law, as exemplified by the 2015 judgment of the UK Supreme Court Scotland in the case of *Montgomery v Lanarkshire*,²²⁷⁵ referred to briefly in chapter 3 of this thesis. The plaintiff in this case was a diminutive and well-known diabetic patient who was pregnant with her first child. It is a well-known fact that women who are diabetics have a tendency to produce macrosomic or big babies with an increased chance of

²²⁶⁴ Rogers v Whittaker [1993] 4 Med LR 79 [83].

²²⁶⁵ Castell v De Greef 1994 (4) SA 408 (C)

²²⁶⁶ Van Oosten "Castell v De Greef and the doctrine of informed consent: Medical paternalism ousted in favour of patient autonomy" 1995 *De Jure* 171-175

²²⁶⁷ Broude v McIntosh 1998 (3) SA 60 (SCA).

²²⁶⁸ Louwrens v Oldwage [2004] 1 All SA 532 (C).

²²⁶⁹ McDonald v Wroe (2006) 3 All SA 565 (C).

²²⁷⁰ Sibisi NO v Maitin (311/13) [2014] ZASCA 156.

²²⁷¹ Richter & Another v Estate Hamman 1976 (3) SA 226 (C).

²²⁷² Sibisi NO v Maitin (311/13) [2014] ZASCA 156

²²⁷³ Pane v MEC Free State Department of Health [2016] ZAFSHC 99

²²⁷⁴ Zwart L "Sibisi NO v Maitin: A dual burden of proof?" June 2015 *De Rebus* 33.
www.derebus.org.za/sibisi-no-v-maitin-a-dual-burden-of-proof/ (Date of use: 28 October 2017)
see also Sibisi NO v Maitin (311/13) [2014] ZASCA 156 [50-51].

²²⁷⁵ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11.

shoulder dystocia.²²⁷⁶ Generally, the alternative to vaginal delivery of a baby in such cases would include the option of delivery by C-section (C/S). Further, the plaintiff and pregnant woman in this case was of a short stature, about 5 feet tall, which would make the chances of delivering a big baby even more difficult, due to cephalopelvic disproportion. Dystocia was described as “a major obstetric emergency associated with a short and long term neonatal and maternal morbidity and associated neonatal mortality” by one of the expert witnesses at trial. Despite knowing these facts about the patient, her attending specialist obstetrician did not disclose all the potential complications to the patient; neither did she offer the patient the option of delivery by C/S. The obstetrician proceeded to deliver the baby via normal vaginal delivery, basing her decision on her usual and accepted practice similar to that of other specialists in England and Scotland, by arguing that most of the pregnant women in the plaintiff’s position would readily elect the option of a C/S. This, however, increases the number of babies delivered by C-section, generally considered undesirable, with increased costs and depletion of resources, etc. Shoulder dystocia is also presents risks for the baby, including damage to the brachial plexus estimated at around 0.2% (1 in 500 cases), and risk of entrapment of the umbilical cord estimated at about 0.1%. The defendant doctor accepted that the risk of dystocia occurring in diabetic mothers was around 9 to 10%, yet she did not disclose the risks and potential complications to the pregnant woman. According to guidance from the Royal College of Obstetricians and Gynaecologists regarding shoulder dystocia:²²⁷⁷

There can be a high perinatal mortality and morbidity associated with the condition, even when it is managed appropriately. Maternal morbidity is also increased, particularly postpartum haemorrhage (11%) and fourth-degree perineal tears (3.8%), and their incidence remains unchanged by the manoeuvres required to effect delivery.

In this case, because of the big size of the baby, there was difficulty in delivering the baby’s shoulders through the birth canal. Following a very difficult delivery by the plaintiff,

²²⁷⁶ RCOG Shoulder dystocia Green-top guideline No. 42 2nd ed (RCOG London 2012) www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg/42/ (Date of use: 28 November 2017).

²²⁷⁷ RCOG Shoulder dystocia updated February 2017 www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg/42/ (Date of use: 28 November 2017) see also RCOG Guideline No 42 on shoulder dystocia (RCOG London 2005).

which included a partial symphysiotomy (division of the symphysis pubis), assisted forceps delivery, and considerable traction, her baby was delivered alive but consequently developed both cerebral palsy due to oxygen deprivation and Erb's palsy due to damage to the brachial plexus during delivery. Mrs Montgomery, the patient and claimant, brought a claim of medical negligence and failure to obtain true informed consent against her obstetrician doctor. In arriving at a decision in this case, in a judgment rendered by Lords Kerr and Reed, the Supreme Court examined the entire history of English jurisprudence on informed consent and negligence starting from the opinion of the English House of Lords in *Maynard v West Midlands Regional Health Authority*,²²⁷⁸ where the court approved the dictum of Lord Clyde in *Hunter v Hanley*²²⁷⁹ that the true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether the doctor has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care, consistent with the Bolam principle.²²⁸⁰ The Court further considered in detail the *Sidaway* case,²²⁸¹ especially the dissenting judgment of Lord Scarman who took as his starting point "the patient's right to make his own decision, which may be seen as a basic human right protected by the common law."²²⁸² Lord Scarman inferred that:

If, therefore, the failure to warn a patient of the risks inherent in the operation which is recommended does constitute a failure to respect the patient's right to make his own decision, I can see no reason in principle why, if the risk materialises and injury or damage is caused, the law should not recognise and enforce a right in the patient to compensation by way of damages.²²⁸³

Further, if (a) the patient suffers damage, (b) as a result of an undisclosed risk, (c) which would have been disclosed by a doctor exercising reasonable care to respect her patient's right to decide whether to incur the risk, and (d) the patient would have avoided the injury if the risk had been disclosed; then the patient will in principle have a cause of action

²²⁷⁸ *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634 [638].

²²⁷⁹ *Hunter v Hanley* 1955 SC 200 [206].

²²⁸⁰ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 [587].

²²⁸¹ *Sidaway v Bethlem Royal Hospital* (1985) 1 AC 871.

²²⁸² *Sidaway v Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 All ER 643 [882].

²²⁸³ *Sidaway v Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 All ER 643 [884-885].

based on negligence. Lord Scarman argued that the decision whether to consent to the treatment proposed did not depend solely on medical considerations, rather, “the doctor's concern is with health and the relief of pain. These are the medical objectives. But a patient may well have in mind circumstances, objectives, and values which he may reasonably not make known to the doctor but which may lead him to a different decision from that suggested by a purely medical opinion.”²²⁸⁴

Lord Scarman then concluded as follows:

To the extent that I have indicated I think that English law must recognize a duty of the doctor to warn his patient of risk inherent in the treatment which he is proposing: and especially so, if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk. Even if the risk be material, the doctor will not be liable if upon a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to his patient's health.²²⁸⁵

The Supreme Court next considered the judgment of the English House of Lords in *Pearce v United Bristol Healthcare NHS Trust*²²⁸⁶ where Lord Woolf observed that:

In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law, as indicated in the cases to which I have just referred, that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.²²⁸⁷

²²⁸⁴ Sidaway v Bethlem Royal Hospital and the Maudsley Hospital [1985] 1 All ER 643 [885-886].

²²⁸⁵ Sidaway v Bethlem Royal Hospital and the Maudsley Hospital [1985] 1 All ER 643 [889-890].

²²⁸⁶ Pearce v United Bristol Healthcare NHS Trust [1999] PIQR P 53.

²²⁸⁷ Pearce v United Bristol Healthcare NHS Trust [1999] PIQR P 53 [para 21].

The *Pearce* case²²⁸⁸ involved an expectant mother whose pregnancy was over term. Her consultant obstetrician took the view that the appropriate course was for her to have a normal delivery when nature took its course, rather than a C-section at an earlier date, and advised her accordingly. In any event, the baby died *in utero*. The case turned on whether the mother ought to have been warned of the risk of death *in utero* of an over term baby.²²⁸⁹ The Court in *Montgomery* next referred to the judgment of the English HL in *Chester v Afshar*,²²⁹⁰ which was based on the issue of causation, where the court held that “that the doctor in question had been under a duty to warn the patient of a small (1%-2%) risk that the proposed operation might lead to a seriously adverse result.”²²⁹¹ The House of Lords held that the rationale for this duty to warn was “to enable adult patients of sound mind to make for themselves decisions intimately affecting their own lives and bodies”.²²⁹² The Court further held that “in making a decision which might have a profound effect on her health and well-being, a patient was entitled to information and advice about possible alternative or variant treatments.”²²⁹³ In arriving at its decision, the Court in *Montgomery* also referred to international law as applied in the Canadian case of *Riebl v Hughes*,²²⁹⁴ and considered in more detail the judgment of the Australian High Court in *Rogers v Whittaker*,²²⁹⁵ where the Court reformulated the test of the materiality of a risk to encompass the situation in which, where the doctor knows or ought to know, the actual patient would be likely to attach greater significance to a risk than the hypothetical reasonable patient might do with certain exceptions. In this case, the Court stated that:

2288 *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR P 53.

2289 *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11 [para 64].

2290 *Chester v Afshar* [2002] 3 All ER FR 552 (CA).

2291 *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11 [para 68].

2292 *Chester v Afshar* [2002] 3 All ER FR 552 [para 5].

2293 *Chester v Afshar* [2002] 3 All ER FR 552 [para 98].

2294 *Riebl v Hughes* (1980) 114 DLR (3d) 1.

2295 *Rogers v Whittaker* [1993] 4 Med LR 79.

[A] risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.²²⁹⁶

The Scottish Supreme Court, in allowing the appeal of Mrs Montgomery, concluded that:

The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in *Sidaway* by Lord Scarman, and by Lord Woolf MR in *Pearce*,²²⁹⁷ subject to the refinement made by the High Court of Australia in *Rogers v Whitaker*²²⁹⁸ [...] An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.²²⁹⁹

In its judgment, the Supreme Court also gave some exceptions to its decision regarding information disclosure to include where it would not be in the best interests of the patient, in cases of necessity such as due to unconsciousness or based on therapeutic privilege.²³⁰⁰ The court further adumbrated three important issues that ought to be taken into consideration in such cases:

(a) Assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude, including the nature of the risk, the effect which its occurrence would have upon the life of

²²⁹⁶ Rogers v Whittaker [1993] 4 Med LR 79 [490].

²²⁹⁷ Pearce v United Bristol Healthcare NHS Trust [1999] PIQR P 53.

²²⁹⁸ Rogers v Whittaker [1993] 4 Med LR 79.

²²⁹⁹ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 87].

²³⁰⁰ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 88].

the patient, and the importance to the patient of the benefits sought to be achieved by the treatment and the alternatives.²³⁰¹

(b) The doctor's advisory role would involve dialogue, to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that the patient is then in a position to make an informed decision. This role be performed effectively only if the information is provided to a patient in a comprehensible manner rather than by bombarding the patient with technical information which a patient cannot reasonably be expected to understand, and also not by routinely demanding patients' signature on a consent form.²³⁰²

(c) The therapeutic exception should not be abused, rather it is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment. Therefore, it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where the patient is liable to make a choice, which the doctor considers to be contrary to his or her best interests.²³⁰³

In addition to the preceding points, while discussing its decision, the Supreme Court considered other socio-legal issues arising from changes in society in recent times. This include the recognition and adoption of the human rights doctrine in national and international laws, which recognize the patient as an individual with the right of autonomy, whose rights ought to be recognized and respected, rather than the Hippocratic tradition, whereby doctors are considered as providing beneficent services to patients based on the paternalistic concept of 'doctor knows best'. Further, the Court alluded to the development of consumer rights in healthcare, where patients had acquired the rights of consumers of healthcare services, and HCPs were providers, creating a new dynamic in the doctor-patient relationship.²³⁰⁴ The Court finally contended that the decisions referring to doctors are equally applicable, *mutatis mutandis*, to all HCPs.²³⁰⁵

²³⁰¹ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 89].

²³⁰² Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 90].

²³⁰³ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 91]

²³⁰⁴ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 87] see also Chima *A primer on medical law* [18-19, 122-123] see also *WMA Manual on ethics* 27.

²³⁰⁵ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11 [para 87].

It is hence submitted, following from the above judgment, that South African courts ought to re-evaluate recent judgments in cases such as *Louwrens v Oldwage*,²³⁰⁶ *McDonald v Wroe*²³⁰⁷ and *Sibisi NO v Maitin*,²³⁰⁸ while taking into consideration the injunctions and intent of the South African Constitution²³⁰⁹ which urges adjudicators to consider 'foreign law' as well as relevant fundamental rights considerations expounded in the Constitution and recent South African legislation, such as the National Health Act²³¹⁰ and regulations, as well as the Consumer Protection Act (CPA) in their judgments.^{2311,2312} For example, the CPA requires healthcare providers to disclose prices or specific cost estimates including variables, prior to provision of healthcare services except in emergency situations.^{2313,2314}

8.2.6 Distinguishing between the common law doctrines of negligence, wrongfulness, assault, battery and lack of informed consent

Recent judgments by South African courts appear to have introduced a new dimension into the adjudication of cases of failure to obtain informed consent, including placing plaintiffs' in the difficult position of providing a dual burden of proof,²³¹⁵ as shown in recent the judgment by the SCA in the case of *Sibisi NO v Maitin*.²³¹⁶ In this case, the court held that if a plaintiff was unsuccessful in proving negligence on the part of the HCP, then any allegation of lack of informed consent falls away and automatically becomes a moot point. This reasoning has also been applied by the High Court recently in case the case of *Pane v MEC Free State*.²³¹⁷

²³⁰⁶ Louwrens v Oldwage [2004] 1 All SA 532 (C).

²³⁰⁷ McDonald v Wroe (2006) 3 All SA 565 (C).

²³⁰⁸ Sibisi NO v Maitin (311/13) [2014] ZASCA 156.

²³⁰⁹ Constitution of the Republic of South Africa 1996.

²³¹⁰ National Health Act 61 of 2003.

²³¹¹ Consumer Protection Act 2008

²³¹² Kirby N "Consumerism and healthcare" February 12 2012 [http:// www.werksmans.com/legal-briefs-view/consumerism-and-healthcare/](http://www.werksmans.com/legal-briefs-view/consumerism-and-healthcare/) (Date of use: 29 October 2017).

²³¹³ Klinck E "Law in practice: Informed consent: Old rules in new formats?" May 7, 2012 www.elsabeklinckassociates.co.za (Date of use: 29 October 2017).

²³¹⁴ Albers J "An ethical and legal appraisal of the new South Africa consumer protection act in terms of diabetes care" 2010 *S Afr J Diabetes Vasc Dis* 8 at 108.

²³¹⁵ Zwartz L "Sibisi NO v Maitin: A dual burden of proof?" June 2015 *De Rebus* 33.

²³¹⁶ Sibisi NO v Maitin (311/13) [2014] ZASCA 156 see also Zwartz L "Sibisi NO v Maitin: A dual burden of proof?" June 2015 *De Rebus* 33.

²³¹⁷ Pane v MEC Free State Department of Health [2016] ZAFSHC 99.

Historically, the charge of ‘negligence’ in informed consent cases was first introduced in the American case of *Natanson v Kline*²³¹⁸ by the Supreme Court of Kansas. Prior to that, cases of lack of informed consent were tried under the charge of battery or trespass as shown in the landmark *Schloendorf* case²³¹⁹ and also illustrated by the South African case of *Stoffberg v Elliot*.²³²⁰

Negligence in English common law refers to the dictum quoted by the court in *Hunter v Hanley*,²³²¹ namely that “the true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether the doctor has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care”, later adopted by McNair J as the Bolam principle in the case of *Bolam v Friern HMC*.²³²² In South African jurisprudence, negligence has been described as occurring “when the conduct of a person falls short of the standard which the law expects of the reasonable person in the particular circumstances of the case.”²³²³ The test for negligence was established in South African law in the case of *Kruger v Coetzee*²³²⁴ where the court held that for the purposes of liability, *culpa* arises when a diligent *pater familias* in the position of the defendant:

- (i) would foresee the reasonable possibility of his conduct injuring another in his person or property and causing him patrimonial loss, and
- (ii) would take reasonable steps to guard against such occurrence, and
- (iii) the defendant failed to take such steps.²³²⁵

In English Common Law, the test for negligence is based on a four-way test consisting of (a) duty of care (b) breach of duty (c) causation and (d) foreseeability.²³²⁶ South African

²³¹⁸ *Natanson v Kline* 186 Kan. 393 (1960)350 P.2d 1093

²³¹⁹ *Schloendorf v Society of New York Hospital* [1914] 211 NY 105 NE 92

²³²⁰ *Stoffberg v Elliot* 1923 CPD 148-150.

²³²¹ *Hunter v Hanley* 1955 SC 200 [206].

²³²² *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 [587].

²³²³ Dutton I *The Practitioners Guide to Medical Malpractice in South African Law* (Siberlink Cape Town 2015) 85 see also Barit *The doctrine of informed consent in South African medical law* 26.

²³²⁴ *Kruger v Coetzee* 1966 2 SA 428 (A).

²³²⁵ *Kruger v Coetzee* 1966 2 SA 428 (A) [426].

²³²⁶ Chima *A primer on medical law* [134-135] see also Khan et al *Clinical Negligence* 2002 [71-203].

common law, on the other hand, requires that the five elements of a delict, vis-à-vis; conduct, causality, wrongfulness, capacity and fault; must be proven in order to succeed with a delictual claim. The fault element may take either the form of *dolus* or *culpa*. However, if a claim is based on medical negligence as the ground of liability, negligence rather than intent, must be proven,²³²⁷ due to the fact that negligence is considered a non-intentional tort, while assault or battery is an intentional tort.²³²⁸ The test for medical negligence relates to reasonable skill and care, foreseeability, and preventability of ensuing harm, and is measured against the standard of the reasonable expert in the circumstances, as established the cases of *Mitchell v Dixon*²³²⁹ and *Van Wyk v Lewis*.²³³⁰ It has been shown in various South African cases such as *Lymberg Jeffries*,²³³¹ *Richter and Another v Estate Hamman*,²³³² and *Broude v McIntosh*,²³³³ that failure to obtain informed consent can be deemed negligent, consistent with the English case of *Bolam v Friern HMC*,²³³⁴ and other judgments in common law jurisdictions, as discussed in the preceding section on comparative law.²³³⁵

Failure to obtain informed consent prior to medical or surgical treatment is technically considered as ‘assault’ or ‘battery’. Assault is defined as the “[...] intentional application of force or violence ... to the person of another,” as shown the case of *Rex v Jolly and Others*.²³³⁶ In assault cases, the fault element takes the form of intention. By definition, “an assault is an act which causes another person to apprehend the infliction of immediate, unlawful force on his person, while battery is the actual application of unlawful force on another person”,²³³⁷ as shown in the English case of *Collins v Wilcock*.²³³⁸ Sometimes there could be an assault without battery, as demonstrated in the English case

²³²⁷ Zwartz L “Sibisi NO v Maitin: A dual burden of proof?” 2015 *De Rebus* 33.

²³²⁸ Jones MA *Textbook on torts* 8th ed (Oxford University Press Oxford 2002) 508-509.

²³²⁹ *Mitchell v Dixon* 1914 AD 519.

²³³⁰ *Van Wyk v Lewis* 1924 AD 438.

²³³¹ *Lymberg v Jeffries* 1925 AD 236.

²³³² *Richter and Another v Estate Hamman* 1976 (3) SA 226 (C).

²³³³ *Broude v McIntosh* 1998 (3) SA 60 (SCA).

²³³⁴ *Bolam v Friern Barnet Health Management Committee* (1957) 2 All ER 118.

²³³⁵ Section 8.2.5 of this thesis.

²³³⁶ *Rex v Jolly and Others* 1923 AD 176.

²³³⁷ Jones *Textbook on Torts* 509.

²³³⁸ *Collins v Wilcock* [1984] 3 All ER 374 [377].

of *Stephens v Myers*,²³³⁹ where the defendant threatened the plaintiff with a clenched fist, making him believe that he was about to be hit, but was stopped before hitting the plaintiff. He was therefore found guilty of assault, but not of battery. Therefore, a surgeon who operates without consent commits a battery, although his intention, far from being hostile, is designed to benefit the patient.²³⁴⁰ Therefore, injury need not result for assault to be founded in law, because assault is an intentional tort. Previously, failure to obtain informed consent had been largely accepted as constituting assault as shown in South African cases such as *Stoffberg v Elliott*,²³⁴¹ and *Esterhuizen v Administrator Transvaal*.²³⁴² However, in recent cases such as the *Sibisi* case²³⁴³ and *Pane v MEC Free state*,²³⁴⁴ South African judgments have suggested that once a case of negligence is not proved, then the charge of lack of informed consent becomes moot.²³⁴⁵ This begs the question whether if negligence is not proven, why the failure to obtain informed consent by defendant doctors or other HCPs is not be considered an assault and therefore unlawful? The standard for wrongfulness or unlawful action in South African common law has been established in the case of *Minister van Polisie v Ewels*,²³⁴⁶ where it was stated that :

Our law has developed to the point where an omission is regarded as unlawful conduct when the circumstances of the case are of such a nature that the omission not only incites moral indignation but also that the legal convictions of the community demand that the omission ought to be regarded as unlawful and that the damage suffered ought to be made good by the person who neglected to do a positive act. In order to determine if there is unlawfulness the question, in a given case of omission, is thus not whether there was the usual “negligence” of the *bonus pater familias*, but whether regard being had to all the facts, there was a duty in law to act reasonably.²³⁴⁷

In light of the above, it is reasonable to argue that the act of obtaining informed consent is one prescribed by law and that omission to obtain informed consent in this day and age,

²³³⁹ *Stephens v Myers* (1830) 4 C & P 349 see also Jones *Textbook on Torts* 509.

²³⁴⁰ Jones *Textbook on Torts* 511.

²³⁴¹ *Stoffberg v Elliott* 1923 CPD 148.

²³⁴² *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T).

²³⁴³ *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156

²³⁴⁴ *Pane v MEC Free State Department of Health* [2016] ZAFSHC 99.

²³⁴⁵ Zwart L “Sibisi NO v Maitin: A dual burden of proof?” 2015 *De Rebus* 33.

²³⁴⁶ *Minister van Polisie v Ewels* 1975 3 SA 590.

²³⁴⁷ *Minister van Polisie v Ewels* 1975 3 SA 590 [597] see also Barit *The doctrine of informed consent in South African medical law* 29.

would violate the rights of individual autonomy and the *boni mores* based on public policy.²³⁴⁸ The South African Constitution guarantees the right to bodily and psychological integrity, amongst other rights.²³⁴⁹ The only way for HCPs to observe and protect these rights, is by obtaining appropriate informed consent from patients or healthcare users. Stated differently, it is submitted that a failure to obtain informed consent prior to medical treatment constitutes a violation of fundamental rights and a redressable wrong, consistent with the observation of Lord Scarman in the case of *Sidaway*, that the right to self-determination is a basic human right: “The existence of the patients right to make his own decision, which may be seen as a basic human right protected by the common law.”²³⁵⁰

In law, righting a wrong is based on the law of torts or delict, whereby the objective is to put the patient back in the position they would have been, if injury had not occurred - “the law of tort is primarily concerned with providing a remedy to persons who have been harmed by the conduct of others.”²³⁵¹ However, looking at the result of the judgments in the case of *Sibisi NO v Maitin*,²³⁵² where the plaintiff lost her appeal at the SCA and was left with a disabled child to care for in perpetuity, and without support and compensation from any source for the wrong intentionally or unintentionally inflicted on her child, and similarly, in *Pane v MEC Free state*,²³⁵³ where the plaintiff was left with a colostomy bag in place and financially destitute, having lost her children and her means of livelihood, one may argue that such judgments, despite the legal arguments, appear inconsistent with the spirit and intent of the new South African Constitution, which is based on foundation of respect for human rights, justice and fairness.²³⁵⁴

²³⁴⁸ Slabbert *International encyclopaedia of laws* [107-108] see also Carstens and Pearmain *Foundational Principles* 937.

²³⁴⁹ The Constitution (s12).

²³⁵⁰ *Sidaway v Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 All ER 643 [649].

²³⁵¹ Jones *Textbook on torts* [1].

²³⁵² *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156.

²³⁵³ *Pane v MEC Free State Department of Health* [2016] ZAFSHC 99.

²³⁵⁴ Constitution of the Republic of South Africa 1996

In the final analysis, Van Oosten quite aptly commented as follows regarding the case of *Castell v De Greef*:²³⁵⁵

[T]he court's preference to place the doctor's duty of disclosure, and its concomitant, the patient's informed consent, within the framework of the wrongfulness element (with *volenti non fit iniuria* [...] rather than the fault element of (intention) of delict [...] This is certainly correct where a medical intervention has been performed without the patient's informed consent, but with due care and skill, and has proved to be beneficial to the patient's health: Here the appropriate action would be assault or *iniuria*, as the case maybe, rather than negligence.²³⁵⁶

8.3 The importance of using empirical methods to study informed consent

This second part of this thesis was designed to use an empirical methodology including quantitative data analysis to evaluate whether HCPs (doctors and nurses) practising in public hospitals in South Africa were knowledgeable about the ethical and legal doctrine of IC, and the current regulatory framework guiding IC in medical practice in South Africa.

In recent times, applied ethicists have started to combine established social scientific methods of inquiry with normative ethical reflection and analysis.^{2357,2358} This is based on the criticism that philosophical bioethics is too abstract and insensitive to social realities and context. According to Emmanuel, "the two most common criticisms of bioethics is that it is divorced from reality and the actual issues that arise in medical practice, research, and health policy debates; and secondly that bioethicists are willing to layout arguments but skittish about actually deciding anything."²³⁵⁹ One symbol of this divorce from reality is the lack of engagement of philosophical ethics with empirical data or 'experience'.²³⁶⁰ Because of such observations, some authors have tried to define empirical ethics or

²³⁵⁵ Castell v De Greef 1994 (4) SA 408 (C).

²³⁵⁶ Van Oosten FFW 1995 *De Jure* 178 see also Carstens and Pearmain *Foundational Principles* 681 and Barit *The doctrine of informed consent in South African medical law* 3.

²³⁵⁷ Sulmasy and Sugarman *Methods of medical ethics* 3-18.

²³⁵⁸ De Vries and Gordijn 2009 *Bioethics* 193-201.

²³⁵⁹ Emanuel *The relevance of empirical research for bioethics* 99.

²³⁶⁰ Ives 2008 *Health Care Ana* 1-6.

bioethics as “normatively oriented medical ethical research that directly integrates empirical research”.²³⁶¹ In this way empirical ethics encompasses both empirical research with normative arguments and analysis, and tries to integrate both elements in such a way that new knowledge is produced, which might not have been possible without combining both methods.²³⁶²

According to Emmanuel, the issue is not whether bioethics should focus on conceptual analysis or empiric research but that it must focus on both.²³⁶³ In terms of practical applications of empirical bioethics, it has been suggested that empirical bioethics may serve three valuable functions in healthcare or contemporary medical practice that enriches the field of bioethics. In this context, empirical data or bioethics can assist with (1) debunking widely held but erroneous views; (2) assessing the importance of ethical concerns; and (3) facilitating the realization of certain ethical values.²³⁶⁴ Other areas in which empirical bioethics and data analysis could play a role would include “assessing the importance of ethical concerns” by helping to resolve the conflict in informed consent regarding the comprehensiveness of information disclosure and understanding of information disclosed, as well as determining the methodological or the ethical concerns surrounding the storage and use of human biological specimens. It can also assist with the realization of ethical values such as respect for autonomy, and in some cases just allocation of scarce healthcare resources.²³⁶⁵ Empirical studies have also shown that people generally have problems in understanding the risks and benefits of medical treatment and decision-making, and this could influence the actual application of existing laws.²³⁶⁶ In view of these multiple roles for empirical bioethics, De Vries and Gordijn²³⁶⁷ have grouped the potential uses of empirical ethics into a five-fold typology as previously elucidated in chapter one of this thesis. Meanwhile Sulmasy and Sugarman summarized two potential reasons for studying the actual conduct of a group with regards to

²³⁶¹ Mertz et al 2014 *BMC Med Ethics* 17.

²³⁶² Mertz et al 2014 *BMC Med Ethics* 17.

²³⁶³ Emanuel *The relevance of empirical research for bioethics* 99.

²³⁶⁴ Emanuel *The relevance of empirical research for bioethics* 99-102.

²³⁶⁵ Emanuel *The relevance of empirical research for bioethics* 104-105.

²³⁶⁶ Musschenga *Reasoning in ethics and law* 183-204.

²³⁶⁷ De Vries and Gordijn 2009 *Bioethics* 194-196.

compliance with moral and ethical dilemmas. One would be to describe compliance with existing moral norms, and secondly, to determine whether policies and procedures designed to operationalise certain moral norms have been successful.²³⁶⁸ Consequently, in recent times, applied ethicists have shifted towards combining empirical, especially social scientific research with normative ethical analysis. Proponents of this approach called ‘empirical bioethics’ or ‘empirical ethics’ have argued that the study of people’s actual moral beliefs, behaviour and reasoning should be the starting point of ethics. Therefore, it has been suggested that the methodologies of the social sciences, especially quantitative and qualitative research, using surveys, interviews and questionnaires is probably the best way to map the reality of peoples actual moral norms.²³⁶⁹

In view of the above observations, I decided to evaluate the practice of IC as stipulated by the National Health Act,²³⁷⁰ and current ethical codes for HCPs, by conducting a cross-sectional quantitative empirical research study to see if HCPs practicing at public hospitals in South Africa, are actually practicing in compliance with the current regulations. Further, to evaluate from the point of view of patients, how compliant HCPs are with current laws and ethical guidelines. In the first part of this thesis, I analysed the ethical, case law and socio-legal issues surrounding IC in medical practice. Based on that analysis I was able establish and define certain issues that may affect the understanding and practice of IC by HCPs in the South African setting.

8.4 The meaning of consent to treatment

According to some authorities in medical ethics and law; ‘consent to treatment’ can be regarded as a special type of agreement which is not governed by the general rules of contractual relationships. Gillon²³⁷¹ has argued previously that consent as a simple agreement is not applicable to the field of medical treatment. He suggests that consent to treatment means “a voluntary, uncoerced decision, made by a sufficiently competent or

²³⁶⁸ Sulmasy and Sugarman in *Methods of medical ethics* 14.

²³⁶⁹ Borry et al 2004 *Med Health Care Philos* 1–3.

²³⁷⁰ National Health Act 61 of 2003 (s6-9).

²³⁷¹ Gillon R *Philosophical medical ethics* (John Wiley & Sons Chichester 1985).

autonomous person on the basis of adequate information and deliberation, to accept rather than reject some proposed course of action that will affect him or her.”²³⁷² Based on this assertion, Mclean²³⁷³ has suggested that consent in medical treatment may consist of two parts, described as “consent as an agreement” and “consent as a permission”.²³⁷⁴ In the former case, consent obliges the doctor or HCP to perform certain duties agreed on between the HCP and the patient. This was illustrated in the American case of *Grimes v KKI*,²³⁷⁵ where the Maryland Court of Appeals held that consent can create a contract enforceable by law if consent agreements contain provisions, where “mutual assent, offer, acceptance, and consideration exist”. The court found that researcher/human subject IC in non-therapeutic research can create a contract, where a contract would mean “a written or spoken agreement intended to be enforceable by law.”²³⁷⁶

It has been suggested that consent, when viewed as a contractual agreement would not give the patient or consentor the unilateral and autonomous right to withdraw from a medical procedure, which entails invasion of bodily integrity, privacy and freedom of choice.²³⁷⁷ On the other hand, “consent as permission” entails an agreement where the consentor, in this case the patient, has the ability and right to terminate such permission at any time by withdrawing the consent or permission given. This has been illustrated in the case of *Ciarlariello v Schactr*²³⁷⁸ where the Supreme Court of Canada held that:

An individual's right to determine what medical procedure will be accepted must include the right to stop the procedure...the patients right to bodily integrity provides the basis for the withdrawal of a consent to a medical procedure even while it is underway. Thus if it is found that the consent is effectively withdrawn during the course of the procedure, then it must be terminated.²³⁷⁹

²³⁷² Gillon *Philosophical medical ethics* 60.

²³⁷³ Mclean AR *Consent to medical treatment and the competent adult* (PhD thesis University of Glasgow 2006).

²³⁷⁴ Mclean *Consent to medical treatment and the competent adult* 131-132.

²³⁷⁵ *Grimes v Kennedy Krieger Institute Inc* 366 MD 29 782 A2d 807 (MD 2001).

²³⁷⁶ *Grimes v KKI* 62-64.

²³⁷⁷ Mclean *Consent to medical treatment and the competent adult* 131-132.

²³⁷⁸ *Ciarlariello v Schactr* SCR 1993 100 DLR 94th 609 SCC.

²³⁷⁹ *Ciarlariello v Schactr* SCR 1993 100 DLR 94th 609 SCC [119].

This understanding of consent as a permission which can be withdrawn by a patient at any time was again demonstrated in the American case of *Moore v Webb*²³⁸⁰ where the Missouri Court of Appeals stated that the relationship between doctor and patient is based on a fiduciary duty of trust and not merely an arms-length contract as in other trade agreements. According to the Court:

This question is not to be ruled by the law of trade and commerce governing transactions between parties who deal at arms-length in the market place. It is to be viewed in the light of the physician-patient relationship which existed between the parties [...]. A physician occupies a position of trust and confidence as regards his patient—a fiduciary position. It is his duty to act with the utmost good faith. This duty of the physician flows from the relationship with his patient and is fixed by law...The law's exaction of good faith extends to all dealings between the physician and the patient...Hence, all transactions between physician and patient are closely scrutinized by the courts which must be assured of the fairness of those dealings. In regard to any contract between physician and patient, it is the rule that the physician has the burden of proving that the patient entered into it voluntarily and advisedly, and without undue influence.²³⁸¹

The above observations may lead one to conclude that “consent to treatment is either not an agreement or it is a particular kind of agreement that does not impose a binding obligation on the consenter.”²³⁸² One can therefore conceive of consent to treatment and healthcare decision-making as comprising two aspects, which include consent as an ‘agreement’ and consent as ‘permission’. Whereas the former creates obligations between the HCP and the patient, the latter waives the obligation of non-interference with the patient’s bodily integrity and well-being.²³⁸³ Therefore as suggested by other commentators, one can also conclude that consent to treatment is a process of shared healthcare decision-making that can encompass both the ethical principles of respect for autonomy and beneficence within the doctor-patient relationship.²³⁸⁴ Ultimately, consent in medical law plays the role of licensing that which would otherwise be battery.²³⁸⁵ “The

²³⁸⁰ Moore v Webb 1961 345 SW 2d 239 (MO App).

²³⁸¹ Moore v Webb 1961 345 S.W.2d 239 (MO App) 243.

²³⁸² Mclean *Consent to medical treatment and the competent adult* 131-176.

²³⁸³ Mclean *Consent to medical treatment and the competent adult* 131-176.

²³⁸⁴ Meisel A and Kuczewiski M “Legal and ethical myths about informed consent” 1996 *Arch Intern Med* 2521-2526.

²³⁸⁵ Grubb et al *Principles of Medical Law* 475.

other role of consent to treatment is to provide the rights bearer with control of that right, which it does by transforming an illegitimate act into a permitted one.”²³⁸⁶ According to Alexander,²³⁸⁷ consent functions as a moral transformative by altering the obligations and permissions that determine the rightness or wrongfulness of others actions.²³⁸⁸

8.5 The validity of informed consent

My analysis of the ethical norms of consent also suggest that IC given by patients in clinical situations in resource-poor settings, where patients are vulnerable due to low education, poverty, and lack of alternative means of obtaining healthcare, as prevalent in most developing countries including South Africa, may not always be valid or true consent. Before a person can give a *valid or true consent*²³⁸⁹ in the context of medical treatment; this requires that the individuals decision must be based on an adequate understanding of what is involved in the medical procedure before giving permission or refusing the medical treatment in question. This requires broadly that such a decision must be made by a person with (a) capacity, (b) based on adequate information, and (c) voluntarily, and without any undue influence or coercion.^{2390, 2391} According to the American court in *Canterbury v Spence*:²³⁹²

True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each...the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice.²³⁹³

The court goes on to state that the patient's reliance on the physician for information is “well-nigh abject” because of the asymmetry of knowledge between a learned/trained

²³⁸⁶ Grimes v KKI 13-15.

²³⁸⁷ Alexander L “The moral magic of consent (II)” 1996 *Legal Theory* 165-174.

²³⁸⁸ Alexander 1996 *Legal Theory* 165-174.

²³⁸⁹ Khan et al *Clinical Negligence* 41-69.

²³⁹⁰ Carsten and Pearmain *Foundational Principles* 878-879.

²³⁹¹ Chima *Consent and patients' rights* 34-35.

²³⁹² *Canterbury v Spence* (1972) 464 2d 772.

²³⁹³ *Canterbury v Spence* (1972) 464 2d 772 [28].

physician HCP and a patient.²³⁹⁴ Therefore, it has been suggested that the doctor or HCP must be willing and has a duty to explain a clinical procedure without necessarily turning the patient or their surrogate decision makers into students of medicine.²³⁹⁵

How much information should a HCP give to a patient or the patient's surrogate before they feel informed enough to make a decision? The issue of the nature and amount of information disclosure is a contested area in medical jurisprudence which has been discussed in previous chapters of this thesis, but will be further summarized below. Nonetheless, it has been established that there are five key elements that make IC valid. This would include:

- (i) Competence or capacity
- (ii) Voluntariness
- (iii) Information disclosure
- (iv) Understanding, and
- (v) Authorization (agreement or refusal) to give consent²³⁹⁶

While there is general agreement by many authorities regarding the key elements of IC as adumbrated above,^{2397,2398} there is evidence to show from the literature review in chapters 2 and 3 of this thesis, that many HCPs sometimes misunderstand the requirements of IC and the ethical principle of respect for autonomy. For example, one author described the concept of respect for autonomy as, "autonomy within ethics means that individuals have the right to information and, on the basis of this, the right to agree or refuse to participate in research".²³⁹⁹ Such an incomplete definition leaves out important aspects of IC including, capacity, comprehension of information disclosed, and voluntariness of action in agreeing or refusing the recommended treatment. Such misconceptions about respect for autonomy and the key elements of IC may lead to

²³⁹⁴ Canterbury v Spence (1972) 464 2d 772 [31].

²³⁹⁵ Lore W "Medical ethics in the protection of patients' rights" 1993 *Medicus* 227-229.

²³⁹⁶ Beauchamp and Childress *Principles of biomedical ethics* 80.

²³⁹⁷ Beauchamp and Childress *Principles of biomedical ethics* 77-98.

²³⁹⁸ Faden and Beauchamp *The history and theory of informed consent* 274.

²³⁹⁹ Shaibu 2007 *Nurs Ethics* 504.

misapplication of the doctrine during nursing care and clinical practice.²⁴⁰⁰ It has been stated that the doctrine of IC is founded on the premise that self-determination should not be blind,²⁴⁰¹ that patients' interests and well-being are best served when patients understand their medical situation and participate in decisions affecting their own health.²⁴⁰² Appelbaum and Roth²⁴⁰³ have also suggested that the requirement that consent to treatment be made by competent patients ensures that some policy goals regarding IC are actually achieved. Firstly, that the autonomy of the competent patient is recognized, secondly that the rights of the incompetent patient is protected, and thirdly that the mandate that the wishes of the competent patient is respected fosters respect for individual autonomy.²⁴⁰⁴

Some commentators distinguish judgments of capacity from judgments of competence by arguing that while HCPs may determine capacity and incapacity, whereas it is the courts who will usually make judgments about competence and incompetence.²⁴⁰⁵ However, others have suggested that when doctors make a determination that a patient lacks decision-making capacity (DMC), the practical effect is the same as a legal determination of incompetence.²⁴⁰⁶ One of the controversial areas or elements of IC relates to determining patients' DMC. This is somewhat related to the age of consent to treatment, fluctuating capacity, the status of incompetent patients and mature minors. In South Africa, as in other jurisdictions, the age of consent to treatment is legally stipulated as 12 years of age.²⁴⁰⁷ This is much lower than the age of consent in other jurisdictions, such as England, where the age of consent is 16 years.²⁴⁰⁸ Children who are found to be 'Gillick competent',²⁴⁰⁹ or mature minors, are allowed to consent to certain medical treatments

2400 Aveyard H 2002 *J Adv Nurs* 243-249.

2401 Meisel and Kuczewski 1996 *Arch Intern Med* 2521-2522.

2402 Meisel and Kuczewski 1996 *Arch Intern Med* 2523.

2403 Appelbaum PS and Roth LH "Clinical issues in assessment of competency"1981 *Am J Psychiatry* 1462-1467.

2404 Appelbaum and Roth1981 *Am J Psychiatry* 1462.

2405 Weinstock R, Copelan R and Bagheri A "Competence to give informed consent for medical procedures" 1984 *Bull Am Acad Psych Law* 117-125.

2406 Grisso T and Appelbaum PS *Assessing Competence to consent to treatment: A guide for physicians and other health professionals* (Oxford university Press New York 1998) 11.

2407 Children's Act 38 of 2005.

2408 UK Children Act 1989 see also Family Law Reform Act 1969 (s8) and Hocton *Law of consent to medical treatment* 78.

2409 Gillick v West Norfolk and Wisbech Area Health Authority [1986] AC 112.

e.g. access to contraceptives, but are denied the right to consent or refuse more complex healthcare services or procedures, such as organ transplantation or life-saving blood transfusion.^{2410,2411} Similarly, in South Africa, while the age of consent to routine medical treatment is legally set at 12 years, mature minors may be able to consent to other treatments, however, refusal of beneficial treatment can be overridden by a parent or the court as upper guardian of minors.²⁴¹² In South Africa, the age of consent to abortion or is also subject to the restrictions and regulations imposed by the Choice on Termination of Pregnancy Act,²⁴¹³ where the law stipulates that ‘any woman of any age’ can consent to termination of pregnancy, thereby creating an anomaly if compared to the above situation with regard to the termination of a pregnancy. These subtle differences in the law are issues which ought to be known to the average HCP practicing in South Africa.

As will be summarized in sections below, based on the empirical data analyzed in chapters 5 to 7 of this thesis, some of these basic legal regulations were not known to many HCPs practicing in this setting as previously reported.²⁴¹⁴

8.6 Standards of information disclosure

One of the more contested areas of medico-legal jurisprudence is on the standard of information disclosure required for IC. In other words, how much information should be disclosed by the HCP to the patient for IC to be considered valid? As explained previously, for a patient or healthcare user to make an informed decision regarding treatment or refusal of treatment, there is concomitant obligation on the part of the HCP to provide all the necessary information to the patient to enable an informed choice. On this consideration, there are two contesting schools of thought. On the one hand there is the

²⁴¹⁰ Chima *Consent and patients’ rights* 35-37.

²⁴¹¹ Khan et al *Clinical Negligence* 52-54.

²⁴¹² McQuoid-Mason D “Parental refusal of blood transfusions for minor children solely on religious grounds-the doctor’s dilemma resolved” 2005 *SAMJ* 29-30.

²⁴¹³ Choice on Termination of Pregnancy Act 1996.

²⁴¹⁴ Chima 2013 *BMC Med Ethics* S3 see also Chima 2015 *Niger J Clin Pract* S46-S56.

'reasonable doctor standard' based on English common law as outlined by McNair J in *Bolam v Friern HMC*,²⁴¹⁵ generally known as the *Bolam* principle, which states that:

A doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of men skilled in that particular art, [...] putting it the other way round, a doctor is not negligent, if he is acting with such a practice, merely because there is a body of opinion that takes a contrary view.²⁴¹⁶

It has been argued that English courts have opted for a paternalistic approach by following the 'reasonable doctor standard', which based information disclosure on the clinical judgement or accepted practice of medical practitioners²⁴¹⁷ as established in *Bolam*²⁴¹⁸ and reaffirmed by the House of Lords in the *Sidaway* case,²⁴¹⁹ where Lord Templeman observed that:

At the end of the day, the doctor bearing in mind the best interests of the patient and bearing in mind the patients right to information which will enable the patient to make a balanced judgement, must decide what information should be given to the patient, and what terms that information should be couched.²⁴²⁰

This idea of abridged information disclosure has also been applied in other court cases such as *Chatterton v Gerson*,²⁴²¹ where Bristow J said that the patient should be informed in 'broad terms', thereby implying that not all information is required and the nature and amount of it to be disclosed to a patient would be based on reasonable doctor standard rather than on the requirements of the patient.

²⁴¹⁵ *Bolam v Friern Health Management Committee* [1957] 1 WLR 582.

²⁴¹⁶ *Bolam v Friern Health Management Committee* [1957] 1 WLR 582 [587].

²⁴¹⁷ Van Oosten *The doctrine of informed consent in medical law* (Peter Lang Frankfurt 1991) 395-461.

²⁴¹⁸ *Bolam v Friern Health Management Committee* [1957] 1 WLR 582.

²⁴¹⁹ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643

²⁴²⁰ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643 [903].

²⁴²¹ *Chatterton v Gerson* [1981] 1 All ER 257.

8.6.1 South African case law on information disclosure

Similarly, in South African common law, the reasonable doctor standard was applied in the case of *Richter and Another v Estate Hamman*,²⁴²² and more recently by the SCA in the case of *Louwrens v Oldwage*,²⁴²³ contrary to the ‘prudent patient standard’ as established by Ackerman J in the *Castell case*²⁴²⁴ and consequently applied by Yekiso J at the High Court in the *Oldwage case*.²⁴²⁵ These conflicting judgments appear to have created some confusion in South African case law regarding the standards of information disclosure required for IC. In the context of South African jurisprudence, prior to the more recent cases of *Castell v De Greef*²⁴²⁶ and the enactment of the NHA,²⁴²⁷ earlier South African court judgments demonstrate that doctors were not required by law to disclose all the possible consequences and complications of medical treatment. It was enough that the patient was informed in broad terms about the serious risks and dangers inherent in the treatment, as demonstrated in cases such as *Lymberg v Jeffries*²⁴²⁸ and *Richter and another v Estate Hamman*,²⁴²⁹ where it was argued that HCPs are not expected to disclose to their patients unusual, uncommon, or remote risks or complications.²⁴³⁰ According to the court in the case of *Rompel v Botha*:²⁴³¹

There is no doubt that a surgeon who intends operating on a patient must obtain the consent of the patient. In such cases where it is frequently a matter of life and death I do not intend to express any opinion as to whether it is the surgeon's duty to point out to the patient *all the possible injuries* which might result from the operation, but in a case of this nature, which may *have serious results* to which I have referred...I have no doubt that a patient should be informed of the *serious risks* he does run. If such dangers are not pointed out to him then, in

²⁴²² Richter & Another v Estate Hamman 1976 (3) SA 226 (C).

²⁴²³ Louwrens v Oldwage [2004] 1 All SA 532 (C).

²⁴²⁴ Castell v De Greef 1994 (4) SA 408 (C).

²⁴²⁵ Louwrens v Oldwage [2004] 1 All SA 532 (C).

²⁴²⁶ Castell v De Greef 1994 (4) SA 408 (C).

²⁴²⁷ National Health Act 61 of 2003.

²⁴²⁸ Lymberg v Jeffries 1925 AD 236.

²⁴²⁹ Richter v Estate Hamman 1976 (3) SA 226 (C)

²⁴³⁰ Van Oosten FFW “Informed consent: patient rights and the doctor’s duty of disclosure in South Africa” 1989 *Med Law* 443-456.

²⁴³¹ Rompel v Botha 1953 (TPD) unreported.

my opinion, the consent to the treatment is not in reality consent-it is consent without knowledge of the possible injuries.²⁴³²

Therefore it has been suggested that generally in South Africa, the duty to disclose consists in fully informing the patient of “the nature purpose and benefits and the probable, substantial and inevitable risks and consequences of the medical intervention, irrespective of whether they are therapeutic or diagnostic in nature.”²⁴³³ In recent times, however, the South African standards for information disclosure during IC appear to have changed with the judgment of the Ackerman J in the *Castell* case,²⁴³⁴ where the court held that for consent to be informed, a patient needs to fully appreciate the nature of the harm or the risk to which he or she is consenting. Further, the court held that the standard of disclosure required is the ‘material risks standard’ where the test of materiality would be based on what a reasonable person in the patient’s position would likely attach significance to, in arriving at a decision, or what the doctor ought to have known would be of significance to that particular patient in arriving at a decision regarding information disclosure.²⁴³⁵ It has been argued that the rationale for the court’s decision in the *Castell* case arose from the South African Constitution of 1996,²⁴³⁶ which recognizes the rights of autonomy by entrenching and codifying the rights to human dignity and bodily integrity in sections 10 and 12(2) of the Bill of Rights.²⁴³⁷ Based on the judgment in the *Castell* case,²⁴³⁸ one may argue that the minimum level of information required to render IC valid based on South African regulations would be that:

- i. the consenting party must have had knowledge and been aware of the nature and extent of the harm or risk
- ii. the consenting party must have appreciated and understood the nature and extent of the harm or risk
- iii. the consenting party must have consented to the harm or assumed the risk

²⁴³² As quoted in Van Oosten 1989 *Med Law* 448.

²⁴³³ Van Oosten 1989 *Med Law* 449.

²⁴³⁴ *Castell v De Greef* 1994 (4) SA 408 (C).

²⁴³⁵ Thomas R “Where to from *Castell v De Greef*? 2007 *SALJ* 188-215.

²⁴³⁶ The Constitution of the Republic of South Africa 1996.

²⁴³⁷ The Constitution of the Republic of South Africa 1996 (s10 and s12).

²⁴³⁸ *Castell v De Greef* 1994 (4) SA 408 (C).

- iv. the consent given by the consenting party must be comprehensive, that is, extends to the entire transaction, inclusive of the consequences^{2439,2440,2441, 2442,2443}

Therefore, in terms of South African law and based on *Castell*,²⁴⁴⁴ a doctor needs to disclose all material risks associated with the proposed treatment, based on a 'prudent patient standard', which is a subjective standard of information disclosure rather than an objective reasonable person standard. The actual common law test for materiality is based on the concept that "a risk is material if the person who consented would not have done so, had the risk been made known to him or her".²⁴⁴⁵

As discussed in this thesis, the NHA²⁴⁴⁶ codified the requirements for IC and information disclosure as part of the legislative framework regulating healthcare services in South Africa. The law recognises the principle of individual autonomy and differentiates between 'users' of healthcare services and 'healthcare providers' which refers to all providers of health care services registered in terms of the Health Professions Act,²⁴⁴⁷ and other related laws such as the Nursing Act.²⁴⁴⁸ This means that the requirements for IC are not limited to doctors alone but equally to all health care professionals (HCPs). The NHA stipulates that all healthcare users (patients), have a right to IC and that users also have a right to participate in decisions affecting their personal health, and therefore must have full knowledge regarding the proposed treatment. The law describes IC in section 7 of the NHA as meaning "consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6."

²⁴³⁹ Van Oosten 1995 *De Jure* 171-175.

²⁴⁴⁰ *Castell v De Greef* 1994 (4) SA 408 (C) [425].

²⁴⁴¹ Carstens and Pearmain *Foundational Principles* 684.

²⁴⁴² Thomas 2007 *SALJ* 191.

²⁴⁴³ Van Oosten 1995 *De Jure* 164-179 see also *Castell v De Greef* 1994 (4) SA 408 [425].

²⁴⁴⁴ *Castell v De Greef* 1994 (4) SA 408 (C) [426-427].

²⁴⁴⁵ Thomas 2007 *SALJ* 188-215 [192].

²⁴⁴⁶ National Health Act 61 of 2003.

²⁴⁴⁷ Health Professions Act 56 of 1974 as amended.

²⁴⁴⁸ Nursing Act No 33 of 2005.

Based on section 6 of the NHA,²⁴⁴⁹ a healthcare user is required to have full knowledge and must be informed of:

- (a) The user's health status [diagnosis];
- (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
- (d) The user's right to refuse health services and the implications, risks, obligations of such refusal.

However, section 6(1) (d) provides an exception to section (a) which allows the HCP not to inform a user of the user's health status, 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,²⁴⁵⁰ thereby supporting the exception of 'therapeutic privilege.'²⁴⁵¹ As discussed earlier, other exceptions to information disclosure are enumerated in section 7 of the NHA.²⁴⁵² For example, where the user is unable to give IC and this is provided by a proxy previously mandated by the user in writing, or consent is given by another person mandated by law or by the patients recognized next of kin. IC may also be waived in circumstances outlined in section 7(c) and section 7(d), discussed earlier. These exceptions make provisions for the doctrines of best interests, therapeutic privilege, necessity, waiver, and public policy; all of which are generally recognized exceptions to the IC doctrine.^{2453,2454,2455} The NHA further requires that HCPs inform the user of all this information in a language the user understands, and in a manner that takes into account the user's literacy level, by implication the users' level of education.²⁴⁵⁶ The level of detail provided by the NHA appears to supersede the disclosure requirements outlined in *Castell v De Greef*.²⁴⁵⁷

²⁴⁴⁹ Section 6 of the National Health Act 2003.

²⁴⁵⁰ National Health Act 2003 s 6 (1) (d).

²⁴⁵¹ Chima 2009 *Trans J Coll Med s Afr* 42 see also Van Oosten 1991 *Med Law* 31-41.

²⁴⁵² National Health Act 2003 section 7 (a-d).

²⁴⁵³ Beauchamp and Childress *Principles of biomedical ethics* 83-88.

²⁴⁵⁴ Chima 2009 *Trans J Coll Med S Afr* 38-44.

²⁴⁵⁵ President's Commission *Report of President's commission for the study of ethical problems in medicine and biomedical and behavioral research* (Washington DC 1982) 1.

²⁴⁵⁶ National Health Act 2003 s6 (2).

²⁴⁵⁷ *Castell v De Greef* 1994 (4) SA 408 (C).

It has been suggested that the requirement of full disclosure, and the right of users to participate in healthcare decision-making pertaining to their health, as well as the users' right of refusal, ensures that the NHA,²⁴⁵⁸ gives effect to respect for patients' autonomy and self-determination, as well as enhancing patients' dignity, which is enshrined in section 10 of the Constitution, where it states that "everyone has inherent dignity and the right to have their dignity respected and protected".²⁴⁵⁹ However it has been reported that up to this point in time, the disclosure requirements as outlined in the NHA have actually never been applied in any South African court decisions.²⁴⁶⁰

There is another dimension to the information disclosure debate which relates to the patient's desire for information. This is a socio-legal issue which is applicable to certain cultures and religions. For example, it has been reported that certain Native American population groups are averse to disclosure of negative information regarding healthcare.^{2461,2462} Similarly, it has been reported that some Nigerian and African patients may not be receptive to negative information disclosure due to cultural or religious reasons.^{2463,2464} Such considerations will also play a part in the amount of information disclosed to the patient, based on the patient's desire for information, or waiver of information disclosure.²⁴⁶⁵ Therefore, HCPs should also be aware of the cultural issues and dimensions when considering the amount and nature of information to be disclosed to a patient.

²⁴⁵⁸ National Health Act 2003.

²⁴⁵⁹ Constitution of the Republic of South Africa 1996 (s10).

²⁴⁶⁰ Thomas 2007 *SALJ* 188-215 [209].

²⁴⁶¹ Asai A 1995 *West J Med* 36-39.

²⁴⁶² Gordon E 1997 *Fordham Urb L J* 1321-1362.

²⁴⁶³ Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

²⁴⁶⁴ Matthew DB "Race religion and informed consent-lessons from social science" 2008 *J Law Med Ethic* 149-173.

²⁴⁶⁵ Beauchamp and Childress *Principles of biomedical ethics* 92-93.

8.6.2 Comparative law on information disclosure

Lord Scarman, in *Sidaway*,²⁴⁶⁶ argued for a ‘prudent patient standard’ in England, as practised in other jurisdictions such as Canada, USA, and even Germany,²⁴⁶⁷ when he stated that “it was a strange conclusion if [...] courts should be led to conclude that our law [...] should permit doctors to determine in what circumstances. [...] a duty arose to warn.”²⁴⁶⁸ The courts in North America have maintained in cases such as *Canterbury v Spence*²⁴⁶⁹ and *Reibl v Hughes*²⁴⁷⁰ that a patient must be informed of all material risks, where those ‘material risks’ would consist of what a reasonable person, in such a patient’s position, would be likely to attach significance to, in deciding whether or not to accept or forego the proposed therapy.²⁴⁷¹ This requirement for disclosure of all material risks has been reaffirmed in more recent cases such as *Grimes v KKI*²⁴⁷² where Cathell J asserted that a human subject of biomedical research is entitled to all material information. However, it must be noted that the standard of disclosure required in biomedical research is somewhat more rigorous than that expected in medical treatment, as distinguished by the court in the Canadian case of *Halushka University of Saskatchewan*.²⁴⁷³

The current situation in English common law and jurisprudence is that Lord Scarman’s ‘prudent patient standard’ of information disclosure has become more accepted, as demonstrated in cases such as *Pearce v United Bristol Health Trust*,²⁴⁷⁴ where Lord Woolf held that a doctor should inform the patient of any significant risks which would affect the judgment of a reasonable patient. Further, in *Chester v Afshar*,²⁴⁷⁵ Sir Dennis Henry argued that it would be considered negligent if the omission to disclose risks fell below the professional standard. In *Chester v Afshar*,²⁴⁷⁶ the English CA held that a consultant

²⁴⁶⁶ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643

²⁴⁶⁷ Gilbert M “Agreements, coercion and obligations” 1993 *Ethics* 679-691.

²⁴⁶⁸ *Sidaway v Board of Governors of Royal Bethlem Hospital* [1985] 1 All ER 643[888-889].

²⁴⁶⁹ *Canterbury v Spence* (1972) 464 2d 772.

²⁴⁷⁰ *Reibl v Hughes* (1980) 114 DLR (3d) 1.

²⁴⁷¹ *Canterbury v Spence* (1972) 464 2d 772 [787].

²⁴⁷² *Grimes v KKI* 366 MD 29 782 A2d 807(2001) [64].

²⁴⁷³ *Halushka v University of Saskatchewan* [1965] 52 WWR 608 see also Morin 1998 *J of Leg Med* 215-218.

²⁴⁷⁴ *Pearce v United Bristol NHS Healthcare Trust* [1998] 48 BMLR 18.

²⁴⁷⁵ *Chester v Afshar* [2002] 3 All ER FR 552.

²⁴⁷⁶ *Chester v Afshar* [2002] 3 All ER FR 552[47].

surgeon was negligent for failing to disclose a 1 to 2% risk of nerve damage, even when an enquiry was made by the patient.²⁴⁷⁷ Nevertheless, the *Bolam* principle persisted in English legal jurisprudence, despite the dissenting opinions by Lord Scarman in *Sidaway*²⁴⁷⁸ and the judgment of the House of Lords in *Bolitho v City and Hackney*,²⁴⁷⁹ where it was finally suggested that decisions regarding information disclosure must be subjected to judicial review for logicity and reasonableness. However, in the most recent decision by the UK Supreme Court in the case of *Montgomery v Lanarkshire Health Board*,²⁴⁸⁰ the Court decided that the current position in UK law should be based on a 'prudent patient and material risks standard' of information disclosure. The facts and judgment in this case were discussed elsewhere in this thesis. Ultimately, the Supreme Court (Scotland) arrived at a decision, which states that the current position in UK law should be that:

An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.²⁴⁸¹

In concurring with the unanimous decision of the Supreme Court rendered by Lords Kerr and Reed, Lady Hale cited a passage from the *Principles of medical law*²⁴⁸² whereby the authors were of the opinion that in view of the judgments of English Courts in *Sidaway*,²⁴⁸³ *Pearce*,²⁴⁸⁴ and *Chester v Afshar*,²⁴⁸⁵ the *Bolam* doctrine²⁴⁸⁶ had more or less been

²⁴⁷⁷ *Chester v Afshar* [2002] 3 All ER FR 552[11].

²⁴⁷⁸ *Sidaway v Bethlem Royal Hospital Governors and Others* [1985] 1 All ER 643.

²⁴⁷⁹ *Bolitho v City and Hackney Health Authority* [1988] AC 232 HL.

²⁴⁸⁰ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

²⁴⁸¹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [87].

²⁴⁸² Grubb et al *Principles of Medical Law* 465.

²⁴⁸³ *Sidaway v Bethlem Royal Hospital Governors and Others* [1985] 1 All ER 643

²⁴⁸⁴ *Pearce v United Bristol NHS Healthcare Trust* [1998] 48 BMLR 18.

²⁴⁸⁵ *Chester v Afshar* [2002] EWCA Civ 724.

²⁴⁸⁶ *Bolam v Friern Health Management Committee* [1957] 1 WLR 582.

supplanted in English law, stating “with a reasonable degree of confidence that the doctrine of informed consent had become entrenched in English law.”²⁴⁸⁷ The Lady then asserted that based on the judgment in *Montgomery v Lanarkshire*,²⁴⁸⁸ Scottish law could now say the same.

In view of discussion above, one may conclude that the Bolam principle, based on the reasonable doctor standard, has now been supplanted by the ‘prudent patient’ and ‘material risks’ standards as prevalent in most common law jurisdictions, and in some cases in South African common law.²⁴⁸⁹ With regard to other common law jurisdictions similar to South Africa, such as Australia, the standard of information disclosure tended towards the Canadian and North American standards, as established in *Reibl v Hughes*²⁴⁹⁰ and *Canterbury v Spence*.²⁴⁹¹ For example, in the case of *F v R* 1983,²⁴⁹² the Australian Supreme court, per King CJ, was of the opinion that:

The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.²⁴⁹³

The court suggested further that the amount of information to be disclosed to a patient by a responsible doctor was determined by many complex factors, including “the nature of the matter to be disclosed; the nature of the treatment; the desire of the patient for information; the temperament and health of the patient; and other surrounding circumstances.”²⁴⁹⁴ The judge therefore concluded that, “to allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of

²⁴⁸⁷ Grubb et al *Principles of Medical Law* 465.

²⁴⁸⁸ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11[107].

²⁴⁸⁹ *Castel v De Greef* 1994 (4) SA 408 (C).

²⁴⁹⁰ *Reibl v Hughes* (1980) 114 DLR (3d) 1.

²⁴⁹¹ *Canterbury v Spence* (1972) 464 2d772 (D.C. Cir. 1972).

²⁴⁹² *F v R* (26) (1983) 33 SASR 189.

²⁴⁹³ *F v R* (26) (1983) 33 SASR 189 [194].

²⁴⁹⁴ *F v R* (26) (1983) 33 SASR 189 [200-205].

the scope of the duty of disclosure, including the question whether there has been a breach of that duty.”²⁴⁹⁵ It held that while expert medical evidence was relevant to findings as to the risks that reside in or result from recommended surgery or other treatment. It will also have a bearing on their materiality, but this is not a question that is to be concluded on the basis of the expert medical evidence alone.²⁴⁹⁶ The rule of information disclosure was previously outlined in *Natanson v Kline*²⁴⁹⁷ where the court stated with regard to IC that: “[...] [t]his rule in effect compels disclosure by the physician in order to assure that an informed consent of the patient is obtained.” The duty of the physician to disclose, however, is limited to those disclosures that a reasonable medical practitioner would make under the same or similar circumstances.”²⁴⁹⁸ In the *Natanson* case ²⁴⁹⁹ the court held that the extent of disclosure required of the physician was to: “[...] *disclose and explain to the patient in language as simple as necessary the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body.*”²⁵⁰⁰ Therefore, in the American cases of *Canterbury v Spence*,²⁵⁰¹ *Natanson v Kline*,²⁵⁰² and *Salgo v Leland Stanford Jr.*,²⁵⁰³ American courts established a duty of information disclosure, albeit limited by exceptions for therapeutic privilege and occasional abeyance to the reasonable doctor standard.²⁵⁰⁴

The *Canterbury*²⁵⁰⁵ Court went further to debate and rejected the objective reasonable doctor and reasonable patient standards as a basis for evaluating the extent of information disclosure arguing that:

²⁴⁹⁵ F v R (26) (1983) 33 SASR 189 [192-193].

²⁴⁹⁶ F v R ((26) (1983) 33 SASR 189 [201-205] see also Giesen D “The patient’s right to know-a comparative law perspective” 1993 Med Law 556.

²⁴⁹⁷ *Natanson v Kline* 186 Kan 393 (1960) 350 P2d 1093

²⁴⁹⁸ *Natanson v Kline* 186 Kan 393 (1960) 350 P2d 1093 [400].

²⁴⁹⁹ *Natanson v Kline* 186 Kan 393 (1960) 350 P2d 1093

²⁵⁰⁰ *Natanson v Kline* 186 Kan 393 (1960) 350 P2d 1093 [408].

²⁵⁰¹ *Canterbury v Spence* (1972) 464 2d 772 (DC Cir).

²⁵⁰² *Natanson v Kline* 186 Kan 393 (1960) 350 P.2d 1093

²⁵⁰³ *Salgo v Leland Stanford Board of Trustees* [1957] 154 Cal.App.2d 560, 317 P.2d 170.

²⁵⁰⁴ Faden and Beauchamp *History and Theory of Informed Consent* [114-150] see also *Canterbury v Spence* (1972) 464 2d [47-49].

²⁵⁰⁵ *Canterbury v Spence* (1972) 464 2d.

Consonantly with orthodox negligence doctrine, the physician's liability for nondisclosure is to be determined on the basis of foresight, not hindsight; no less than any other aspect of negligence, the issue on nondisclosure must be approached from the viewpoint of the reasonableness of the physician's divulgence in terms of what he knows or should know to be the patient's informational needs.²⁵⁰⁶

The *Canterbury* court alluded to the 'subjective patients' and 'material risk' standards, by stating that:

The scope of the physician's communications to the patient... must be measured by the patient's need, and that need is the information material to the decision. Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked. And to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure... Optimally for the patient, exposure of a risk would be mandatory whenever the patient would deem it significant to his decision, either singly or in combination with other risks. Such a requirement, however, would summon the physician to second-guess the patient, whose ideas on materiality could hardly be known to the physician. That would make an undue demand upon medical practitioners, whose conduct, like that of others, is to be measured in terms of reasonableness... If, but only if, the fact-finder can say that the physician's communication was unreasonably inadequate is an imposition of liability legally or morally justified...²⁵⁰⁷

From the foregoing, the court in *Canterbury*,²⁵⁰⁸ while recognizing the need to disclose all material risks, was not able to base the disclosure on the 'subjective' reasonable patient standard, arguing that this would place an onerous burden on doctors and HCPs to try to second-guess what each patient would have wanted to know in hindsight. Others have argued that basing information disclosure on the reasonable person standard on the other hand, would not fully recognize individual autonomy, but would rather use the proverbial standard of a reasonable person, which would not take into consideration individual needs such, as personal cultural or religious belief systems, or individual idiosyncrasies.

²⁵⁰⁶ Canterbury v Spence (1972) 464 2d [42].

²⁵⁰⁷ Canterbury v Spence (1972) 464 2d 772 (DC Cir 1972) [41-42].

²⁵⁰⁸ Canterbury v Spence 464 F.2d 772 (DC Cir 1972).

8.7 Comprehension of information disclosed

Although information disclosure and knowledge of that information are necessary for the comprehension of information, plain 'knowledge' is generally not sufficient. The patient or person consenting must also have appreciation of the information disclosed. According to Van Oosten, "information as a *conditio sine qua non* means that information must also be appreciated."²⁵⁰⁹ Real comprehension would involve the ability to use information rationally. Therefore, for a patient to understand the information imparted by a HCP, the patient must not only be able to listen attentively to the HCP, but the HCP must also appreciate that for information to have been communicated successfully, it requires comprehension by the patient, in that the patient must pay attention to that information, understand it, accept, retain the information and then put that information to use in a rational manner.²⁵¹⁰ Francis and Johnston²⁵¹¹ argue that the true test for comprehension is the patient's capacity to understand information; and that the HCP needs to ascertain that the patient actually has the capacity to understand the information conveyed in a non-technical language.²⁵¹² The British Medical Association (BMA)²⁵¹³ guidelines stipulate with regard to understanding that the patient must be shown to:

- Understand in simple language what the medical treatment is, its purpose and nature and why it is being proposed
- Understand its principal benefits, risks and alternatives
- Understand in broad terms what will be the consequences of not receiving the proposed treatment
- Retain the information for long enough to make an effective decision
- Make a free choice (free from pressure or undue coercion)

²⁵⁰⁹ Van Oosten 1989 *LLD thesis* [448-452] see also Barit *The doctrine of informed consent in South African medical law* 17.

²⁵¹⁰ President's Commission 89 see also Van Oosten 1989 *LLD Thesis* 455 and Carstens and Pearmain *Foundational Principles* 885-886.

²⁵¹¹ Francis R and Johnston C *Medical treatment: Decisions and the law-the mental capacity Act in action 2nd ed* (Bloomsbury Professional London 2010) Chapter 2 see also Chima *Consent and patients' rights in human biomedical research* 40.

²⁵¹² Francis and Johnston *Medical treatment: Decisions and the law* (Bloomsbury Professional London 2010) 2.

²⁵¹³ British Medical Association *BMA Consent Toolkit* 2009 http://www.bma.org.uk/-/media/files/pdfs/.../consenttoolkitdec2009_full.pdf (Date of use: 20 February 2016).

8.7.1 Language and effective communication

Although the above requirements are generally applicable in medical treatment, the magnitude of difficulty for understanding required in multicultural and multilingual communities and developing countries could be even higher,²⁵¹⁴ especially in countries which have multiple languages, such as the 11 official languages of South Africa.²⁵¹⁵

Parts of the empirical data reported in this thesis reveal that the population groups using public healthcare services in South Africa are not highly educated.^{2516,2517} In addition, many of the patients do not speak the same primary language as the HCPs especially doctors.²⁵¹⁸ In these types of settings it may be necessary to obtain the services of an interpreter or an intermediary, such as a patient advocate or other healthcare worker (HCW), to assist in putting the information in the patient's native language, or 'in language understandable to the patient', in order to fulfil the obligation for understanding prior to IC; consistent with the requirements in the NHA, which stipulates that: "The health care provider concerned must, where possible, inform the user...in a language that the user understands and in a manner which takes into account the user's level of literacy."²⁵¹⁹ Language barriers can have a negative impact on healthcare services, leading to errors such as misdiagnosis, failure of preventive healthcare and non-adherence by patients to prescribed medications.²⁵²⁰ This could ultimately lead to accusations of negligence and award of damages against doctors and other HCPs.^{2521,2522}

²⁵¹⁴ Bhan A, Majd M and Adejumo A "Informed consent in international research: Perspectives from India, Iran and Nigeria" 2006 *MUMJ* 36-41.

²⁵¹⁵ EThekweni municipality *EThekweni language policy*
<http://www.Durban.gov.za.eThekweniLanguagepolicy.pdf> (Date of use: 19 August 2014).

²⁵¹⁶ Chima 2015 *Niger J Clin Pract* 51.

²⁵¹⁷ Clark et al 2011 *J Surg Educ* 145.

²⁵¹⁸ Chima 2013 *BMC Med Ethics* S3 [13].

²⁵¹⁹ National Health Act 61 of 2003 section 6(2).

²⁵²⁰ Flores 2006 *N Engl J Med* 230.

²⁵²¹ Schenker et al 2007 *J Gen Intern Med* 294–299 see also Yeo S "Language barriers and access to care" 2004 *Annu Rev Nur Res* 59-73 [63-65].

²⁵²² Perkins J "Overcoming language barriers to health care" 1999 *Popular Government* 38-44.

Issues of language difficulty and informed consent related to healthcare services are not limited to South Africa.^{2523,2524} A previous report related to this study indicates that the absence of appropriately trained interpreters is a major barrier to IC for doctors working in public hospitals, as reported in chapter 5 of this thesis and elsewhere.²⁵²⁵ Another study from Limpopo province, South Africa, reports that language difficulties create significant problem for HCPs and could impact on patients' rights to IC and confidentiality in that healthcare setting.²⁵²⁶

Considerations such as these have led the Council for International Organizations of Medical Sciences (CIOMS)²⁵²⁷ to recommend that, "informing the individual patient must not be simply a ritual recitation of the contents of a written document", but rather that "the investigator or HCPs must convey the information, whether orally or in writing, in language that suits the individual's level of understanding", bearing in mind that the "prospective subject's ability to understand the information necessary to give IC also depends on that individual's maturity, intelligence, education, and belief system," as well as "the HCPs ability and willingness to communicate patiently and with sensitivity."^{2528,2529}

8.8 Socio-cultural factors impacting on informed consent in South Africa

Cultural issues may be described as all aspects of the society that influence beliefs, opinions, and choices, such as economic globalization, religion, and politics, amongst others. There are complex issues that face every country regarding education, healthcare, and governance. The ability or inability to explore these cultural influences may impact on decisions affecting citizens, and may be critical to solving pervasive problems and conflicts.²⁵³⁰ Some have suggested that culture plays a crucial role in the contemporary

²⁵²³ Tate et al 2016 *Prehosp Emerg Care* 1-11.

²⁵²⁴ Clark et al 2011 *J Surg Educ* 143-147.

²⁵²⁵ Chima 2013 *BMC Med Ethics* S3 [8-9].

²⁵²⁶ Schlemmer and Mash 2006 (96) *SAMJ* 1084-1087

²⁵²⁷ CIOMS *International ethical guidelines for health-related research involving humans* (CIOMS-WHO Geneva 2016) 34.

²⁵²⁸ CIOMS *Guidelines for biomedical research* (CIOMS-WHO Geneva 2002) 34.

²⁵²⁹ CIOMS *Guidelines for biomedical research* (CIOMS-WHO Geneva 2002) 33.

²⁵³⁰ Institute for Humane Education "Cultural issues" <http://humaneeducation.org/become-a-humane-educator/what-is-humane-education/cultural-issues/> (Date of use: 2 November 2017).

discourse on development, and policy makers have acknowledged that the social and cultural norms of a people can influence their attitude and choices.²⁵³¹ However, one of the criticisms leveled against traditional bioethics has been that it ignores the role of social and cultural factors in the ethical-decision making process, prompting some scholars from the developing countries, to see the globalization²⁵³² as a form of neocolonialism and attempt by the developed world agencies to advance their biomedical agenda on resource poor countries and communities.²⁵³³ Such critics have gone on to call for the recognition of truly global bioethics that acknowledge the existence of alternative ethical frameworks.²⁵³⁴ Some commentators have argued for culturally sensitive bioethics or 'ethnoethics', described as the examination of ethical issues in biomedicine in a non-western cultural context:

This would include moral norms and issues in health care as understood and responded to by members of these societies. Ethnoethics should be informative not only about cross-cultural variation in ethical principles of medicine, but also about variations in issues which in different societies become defined as morally relevant or problematic. Ethnoethical information should contribute to the discourse of medical ethics, not only by illuminating culturally distinctive moral views and problems, but also by helping to provide a more realistic and knowledgeable basis for the exploration of cross-cultural ethical similarities."²⁵³⁵

When applying culture in the context of South Africa, the first consideration may be the issue of high unemployment, with approximately 25-30% of the population currently unemployed,^{2536,2537} as well as that of the low a labour force participation rate of about

2531 Olasunkanmi A "Development in Africa: The need for a culture-sensitive approach" 2011 *J Soc Anth* 97-98.

2532 Valadier P "La mondialisation et les cultures-Globalization and culture" 2001 *Études* 11/2001 505-515 www.cairn.info/revue-etudes-2001-11-page-505.htm (Date of use: 2 November 2017).

2533 Mbugua K "Respect for cultural diversity and the empirical turn in bioethics: A plea for caution" 2012 *J Med Ethics Hist Med* 1-5.

2534 Mbugua K "Is there an African bioethics?" 2009 *Eubios J Asian Int Bioethics* 2-5.

2535 Leiban RW "Medical anthropology and the comparative study of medical ethics" in *Social science perspectives on medical ethics* Weisz G (ed) (University of Pennsylvania Press Philadelphia 1990) 221-240 see also Mbugua 2012 *J Med Ethics Hist Med* 2.

2536 Trading Economics "South Africa unemployment rate 2000-2017" <http://www.tradingeconomics.com/south-africa/unemployment-rate> [Date of use: 3 November 2017).

2537 Chima 2015 *Niger J Clin Pract* 50.

54%, compared to the global average of 69%.²⁵³⁸ There are also historical and residual inequities within South African population groups, because of apartheid^{2539,2540,2541,2542} Under such circumstances, basic health care is unaffordable, and out of reach of the majority of the population who are mostly unemployed and indigent.²⁵⁴³ There is also a dichotomy in the organization of South African healthcare services, consisting of private healthcare services patronized by about (20%) of the population who can afford health insurance, or have financial means to pay for private healthcare, compared with the public health services which are used by the majority (80%) of indigent patients and citizens.^{2544,2545} This dual healthcare system is further characterized by better infrastructure in private hospitals because of commercial competition and better funding, and arguably better educated and more knowledgeable patients and consumers of healthcare services. The dual healthcare system may influence the practice of IC in South Africa,²⁵⁴⁶ similar to what has been reported elsewhere.²⁵⁴⁷

Furthermore, most African societies being culturally complex and paternalistic in nature, may require that consent approval be obtained from community elders/extended family members, or men as heads of households before the actual patients or human subjects of research, can provide consent.^{2548, 2549} The challenge in this setting then, is to ensure that IC is truly voluntary and that community or surrogate consent is not substituted for individuals' consent, which ideally should be obtained voluntarily in the absence of coercion and other undue influences.²⁵⁵⁰

2538 Vollgraaff R "Little hope of hitting job-creation target" 2011-02-20 *Sunday Times* South Africa.
2539 Mhlongo and Mdingi 1997 *BMJ* 252.
2540 London and Baldwin-Ragaven 2008 *Curationis* 5-18.
2541 TRC *Truth and Reconciliation Commission Report-Institutional hearings: The health sector* 109-164.
2542 Moodley and Kling 2015 *AMA J Ethics* 966-972.
2543 Chima 2015 *Niger J Clin Pract* 51 see also Maphai 1989 *Social Dynamics* 1-24.
2544 Department of Health *KwaZulu-Natal Strategic Plan 2015-2019* (DOH KZN 2015) 20-21.
2545 Rowe and Moodley 2013 *BMC Med Ethics* 15.
2546 Rowe and Moodley 2013 *BMC Med Ethics* 15.
2547 Yeo S "Language barriers and access to care" 2004 *Annu Rev Nur Res* 59-73.
2548 Tindana et al *IRB* 2006 1-6.
2549 Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.
2550 Ijsselmuiden and Faden 1992 *N Engl J Med* 830-834 see also National Bioethics Advisory Commission *Ethical and Policy Issues in Research Involving Human Participants* (NBAC Washington DC 2000).

The issues and considerations outlined above present challenges to ensuring that IC obtained from patients in clinical practice in South Africa is based on full information disclosure, and that it is comprehensible, voluntary and autonomous. The empirical study in this thesis was directed at an investigation of the role of HCPs, specifically medical doctors and professional nurses in the ensuring that IC provided by patients during routine healthcare services in South Africa is truly valid. A discussion of the findings from the empirical study is detailed below.

8.9 FINDINGS AND IMPLICATIONS OF THE EMPIRICAL STUDY

8.9.1 Information disclosure

In terms of information disclosure, the empirical part of this study confirms that some components of the requirements for information disclosure, as stipulated by the NHA,²⁵⁵¹ are being complied with by HCPs in South Africa. This includes information about diagnosis (health status of the user); disclosed by 97% of doctors and 77% of nurses. This disclosure was also corroborated by 81% of patients sampled. Further, treatment options, benefits of treatment, treatment risks and risks of refusing recommended treatment was disclosed by over 80% of doctors. This information was corroborated by 60-80% of nurses, while 50-60% of patients agreed with the disclosure of treatment risks and benefits, as shown in table 8.1 below. On the other hand, this study also reveals that there were some inconsistencies and incompleteness in the amount of information disclosed by HCPs to patients. For example, in the case of 'recommended treatment', only 28% of patients agreed that this information was disclosed as previously reported,²⁵⁵² when compared with 89% of doctors,²⁵⁵³ and 65% of nurses.²⁵⁵⁴

²⁵⁵¹ National Health 61 of 2003 s6 (1).

²⁵⁵² Chima 2015 *Niger J Clin Pract* 51.

²⁵⁵³ Chima 2013 *BMC Med Ethics* 7.

²⁵⁵⁴ Chima "Understanding and practice of informed consent by professional nurses in South Africa" 97.

With regard to ‘risks of refusing recommended treatment’, while 83% of doctors and 89% of nurses said this information as disclosed, only 25% of patients acknowledged receiving this information. Finally, in terms of ‘right of refusal’ which is required by South African regulations as contained in the NHA,²⁵⁵⁵ only 28% of patients agreed that this information was disclosed,²⁵⁵⁶ while 65% of doctors, and 67% of nurses, reported that this information was usually disclosed.^{2557,2558} Such inconsistencies could indicate a lack of appreciation or misunderstanding of information, or lack of recall of disclosure, or partial recall by patients, as reported from other studies.^{2559,2560,2561} It could also indicate that while HCPs are theoretically aware of these legal requirements, in practice they rarely convey this information to patients as required by law. Overall, both HCPs and patients agreed that the amount of information disclosed was adequate with majority of respondents agreeing that enough information was disclosed as reported by 74-85% of all participants as shown in table 8.1 below.

8.9.2 Standards of information and risk disclosure

It has been argued that the ‘prudent patient and material risks’ standards were adopted into South African jurisprudence after the *Castell case*.^{2562,2563,2564} However from our current study it appears that these standards have not been clearly understood or adopted by HCPs in South Africa. Based on results from this empirical study, the vast majority of doctors (92%) and nurses (80%) generally disclosed only the ‘most common risks’ to

²⁵⁵⁵ National Health 61 of 2003 s6 (1).

²⁵⁵⁶ Chima 2015 *Niger J Clin Pract* 51.

²⁵⁵⁷ Chima 2013 *BMC Med Ethics* S3 [7].

²⁵⁵⁸ Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97].

²⁵⁵⁸ National Health 61 of 2003 s6 (1).

²⁵⁵⁹ Stunkel L et al “Comprehension and informed consent: Assessing the effect of a short consent form” 2010 *IRB: Ethics & Human Research* 1-9.

²⁵⁶⁰ Schenker Y “Interventions to improve patient comprehension in informed consent for medical and surgical procedures: A systematic review” 2011 *Med Decis Making* 151–173.

Lindegger G et al “Beyond the checklist: Assessing understanding for HIV vaccine trial participation in South Africa” 2006 *J Acquir Immune Defic Syndr* 560-566 see also Taiwo and Kass “Post-consent assessment of dental subjects understanding of informed consent in oral health research in Nigeria” 2009 *BMC Med Ethics* 11.

²⁵⁶² Van Oosten FFW 1995 *De Jure* 164-179.

²⁵⁶³ Carstens and Pearmain *Foundational Principles* 711-716.

²⁵⁶⁴ *Castell v De Greef* 1994 (4) SA 408 (C).

patients, while doctors (88%) would also disclose the ‘most serious’ risk.^{2565,2566} Further, from the current study only, 21% of doctors and 36% of nurses reported disclosing all material risks (see table 8.2), as suggested by the judgment in the *Castell case*.^{2567,2568} The majority of patients from this study on the other hand preferred to know ‘all of the risks’ (78%) involved in treatment, before medical procedures as previously reported²⁵⁶⁹ (see table 8.2). Similarly, when asked what is the required standard of information disclosure in South Africa, 60% of doctors and 56% of nurses chose the ‘reasonable doctor standard’, while 48% of doctors and 47% of nurses chose the ‘prudent patient standard’. In this study, only 21% of doctors and 36% of nurses chose the ‘material risks’ standard as the required standard for risk disclosure as shown in table 8.2 below. This suggests that there is no clear appreciation or understanding of the ‘prudent patient’ and ‘material risks’ standards as the current standard of information disclosure by South African HCPs.

²⁵⁶⁵ Chima 2013 *BMC Med Ethics* S3 [8].

²⁵⁶⁶ Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97].

²⁵⁶⁷ *Castell v De Greef* 1994 (4) SA 408 (C) [426]

²⁵⁶⁸ Van Oosten FFW1995 *De Jure* 164-179 see also Carstens and Pearmain *Foundational Principles* 711-716.

²⁵⁶⁹ Chima 2015 *Niger J Clin Pract* 52.

Table 8.1: Information disclosed by doctors and nurses to patients

INFORMATION DISCLOSED	Doctors (168) Yes Number (%)	Nurses (355) Yes Number (%)	Patients (404) Yes Number (%)	P- value Pearson chi-squared test
Diagnosis	162 (96.4)	265 (76.6)	326 (80.9)	Chi square = 31.040; p = 0.000
Treatment options	136 (81.0)	233 (67.5)	165 (40.9)	Chi square = 97.504 p = 0.000
Recommended treatment	149 (88.7)	223 (64.5)	113 (28.0)	Chi-square= 204.858; p = 0.000
Risk of refusing recommended treatment	140 (83.3)	277 (80.1)	99 (24.6)	Chi square 294.192; p = 0.000
Risks of Treatment	147 (87.5)	238 (68.8)	229 (56.8)	Chi square = 51.272 p = 0.000
Benefits of Treatment	150 (89.3)	246 (71.1)	245 (60.8)	Chi square = 46.127; p = 0.000
Right of refusal	109 (64.9)	232 (67.1)	113 (28)	Chi square = 132.788; p= 0.000
Enough information (satisfaction with disclosure)	126 (76.4)	294 (85)	290 (74.2)	Chi square =134.884 p = 0.000
Costs of treatment	20 (11.9)	81 (23.4)	Not asked*	Chi-square = 9.482; p= 0.002

*Treatment costs are reportedly free at public hospitals in South Africa.

8.9.3 Methods of obtaining IC from patients

Most HCPs in this study (51%) doctors and 49% of nurses claimed that they usually obtained 'written consent' from patients as previously reported^{2570, 2571} Another 35% of doctors and 39% of nurses said they used both methods to obtain consent from patients (see table 8.3). By contrast, 73% of patients in this study claimed that consent was obtained 'verbally' while only 5% agreed that both verbal and written consent was used to obtain IC by HCPs.²⁵⁷² This obvious inconsistency cannot be easily explained. In this case, one can suggest that either HCPs are unaware that the proper method of obtaining consent legally in complex cases, is in writing,²⁵⁷³ and therefore claimed this method in order to avoid any accusations of impropriety. However, from the patient's responses it is clear that usual practice of obtaining IC is verbally. It could also be that the majority of patients who participated in this study were involved in minor procedures not requiring written consent, since written consent is only required in specific cases such as biomedical research or complex surgical procedures.^{2574,2575} However, it must be stated that both verbal and written consent are legally valid as long as all the key elements of IC are observed when communicating with patients before obtaining IC and treatment authorization.^{2576,2577}

²⁵⁷⁰ Chima 2013 *BMC Med Ethics* 8.

²⁵⁷¹ Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97].

²⁵⁷² Chima 2015 *Niger J Clin Pract* 52.

²⁵⁷³ National Health 61 of 2003 (s9).

²⁵⁷⁴ National Health 61 of 2003 (s9).

²⁵⁷⁵ HPCSA *Guidelines for good practice in the healthcare professions: Seeking patients' informed consent-the ethical considerations* (HPCSA Pretoria 2008) 10-11.

²⁵⁷⁶ HPCSA *Guidelines for good practice in the healthcare professions* (HPCSA Pretoria 2008) 10.

²⁵⁷⁷ Beauchamp and Childress *Principles of biomedical ethics* 57-112.

Table 8.2: Nature of risks disclosed by doctors and nurses and preferred disclosure by patients

Risks Disclosed	Doctors		Nurses		P- value Pearson χ^2
	Yes (%)	No (%)	Yes (%)	No (%)	
Most common Risks	152/165(92)	13/165 (8)	256/320 (80)	59/320 (18)	P = 0.002
Most Serious Risks	144/164 (88)	18/164 (11)	134/319 (42)	177/319 (56)	P = 0.000
All Material Risks	35/165 (21)	117/165 (71)	114/318 (36)	183/318 (58)	P = 0.004

Patients

Preferred disclosure	risk Yes (%)
All of the risks	304 (78)
Some of the risks	22 (6)
None of the Risks	22 (6)
Don't Know	43 (11)

Table 8.3: Methods of obtaining IC and enhancing patient understanding

Methods of obtaining or providing consent	Doctors Yes (%)	Nurses Yes (%)	Patients Yes (%)	P-value Pearson χ^2
Written	84/165 (50.9)	167/343 (48.7)	19/374 (19.0)	$p = 0.000$
Verbal	11/165 (6.7)	26/343 (7.6)	274/374 (73.3)	
Both	57/165 (34.5)	135/343 (39.4)	19/374 (5)	
It depends	13/165 (7.9)	15/343 (4.4)	(2.7)	
Methods used to explain to patients				
Words (verbal)	162/168 (96.4)		358/404 (89.3)	
Pictures/photos	34/168 (20.2)		32/404 (8)	
Diagrams	70/168 (41.7)		21/404 (5.2)	
Interpreters	121/168 (72)		14/404 (3.5)	

8.9.4 Understanding of information disclosed

As previously reported, the majority of patients participating in this study (91%) said they understood the information disclosed or provided by HCPs as previously reported,²⁵⁷⁸ and discussed in chapter 7 of this thesis. With regard to asking questions about their treatment, 70% of patients also responded affirmatively, while those who did not ask questions claimed that they either did not know what to ask, trusted the HCPs, or were already familiar with their medical condition and the treatment involved. Others complained that the HCPs were sometimes too busy for them to be able to ask questions.²⁵⁷⁹ In order to enhance patient understanding most doctors and nurses claimed the used the patients local language in addition to English to communicate with patients. Further, doctors in this study also admitted to using diagrams and pictures (20-40%), to try and enhance patient

²⁵⁷⁸ Chima 2015 *Niger J Clin Pract* 52.

²⁵⁷⁹ Chima 2015 *Niger J Clin Pract* 53.

understanding (see table 8.3 above). Another 72% of doctors and 56% of nurses claimed they used interpreters in order to be able to communicate effectively with patients.^{2580,2581} However, regarding the use of interpreters, this assertion by HCPs was only confirmed or corroborated by 4% of patients.²⁵⁸² The reasons for such a large discrepancy are not very clear, however, one may suggest that the reason could be related to the fact that most interpretations in this setting are usually carried out by co-opted nurses²⁵⁸³ as part of their role of 'cultural brokerage', in addition to other HCWs,²⁵⁸⁴ and sometimes family members.²⁵⁸⁵ It is therefore possible that patients may have misunderstood 'interpreter services' as part of the regular HCW role during healthcare services, while doctors and nurses would be better situated to understand that interpretation is outside of the normal job description for HCPs.^{2586,2587,2588}

8.9.5 Time spent on informed consent by HCPs

With regard to the amount of time spent on IC by HCPs, most doctors (53%)²⁵⁸⁹ and majority of nurses (41%) reported that they spent about 5 to 10 minutes on obtaining IC from patients.²⁵⁹⁰ This was followed by 20% of doctors who spent 10 to 20 minutes, and another 24% who reported spending less than 5 minutes on IC.²⁵⁹¹ In addition, 24% of nurses reported spending 10 to 20 minutes, while another 16% spent less than 5 minutes on IC.²⁵⁹² From the patient's perspective; 29% of patients reported that HCPs spent about

2580 Chima 2013 *BMC Med Ethics* S3 [9].

2581 Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97].

2582 Chima 2015 *Niger J Clin Pract* 52.

2583 Jezewski 1990 *West J Nurs Res* 497-513 see also Shaibu 2007 *Nurs Ethics* 507.

2584 Stellenberg and Dorse 2014 *Curationis* Art #38 <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 19 April 2016).

2585 Perkins J "Overcoming language barriers to health care" 1999 *Popular Government* 39-40.

2586 Stellenberg and Dorse" 2014 *Curationis* <http://dx.doi.org/10.4102/curationis.v37i1.38> (Date of use: 19 April 2016).

2587 Chima 2013 *BMC Med Ethics* S3 [9] See also Jezewski 1990 *West J Nurs Res* 497-513 and Shaibu 2007 *Nurs Ethics* 503-509.

2588 Perkins 1999 *Popular Government* 38-44.

2589 Chima 2013 *BMC Med Ethics* S3 [6-8].

2590 Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97-98].

2591 Chima 2013 *BMC Med Ethics* S3 [6-8].

2592 Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97-98].

5 to 10 minutes on IC, another 23% said 10 to 20 minutes was spent, while about 15% reported that HCPs spent less than 5 minutes.²⁵⁹³ From these corroborative observations, it is clear that the majority of HCPs spent less than 20 minutes overall on the IC process (see figure 8.1 below). However, whether this represents the length of the entire clinical encounter between HCPs and patients, or just the amount of time spent on IC is not clear from these results. On the other hand, the reported length of less than 20 minutes is consistent with reports from the USA where doctors generally spend approximately 15 minutes on each outpatient visit by a patient.²⁵⁹⁴ This range of time is also reasonably consistent with the National PHC staffing norms of 1:30 patients for Medical Officers (16 minutes per patient per day); and 1:40 patients for professional Nurses (12 minutes per patient per day) in an 8-hour working period.²⁵⁹⁵ One can therefore suggest from this study, that the amount of time reported here likely represents the length of the entire consultation between HCPs and patients in this setting, rather than the amount of time spent on IC alone. Further, many doctors in this cohort reported that the amount of time was not enough for a proper IC process with the patients, due to large patient workloads and other reported challenges and barriers to IC in this setting as shown in figure 8.2 and table 8.4 below.

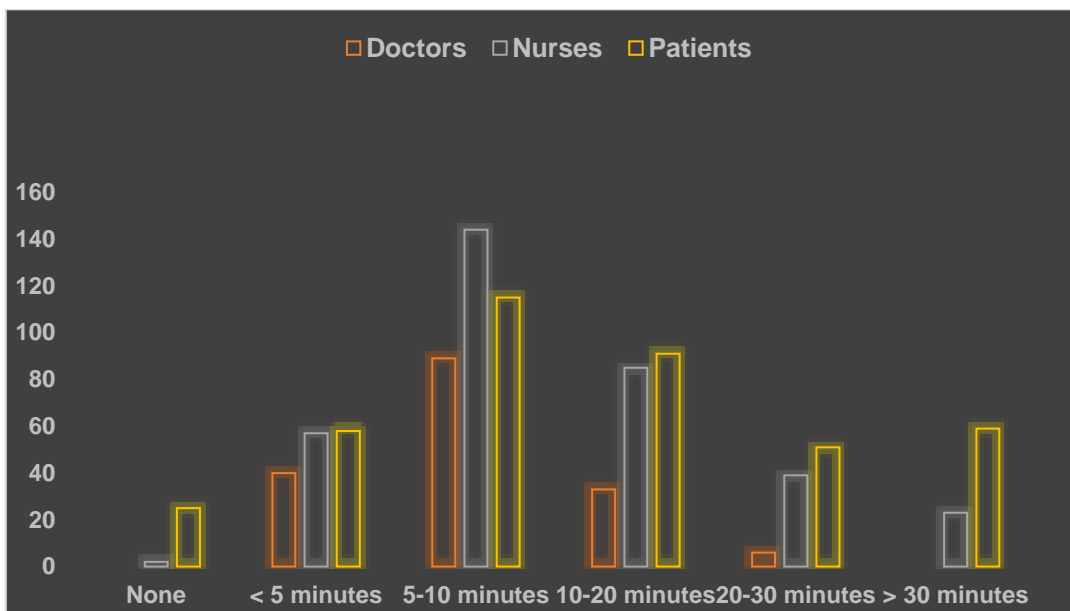


Figure 8.1: Time spent on informed consent according to doctors, nurses and patients

²⁵⁹³ Chima 2015 *Niger J Clin Pract* 51.

²⁵⁹⁴ Kaplan 2004 *Am J Prev Med* 81-83 [81].

²⁵⁹⁵ KwaZulu-Natal Strategic plan 2010-2014 (KZN DOH 2010) 14.

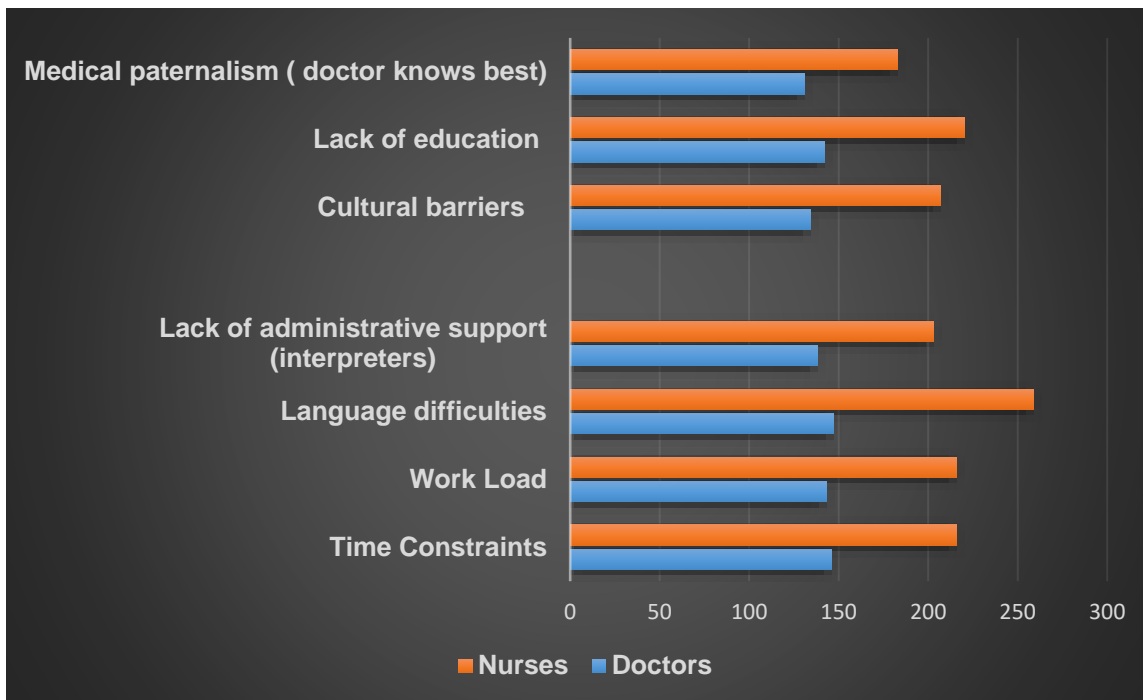


Figure 8.2: Challenges and barriers to IC identified by doctors and nurses

8.9.6 Barriers to informed consent

In the current study, the number one challenge or barrier to IC identified by HCPs (both doctors and nurses) was the issue of ‘language barriers’, which was identified by 88% doctors²⁵⁹⁶ and 73% nurses.²⁵⁹⁷ Other barriers also ranked highly by HCPs include the issues of ‘time constraints and workload’, ‘lack of education’ and lack of administrative support in the form of interpreters’, as shown table 8.4 and figure 8.2. The three combined issues of language, poor education, and the need for interpreters, point to the importance of language in the practice of IC in this setting consistent with studies reported from other multicultural jurisdictions.²⁵⁹⁸

²⁵⁹⁶ Chima 2013 *BMC Med Ethics* S3 [8].

²⁵⁹⁷ Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97].

²⁵⁹⁸ Perkins 1999 *Popular Government* 38-44 see also Schenker 2011 *Med Decis Making* 151–173.

It has been demonstrated that language barriers may have a deleterious effect on healthcare practice generally; leading to such unforeseen outcomes like misdiagnosis, failure of preventive advice, or non-compliance with prescribed medications which may result on charges of medical negligence against doctors and other HCPs.^{2599,2600} The problems of language barriers during IC and clinical practice are not limited to South Africa, and has been reported in multicultural developed countries such as the USA.^{2601,2602,2603}

Another South African study conducted at district hospitals in the Limpopo province found evidence of language as a barrier that impacts negatively on patients' rights to confidentiality, IC, and the overall quality of healthcare practice.²⁶⁰⁴ This is compounded by the problem of lack of professional interpreters in local hospitals, which increases the workload of nurses who are usually called upon to act as interpreters in this setting, in the practice of cultural brokerage.^{2605,2606} This may also explain the increased patient workload reported by nurses in this study and others, leading to a high turnover of nurses due to job pressures and lack of job satisfaction.^{2607,2608,2609,2610}

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- 2599 Wu A et al "The interpreter as cultural educator of residents" 2006 *Arch Pediatr Adolesc Med* 1145-1150.
- 2600 Flores 2006 *N Engl J Med* 230.
- 2601 Flores 2006 *N Engl J Med* 229-331.
- 2602 Schenker et al 2007 *J Gen Intern Med* 294–299.
- 2603 Gordon 1997 *Fordham Urb L J* 1321-1362.
- 2604 Schlemmer and Mash 2006 *SAMJ* 1086.
- 2605 Jezewski 1990 *West J Nurs Res* 497-513.
- 2606 Shaibu S 2007 *Nurs Ethics* 503-509.
- 2607 Pillay R 2009 *Hum Resour Health* 7-15.
- 2608 Matlakala MC "The views of intensive care nurses regarding short-term deployment" 2015 *Curationis* Art1#1478 <http://dx.doi.org/10.4102/curationis.v38i1.1478> (Date of use: 19 April 2016).
- 2609 Hamilton K and Yau J *The global tug-of-war for health care workers* (IOM World Migration Report 2009) <http://www.migrationinformation.org/Feature/display> (Date of use: 21 November 2014).
- 2610 Zelnick and O'Donnell 2005 *J Public Health Policy* 163-185.

Table 8.4: Barriers to informed consent identified by doctors and nurses

Challenges	Respondent		Median score Doctors/Nurses	P-value
	Doctors Yes (No.)	Nurses Yes (No.)		
Time Constraints	146	216	2.00/3.00	0.120
Work Load	143	216	3.00/2.00	0.171
Language difficulties	147	259	2.00/1.00	0.002
Lack of administrative support, (E.g. Interpreters)	138	203	4.00/3.00	0.022
Cultural barriers	134	207	5.00/3.00	0.000
Lack of education	142	220	4.00/3.00	0.002
Medical paternalism (Doctor knows best)	131	183	7.00/6.00	0.000

Note: p-value calculated using Independent samples Mann-Whitney U test; significance level = 0.05

8.9.7 Voluntariness of informed consent in practice

One of the more difficult parts of IC that cannot be easily assessed using empirical methods is the voluntariness of IC. This is due to the fact that voluntariness is generally based on the “state of mind of the patient” relative to the decision to be made at a particular time.²⁶¹¹ Voluntariness may also be impacted by the patient’s clinical condition and cultural belief system in relation to the concept of volition. In more traditional societies such as in Africa,^{2612, 2613} and Asia,^{2614,2615,2616} the influence and respect for family and elders within the community may be important in decision-making due to cultural norms.^{2617,2618} While these types of interference or involvement in healthcare decision-making could be

²⁶¹¹ Nelson RM et al “The concept of voluntary consent” 2011 *AJOB* 6-16.

²⁶¹² Ezeome and Marshall 2009 *Dev World Bioethics* 138-148.

²⁶¹³ Gordon 1986 *Fordham Urb LJ* 1321-1362.

²⁶¹⁴ Susilo et al 2013 *Nurs Ethics* 413-425.

²⁶¹⁵ Lee et al 2009 *Int J Nursing Stud* 1580-1584.

²⁶¹⁶ Masaki et al 2014 *BMC Med Ethics* 15.

²⁶¹⁷ Tindana et al 2006 *IRB* 1-6.

²⁶¹⁸ Frimpong-Mansoh 2008 *Dev World Bioeth* 104-114.

considered undue influence in Western societies focused on individual libertarian autonomy, African communities generally thrive on communalism based for example on the concept of *Ubuntu* which proclaims, “I am, therefore we are”. This ideology is derived from an understanding of collective responsibility and acquiescence to the will and goals of the community rather than individual welfare.^{2619,2620} It is generally recognized that voluntariness in IC relates to the absence of coercion, undue influence, fraudulent misrepresentation or deception which are generally agreed as being unethical.²⁶²¹ In the current study, I tried to determine the voluntariness of participants by asking indirect questions from HCPs, such whether they would allow patients to choose a particular procedure or treatment during a clinical encounter. On this question, 53% of doctors answered affirmatively, while only 40% nurses said they would allow patients to choose a particular treatment. With regard to voluntary actions or choices by patients; when patients were asked if they made the decision regarding treatment choices of their own free will, the majority of patients in this cohort (76%), said they made their decisions without an input from any other person.²⁶²² A few however said they involved surrogates in their decision-making, such as family members and friends, and occasionally a HCP for a second opinion.²⁶²³ However, a minority of patients said they were afraid to ask questions because they might be refused treatment by HCPs, while another said that patients were sometimes in a difficult position where they had to say yes to everything. Table 7.6 in this thesis presents the reported verbatim responses from patients. In this regard.²⁶²⁴

8.9.8 Use of implied and presumed consent by HCPs

HCPs in this study were also asked explain to what extent they used implied and/or presumed consent during clinical practice. On this question, around 65% of doctors said they would use it when the patients showed up at the clinic or were admitted to the ward; while 57% of nurses said they would act likewise. Most doctors and nurses said they were

²⁶¹⁹ Chima 2015 *Niger J Clin Pract* S1-S7.

²⁶²⁰ Metz and Gaie 2010 *J Moral Educ* 273-90.

²⁶²¹ Beauchamp and Childress *Principles of biomedical ethics* [93-98].

²⁶²² Chima 2015 *Niger J Clin Pract* [51-53].

²⁶²³ Chima 2015 *Niger J Clin Pract* 53.

²⁶²⁴ Chima 2015 *Niger J Clin Pract* 52.

more likely to use implied or presumed consent in emergency situations (43%); as per table 8.5 below. In terms of how often they actually used implied or presumed consent in practice, about 59% of doctors said they used it sometimes or rarely, while about 43% of nurses answered likewise. Another 24% of doctors said they ‘never’ used implied or presumed consent, compared to 40% nurses. On the other hand, about 11% of doctors and 16% nurses said they used it ‘all the time’ (see figure 8.3 below). However, when asked to actually define what they understood by implied or presumed consent; the responses from doctors and professional nurses seemed to suggest that there was a misunderstanding of the concept of implied or presumed consent; implying some residual of elements medical paternalism during clinical practice, with the potential to compromise patients’ autonomy in this setting. In defining implied or presumed consent, many doctors and nurses suggested that when a patient showed up at the clinic or the doctor’s office for consultation, that this automatically implied ‘seeking help’ from the patient and that the HCP could presume that the patient was consenting to treatment. Health care practitioners’ understanding of implied/ presumed consent included statements such as: “By routine of the patient coming to the healthcare facility- he is consenting to treatment.” Others, “by virtue of the fact that you have sought my help” and “patient presents themselves requesting treatment.” On the other hand, when patients were asked whether they could change their minds regarding the treatment recommended by a HCP, about 87% of patients said they could. However, a few patients said they could not change their minds because of lack of alternative means of obtaining healthcare and fear of losing or being denied the free treatment provided in public hospitals.²⁶²⁵ See verbatim responses from patients as shown table 7.6 of this thesis. Overall the patients in this study seemed to have acted voluntarily when accessing treatment from public hospitals, while the use of implied and presumed consent by HCPs may denote residual aspects of ‘doctor knows best’ or medical paternalism in this clinical setting.^{2626,2627}

²⁶²⁵ Chima 2015 *Niger J Clin Pract* 52.

²⁶²⁶ Chima 2015 *Niger J Clin Pract* 52.

²⁶²⁷ Chima 2013 *BMC Med Ethics* S3 [10].

Table 8.5: Use of implied/presumed consent by HCPs in clinical practice

Implied/presumed consent	Doctors Yes (%)	Nurses Yes (%)	Total %	p- value
When do you use implied/presumed consent:				
When patients' present at the clinic?	49/145 (33.8)	73/280 (26.1)	122/425(28.7)	$\rho=0.004$
When patients are admitted to the ward?	45/144 (31.3)	87/281 (31)	132/425(31.1)	$\rho=0.057$
In an emergency?	69/145 (47.6)	117/284 (41.2)	186/429(43.4)	$\rho=0.211$
How often do you use implied/presumed consent?				
Some of the time or occasionally	53/137 (38.7)	44/218 (20.2)		$\rho=0.000$
Seldom or rarely	36/137(26.3)	51/218 (23.4)		
All of the time	15/137(10.9)	35/218 (16.1)		
Never	33/137 (24.1)	88/218 (40.4)		

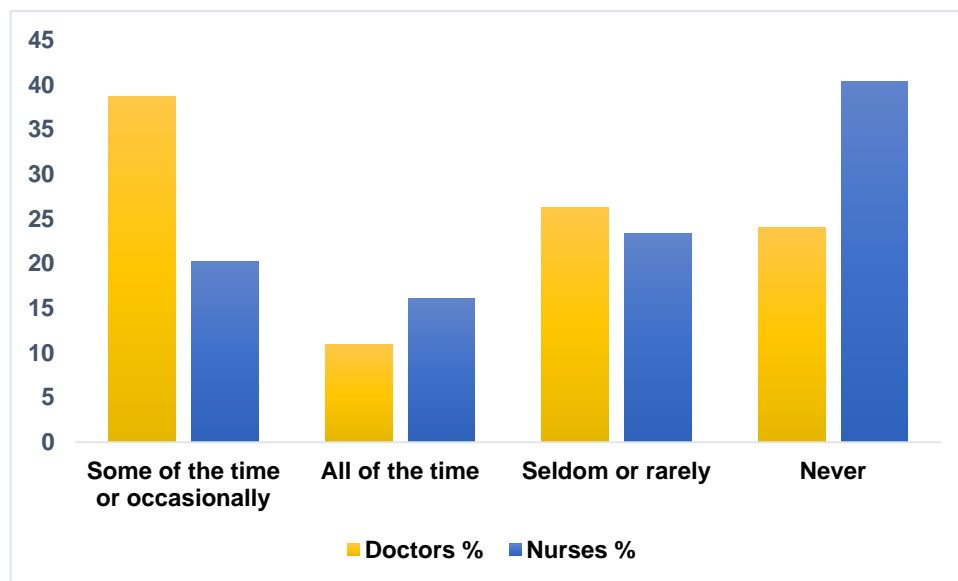


Figure 8.3: Use of implied/presumed consent-doctors vs. nurses

8.9.9 The problem of hospital consent forms

When asked whether the current generic consent forms used in public hospitals are adequate or satisfactory, 63% of doctors and 81% of nurses responded affirmatively (see table 8.7 below). Those doctors who responded negatively gave various reasons regarding the inadequacy of the current form used in public hospitals. Some said the consent form does not give an opportunity for detailing complications or what was discussed with patients, since different clinical conditions may require certain mandatory disclosures. Others complained that the current form does not take into consideration 'privacy, language and cultural values'. Others complained that the forms as currently constituted somehow forced patients to answer 'yes' to everything, while others complained that the form contains no binding space to specify that consent was obtained or that treatment alternatives were discussed.²⁶²⁸ Further evidence of inadequacy of consent forms in provincial hospitals was obtained indirectly in the case of *Pane v MEC Free State*,²⁶²⁹ where one of the expert witness complained that the current consent form was so inadequate that he had to design his own for personal use during clinical practice. It has been argued that the current consent forms used in in South African public hospitals are too vague, and due to this vagueness, local courts may classify such documents as void.²⁶³⁰ Such voiding usually occurs "where the vague and uncertain language justifies the implication that the parties were never *ad idem*, or where the unspecified details of the contract are questions of fact only capable of determination by evidentiary analysis."²⁶³¹ It has also been stated that getting a patient to sign a consent form, where full information had not been disclosed to the patient, might not be effective defense in cases of negligence or assault, since the consent had been expressed in form only, and is not truly valid consent as suggested in *Chatterson v Gerson*.²⁶³² Further, the judge in the English case of *Taylor v Shropshire*²⁶³³ concluded that he regarded the consent form signed before an operation as "pure window dressing [in that case] and designed simply to avoid

²⁶²⁸ Chima 2013 *BMC Med Ethics* S3 [6-8].

²⁶²⁹ *Pane v MEC Free State Department of Health* [2016] ZAFSHC 99.

²⁶³⁰ Van Dokkum N "Hospital consent forms" 1996 *STELL LR* 249-255 [253].

²⁶³¹ Van Dokkum 1996 *STELL LR* 254.

²⁶³² *Chatterson v Gerson* 1981 QB 432 [443].

²⁶³³ *Taylor v Shropshire Health Authority* (1998) *Lloyds Rep Med* 395 QBD.

the suggestion that a patient has not been told.”²⁶³⁴ In any event, patients’ consent to a medical procedure or treatment is limited to that procedure alone, therefore standard consent forms which may state in part that “I the undersigned, do hereby consent and agree to all medical treatments, operations, anesthetics, deemed advisable by the attending surgeons, specialists and doctors...,”²⁶³⁵ or which tend to exculpate the employer and all employees from liability for negligence may be too vague to entitle enforcement in a court of law.²⁶³⁶ Therefore, it has been suggested that a customized consent form, spelling out all potential sequelae of the procedure ²⁶³⁷ or an *abstract form* which provides space for the HCP to detail what was disclosed and what must be done for the patient,²⁶³⁸ are probably preferable options for clinical practice in South Africa. The latter options are arguably more responsive to the complaints and observations by doctors in this study and may suggest a need for reformatting of current hospital consent forms in light of the new requirements imposed by the National Health Act.²⁶³⁹ Van Dokkum rightly asserts that, “with the movement of South African law towards the patient-orientated approach, as evinced in *Castell v De Greef*,²⁶⁴⁰ it is apparent that the standardised consent form so widely used in our hospitals has become inadequate and inappropriate”.²⁶⁴¹ This is an untenable situation, which requires urgent remedy to avoid liability by hospitals and HCPs.

8.9.10 Decision-making capacity or competence

In the common law, there is a general presumption of capacity, in that any adult is presumed to have the capacity to consent to treatment, unless proven otherwise based on acceptable evidence. According to Lord Donaldson in the case of *Re T*:²⁶⁴²

²⁶³⁴ Taylor v Shropshire Health Authority (1998) Lloyds Rep Med 395 QBD see also Hocton *The law of consent to medical treatment* 12.

²⁶³⁵ Van Dokkum 1996 *STELL LR* 251.

²⁶³⁶ Hocton *Law of consent to medical treatment* 12-13.

²⁶³⁷ Van Dokkum 1996 *STELL LR* 254-255.

²⁶³⁸ Van Oosten FFW “Disclosure documents and informed consent: The pros and cons” 1993 *Med Law* 651-656.

²⁶³⁹ National Health Act 61 of 2003 (sections 6-9).

²⁶⁴⁰ *Castell v De Greef* 1994 (4) SA 408 (C).

²⁶⁴¹ Van Dokkum 1996 *STELL LR* 255.

²⁶⁴² *Re T (An adult: Consent to medical treatment)* [1992] 2 FLR 458.

Prima facie every adult has a right and capacity to decide whether or not he will accept medical treatment, even if refusal may risk permanent injury to his health or even lead to premature death [...]. However, the presumption of capacity to decide, which stems from the fact that the patient is an adult is rebuttable [...]. An adult may be deprived of his capacity to decide either by long-term mental incapacity, or retarded development, or temporary factors such as unconsciousness or confusion, or the effects of fatigue, pain or drugs.²⁶⁴³

Lack of capacity cannot be established by a person's appearance, intelligence, educational level, or any condition or aspect of behavior which might make others to believe or make unjustified assumptions regarding the person's mental capacity.^{2644,2645} In the current study, about 67% of doctors said they would presume that an adult has the capacity to consent to treatment. However only 59% of doctors routinely tested their patients for DMC.²⁶⁴⁶ On the other hand, 55% of nurses said they would presume that their patients had capacity, while 76% said they would routinely assess their patients for DMC prior to treatment. When asked to rank certain criteria such as age, level of consciousness, educational level, appearance and sex as factors associated with or used in assessing mental capacity, the majority of doctors and nurses were able to rank these factors accurately in descending order of importance. When asked what methods they would use to assess patients' mental capacity in difficult cases, most doctors said they would use the mini-mental state examination (MMSE), Glasgow coma scale (GCS), or orientation in time place and person to ascertain a patient's capacity in difficult cases.²⁶⁴⁷ Nurses generally gave similar responses to doctors, with more nurses adding they were more likely to assess patient's DMC based on the patient's level of consciousness. Also, more nurses than doctors responded that they did not know the correct answer to this question, probably related to nurses' experience and perception of their role in clinical practice. It is interesting to note however that previous studies in other jurisdictions regarding methods used for assessing mental capacity by physicians concluded that both

²⁶⁴³ Re T (An adult: Consent to medical treatment) [1992] 2 FLR 458 [115] see also Hocton *Law of consent to medical treatment* 66.

²⁶⁴⁴ Chima 2009 *Trans J Coll Med S Afr* 42-43.

²⁶⁴⁵ UK Mental Health Act 2005.

²⁶⁴⁶ Chima 2013 *BMC Med Ethics* S3 [9].

²⁶⁴⁷ Chima 2013 *BMC Med Ethics* S3 [9].

the MMSE and the GCS should be considered as “blunt instruments” when assessing patient’s capacity clinically.²⁶⁴⁸

It has been shown that decisions about a patients’ capacity are ultimately based on legal judgments,²⁶⁴⁹ while in practice, the assessment of patients DMC to give or withhold consent to medical treatment is a more often a matter of clinical judgment.^{2650,2651} However, some authorities have asserted that there is no difference in assessment of competence between clinicians and the courts, because it usually clinicians, especially psychiatrists, that are involved in assessment of capacity in routine clinical practice based on the fact that it would probably be impracticable and expensive to approach the courts in every single case for assessment of capacity.²⁶⁵² In the context of South Africa, it must be noted that in the terms of the Mental Health Care Act,²⁶⁵³ all medical doctors are also considered to be to be mental health care practitioners and are required to be able upon request to ascertain a patient’s DMC in both clinical and medico-legal cases.

8.9.11 General knowledge of current local laws and regulations pertaining to informed consent by HCPs

To assess the basic knowledge of local laws relating to medical treatment in South Africa, HCPs were asked to identify the current age of consent to routine medical treatment in South Africa. On this question, only 71% of doctors²⁶⁵⁴ could correctly identify 12 years as the current age of consent to treatment for minors in South Africa as stipulated in the Children’s Act.²⁶⁵⁵ On the other hand, only 30% of nurses could accurately identify the

²⁶⁴⁸ Appelbaum PS “Assessment of patients’ competence to consent to treatment” 2007 *N Engl J Med* 1834-1840.

²⁶⁴⁹ Richmond v Richmond (1914) 111 LT 273 see also Re MB (an adult: medical treatment) [1997] 8 *Med LR* 217.

²⁶⁵⁰ The BMA with the Law Society *Assessment of medical capacity: Guideline for doctors and lawyers* (BMA London 1995) 66.

²⁶⁵¹ Biggs H *Euthanasia: Death with dignity and the law* (London Bloomsbury 2001) 83.

²⁶⁵² Appelbaum and Roth 1981 *Am J Psychiatry* 1462-1467.

²⁶⁵³ Mental Health Care Act 17 of 2002.

²⁶⁵⁴ Chima 2013 *BMC Med Ethics* S3 [10].

²⁶⁵⁵ Children’s Act 38 of 2005 as amended.

age of consent to treatment for minors in South Africa.²⁶⁵⁶ Furthermore, when asked to identify the age of consent to termination of pregnancy (TOP) in South Africa as established in the Choice on Termination of Pregnancy Act,²⁶⁵⁷ only about 30% of doctors (47/159),²⁶⁵⁸ and 8% of nurses(25/327),²⁶⁵⁹ could accurately pinpoint the correct answer as ‘any woman of any age’ as established by law.²⁶⁶⁰ On the other hand, about 25% of patients could accurately identify the current age of consent to treatment as 12 years as stipulated by current South Africa law. Conversely, only 30% of nurses were able to pinpoint the age of consent to treatment as ‘12years’. See table 8.6 below. These responses clearly indicate that most HCPs practicing in South Africa are not as knowledgeable as one would expect about basic legal requirements, which implies that HCPs, especially nurses, may not have an adequate understanding of legal requirements relating to IC and routine medical treatment, in order to provide the necessary advice to the patients, in terms of their role of ‘cultural brokerage’ in this setting.²⁶⁶¹ Further, with regard to knowledge of the age of consent to treatment, the percentage of correct responses between nurses and patients show that professional nurses are not any more knowledgeable than their untrained or unqualified patients. Similarly, it must be indicated that the level of knowledge displayed by patients with regard to age of consent is also poor, considering that the majority of patients in this cohort have some form of secondary or tertiary education.²⁶⁶² These observations may have implications for the patients’ ability to demand their rights when challenged. With regard to age of consent for TOP, it was further disappointing that the majority of professional nurses who were more than 90% female in this cohort, could not correctly identify the age requirements for TOP. This observation is at variance with their role relating to ‘cultural brokerage’²⁶⁶³ and anticipated leadership role in healthcare services in resource poor communities like South

²⁶⁵⁶ Chima *Understanding and practice of informed consent by professional nurses in South Africa* [97].

²⁶⁵⁷ Choice on Termination of Pregnancy Act 92 of 1996.

²⁶⁵⁸ Chima 2013 *BMC Med Ethics* S3 [9].

²⁶⁵⁹ Chima *Understanding and practice of informed consent by professional nurses in South Africa* [98].

²⁶⁶⁰ Choice on Termination of Pregnancy Act 92 of 1996.

²⁶⁶¹ Jezewski 1990 *West J Nurs Res* 497-513 see also Shaibu 2007 *Nurs Ethics* 503-509.

²⁶⁶² Chima 2015 *Niger J Clin Pract* 50.

²⁶⁶³ Shaibu 2007 *Nurs Ethics* 503-509 see also Jezewski 1990 *West J Nurs Res* 497-513.

Africa.^{2664,2665,2666} It may also indirectly influence patients' ability to exercise their right to reproductive health as stipulated in the Constitution.²⁶⁶⁷ Further, the age of consent to treatment was reduced by the government to take into consideration, the issue of child-headed households in South Africa,²⁶⁶⁸ which increased as a result of the AIDS pandemic. Similarly, the age of consent to TOP is now the decision of a woman of any age, in an attempt to mitigate the issue of illegal abortions and maternal morbidity associated with it.

It is rather disconcerting that such laudable objectives may be compromised by some HCPs inability to keep up with important changes in the law, which could deny patients adequate and timely treatment.

²⁶⁶⁴ Ditlopo P et al "Contestations and complexities of nurses' participation in policy-making in South Africa" 2014 *Glob Health Action* <http://dx.doi.org/10.3402/gha.v7.25327> (Date of use: 19 April 2016).

²⁶⁶⁵ Shariff N and Potgeiter E "Extent of East-African nurse leaders' participation in health policy development" 2012 *Nurs Res and Pract* doi:10.1155/2012/504697.

²⁶⁶⁶ World Health Organisation *Strategic directions for strengthening nursing and midwifery services 2011-2015* (WHO Geneva 2011) www.who.int/hrh/resources/nmsd/en/index.html (Date of use: 19 April 2016).

²⁶⁶⁷ The Constitution s12 (2) (a).

²⁶⁶⁸ Children's Act 38 of 2005 (s129-130 and s137).

Table 8.6: Knowledge of basic local healthcare laws by HCPs and Patients

	12years No. (%)	15years Yes (%)	18years Yes (%)	21years Yes (%)	Don't Know (%)	P-value Pearson λ^2
Age of consent to treatment in South Africa?						$\rho = 0.000$
<i>Doctors</i>	111/157 (70.7%)	17/157 (10.8%)	24/157 (15.3%)	3/157 (1.9%)	2/157 (1.3%)	
<i>Nurses</i>	99/331 (29.9%)	33/331 (10%)	183/331 (55.3%)	12/331 (3.6%)	4/331 (1.2%)	
<i>Patients</i>	94/373 (25.2%)	96/373 (25.7%)	122/373 (32.7%)	40/373 (10.7%)	21/373 (5.6%)	
At what age can a woman request TOP in South Africa?	12 years No. (%)	15years No. (%)	18years No. (%)	Any age No. (%)	Don't know No. (%)	$\rho = 0.000$
<i>Doctors</i>	81/159 (50.9%)	21/159 (13.2%)	6/159 (3.8%)	47/159 (29.6%)	4/159 (2.5%)	
<i>Nurses</i>	190/327 (58.1%)	25/327 (7.6%)	76/327 (23.2%)	25/327 (7.6%)	11/327 (3.4%)	
<i>Patients</i>	Not asked					

Notes: TOP = termination of pregnancy; Age for TOP= not included in patients questionnaire. In terms of South African law, the age of consent for routine medical treatment in South Africa is '12years',²⁶⁶⁹ and for TOP 'any woman of any age'²⁶⁷⁰

²⁶⁶⁹ Children's Act 38 of 2005 as amended.

²⁶⁷⁰ Choice on Termination of Pregnancy Act 92 of 1996.

Table 8.7: Comparison of doctors and nurses current knowledge and practice of informed consent

Relevant questions	Doctors(Yes) No. (%)	Doctors No. (/%)	Nurses(Yes) No (%)	Nurses (No) No. (%)	P-value Pearson λ^2
Language of communication?					
<i>English</i>	108/168(64%)	60/168(36)	135/350(39)	213/350(61)	$\rho=0.000$
<i>Patients local language</i>	75/168 (45)	90/168(54)	206/350(59)	140/350(40)	$\rho=0.010$
<i>Both English & Local</i>	116/168 (69)	49/168(29)	195/350(56)	150/350(43)	$\rho=0.011$
Methods of obtaining consent?					
<i>Verbal</i>	11/165(7)		26/343(8)		$\rho=0.333$
<i>Written</i>	84/165(51)		167/343(49)		
<i>Both verbal and written</i>	57/165(35)		135/343(39)		
Who normally obtains consent?					
<i>Nurse</i>	10/165(6)	155/165(94)	50/342(15)	292/342(85)	$\rho=0.003$
<i>Junior doctors</i>	74/166(45)	92/166(55)	71/342(21)	271/342(79)	$\rho=0.000$
<i>HCP performing procedure/treating</i>	110/166(66)	56/166(34)	270/342(79)	72/342(21)	$\rho=0.002$
<i>Any available HCP</i>	18/166(11)	148/166(89)	25/342(7)	317/342(93)	$\rho=0.122$
Standard to be used for information disclosure					
<i>'Reasonable doctor' standard</i>	97/161(60)	46/161(27)	165/295(56)	82/295(28)	$\rho=0.329$
<i>'Prudent patient' standard</i>	76/159(48)	60/159(38)	138/291(47)	107/291(37)	$\rho=0.928$
Responsibility for adequate information disclosure					
<i>HCP responsibility</i>	100/162(62)	62/182(38)	196/325(60)	129/325(40)	$\rho=0.762$
<i>Patients responsibility</i>	8/162(5)	154/162(95)	40/326(12)	286/326(88)	$\rho=0.006$
<i>HCP & Patient jointly responsible</i>	66/162(41)	96/162(59)	121/325(37)	204/325(63)	$\rho=0.257$
Time Spent on information disclosure					
<i>Sufficient or adequate</i>	93/168(55)	66/168 (39)	185/353(52)	145/353(41)	$\rho=0.769$
Current hospital consent form					
<i>Satisfactory or Adequate</i>	105/168(63)	51/168(30)	281/345(81)	42/345(12)	$\rho=0.000$

Notes: HCP = Healthcare professional; minor scores of 'don't know' and, 'it depends' not shown

8.9.12 Comparison of informed consent aggregate scores (ICAS) between HCPs

To compare knowledge, understanding and practice of IC across different categories of HCPs and occupational ranks of doctors and nurses, I developed an aggregate score using a modified version of the criteria and method described by Sugarman and others.²⁶⁷¹ . In this study, I selected a series of 12 questions from the questionnaire for HCPs²⁶⁷² by extracting questions relating to information disclosure, voluntariness, capacity, and

²⁶⁷¹ Sugarman et al 2005 *Clinical Trials* 34-41.

²⁶⁷² See Appendix 1 of this thesis

understanding of IC,²⁶⁷³ as per table 8.9 below. The selected questions are also consistent to the requirements for information disclosure as stipulated in section 6 of the NHA.²⁶⁷⁴ Each of the selected questions was given a rank score of 1 (one), and the aggregate score represents the ICAS. The questions used to calculate the ICAS are shown Table 5.7 of this thesis. The internal consistency of the questions used for ICAS was evaluated using Cronbach's alpha.²⁶⁷⁵ In this case the alpha score for this questions was 0.646. This scoring is within the range of 'high' which denotes the fact that questions are moderately closely related and have a high reliability.²⁶⁷⁶

In terms of ICAS scores, overall, the difference in scores between all categories of doctors and nurses was statistically significant with doctors having a median ICAS of 10, compared to nurses with a median score of 8. This difference between doctors and nurses was statistically significant using the Mann-Whitney U test for independent variables $\rho < 0.001$. Further, comparison of ICAS scores between different ranks of doctors showed that interns and registrars had the lowest median score of around 9, while medical officers and consultant/specialists had a median score of 10 (see figure 8.4 below). However, this difference was not statistically significant.²⁶⁷⁷ Comparison of doctors ICAS by clinical specialty using the Kruskal-Wallis test showed that anesthesiologists and radiologists had the lowest ICAS score with a median of 7 and 8 respectively, while the highest median score of 10.5 was achieved by OBGYN doctors, internists, and general practitioners,²⁶⁷⁸ (see figure 8.5 below). On the other hand, comparison of the ICAs score between professional nurses and enrolled nurses showed that professional nurses' ICAS was 9 on average, while enrolled nurses scored 7. However this difference was not statistically significant using the Mann-Whitney U test for independent variables ($\rho = 0.090$).²⁶⁷⁹

²⁶⁷³ Chima 2013 *BMC Med Ethics* S3 [12].

²⁶⁷⁴ National Health Act 61 of 2003 section 6(1).

²⁶⁷⁵ Statistical Consulting Group UCLA "Introduction to SAS"
[www.https://stats.idre.ucla.edu/sas/modules/sas-learning-module-introduction-to-the-features-of-sas](https://stats.idre.ucla.edu/sas/modules/sas-learning-module-introduction-to-the-features-of-sas) (Date of use: 30 January 2018).

²⁶⁷⁶ Tavakol and Dennick "Making sense of Cronbach's alpha" 2011 *IJME* 53-55 see also Flores JWC https://www.researchgate.net/post/How_do_i_interpret_my_Alpha_value (Date of use: 30 January 2018).

²⁶⁷⁷ Chima 2013 *BMC Med Ethics* S3 [12].

²⁶⁷⁸ Chima 2013 *BMC Med Ethics* S3 [12].

²⁶⁷⁹ Chima *Understanding and practice of informed consent by professional nurses in South Africa* 98.

Further analysis showed that there was no statistical difference between various nursing domains, even though nurses working in trauma and casualty had the highest ICAS of 10. This difference in ICAS scores amongst nurses working in various nursing domains was not statistically significant when compared using Kruskal-Wallis test ($p = 0.293$). The implications of these ICAS scores appear to show some differences in the knowledge and consequent application of IC regulations amongst different categories of HCPs. However, doctors showed more overall knowledge regarding IC regulations than nurses, which could be expected, considering their different roles in the clinical setting and the IC process. More importantly, there appeared to be no statistical difference in knowledge between professional nurses with a minimum 4 years nursing qualification and enrolled nurses with a minimum of 2 years nursing diploma in terms of knowledge of current legal and ethical positions regarding IC. Ordinarily, one would say that doctors should be more familiar with the rules and regulations pertaining to IC because they have more direct diagnostic and treatment responsibilities in the healthcare context. However, the NHA²⁶⁸⁰ implies that the IC rules apply to all HCPs.²⁶⁸¹ Further; other legal authorities have suggested that the informed consent regulations should apply *mutatis mutandis* to all HCPs.²⁶⁸² This implies that all categories of HCPs involved in patient care, including nurses and others, must become familiar with the rules and regulations regarding informed consent. The results of this study suggest that the knowledge of professional nurses in South Africa regarding the rules and local laws governing IC in clinical practice may not be up to the required standard, as suggested by other reports.^{2683,2684,2685}

²⁶⁸⁰ Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11[87].

²⁶⁸¹ National Health Act 61 Of 2003 S (6) (1).

²⁶⁸² Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11[87].

²⁶⁸³ Richards L and Potgeiter E "Perceptions of registered nurses in four state health institutions on continuing formal education" 2010 *Curationis* 41-50.

²⁶⁸⁴ Morolong and Chabeli "Competence of newly qualified registered nurses from a nursing college" 2005 *Curationis* 38-50.

²⁶⁸⁵ Mandava A *et al* "The quality of informed consent: mapping the landscape. A review of empirical data from developing and developed countries" 2012 *J Med Ethics* 356e365.

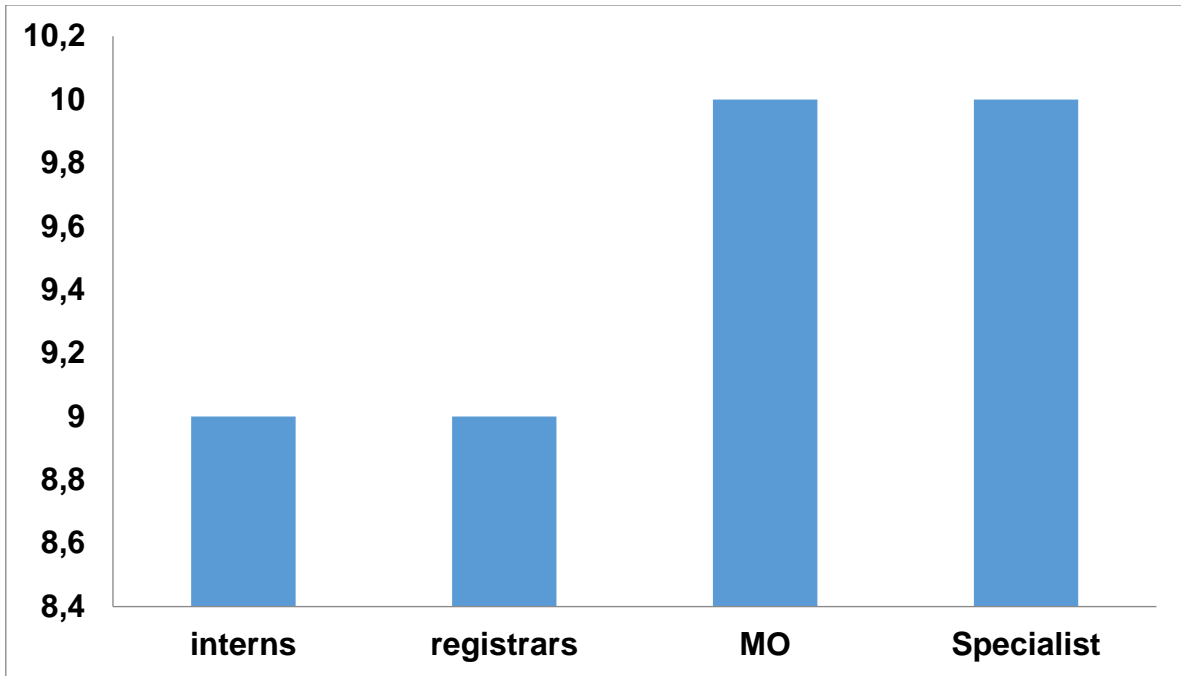


Figure 8.4: Doctors ICAS by occupational rank

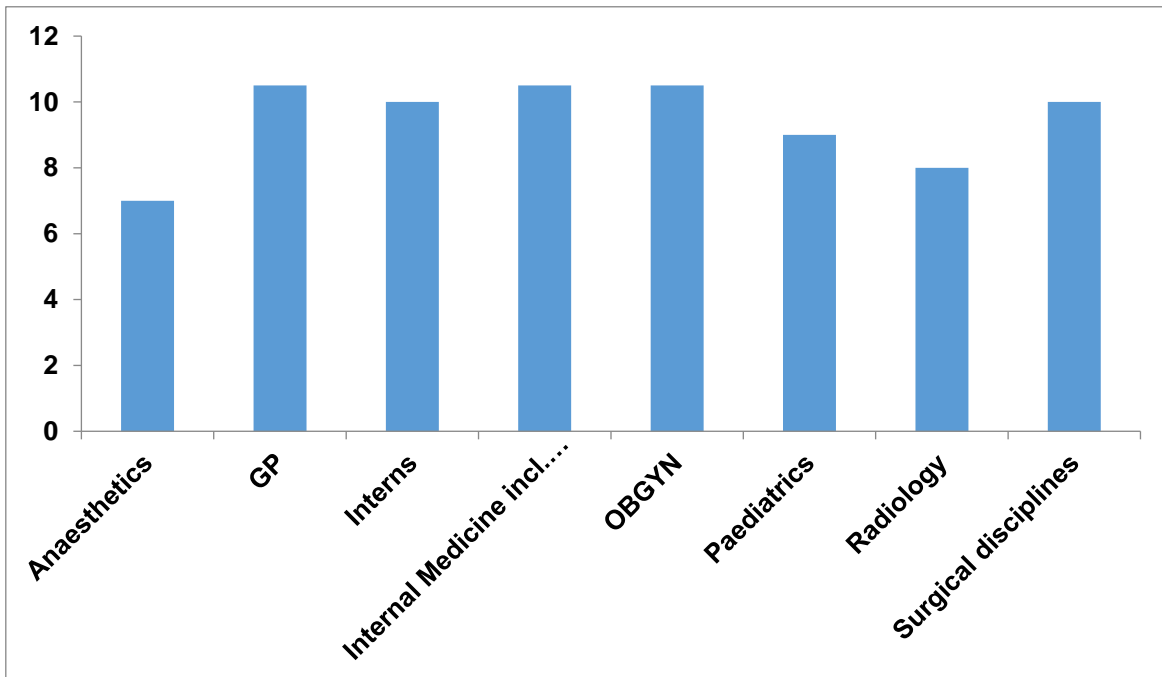


Figure 8. 5: ICAS scores by clinical sub-discipline or specialty

8.10 Summary of chapter 8

This chapter summarises and synthesises the findings from both the literature review, especially relevant case law pertaining to IC in South Africa, and the empirical research findings from this study. In this analysis, I took into consideration the perspectives derived from the background studies and literature review on the legal and ethical doctrine of IC as stipulated by law, policy and ethical guidelines. At the beginning of this chapter, I describe the role of empirical research as a tool or methodology, which can be used to evaluate moral norms, such as the rules and regulations that have been put in place to ensure that certain basic standards of practice are achieved in the healthcare setting, with particular reference to IC regulations in medical practice. This is followed by an analysis of the meaning of consent in medical treatment. From this analysis, I conclude that consent to treatment may be considered as a special type of agreement between a doctor or HCP and the patient, which is different from the usual arms-length contractual relationship between individuals or juristic persons. In this sense, 'consent to treatment' is based on the fiduciary relationship between a HCP and the patient, which may allow the patient to withdraw from the contractual relationship or the consent given for a specific medical treatment or procedure, or to terminate the agreement, without any legal repercussions.

Further, I analysed the factors that would make IC valid during medical treatment and concluded that this is based on the fulfilment of the five key elements of IC between a patient and the HCP, which should include full information disclosure, capacity to understand the information disclosed, comprehension of that information, and voluntariness, while taking into consideration patients' language, literacy levels, and cultural values, based on a subjective reasonable patient standard. Valid IC also requires volition on the part of the patient or consenter which denotes the power to use one's free will in the absence of any undue influence, coercion or manipulation by the HCP; and finally agreement or authorization of the medical procedure or intervention by the patient.

Moreover, I analysed current South African case law and comparative foreign case law, and observed that South African common law is lagging behind international practice or

standards of IC, in the context of recent judgments by the SCA and provincial high courts in cases such as the *Oldwage* case,²⁶⁸⁶ *McDonald v Wroe*,²⁶⁸⁷ *Sibisi No v Maitin*,²⁶⁸⁸ and *Pane v MEC Free State*.²⁶⁸⁹

Based on analysis of the judgments in these cases, I concluded that South African courts are somewhat inconsistent in their application of the informed consent doctrine based on the prudent patient and material risks standards of information disclosure as established in *Castell v De Greef*.²⁶⁹⁰ Further, South African courts appear reluctant to expand the South African jurisprudence on informed consent by reference to applicable foreign laws and court judgments, as stipulated in the Constitution.²⁶⁹¹ By contrast, related common law jurisdictions such as England and Australia, as well as the courts in North America, have fully adopted the doctrine of informed consent based on the prudent patient and material risks standard of information disclosure; as illustrated by cases such as the recent judgment of the UK Supreme Court, Scotland, in the case of *Montgomery v Lanarkshire*,²⁶⁹² as well as the well-established judgment of the Australian High Court in *Rogers v Whitaker*,²⁶⁹³ and the Canadian Supreme Court in the case of *Reibl v Hughes*.²⁶⁹⁴ American case law has previously adopted this standard in the landmark judgment of the DC Circuit Court of Appeals in the case of *Canterbury v Spence*.²⁶⁹⁵ I have further analysed the importance of empirical studies in bioethics, which shows that empirical bioethics can help facilitate the move from philosophical ethical analysis to ethically justifiable behaviour. Further, empirical data may be used to enhance ethical analysis, and justify it by testing consequentialist claims, and in evaluating current practice when compared to expected normative behaviour, as well helping to identify and

²⁶⁸⁶ Louwrens v Oldwage [2004] 1 All SA 532 (C).

²⁶⁸⁷ McDonald v Wroe [2006] 3 All SA 565 (C) [568].

²⁶⁸⁸ Sibisi NO v Maitin (311/13) [2014] ZASCA 156.

²⁶⁸⁹ Pane v MEC Free State Department of Health [2016] ZAFSHC 99.

²⁶⁹⁰ Castell v De Greef 1994 (4) SA 408 (C).

²⁶⁹¹ Constitution of the Republic of South Africa 1996 s39 (1) (b-c).

²⁶⁹² Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11.

²⁶⁹³ Rogers v Whitaker [1992] HCA 58; (1992) 175 CLR 479.

²⁶⁹⁴ Reibl v Hughes (1980) 114 DLR (3d) 1 (SCC).

²⁶⁹⁵ Canterbury v Spence (1972) 464 F 2d 772.

document new moral dilemmas.^{2696,2697} I also identified some socio-cultural factors that could impact on the practice of informed consent in the multicultural setting of South Africa.

In the second part of this chapter, I summarized and analysed the findings and implications of the empirical research study reported in chapters 5 to 7 of this thesis. Some pertinent findings include the fact that HCPs (doctors and nurses) generally disclose most, but not all of the key requirements for IC as stipulated by the NHA²⁶⁹⁸ and related ethical guidelines.²⁶⁹⁹ I also reported that the majority of participants in this research study including doctors, nurses, and patients, were generally satisfied by the amount of information disclosed during medical treatment. Further, based on the finding from this study, one can conclude that most HCPs are not fully aware or conversant with the legal and ethical standards of IC, including the requirement that the current standard of information disclosure should be based on the 'prudent patient and material risks standards'. In addition, knowledge of basic healthcare laws by HCPs is deficient particularly amongst professional nurses. Based on data triangulation, was I also able to identify some inconsistencies between the responses by HCPs and patients. For example while HCPs reported that IC was obtained in writing in the majority of cases; patients on the other hand reported that they gave IC verbally during most clinical encounters. Furthermore, while HCPs claimed to have disclosed certain elements of IC such as recommended treatment, risks of refusing treatment, and the right of refusal, to patients, the majority of patient respondents reported that this was not the case.

I also identified and analysed some barriers or challenges associated with obtaining IC in this setting, which include language barriers, educational level of patients, large patient

²⁶⁹⁶ Solomon MZ "Realizing bioethics' goals and practice: ten ways 'is' can help 'ought' 2005 *Hast Cent Rep* 40-47 see also Mbugua K "Respect for cultural diversity and the empirical turn in bioethics: a plea for caution" 2012 *J Med Ethics Hist Med* 2 and Ives J "Encounters with experience: empirical bioethics and the future" 2007 *Health Care Anal* 1-6.

²⁶⁹⁷ Sulmasy and Sugarman *Methods of medical ethics* 13-18 see also Borry et al "Empirical research in bioethics journals: a quantitative analysis" 2006 *J Med Ethics* 240-245.

²⁶⁹⁸ National Health Act 61 of 2003.

²⁶⁹⁹ HPCSA *Guidelines for good practice in the healthcare professions: Seeking patients' informed consent-The ethical considerations* (HPCSA Pretoria 2008).

workloads, and the absence of interpreters and administrative support. Further, I identified the fact that there was a difference in the level of knowledge regarding the ethical and legal guidelines for IC amongst HCPs with professional nurses showing more deficiency of knowledge about basic healthcare laws and regulations, when compared to doctors. I also identified and analysed the fact that the majority of HCPs generally spent about 5 to 10 minutes on IC process and the typical clinical consultation in this setting. However, this was consistent with and comparable to the length of time spent on a clinical outpatient encounter between and patients and doctors in other jurisdictions, including developed countries. This amount of time spent in public hospitals under study is also consistent with the recommended national public health staffing norms and workload for South Africa.²⁷⁰⁰ Furthermore, I was able to show that the current informed consent forms used in provincial hospitals appear inadequate in the context of the new IC regulations and the respect for patients' rights and human dignity, evinced by the South African Constitution. Finally, it was concluded that the major barrier to informed consent in this setting is due to language, which needs to be remedied, as recommended in chapter 9 of this thesis.

²⁷⁰⁰ Kwazulu-Natal Strategic plan 2010-2014 (KZN DOH 2010) 14.

CHAPTER 9: CONCLUSIONS AND RECOMMENDATIONS

9.1 INTRODUCTION

It makes sense to conclude this research report by summarizing some of the advantages of using an empirical research methodology to study the legal and ethical norms of IC in this setting or specifically in the context of clinical practice in South Africa.

It has been argued that, unlike issues in biomedical research ethics, ethical challenges arising in the daily clinical care of medicine in Sub-Saharan African (SSA) countries have not yet been studied in a systematic manner.²⁷⁰¹ Further, that this aspect of medical law and ethics has to be viewed as distinct entity from human biomedical research,²⁷⁰² even though some of the ethical guidelines and laws regulating IC and clinical practice are the same.²⁷⁰³ Most patients in SSA are more likely to require medical treatment than become human subjects of biomedical research during their lifetime, due to the endemic infectious diseases and other clinical conditions prevalent in Africa.^{2704,2705} Unfortunately, more attention is usually devoted to the ethical issues regarding biomedical research than clinical practice in most African countries and communities. However, it is important to recognize that recent research studies from developed countries, such as the USA, have identified the significance of IC as an important tool for preventive medicine.²⁷⁰⁶ In recent times, advocates of shared and informed healthcare decision-making have also demonstrated that IC promotes patient comprehension and autonomy, reduces unwanted

²⁷⁰¹ Sippel D et al "Clinical ethics in Gabon: The spectrum of clinical ethical issues based on findings from in-depth interviews at three public hospitals" 2015 *PLoS ONE* e0132374.

²⁷⁰² Sippel et al 2015 *PLoS ONE* e0132374.

²⁷⁰³ Chima 2006 *BMJ* 848-851.

²⁷⁰⁴ Chima *Contemporary ethical issues and regulation of biomedical research in Africa* 19-38 see also Chima SC and Mamdoo F "Ethical and legal dilemmas around termination of pregnancy for severe fetal anomalies: A review of two African neonates presenting with ventriculomegaly and holoprosencephaly" 2015 *Niger J Clin Pract* S31-38.

²⁷⁰⁵ Chima SC et al "Progressive multifocal leukoencephalopathy and JC virus genotypes in West African patients with acquired immunodeficiency syndrome: A pathological and DNA sequence analysis of 4 cases" 1999 *Archiv Pathol Lab Med* 395-403 see also Famoroti TO, Fernandes L and Chima SC "Stigmatization of people living with HIV/AIDS by healthcare workers at a tertiary hospital in KwaZulu-Natal, South Africa: A cross-sectional descriptive study" 2013 *BMC Med Ethics* S6.

²⁷⁰⁶ Kaplan 2004 *Am J Prev Med* 81-83.

medical procedures and malpractice claims, improves patient compliance to treatment,²⁷⁰⁷ and decreases overall costs of healthcare service delivery.^{2708,2709} Therefore, if practiced properly, IC and shared healthcare decision-making can become valuable tools in preventative medicine which is sorely needed in South Africa and other developing countries.

Empirical bioethics have been defined as a form of research enterprise that integrates both normative ethical analyses with empirical research data to produce new knowledge that would not have been generated without a combination of both methodologies.²⁷¹⁰ The ultimate goal of empirical inquiry is to improve the overall quality of healthcare.^{2711,2712} In this role, Kon²⁷¹³ has described four hierarchical categories of empirical bioethics, which can build on one another to assist in final ethical decision-making. These categories of empirical ethical enquiry are described as: (1) “lay of the land” studies which are usually overviews of current practices and the status quo; (2) “ideal versus reality studies”, which attempt to map out how well clinical practice matches normative ethical principles or ideas; (3) “improving care studies”, which focuses on how we can bring ethical ideals closer to match normative practice; and (4) “changing ethical norms” studies, which focus on how we can bring together data from various empirical studies to inform or change current ethical norms.²⁷¹⁴ Other ethicists, such as Borry and others,²⁷¹⁵ have described three possible roles for empirical research in bioethics. Firstly, it can assist in describing morally relevant facts; secondly, it can assist in the analysis of moral questions since empirical research possesses “the normative power of the factual”.²⁷¹⁶ Thirdly, empirical research can assist in evaluating the decision-making process by pointing out unanticipated

²⁷⁰⁷ Flores 2006 *N Engl J Med* 229-331 see also Schenker et al 2007 *J Gen Intern Med* 294–299.

²⁷⁰⁸ Kaplan 2004 *Am J Prev Med* 81-83.

²⁷⁰⁹ King and Moulton 2006 *Am J Law Med* 429-501.

²⁷¹⁰ Mertz M et al “Research across the disciplines: a road map for quality criteria in empirical ethics research” 2014 *BMC Med Ethics* 17.

²⁷¹¹ Emanuel The relevance of empirical research for bioethics 99-110.

²⁷¹² Borry et al 2004 *Med Health Care Philos* 42.

²⁷¹³ Kon AA “The role of empirical research in bioethics” 2009 *AJOB* 59-65.

²⁷¹⁴ Kon 2009 *AJOB* 59-62.

²⁷¹⁵ Borry et al 2004 *Med Health Care Philos* 41-53 see also Solomon MZ “Realizing bioethics’ goals and practice: ten ways ‘is’ can help ought” 2005 *Hast Cent Rep* 40-47.

²⁷¹⁶ Borry et al 2004 *Med Health Care Philos* 43.

conflicts, consequences or alternative outcomes.²⁷¹⁷ It has been suggested by Maguire,²⁷¹⁸ that ethical and moral questions should be based on a six point algorithm of, “what, why, how, who, where and when”.²⁷¹⁹ Further it is argued that correctly responding to these six questions can resolve some ethical dilemmas or moral conflicts easily, while answering only a few of these questions would mean that whatever decision made would only be based on a partial reality.²⁷²⁰ Again, it has been proposed that ethics should not be merely content with describing facts, but should also engage on judgments about those facts to arrive at a right decision. Finally, decisions arrived at must always be subjected to further analysis and evaluation in the light of new evidence. Therefore, doctors and other HCPs as well as ethicists, should be willing to change or alter their positions in future based on the emergence of new facts or evidence.²⁷²¹

In view of the above observations, the current study was designed to ascertain whether IC as practiced by HCPs in public hospitals in South Africa, was consistent with the legal and ethical framework guiding IC, since description of the actual conduct of a group has been identified as one of the goals of empirical ethics.²⁷²²

In addition, I wanted to ascertain the actual moral opinions of the people involved in the practice of IC in this setting, vis-a-vis, patients, doctors and nurses; by using a quantitative methodology including data triangulation to evaluate whether such practice is consistent with the expected norms, or if there are any variations or barriers to the actual practice of IC in this setting. The overarching idea is to make ethics more context-sensitive as well as evaluate the actual reasoning patterns of those involved IC practice in South African public hospitals.

²⁷¹⁷ Borry et al 2004 *Med Health Care Philos* 43.

²⁷¹⁸ Maguire D *Death by choice* (Doubleday & Co New York 1984) 66.

²⁷¹⁹ Maguire *Death by choice* 66.

²⁷²⁰ Borry et al 2004 *Med Health Care Philos* 41-53.

²⁷²¹ Borry et al 2004 *Med Health Care Philos* 41-53 see also Chima *A primer in medical law* 334-344.

²⁷²² De Vries and Gordijn 2009 *Bioethics* 193.

9.2 CONCLUSIONS DRAWN FROM ANALYSIS OF CASE LAW AND CURRENT SOUTH AFRICAN LEGISLATION

Overall, this study reveals that the regulatory framework for IC practice in South Africa is robust, based on the legal requirements in the NHA,²⁷²³ and the principles laid down in the Constitution and the Bill of Rights.²⁷²⁴ This is further supported by some common law judgments, especially the landmark judgment of a full bench of the Cape High Court in the *Castell* case,²⁷²⁵ which arguably adopted the ‘prudent patient’ and ‘material risks’ standards of information disclosure during IC into South African legal jurisprudence.²⁷²⁶ Unfortunately, recent judgments by the SCA in the *Oldwage* case²⁷²⁷ and *Sibisi NO v Maitin*²⁷²⁸ appear to show the SCA vacillating between the reasonable doctor standard as applied in the case of *Richter and another v Estate Hamman*²⁷²⁹ and the prudent patient standard as established in the *Castell* case.²⁷³⁰ This thesis demonstrated that the approach adopted by the SCA in the *Oldwage* case²⁷³¹ is in total contrast and in conflict with the judgment in *Castell v De Greef*.²⁷³² According to some legal authorities, “*the two judgments in the context of the liability of a doctor for failure to inform the patient are mutually destructive on the same facts and cannot co-exist in harmony.*”²⁷³³ Furthermore, it has been argued that the provisions of the Constitution relating to the rights to bodily and psychological integrity, as well as the right to security and control over one’s body, as stipulated in section 12(2) of the Constitution,²⁷³⁴ have not been fully addressed or implemented in the recent judgments by the SCA and other South African court judgments.^{2735,2736} In addition, the applicable legislative requirements as adumbrated in

²⁷²³ National Health Act 61 of 2003.

²⁷²⁴ Constitution of the Republic of South Africa 1996.

²⁷²⁵ *Castell v De Greef* 1994 (4) SA 408 (C).

²⁷²⁶ Van Oosten 1995 *De Jure* 171-175 see also Carstens and Pearmain *Foundational Principles* 681-694.

²⁷²⁷ *Louwrens v Oldwage* [2004] 1 All SA 532 (C).

²⁷²⁸ *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156.

²⁷²⁹ *Richter v Estate Hamman* 1976 (3) SA 226 (C).

²⁷³⁰ *Castell v De Greef* 1994 (4) SA 408 (C) [425-426].

²⁷³¹ *Louwrens v Oldwage* [2004] 1 All SA 532 (C).

²⁷³² *Castell v De Greef* 1994 (4) SA 408 (C).

²⁷³³ Carstens and Pearmain *Foundational principles* 686.

²⁷³⁴ Constitution of the Republic of South Africa 1996.

²⁷³⁵ Carstens and Pearmain *Foundational principles* 686 see also Britz and Roux-Kemp 2012 *S Afr Med J* 746-748.

²⁷³⁶ Zwart L “Sibisi NO v Maitin: A dual burden of proof?” June 2015 *De Rebus* 33.

sections 6 to 8 of the NHA²⁷³⁷ are not being implemented by South African courts.²⁷³⁸ As illustrated by court judgments in the *Sibisi case*,²⁷³⁹ and *Pane v MEC Free State*,²⁷⁴⁰ South African courts also appear to have introduced a secondary standard of proof in informed consent cases, which may now impose on aggrieved plaintiffs a dual burden,²⁷⁴¹ whereby, a claimant or plaintiff needs to prove both negligence, as well as lack of informed consent, to succeed in informed consent cases. In both cases mentioned above, the plaintiffs lost their claims for damages regarding failure to obtain informed consent by doctors, when the courts concerned ruled that once the claimant is unable to prove negligence, then the claim for lack of informed consent automatically falls away or becomes moot.²⁷⁴² This new standard of proof in informed consent cases is criticized by some legal scholars.^{2743,2744} In another questionably contradictory judgment, a full bench of the Cape High Court overruled the judgment of a high court judge in the case of *McDonald v Wroe*.²⁷⁴⁵ The court *a quo* had found on behalf of the plaintiff in this case, based on the fact that the dentist did not fully disclose the potential risks of undergoing a wisdom teeth extraction, especially by a general dentist rather than a specialist surgeon. The said risk materialized in the form of facial palsy due to injury to the inferior alveolar nerve, and the patient claimed damages for negligence and lack of informed consent by the dentist.²⁷⁴⁶ In its later judgment, the full bench of the High Court overturned this judgment basing its decision on direct causation, rather than the indirect causation or public policy interests as established by the English House of Lords in the case of *Chester v Afshar*.²⁷⁴⁷ This recent judgment

²⁷³⁷ National Health Act 2003.

²⁷³⁸ Carstens and Pearmain *Foundational Principles* 686 see also Britz and Roux-Kemp 2012 *S Afr Med J* 746-748.

²⁷³⁹ Sibisi NO v Maitin (311/13) [2014] ZASCA 156.

²⁷⁴⁰ Pane v MEC Free State Department of Health [2016] ZAFSHC 99.

²⁷⁴¹ Zwart 2015 *De Rebus* 33.

²⁷⁴² Sibisi NO v Maitin (311/13) [2014] ZASCA156 [44-51] see also Pane v MEC Free State DOH [2016] ZAFSHC 99 [23-25 and 45-50].

²⁷⁴³ Zwart 2015 *De Rebus* 33 see also Barit *The doctrine of informed consent in South African medical law* 26-35 and Klinck E "Law in practice: Informed consent-Old rules in new formats?" www.elsabeklinckassociates.co.za (Date of use: 29 October 2017) as well as Esterhuysen www.bowmanslaw.com/insights/tax/medical-negligence (Date of use: 25 October 2017).

²⁷⁴⁴ Hogan Lovells www.hoganlovells.com/publications/the-doctors-duty-to-inform (Date of use: 28 October 2017).

²⁷⁴⁵ McDonald v Wroe [2006] 3 All SA 565 (C) [568].

²⁷⁴⁶ Ellis E "Dentist to pay damages after wisdom teeth op" 11 March 2006 <http://www.iol.co.za/news/south-africa> (Date of use: 5 November 2017) see also Baron http://www.deneysreitz.co.za/directors/Monique_baron.html (Date of use: 5 November 2017).

²⁷⁴⁷ Chester v Afshar (2004) 4 All ER 587 [596].

has also been criticized for its failure to take the patients' constitutional rights into consideration,²⁷⁴⁸ as well as the informed consent regulations as stipulated in the NHA.²⁷⁴⁹

In light of the above contradictory and conflicting judgments by South African courts, a need arises to re-evaluate the doctrine of informed consent by the constitutional court, based on public policy considerations, with a view to clearly define the standard of information disclosure to be followed by South African courts, in cases of failure to obtain valid informed consent. This needs to be done in the context of constitutional obligations to respect and enhance human dignity, as stipulated in section 10 of the Bill of Rights, as well as the individual's rights to bodily and psychological integrity as stipulated in section 12.²⁷⁵⁰ In re-evaluating this standard, the court ought to take into consideration foreign law judgments, as provided for by section 39(1) (c) of the Constitution.²⁷⁵¹ Of particular interest would be the recent judgment of the UK Supreme Court, Scotland, in the case of *Montgomery v Lanarkshire*,²⁷⁵² which thoroughly re-examined and accepted the prudent patient and material risks standard as the accepted standard of information disclosure, with regard to the legal doctrine of informed consent in English law, as well as all notable common law jurisdictions. Secondly, the Constitutional court ought to also re-evaluate the dual burden of proof currently imposed on claimants, by differentiating between the failure of a HCP to obtain valid informed consent as intentional wrongdoing, assault or *iniuria*, as distinct from the unintentional tort of negligence in informed consent cases, consistent with similar observations by other South African and international legal scholars.^{2753,2754}

²⁷⁴⁸ Esterhuysen www.bowmanslaw.com/insights/tax/medical-negligence (Date of use: 25 October 2017).

²⁷⁴⁹ National Health Act 2003 (S6-9).

²⁷⁵⁰ The Constitution of the Republic of South Africa 1996 (s12).

²⁷⁵¹ The Constitution (s39) (1) c.

²⁷⁵² *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11 [87].

²⁷⁵³ Carstens and *Pearmain Foundational Principles* 681 see also Van Oosten 1989 M&L 443-456 [452] and Barit *The doctrine of informed consent in South African medical law* 26-35.

²⁷⁵⁴ Jones *Textbook on Torts* 8th ed [507-511 and 527-528].

9.3 CONCLUSIONS TO BE DRAWN FROM THE EMPIRICAL RESEARCH STUDY

Analysis of the responses by HCPs and patients in this study reveals that while many HCPs, especially doctors, appear conversant with the key elements of the IC doctrine, the implementation of this doctrine in clinical practice fell short of the expected standard.

One can determine the level of knowledge and extent of implementation by reference to the original objectives of this study, which were to ascertain whether sufficient and comprehensive information was provided to patients prior to consent to medical treatment; whether patients actually understand the information provided by HCPs, including the risks and benefits of the treatment; whether patients giving IC generally have the capacity to consent to such treatment; and whether patients give consent or refusal to recommended treatment voluntarily without coercion, undue influence or manipulation; and finally, whether IC provided by patients undergoing medical treatment in South African public hospitals, is truly valid and consistent with current regulations.

Information disclosure: In terms of information disclosure, while the majority of doctors and nurses reported disclosing elements such as diagnosis, benefits and risks of treatment, a lesser percentage of HCPs were not disclosing information about the patients' rights of refusal, treatment options, and risks of refusing recommended treatment. From the empirical data obtained, although the HCPs in this study claimed to have disclosed the latter requirements adequately; triangulation of results by comparison with patients' responses, revealed that the HCPs responses were inconsistent with the actual reported patterns of disclosure by patients.²⁷⁵⁵ This poor implementation in practice with regard to IC appears consistent with previous studies from South Africa.²⁷⁵⁶ This observation of poor implementation of the IC doctrine in clinical practice is further corroborated by studies on IC practice by doctors from other countries in Africa such as Nigeria²⁷⁵⁷ and Gabon,²⁷⁵⁸ and more developed countries such as Spain²⁷⁵⁹ and the

²⁷⁵⁵ Chima 2015 *Niger J Clin Pract* 52-53.

²⁷⁵⁶ Henley L et al 1995 *SAMJ* 1273-1278.

²⁷⁵⁷ Ogundiran and Adebamowo 2010 *J Med Ethics* 741-745.

²⁷⁵⁸ Sippel et al 2015 *PLoS ONE* e0132374.

²⁷⁵⁹ Lopez PR "Informed consent in surgery-distance between theory and practice" 2013 *Cir Esp* 551-553.

USA.²⁷⁶⁰ From the patients' perspective, however, most patients in this study reported being generally satisfied with the level of information disclosure, with over 90% responding positively.²⁷⁶¹ However, this overwhelming response should be interpreted cautiously, since most patients may not be fully aware of the legal requirements for IC and the extent of patients' rights to information disclosure, as stipulated by law. Further, studies from other countries also reveal that while patients may respond enthusiastically regarding the level of information disclosure during clinical practice, when challenged by questioning, most patients may not actually remember the details and nature of information disclosed.²⁷⁶²

Comprehension of disclosed information: The major barrier to IC identified by this cohort of HCPs was due to 'language barriers', which were ranked as the number one challenge by both doctors and nurses. This was followed by 'lack of education', 'workload and time constraints', and 'lack of administrative support, such as interpreters'.^{2763,2764} The findings from this study with regard to language as a barrier to IC has been reported by other authors from South Africa,²⁷⁶⁵ as well as from other multilingual and multicultural societies such as the USA.^{2766, 2767} Generally, because of such language barriers, several authors have suggested that nurses and other HCP have had to take on the additional role of interpretation for doctors as a form of 'cultural brokerage',^{2768,2769} which would further increase nurses' workload, already complicated by large patient numbers. The issues of workload and time constraints were also major challenges reported by nurses and doctors from this study, as additional reasons for spending less time on the IC

²⁷⁶⁰ Bazemore N "Not all doctors get informed consent-Here's why it's hurting patients" Forbes.com
LLC™<http://www.forbes.com/sites/amino/2016/03/28/notalldoctorsgetinformedconsenthereswhyitshurtingpatients/print/> (Date of use: 6 April 2016).

²⁷⁶¹ Chima 2015 *Niger J Clin Pract* 53.

²⁷⁶² Burns P, Keogh I and Timon C "Informed consent: a patients' perspective" 2005 *J Laryngol Otol* 19-22.

²⁷⁶³ Chima 2013 *BMC Med Ethics* S3 [13].

²⁷⁶⁴ Chima *Understanding and practice of informed consent by professional nurses in South Africa* 97.

²⁷⁶⁵ Schlemmer and Mash 2006 *SAMJ* 1084-1087.

²⁷⁶⁶ Flores 2006 *N Engl J Med* 229-331.

²⁷⁶⁷ Schenker et al 2007 *J Gen Intern Med* 294-299.

²⁷⁶⁸ Shaibu 2007 *Nurs Ethics* 507.

²⁷⁶⁹ Jezewski 1990 *West J Nurs Res* 497-513.

process. One may conclude that the additional role of 'nurse as interpreter' and cultural broker imposed on nurses, may be associated with increased job attrition, lack of job satisfaction, and 'burn-out', especially amongst nurses, as previously reported from KwaZulu-Natal and other provinces in South Africa.^{2770,2771,2772,2773}

Additional enquiries from HCPs regarding methods used to enhance comprehension by patients yielded information that apart from interpreters, doctors also used audio-visual aids, such as diagrams and pictures as well as communicating with patients in English and their local language. Similarly, many nurses claimed to communicate with patients using the patient's local language. However, these responses were not corroborated by patients, who said most of the communication from HCPs occurred verbally by means of English language.²⁷⁷⁴ However, despite these observations, the majority of patients (90%), said they understood the information provided by HCPs. Based on the above, one concluded that despite the limited information disclosed by HCPs to patients, the evidence suggests that this information was understood and comprehended by the patients. However, lack of appreciation of the information as previously discussed, could also be a hindrance to informed consent,²⁷⁷⁵ in this setting.

Voluntariness of IC: In terms of voluntariness, most doctors in this study said they would be willing to allow patients to choose their own treatment amongst different options, while only 40% of nurses would agree to this. To further explore if HCPs were respecting patients voluntariness during healthcare decision-making, I asked HCPs if they used either implied or presumed consent during clinical practice. In this case, over 50% of doctors and nurses said they would use it when patients were admitted to the ward or

²⁷⁷⁰ Mmamma et al 2015 *Curationis* Art #1566 <http://dx.doi.org/10.4102/curationis.v38i2.1566> (Date of use: 20 April 2016).

²⁷⁷¹ Khunou SH and Davhana- Maselesele M "Level of job satisfaction amongst nurses in the North-West Province South Africa: Post occupational specific dispensation" 2016 *Curationis* Art #1438 <http://dx.doi.org/10.4102/curationis.v39i1.1438> (Date of use: 20 April 2016).

²⁷⁷² Pillay 2009 *Hum Resour for Health* 7-15.

²⁷⁷³ Zelnick and O'Donnell "The impact of the HIV/AIDS epidemic on hospital nurses in KwaZulu Natal South Africa: Nurses' perspectives and implications for health policy 2005 *JPHP* 163-185.

²⁷⁷⁴ Chima 2015 *Niger J Clin Pract* 50-52.

²⁷⁷⁵ Barit *The doctrine of informed consent in South African medical law* 17 see also Van Oosten 1989 *LLD thesis* 20.

showed up at the clinic. The majority of HCPs also admitted that they used implied or presumed consent mostly in emergency situations. During regular practice, however, about 60% of HCPs said they used it sometimes or rarely, while a minority said they used it all the time. On the other hand, when patients were asked if they made their decisions freely without coercion or undue pressure, the majority of patients, about 95%, answered affirmatively, with only a few claiming they sought assistance from surrogates. When asked if they could reject the treatment recommended by a doctor or HCP if they wanted to, the majority of patients said yes, but some said they only did as ordered by doctors: "The doctors tell you what needs to be done and you do it," which shows that there are still elements of paternalism or 'doctor knows best' in local medical practice. Other patients reported that they were afraid to ask questions or reject the treatment provided even if they did not like it; to avoid losing the free treatment provided in public hospitals or because they did not have alternative means of obtaining healthcare. Based on this evidence, one can conclude that the IC provided in this setting was relatively voluntary, but this voluntariness was sometimes limited by the patient's belief systems, poverty, indigence and vulnerability. However, the reported use of implied and presumed consent by HCPs, as well as the some patient's unquestioning compliance with HCP instructions, means that there are still residual elements of medical paternalism, albeit 'soft' or 'weak' paternalism^{2776,2777} being practiced in this setting.

Capacity to consent to treatment: When HCPs were asked if they generally presumed that most patients had the capacity to consent to treatment, majority of HCPs answered affirmatively. However, some HCPs correctly identified that it depends on the patient's level of consciousness among other considerations. Most HCPs were also able to correctly rank the criteria for establishing capacity in patients. Further, many were able to accurately identify some criteria for assessing patient capacity in difficult situations. However, when asked to identify the correct age of consent to treatment in South Africa, only 70% of doctors and 30% of nurses, could accurately identify the age of '12 years' as correct age as stipulated by current law.²⁷⁷⁸ This indicates that while HCPs were aware of

²⁷⁷⁶ Weiss GB "Paternalism modernized" 1985 *J Med Ethics* 184-187.

²⁷⁷⁷ Chima 2009 *Trans J Coll Med S Afr* 43.

²⁷⁷⁸ Children's Act 38 of 2005 as amended.

the clinical criteria for ascertaining patient consciousness and DMC capacity, many were deficient in their knowledge of the legal requirements relating to capacity to consent and IC. On the other hand, only 25% of patients were able to accurately identify the age of consent to treatment as 12 years. This percentage was closer to the 30% accuracy level reported by nurses, which implies that knowledge of this aspect of basic healthcare law by nurses was no different from the general population, probably indicative of inadequate training amongst this category of HCPs.

Consent or authorization of treatment and voluntariness. The final element in the IC process is the authorization of treatment by patients after full information disclosure and comprehension. In terms of the methods for obtaining actual authorization of treatment from patients, a majority of HCPs claimed that IC was obtained in written format, which was inconsistent with the majority of patients in this study who reported that treatment authorization or consent was obtained verbally in most cases.²⁷⁷⁹ It must be noted, however, that valid consent can be provided either in writing or verbally, as long as the patient has the necessary capacity, and has understood the information disclosed.²⁷⁸⁰ When patients were asked whether they were advised that they had the right to either accept or reject the recommended treatment, only 42% of patients said they were told they could accept or refuse the treatment. When asked if they felt threatened or were afraid to say 'no'; 91% of patients said they did not feel threatened or afraid to say no. Patients who said they were afraid, said they did so because they did not want to lose the free treatment provided or be ignored by the HCPs.²⁷⁸¹ When patients were asked if they were given any perverse incentive or persuaded to accept any particular treatment, the majority about 97% answered negatively. From these responses, one may conclude that the authorization of treatment by patients in this setting was generally free of undue influence and coercion, and substantially voluntary.

²⁷⁷⁹ Chima 2015 *Niger J Clin Pract* 52.

²⁷⁸⁰ HPCSA *Seeking patients' informed consent: The ethical considerations* (HPCSA Pretoria 2008)10-11.

²⁷⁸¹ Chima 2015 *Niger J Clin Pract* 51.

Time spent on IC: Most HCPs in this study spent about 5 to 10 minutes on the IC process, with the majority spending a total of 5 to 20 minutes on the IC process, or the entire clinical encounter as corroborated by patients. This amount of time is consistent with the reports from other parts of the world like USA, where the reports of the average time at a primary care visit was estimated at around 15 minutes.²⁷⁸² This time duration is also consistent with the national PHC norms for time spent and workload for HCPs in South Africa.²⁷⁸³

General knowledge of IC principles and medico-legal regulations: There was a statistically significant difference in knowledge of basic ethical and legal principles of IC between doctors and nurses; as well as between different categories of doctors, with specialist doctors, medical officers and general practitioners being more knowledgeable than trainee doctors (registrars and interns).²⁷⁸⁴ There was also a gap in knowledge of basic local laws among HCPs, with about 30% of doctors and 70% of nurses not being aware of the current legal age of consent to routine medical treatment in South Africa.²⁷⁸⁵ Further, a majority of HCPs in this study did not know the unique legal position regarding the age of consent to TOP, as stipulated by the Choice on Termination of Pregnancy Act in South Africa.²⁷⁸⁶ Furthermore, a majority of the patients reported that they were not coerced by HCPs or influenced by other surrogates, including family members, during the process of healthcare decision-making. These responses by patients are inconsistent with reports from other parts of Africa or other multicultural societies, where family and community involvement in healthcare decision-making are the norm.^{2787,2788,2789} However, this may suggest that most South African patients may be westernized in their approach to individual autonomy, or are more aware of patients' rights due to wide dissemination of the Patients' Rights Charter, as required by law in South African hospitals.²⁷⁹⁰

²⁷⁸² Kaplan RM 2004 *Am J Prev Med* 81.

²⁷⁸³ Kwazulu-Natal Strategic plan 2010-2014 (KZN DOH 2010)14.

²⁷⁸⁴ Chima 2013 *BMC Med Ethics* S3.

²⁷⁸⁵ Children's Act 38 of 2005 as amended.

²⁷⁸⁶ Choice on Termination of Pregnancy Act 92 of 1996.

²⁷⁸⁷ Gordon E 1986 *Fordham Urb L J* 1321-1362.

²⁷⁸⁸ Ezeome and Marshall 2009 *Dev World Bioeth* 138-148 see also Irabor and Omonzejele 2009 *Dev World Bioeth* 34-42.

²⁷⁸⁹ Lee et al 2009 *Int J Nursing Stud* 1580-1584 see Masaki et al 2014 *BMC Med Ethics* 15 and Tindana et al 2006 *IRB* 1-6.

²⁷⁹⁰ HPCSA National Patients' Rights Charter (HPCSA Pretoria 2008)

Patient-identified barriers to IC in this study, included poor communication skills by HCPs, especially with some patients claiming they were unable to ask questions because doctors were too fast, too aggressive, and needed to improve their communication skills. Other potential barriers revealed by this study was the problem of poverty and indigence, because many of the patients using South African public hospitals are unemployed²⁷⁹¹ and therefore may be considered vulnerable due lack of alternative means of obtaining healthcare consistent with certain criteria for vulnerability.^{2792,2793,2794}

General conclusions: From the above, one may draw the following general conclusions from the empirical research study.

This study confirms previous observations that doctors and nurses practising in South Africa were generally aware of the key elements of IC, but implementation in practice was inadequate. Secondly, HCPs were somewhat deficient in their knowledge of basic local laws. Further, there were real barriers in the practice of IC in this setting due to language difficulties and the absence of administrative support in the form of trained interpreters to assist with patient communication and this may interfere with the quality of healthcare service delivery. In addition, the current consent forms used in public hospitals were also considered inadequate by doctors.

The study also confirms that the majority of patients using the public healthcare services were indigent and vulnerable due absence of alternative means of obtaining healthcare, poverty, and low educational levels. Therefore, patients' rights may not be fully respected due to this vulnerability and the power asymmetry between HCPs, especially doctors and their patients. Thus, many HCPs in this study reported using implied and presumed consent, especially when patients showed up to the clinic or were admitted to clinical

²⁷⁹¹ Chima 2015 *Niger J Clin Pract* 50-51.

²⁷⁹² Chima SC *Contemporary ethical issues and regulation of biomedical research in Africa* 19-38.

²⁷⁹³ Chima *A primer on medical law* 169.

²⁷⁹⁴ Kwazulu-Natal Strategic plan 2015-2019 (KZN DOH 2015) 15-22.

wards in public hospitals; indicating some residual practices of medical paternalism at public hospitals in EThekweni municipality, KZN province, South Africa.

9.4 LIMITATIONS OF THIS STUDY

The results from this study must be examined in the light of the fact that it was conducted in an urban metropolitan municipality in South Africa, with the possibility that patients in this region may be more educated and knowledgeable than those from the rural areas in South Africa, in terms of their knowledge and awareness regarding patients' rights and IC. It is possible that a study from a more rural population group in KZN or elsewhere in South Africa may yield a different result. Further, there is also a possibility that because the study was located in a major city with teaching hospitals and potentially more knowledgeable HCPs, the HCPs examined may be more aware of the ethical and legal rules of IC, therefore studies from other cohorts of HCPs, either those practicing in rural areas or more cosmopolitan cities like Cape Town or Johannesburg, may yield a different result based on alternative responses. Further, as the number of medical doctors that participated in this study was limited to 168, it is possible that a larger cohort might yield different outcomes or results, although the fact that the HCPs included were from all the major clinical domains in public hospitals, with different training and professional backgrounds. For these reasons, it is more likely than not that the results obtained in this study are consistent with normal practice of IC by HCPs in South Africa.

Finally, in conducting this study, I assumed that both HCPs and patients provided accurate and truthful responses to the questions asked. If this is not the case, then the results may not be factually accurate; however, the process of randomization applied in participant and hospital selection, and the voluntary and anonymous nature of the study, as well as the technique of triangulation, helped to ensure consistency and minimize bias in the empirical study reported here. Future studies may be directed at replicating the results from this study in a private practice setting, as well as conducting more detailed comparative studies using either qualitative or quantitative methodology to further elucidate on the practice of IC in South Africa.

9.5 CENTRAL CONCLUSIONS

Based on the findings in from study I was able to arrive at the following central conclusions:

- I. Informed consent regulations as stipulated by domestic laws, regulations and ethical codes are generally consistent with international best practice and guidelines. However, analysis of case law from this study has revealed some inconsistencies and contradictory judgments by South African courts, which are not consistent with the current legislation regarding informed consent as stipulated in the National Health Act 2003.²⁷⁹⁵ Furthermore, such judgments appear to be at variance with constitutional provisions for bodily and psychological integrity in section 12(2) (b), as well the requirements for respect for human dignity as stipulated in section 10 of the Constitution.²⁷⁹⁶ Finally, comparative law from other common law jurisdictions seem to indicate that while South African courts are vacillating between the ‘reasonable doctor’ and the prudent patient’ standards of information disclosure with regards to informed consent, other comparable common law jurisdictions have firmly adopted and accepted the ‘prudent patient and material risks standards’ as the required standard in most common law jurisdictions. Furthermore, South African courts do not seem to heed the call to ‘consider foreign law’, as stipulated by section 39(1) (c) of the Constitution.²⁷⁹⁷
- II. Informed consent as practiced in local public hospitals by HCPs is only partially compliant with the requirements stipulated by the National Health Act 2003.
- III. Knowledge of the South African legal framework relating to the practice of informed consent by HCPs is somewhat deficient, especially amongst professional nurses.
- IV. The main barriers to the informed consent process in the South African public hospitals was due to ‘language barriers’, followed by ‘lack of education’ by patients, excessive workload and time constraints on HCPs, coupled with ‘lack of administrative support’, such as interpreters. All of these factors arguably combine

²⁷⁹⁵ National Health Act 61 of 2003.

²⁷⁹⁶ The Constitution of the Republic of South Africa 1996 s12 (2) (b).

²⁷⁹⁷ The Constitution s39 (1) c.

to interfere with the process of obtaining informed consent in the South African public hospitals, and may influence the healthcare professional-patient relationship, job satisfaction amongst HCPs, and the overall quality of healthcare service delivery.

- V. The current 'consent forms' used in local hospitals are inadequate and may need to be modified to comply with current standards of information disclosure relevant local laws, especially the information disclosure requirements as stipulated in section 6(1)(a)-(d) of the National Health Act.²⁷⁹⁸
- VI. Patients using public hospitals in South Africa may be considered vulnerable, consistent with WHO definition of vulnerability which includes poverty, poor education and lack of alternative means of obtaining healthcare.²⁷⁹⁹
- VII. Despite their vulnerability however, the majority of patients in this setting still want to be involved in decisions regarding their healthcare, exhibiting a preference for shared decision-making, rather than simple informed consent, and requesting better communication skills from HCPs.

Based on the above conclusions from this research study, I was able to make the following recommendations regarding the understanding and practice of informed consent by HCPs, the need for continuing professional education on healthcare law and ethics for HCPs and patients in South Africa.

9.6 RECOMMENDATIONS

1. One major recommendation arising from this study would be the need for establishment of a cadre of 'professional interpreters' cum patient advisors into local public healthcare services, to help improve the quality of HCP-patient communication and clinical practice in general. It also suggested that the introduction of this cadre of workers would generally improve the overall quality of

²⁷⁹⁸ National Health Act 61 of 2003.

²⁷⁹⁹ UNAIDS *International Guidelines on HIV/AIDS and Human Rights-Consolidated version* (UNAIDS Geneva 2006) 79-81 see also Chima *A primer on medical law* 169.

healthcare services, by reducing nurses' and other HCWs workloads; who are generally required to act as impromptu interpreters and advisors as part of 'cultural brokerage' in public hospitals. One may speculate that the introduction of this cadre of interpreters/patient advisors into the local healthcare workforce, may assist in minimizing job attrition, by reducing HCPs 'burn-out' and increased job satisfaction, thereby improving treatment outcomes and the overall quality of healthcare service delivery in South African public hospitals.

2. The second important recommendation would be continued professional development training for HCPs in the areas of medical law, bioethics and human rights, especially by introducing courses in bioethics and medical law into nursing schools curricula, where they do not currently exist. In addition, that these courses should be taught by appropriately trained HCPs with a professional background and specific training in medical law and ethics. This recommendation is consistent with previous recommendations by the Truth and Reconciliation Commission (TRC) in 1996 which stated that:

Training in human rights must be a fundamental and integral aspect of curricula for healthcare professionals. This training should address factors affecting human rights practice, such as knowledge, skills, attitudes, and ethical research practices. Knowledge of and competence and proficiency in the standards (both national and international) to which [health professionals] will be held accountable should be a requirement for qualification and registration.²⁸⁰⁰

3. The third important recommendation in this report arises from analysis of current South African case law on informed consent cases. There is a need for a re-evaluation of recent judgments by South African courts to eliminate contradictory and conflicting judgments by different courts, including the need to resolve the question of information disclosure standards in the light of current legislation and the principles laid down in the Constitution. There is also a need to resolve the question of the 'dual burden' of proof for plaintiffs in informed consent cases, as

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Truth and Reconciliation Commission Report "Institutional hearings: The health sector" (CTP Book Printers Cape Town 1998)109-164.

well as a need to distinguish between intentional ‘wrongdoing’ or assault due to deliberate failure of a HCP to obtain informed consent in accordance with the guidelines stipulated in the National Health Act,²⁸⁰¹ as opposed to unintentional ‘negligence’ occurring during healthcare practice, whereby a plaintiff would need to prove all the required elements of clinical negligence in order to be awarded damages. It is suggested that a resolution of this question would be in accordance with constitutional requirements to respect human dignity.²⁸⁰² For example, in two recent cases by South African courts, discussed in this thesis, that is, *Sibisi NO v Maitin*²⁸⁰³ and *Pane v MEC Free state*,²⁸⁰⁴ both claimants were left without indemnification and in a terrible position following loss of their claims due to inability to prove negligence. Such judgments are not consonant with the spirit and intent of the human rights and dignity provision in the Constitution and related South African and international laws.

4. The current ‘consent forms’ used in public hospitals in South Africa ought to be revised to comply with the information disclosure requirements adumbrated in the National Health Act. This may be done by adding a list of required questions or disclosures derived from section (6) (1) (a)-(d) of the National Health Act.²⁸⁰⁵ Such a list of questions has been elucidated in the questions used for ICAS²⁸⁰⁶ evaluation in this thesis. A similar “informed consent checklist” derived from the National Health Act has also been advocated by other legal scholars on informed consent in South Africa.²⁸⁰⁷
5. There should be ongoing publicity and general education of the populace regarding their rights to informed consent and other patients’ rights issues, as enshrined in South African law, especially the ‘rights and duties of healthcare users and providers’ as codified in chapter two of the National Health Act.²⁸⁰⁸

²⁸⁰¹ National Health Act 61 of 2003.

²⁸⁰² Section 10 of the Bill of Rights and Constitution.

²⁸⁰³ *Sibisi NO v Maitin* (311/13) [2014] ZASCA 156.

²⁸⁰⁴ *Pane v MEC Free State DOH* [2016] ZAFSHC 99.

²⁸⁰⁵ National Health Act 61 of 2003 (S6).

²⁸⁰⁶ ICAS (Informed Consent Aggregate Score) see Chima 2013 *BMC Med Ethics* S3 [11].

²⁸⁰⁷ Barit *The doctrine of informed consent in South African medical law* 69.

²⁸⁰⁸ National Health Act 61 of 2003 (chapter 2).

6. HCPs ought be further educated in the areas of enhanced communication skills to improve patient outcomes, preventive healthcare, and the need for shared and informed healthcare decision-making, as requested by patients in this study.
7. With regard to future research, the empirical aspect of this study is somewhat consistent with the four-fold typology and hierarchy of empirical ethics suggested by Alexander Kon.²⁸⁰⁹ This study conforms most closely to the “*lay of the land*” and “*ideal versus reality*” studies as postulated by Kon.²⁸¹⁰ Therefore, future studies may be directed first, at comparative studies of IC in private hospitals in South Africa, to see if there are any significant differences in the practice of IC in the private healthcare setting when compared to the practice in public hospitals reported in this thesis. More detailed studies using qualitative or quantitative methodology could then explore IC practice in different hospital departments, clinics and units as well as studies in hospital wards, to see how nursing practices are actualized at the unit level. These latter studies will conform more to Kon’s “improving care” and “changing ethical norms in practice” aspects of empirical ethics.²⁸¹¹ All of these future studies will assist in improving the overall quality of informed consent and patient care, as well preventive services in South African hospitals and medical practice

²⁸⁰⁹ Kon AA “The role of empirical research in bioethics” 2009 *AJOB* 59-65.

²⁸¹⁰ Kon 2009 *AJOB* 60.

²⁸¹¹ Kon 2009 *AJOB* 61-63.

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Universal Declaration of Human Rights (United Nations 1948)

LIST OF ABBREVIATIONS

Journal Abbreviations

AJOB	American Journal of Bioethics
All ER	All England Law Reports
AHRLR	African Human Rights Law Reports
Am J Hum Genet	American Journal of Human Genetics
Am J Law Med	American Journal of Law and Medicine
Am J Med	The American Journal of Medicine
Am J Prev Med	American Journal of Preventive Medicine
Am J Psychiatry	American Journal of Psychiatry
Am Jur Physicians and Surgeons	American Jurisprudence Physicians and Surgeons
AMA J Ethics	American Medical Association Journal of Ethics
Applied Nurs Res	Applied Nursing Research
Arch Dis Child	Archives of Diseases of Childhood
Arch Intern Med	Archives of Internal Medicine
Arch Pathol Lab Med	Archives of Pathology and Laboratory Medicine
Arch Pediatr Adolesc Med	Archives of Pediatrics and Adolescent Medicine
Aust J Physiother	Australian J of Physiotherapy
BJU International	British Journal of Urology International
BMC Med Ethics	BMC Medical Ethics
BMJ	British Medical Journal
Bull Am Acad Psych Law	Bulletin of the American Academy of Psychiatry and the Law
C i r E s p	Cirugia Espanola
C.J.L.S	Canadian J of Law and Society
Cancer Suppl	Cancer Supplement
Cardozo L Rev	Cardozo Law Review
CILSA	Comparative and International Law Journal of Southern Africa

Clin Eff Nurs	Clinical Effectiveness in Nursing
Clin Genet	Clinical Genetics
Clin Psych Rev	Clinical Psychiatry Review
Clin Trials	Clinical Trials
Clio Med	Clio Medica: Studies in the History of Medicine and Health
CSIR	Council for Social and Industrial Research
CWG	Cash Working Group, Jordan
Conn Med	Connecticut Medicine
Croat Med J	Croatian Medical Journal
Dev World Bioeth	Developing World Bioethics
East Afr Med J	East African Medical Journal
EMBO	European Molecular Biology Organization
Ethics Med Public Health	Ethics Medicine and Public Health
Ethical Theory Moral Pract	Ethical Theory and Moral Practice
Europ J Hum Genet (EJHG)	European Journal of Human Genetics
Europ J Pal Care	European Journal of Palliative Care
FORDHAM Urb L.J	Fordham Urban Law Journal
Glob Health Action	Global Health Action
Hastings Cent Rep	Hastings Center Report
HSR	Health Services Research
Hum Resour Health	Human Resources for Health
Int J Nursing Stud	International Journal of Nursing Studies
Int J Environ Res Public Health	International Journal of Environmental Research and Public Health
IJME	International Journal of Medical Education
IPJP	Indo-Pacific Journal of Phenomenology
IRB	Institutional Review Board
IRB: Ethics & Human Research	Institutional Review Board: Ethics and Human Research
J Acquir Immune Defic Syndr	Journal of Acquired Immunodeficiency Syndrome

J Adv Nurs	Journal of Advanced Nursing
J Contemp Health L & Pol'y	Journal of Contemporary Health Law and Policy
J Gen Intern Med	Journal of General Internal Medicine
J Health Soc Behav	Journal of Health and Social Behaviour
J Health Soc Behav	Journal of Health and Social Behaviour
J Laryngol Otol	The Journal of Laryngology and Otology
J Med Libr Assoc	Journal of the Medical Library Association
J Med Ethics	Journal of Medical Ethics
J Moral Educ	Journal of Moral Education
J Natl Cancer Inst	Journal of the National Cancer Institute
J of Leg Med	Journal of Legal Medicine
J of Surg Educ	Journal of Surgical Education
J Paediatr Child Health	Journal of Paediatrics and Child Health
J Public Health Policy	Journal of Public Health Policy
J Med Ethics Hist Med	Journal of Medical Ethics and History of Medicine
Lancet Oncol	The Lancet Oncology
Law Q. Rev	Law Quarterly Review
Life Sci Soc Policy	Life Sciences, Society and Policy
Lloyds Rep Med	Lloyds Medical Law Reports
Med Health Care Philos	Medicine Healthcare and Philosophy
Med L Rev	Medical Law Review
Med Law	Medicine and Law
MUMJ	McMaster University Medical Journal
N Engl J Med	New England Journal of Medicine
Nat Rev Genet	Nature Reviews Genetics
Niger J Clin Pract	Nigerian Journal of Clinical Practice
Nurs Ethics	Nursing Ethics
Nurse Res	Nursing Research
Nurs Res and Pract	Nursing Research and Practice
Nurse Res	Nurse Researcher
OJIN	The Online Journal of Issues in Nursing

Patient Educ Couns	Patient Education and Counselling
PER/PELJ	Potchefstroomse Elektroniese Regsblad/ Potchefstroom Electronic Law Journal
Prehosp Emerg Care	Prehospital Emergency Care
S Afr J B L	South African Journal of Bioethics and Law
S Afr J Sci	South African Journal of Science
S Afr Med J	South African Medical Journal
SAJBL	South African Journal of Bioethics and Law
SALJ	South African Law Journal
SAMJ	South African Medical Journal
Semin Oncol Nurs	Seminars in Oncology Nursing
Soc Sci Med	Social Science and Medicine
Stan L & Policy Rev	Stanford Law and Policy Review
STELL LR	Stellenbosch Law Review
THRHR	Tydskrif vir hedendaagse Romeins-Hollandse Reg
Trans J Coll Med S Afr	Transactions: Journal of the Colleges of Medicine of South Africa
West J Nurs Res	Western Journal of Nursing Research
Wis L Rev	Wisconsin Law review
Wis L Rev	Wisconsin Law Review
Yale L J	Yale Law Journal

General Abbreviations

ACERP	Asian Conference on Ethics Religion and Philosophy
AHA	American Hospital Association (USA)
AHA	Area Health Authority (UK)
AMA	American Medical Association
Aust High Ct	Australian High Court
BICEP	Brief informed consent evaluation protocol
BMA	British Medical Association
CA	Court of Appeals

Cal Sup Ct	California Supreme Court
CC	Constitutional Court
CEO	Chief executive officer
CIOMS	Council for International Organizations of Medical Sciences
Conn. <i>Super. Ct</i>	Connecticut Supreme Court
DHEW	Department of Health Education and Welfare
DHHS	Department of Health and Human Services
DMC	Decision making capacity
DOH	Department of Health
GCS	Glasgow Coma Scale
GG	Government Gazette
GMC	General Medical Council
GP	General Practitioner
HA	Health Authority
HCP	Healthcare Professional
HCW	Healthcare Worker
HFEA	Human Fertilization and Embryology Authority
HMC	Health Management Committee
HMSO	Her Majesty's Stationery Office
HPCSA	Health Professions Council of South Africa
HTA	Human Tissue Authority
IAFOR	International Academic Forum
IBC	International Bioethics Committee
IBM	International business machines
IC	Informed Consent
ICAS	Informed Consent Aggregate Score
IFAS	Institute for Agricultural Studies (University of Florida)
ICCPR	International Convention on Civil and Political Rights
ICESCR	International Covenant on Social Economic and Cultural Rights

IMRAD	Introduction-Methods-Results-and-Discussion
IOM	International Organization for Migration
KZN	KwaZulu-Natal Province
MacCAT-T-	Macarthur Competence Assessment Tool-Treatment
MD	Maryland
MDCN	Medical and Dental Council of Nigeria
MMSE	Mini Mental Status Examination
Mo App Ct	Missouri Appeals Court
MO	Medical Officer
NBAC	National Bioethics Advisory Commission
NC	North Carolina
ND Okla.	Oklahoma District Court
NHA	National Health act
NHREC	National Health Research Ethics Committee
NHS	National Health Service
Nig SC	Nigerian Supreme Court
NJ	New Jersey
OBGYN	Obstetrics and gynecology
Ont.	Ontario Canada
PAHO	Pan American Health Organization
PHC	Primary Health Care
PI	Principal Investigator
Que	Quebec Canadá
RCT	Randomized Clinical Trial
REC	Research Ethics Committee
SANC	South African Nursing Council
SCA	Supreme Court of Appeal
SCA	Supreme Court of Appeal
SCC	Supreme Court of Canada
SD	Standard deviation
SPSS	Statistical Package for Social Sciences

Sup Ct Mass	Supreme Court of Massachusetts
Sup. Ct. NJ	Supreme Court of New Jersey
TOP	Termination of pregnancy
TRC	Truth and Reconciliation Commission
UDHR	Universal Declaration of Human Rights
UDHR	Universal declaration of human rights,
UK	United Kingdom
UKZN	University of KwaZulu-Natal
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNCESCR	United Nations Covenant on Economic Social and Cultural Rights
UNESCO	United Nations Educational Scientific and Cultural Organization
UNISA	University of South Africa
US	United States
USA	United States of America
WHO	World Health Organization
WMA	World Medical Association

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ANNEXURES 1-3: Peer-reviewed publications derived from this study

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3. Chima S “Understanding and Practice of Informed Consent by Professional Nurses in South Africa: An Empirical Study-Brief Report” *Official Conference Proceedings Asian Conference on Ethics, Religion & Philosophy (ACERP)* March 17-2 2017 The International Academic Forum (IAFOR), Kobe, Japan
www.iafor.org

ANNEXURE 1

RESEARCH ARTICLE

OPEN ACCESS

Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study

Sylvester C Chima [Email author](#)

BMC Medical Ethics 2013 **14** (Suppl 1):S3

DOI: 10.1186/1472-6939-14-S1-S3

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Published: 19 December 2013

Abstract

Background:

Informed consent is a legal and ethical doctrine derived from the principle of respect for autonomy. Generally two rights derived from autonomy are accorded legal protection. The constitutional right to bodily integrity followed by the right to bodily well-being, protected by professional negligence rules. Therefore healthcare professionals treating patients' without valid consent may be guilty of infringing patients' rights. Many challenges are experienced by doctors obtaining informed consent in complex multicultural societies like South Africa. These include different cultural ethos, multilingualism, poverty, education, unfamiliarity with libertarian rights based autonomy, and power asymmetry between doctors and patients. All of which could impact on the ability of doctors to obtain legally valid informed consent.

Methods:

The objective of this study was to evaluate whether the quality of informed consent obtained by doctors practicing in South Africa is consistent with international ethical standards and local regulations. Responses from 946 participants including doctors, nurses and patients was analyzed, using a semi-structured self-administered questionnaire and person triangulation in selected public hospitals in Durban, KwaZulu-Natal, South Africa.

Results:

The median age of 168 doctors participating was 30 years with 51% females, 28% interns, 16% medical officers, 26% registrars, 30% consultant/specialists. A broad range of clinical specialties were represented. Challenges to informed consent practice include language difficulties, lack of interpreters, workload, and time constraints. Doctors spent 5-10 minutes on consent, disclosed most information required to patients, however knowledge of essential local laws was inadequate. Informed consent aggregate scores (ICAS) showed that interns/registrars scored lower than consultants/specialists. ICAS scores were statistically significant by specialty ($p = 0.005$), with radiologists and anaesthetists scoring lowest, while internists, GPs and obstetricians/gynaecologists scored highest. Comparative ICAS scores showed that professional nurses scored significantly lower than doctors ($p \leq 0.001$).

Conclusions:

Keywords: Africa, Autonomy, Patients' rights, Informed consent, Doctors, Empirical ethics, Nurses, Laws, Regulations

Background

Informed consent is a legal doctrine in medical practice, derived from the ethical principle of respect for autonomy. It has been argued that "prima facie, every competent adult has the right to decide whether to consent or refuse any medical treatment, even if such refusal could lead to death" [1]. However, this right to respect for autonomy is a rebuttable right, which could be overridden under certain conditions such as where there is temporary or permanent mental incapacity due to unconsciousness, infancy, or severe mental retardation [2]. Respect for autonomy in medical law and ethics refers to self-determination or freedom of choice. This ethical principle that each person has a right to determine what can be done to his or her own body during medical treatment has found expression in many national health statutes and international ethical codes through the doctrine of informed consent. Autonomy itself has never been found to be a legally enforceable right; rather two other rights derived from the principle of respect for autonomy have been universally accorded legal protection. The first is the right to bodily integrity protected by legal rules against assault or battery. The second is the right to

bodily well-being, protected by professional negligence rules [2, 3]. Next to these is the right to liberty or the condition of being free [4]. A patient's right to autonomy and informed consent during medical treatment was popularized as a legal doctrine by Cardozo J in the *Schloendorff* case [5] where he opined that, "every human being of adult years and sound mind has a right to determine what shall be done with his own body, and the surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages". This opinion was later reaffirmed by the US Supreme Court in the *Cruzan* case [6] where the court stated that:

No right is held more sacred or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of another.

Therefore a physician, who treats a patient without consent or exceeds the consent given by a patient, may be guilty of infringing the patient's right to bodily integrity and bodily well-being [7]. As summarized by Lord Goff in *Airedale NHS Trust v. Bland* [1]:

The first point to make is that it is unlawful so as to constitute both the tort and crime of battery, to administer medical treatment to an adult who is conscious and of sound mind, without his consent...such a patient is completely at liberty to decline to undergo treatment, even if the result of his doing so will be that he will die.

Informed consent as an ethical doctrine.

The UNESCO International Bioethics Committee (IBC) report on consent argues that, 'autonomy implies responsibility'. That the power to decide for one's self entails *ipso facto* acceptance of the consequences of one's actions, which can have far reaching consequences especially in matters of health [8]. Therefore, a person needs to be informed of the precise consequences of his/her choice, and this in turn leads one to consider the conditions under which consent is obtained. Respect for the autonomy of persons making decisions, while taking responsibility for those decisions, is closely

aligned to article 1 of the Universal Declaration of Human Rights (UDHR) which holds that all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood [8, 9]. In view of the foregoing, it could be argued that the doctrine of informed consent has evolved into a rule of law that requires that no diagnostic or therapeutic procedure should be performed on a patient, without full disclosure of the risks of the procedure and any alternatives to it, prior to giving consent.

The nature of informed consent

Informed consent has been defined as an autonomous authorisation by individuals of a medical intervention [10,11]. Others have described a complementary view of informed consent as a conversation that follows specific rules [12]. Such a conversation, should ideally be initiated by the physician or healthcare professional and involves transparency, engagement by both parties, and continues throughout the period of healthcare intervention. This conversation may also require evidence that it occurred in the form of a witnessed signature, co-signed consent documents, or medical progress notes [12]. As a general rule, medical treatment should not proceed unless the doctor has first obtained the patient's consent which may be either express or implied. The consent given by a patient can be withdrawn at anytime [13] and could be vitiated by any change in circumstances, which are not communicated to and approved by the individual consenting.

What makes consent valid?

Generally, for consent to be considered valid or truly informed, five key requirements must be fulfilled [10, 11, 14]. These would be:

- (a) *Information disclosure*: provision of adequate information
- (b) *Competence*: capacity to understand that information
- (c) *Voluntariness*: decision making in the absence of coercion or deception
- (d) *Comprehension*: understanding of information provided
- (e) *Consent*: agreement to the proposed treatment or procedure

It has been argued that informing the patient must not be simply a ritual recitation of the contents of a written document. Rather the healthcare professional must try to convey the information, whether orally or in writing, in language that suits the individual's level of understanding [15]. The healthcare professional obtaining consent should bear in mind that the prospective subject's ability to understand the information necessary to give consent depends on that individual's maturity, intelligence, educational level, and belief system. It also depends on the clinician's ability and willingness to communicate with patience and sensitivity [16]. According to the US District Court of Appeal in *Canterbury v. Spence* [17]:

The patient's right to self-determination can be effectively exercised only if the patient possesses enough information to enable intelligent choice... True consent to what happens to one's self is the informed exercise of choice and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. From these axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by the physician to the patient to make such a decision possible.

It was further asserted in the case of *Salgo v. Leland Stanford University* that: "A physician may violate his duty to his patient and subject himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment" [18]. Because of this potential for violation of patient's rights and dignity during the informed consent process, it has been suggested the quality of informed consent given by patients during various clinical encounters, should be scientifically investigated for validity, completeness, and consistency with established ethical and legal principles.[19, 20].

Informed consent in South Africa

Informed consent before medical procedures is constitutionally protected right in South Africa. This was demonstrated in the case of *Minister of Safety and Security v. Xaba* [21]. Here the police wanted a court order to compel an accused person to undergo a surgical procedure in order to obtain a bullet to be used in evidence against

the accused. The Court refused this request; arguing that such an order would violate the defendant's constitutional rights to bodily and psychological integrity, including the right to security and control of one's body [22]. Patients consent, as a requirement for all lawful medical interventions, is a well-established principle in South African common law [23]. The earliest cases in this area were *Stoffberg v. Elliot* 1923 [24] and *Esterhuizen v. Administrator Transvaal* 1957 [25]. In the former case a patient whose member was wrongfully amputated due to penile cancer without informed consent, sued his doctors for damages in action for assault. While instructing the jury, Watermeyer J opined that:

In the eyes of the law, every person has certain absolute rights, which the law protects. They are not dependent upon a statute or upon a contract, but they are rights to be respected, and one of those rights is the right of absolute security of the person....Any bodily interference with or restraint of a man's person which is not justified in law or excused by law, or consented to, is a wrong, and for that wrong the person whose body has been interfered with has a right to claim such damages as he can prove he has suffered owing to that interference.

In the case of *Esterhuizen v. Administrator Transvaal*, a 10-year-old child diagnosed with Kaposi's sarcoma was initially treated with superficial radiation with her parents' consent. However, following recurrence of the tumour she was subjected to radical radiation therapy which resulted in severe burns necessitating amputation of her limbs. The Court held that while the superficial radiation was duly performed with appropriate consent from the parents, the latter procedure was performed without the informed consent of the child's guardians. The court rejected the defence arguments for implied consent based on the fact that her parents had previously consented to a similar treatment, as well as arguments that the treatment was in the child's best interest. Holding that because the radical treatment was vastly different from the prior superficial radiation, it was necessary that the child's parent should have been adequately informed of the dangers inherent in the new treatment, before such consent to be considered valid [25]. A more recent judgment in the case of *Castell v. De Greef* [26] by Ackerman J seems to have consolidated the doctrine of informed consent into South African jurisprudence. The consequences of the latter decision on South African medical law were that the

following principles have generally been adopted into the clinical practice of medicine locally [22, 27]:

a shift from medical paternalism to patient autonomy

a shift from the 'reasonable doctor' standard to the 'prudent patient' standard

a shift in disclosure to the 'material risk' standard, where the level of disclosure required is what a reasonable patient would consider pertinent before making a decision

It has been suggested that the Court appears to place the patients' informed consent within the framework of *volenti non fit injuria* or voluntary assumption of risk rather than delict [22, 27]. The *National Health Act* (NHA) promulgated in 2003 [28] codified the requirements for informed consent into South African law. Section 7 of this act stipulates that health services may not be provided to a healthcare user without the user's informed consent, unless "the user is unable to give informed consent and such consent is given by another person, mandated by the user in writing to grant consent on his or her behalf; or authorized to give such consent in terms of any law or court order; or where the user is unable to give informed consent and no person is mandated or authorized to give such consent" [22, 28]. The law further requires that every health care provider must inform a user of "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" [28]. Section 6 of the NHA stipulates that information disclosed to patients must include the following:

(a) The range of diagnostic procedures and treatment options generally available to the user.

(b) The benefits, risks, and consequences generally associated with each option; and

(c) The user's right to refuse health services and explain the implications, risks, obligations of such refusal [22, 28]. The NHA also requires that the health care providers must inform the user of this information in a language that the user understands and in a manner which takes into account the user's level of literacy [28].

The potential impact of the socio-cultural milieu in South Africa on informed consent

In South Africa about 25% of the population is unemployed, with a low labour force participation rate of 54% compared to a global average of 69% [29]. There are also historical inequities within population groups because of the legacy of apartheid [30, 31]. Therefore basic health care is unaffordable or out reach for most of the local population, therefore the majority still patronize traditional healers for healthcare services. It has been suggested that in this environment, the practice of informed consent is light years away for the majority of the black population [30]. Under such circumstances, any offer of medical assistance is often seen as better than nothing, thus encouraging undue influence, coercion and medical paternalism [30, 32]. There is a further dichotomy in the organization of the healthcare services in South Africa, which is dual in nature consisting of private hospitals or medical practice patronized by about 20% of the population who can afford health insurance or possess the financial means to pay for private healthcare. Meanwhile the public health services are patronized by the remaining 80% of indigent citizens [33]. This evident dichotomy in healthcare service delivery may also influence the practice of informed consent in South Africa. Furthermore, most African societies being culturally complex and paternalistic in nature may require that approval be obtained from community elders, extended family members, or men/husbands as heads of households, before the actual patients can provide consent [34]. One of the challenges in this environment is how to ensure that informed consent is truly voluntary and that community or surrogate consent is not substituted for individuals' consent [35]. The issues and considerations outlined above present challenges to ensuring that consent provided in clinical practice in African communities is informed, comprehensible and autonomous. For the purposes of this study I have focussed my investigation on evaluating the quality of informed consent practices by medical doctors in public hospitals in South Africa, while taking into consideration the various key elements of informed consent, such as information disclosure, competence, voluntariness and comprehension by patients.

The benefits of using empirical methods to study informed consent

Sulmasy and Sugarman have described two potential reasons for studying the actual conduct of a group with regards to compliance with moral and ethical dilemmas. The first is to establish compliance with existing moral norms, and the second is to determine whether policies and procedures designed to operationalise certain moral norms have been successful [36]. In many countries including South Africa, current law requires that doctors must obtain informed consent from patients before involving them in medical treatment, where informed consent is defined as, "consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6", NHA [22, 28]. However, empirical studies have shown that people generally have problems in understanding the risks and benefits of medical treatment and decision making, and this could impact on the actual application of existing laws [37]. For example, a previous study on Dutch nurses charged with taking care of nursing home residents with due consideration to patients' rights and respect for autonomy, revealed that these nurses did not comply with existing regulations [38]. Based on such observations, it has been suggested that to guide action; ethical guidelines must be based in reality and should be formulated in such a way that they are continuous with accepted moral norms [39]. Further, it is has been suggested that empirical ethics should be used to defend or criticize concrete moral principles or practices rather than make general claims about moral concepts [40]. Consequently, in recent times, applied ethicists have shifted towards combining empirical, especially social scientific research methods with normative ethical analysis. Proponents of this approach to empirical ethics have argued that the study of people's actual moral beliefs, behaviour and reasoning should be the starting point of ethics. It is acknowledged that the methodologies of the social sciences, especially quantitative and qualitative research, using surveys, interviews and questionnaires is probably the best way to map the reality of peoples actual moral norms [41]. In view of the above I have used the methodology of empirical ethics, by means of a quantitative semi-structured questionnaire based survey and person triangulation [42, 43] to study the contemporary practice of informed consent amongst healthcare professionals and patients in KwaZulu-Natal (KZN) province, South Africa. Here I report the result of findings from medical doctors practising in EThekweni metropolitan municipality (Durban), KZN.

Methods

Objectives of the study

The general objective of this study was to evaluate the quality of informed consent obtained by doctors and nurses from patients attending public hospitals in South Africa. Specifically I wanted to establish whether sufficient information was provided to patients before consent is sought. To establish whether patients involved in clinical procedures understand the information given to them. To establish whether consent is obtained from patients is voluntary, and to confirm if the informed consent provided by patients attending public hospitals in South Africa is truly valid.

Research design

This study was a descriptive cross-sectional study in contemporary clinical practice settings. I also tried to apply the technique of triangulation [42, 43] by obtaining data from medical doctors, professional nurses, and patients simultaneously using separate semi-structured questionnaires. Questionnaires were distributed to participants in hospital clinics and wards in real-time during clinic hours. The real-time approach within the hospital environment allowed doctors, nurses and patients to describe their experience with the informed consent process as it is, thereby bringing out the required information. Three trained research assistants distributed and collected the questionnaires from healthcare professionals over a 3-month period from April to June 2012. They also conducted patient interviews using the appropriate questionnaire. To increase the response rate repeated visits was sometimes necessary to collect completed questionnaires from doctors and nurses.

Research instruments

Data was collected using a self-administered semi-structured questionnaires for healthcare professionals (doctors and nurses), and face-to-face interviews for patients. Two different semi-structured questionnaires were applied to patients and healthcare professionals respectively. The questionnaire for healthcare professionals consisted of 4

sections. The first section collected information on participant demographics. The second section was used to gather information on informed consent practices, such as time spent on obtaining informed consent, patient workload, information disclosed to patients, language and methods used, understanding of information by patients, and challenges faced by healthcare professionals when obtaining informed consent. The third section dealt with generic questions on local laws and regulations on informed consent such as the legal age of consent and standards of information disclosure. The fourth section dealt with understanding and use of implied and presumed consent by doctors and nurses (Additional file [1](#)). The questionnaire for healthcare professionals was informally evaluated by selected healthcare personnel and modified prior to distribution to participants. Questionnaires were distributed by hand to all participants. The study design and research instruments were evaluated and approved by a qualified biostatistician.

Study location and sampling procedure

The study was conducted in the outpatient clinics and wards at randomly selected public hospitals within EThekweni metropolitan municipality, KZN. EThekweni comprises a major urban city (Durban) surrounded by semi-urban areas (townships). The population of this area is approximately 3.2 million (2010 estimate) [[44](#)]. According to information from KZN department of Health, there are 17 public hospitals within this municipality ranging from tertiary to district hospitals [[45](#)]. Multi-stage stratified random sampling was used to select participating hospitals. The 17 hospitals identified were then arranged alphabetically for stratified sampling. It has been statistically estimated 30% of any population is adequate when conducting a descriptive study [[46](#)]. Purposive sampling was also used to include the two central tertiary hospitals within the municipality because they contain the largest number of medical doctors including specialists as well as professional nurses. The rest of the public hospitals within the municipality were randomly sampled. A total of 5 hospitals from Durban and one outlying hospital in nearby Pietermaritzburg with rotating surgical registrars from Durban were included in the study. Therefore a total of 6 provincial public hospitals were included in this study.

Target population

Medical doctors, professional nurses and patients at selected public hospitals were randomly targeted to participate in this study.

Inclusion criteria

Almost all medical doctors, professional nurses and patients within the selected hospitals were eligible to participate in the study.

Sample size

Preliminary sample size for each group of study participants was calculated using a web based freely accessible sample size calculator, Raosoft® [47]. Based on the formula for sample size and margin of error from Raosoft, the estimated sample size for each category of participants was for the recruitment of 360 medical practitioners; 373 professional nurses and 385 patients. Giving a total estimated sample size of 1118 participants. Available data on healthcare personnel indicated that there were about 5670 medical doctors and 24360 professional nurses registered in KZN in 2010, although there are disagreements on the total number of doctors practicing within South Africa and its provinces with high mobility and vacancy rates [33, 48]. Due to the fact that hospitals within the municipality serve as institutions for training of doctors and nurses, there is a constant rotation of medical personnel throughout the district and the province, and since the results were to be extrapolated to the practice of doctors generally in South Africa, I based my initial estimates on the total number of doctors and nurses practicing within KZN province as obtained from health personnel statistics [49]. Overall, because of the low numbers of health personnel, there was minimal difference in estimated sample size regardless of whether sample calculations were based on healthcare professionals within the municipality, practicing in the public sector, or within the province [47, 49].

Data analysis and statistical methods

Data from the questionnaires were captured directly into statistical package for social sciences (SPSS) by a research assistant. The captured data was then checked for completeness and accuracy by the PI (SCC) and a qualified biostatistician. Data was

later analyzed using SPSS (version 21) [50]. Descriptive statistics such as proportions, median, mode and interquartile range were used to summarize the data. Scores for comprehension, understanding, information disclosure, voluntariness and informed consent aggregate scores were worked out from the responses. The Mann-Whitney test was used to examine the difference in scores between different categories of healthcare professionals in public hospitals. Kruskal-Wallis test was used to examine the relationship between area of specialization and scores, and occupational rank and scores. Chi-square or Fisher's exact tests were used to test for association between categorical variables in the study.

Ethical considerations

Ethical approval was obtained from a sub-committee of University of South Africa (UNISA) Research Ethics Committee. The study including the biostatistics methodology was also reviewed and approved by the health research and knowledge management sub-component of the KZN Department of Health. Approval was also obtained from the CEOs or medical managers of each of the randomly selected hospitals included in the study. Finally, written informed consent was obtained from each participant after full information disclosure prior to participation in the study.

Results

Demographic characteristics of participating doctors are as shown in Table 1. There was a broad representation of all clinical specialties with participating doctors from all major clinical specialties (Table 1). The overall response rate for this study was 85%, with a total of 946 respondents including doctors, nurses and patients, out of an initial estimate of 1118 participants. After a critical review of captured data a total of 19 participants were excluded due to ineligibility. Therefore a total of 927 individuals were finally included in the study, comprising 168 doctors, 355 professional nurses and 404 patients. Here I report the results of doctor's responses to the questionnaires on the quality of informed consent. The response rate for doctors was 47% of initial estimates. The cohort of participating doctors was then regrouped into 8 major clinical disciplines or specialties for further analysis (Figure 1). The average number of patients seen by

doctors in this cohort ranged from 1 to 120 patients/day (median = 20 patients/day). The majority of doctors spent about 5 to 10 minutes providing information to patients prior to treatment decision (Figure 2). When asked whether the amount of time was sufficient, 55.4% of doctors answered 'yes' (Table 2). Those who thought the time spent was inadequate gave various reasons including language barriers and uneducated patients requiring more time for explanations. Others complained of time constraints, administrative responsibilities and large patient numbers being factors militating against spending more time explaining procedures in order to obtain valid informed consent from patients (Table 3). While others explained that the time spent depends on the procedure. Some stated that the time spent was "definitely inadequate" with comments like "in an ideal world, patients [should be] counselled for at least 30 minutes with enough time for questions and clarifications".

Table 1 Participant demographics

Doctor characteristics		Valid percent (%)
AGE		
Median	30 years	
Range	22-77 years	
Gender		
Male	78	49.1
Female	81	50.9
Missing data	9	-
Occupational Ranks		
Interns	47	28
Registrars	44	26.2
Medical Officers (MO)	26	15.5
Consultant/Specialists	51	30.4

Doctor characteristics		Valid percent (%)
Total	168	100
<i>Clinical disciplines/ sub-disciplines</i>		
Paediatrics	42	25
Obstetrics and Gynaecology	18	10.7
Internal Medicine	23	13.7
General Surgery	13	7.7
Urology	11	6.5
General Practice (GP)	11	6.5
Orthopaedic s	8	4.8
Dermatology	5	3
Radiology	5	3
Anaesthetics	4	2.4
Cardiology	2	1.2
Gastroenterology	2	1.2
HIV Medicine	1	0.6
Emergency Medicine	1	0.6
Maxillofacial Surgery	1	0.6
Neurology	1	0.6
Neonatology	1	0.6
Oncology	1	0.6
Medical management	1	0.6
<i>Practice location</i>		

Doctor characteristics		Valid percent (%)
Public	166	99.4
Private	1	0.6
Missing data	1	-

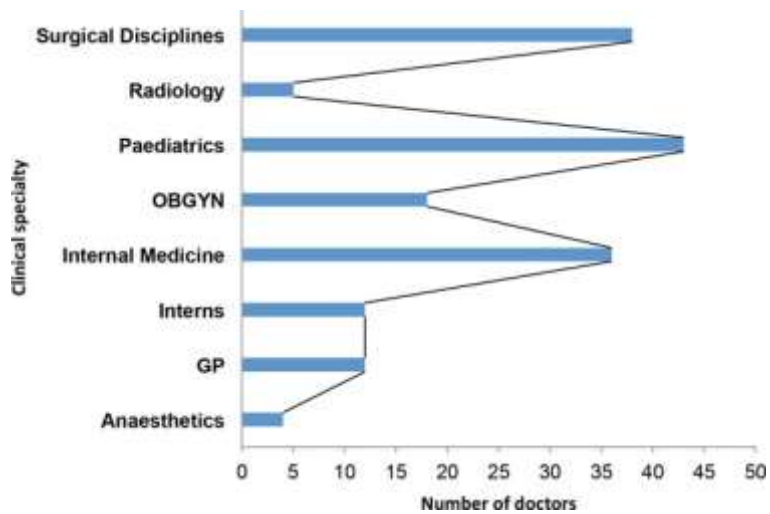


Figure 1 Participating doctors by clinical sub-discipline or specialty.

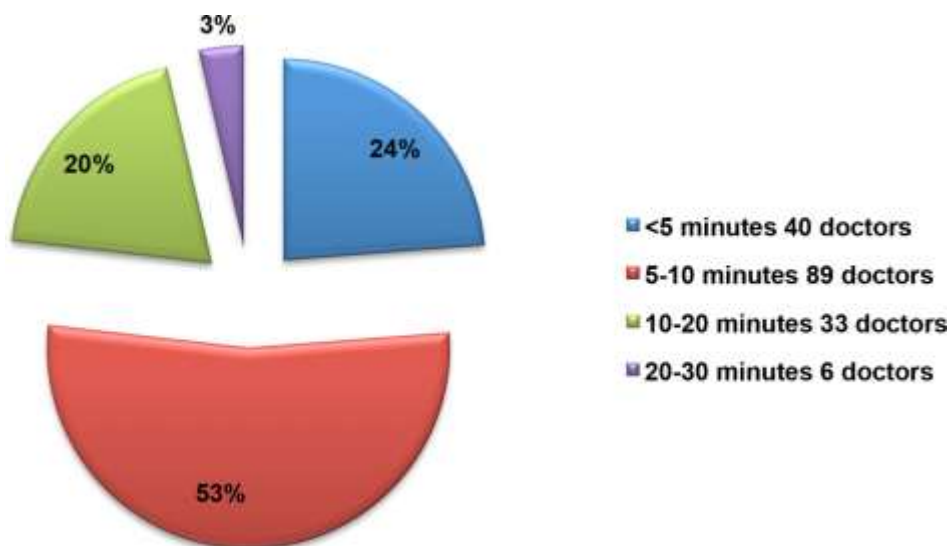


Figure 2 Time spent by doctors on giving information to patients.

Table 2 Information given to patients by doctors prior to obtaining consent

Information disclosed to patients	Yes (%)	No (%)	Don't know (%)
Diagnosis	162 (96.4)	6 (3.6)	-
Treatment options	136 (81)	32 (19)	-
Recommended treatment	149 (88.7)	19 (11.3)	-

Information disclosed to patients	Yes (%)	No (%)	Don't know (%)
Risk of refusing recommended treatment	140 (88.3)	28 (16.7)	
Cost of medical treatment	20 (11.9)	148 (88.1)	
Information on general risks	147 (87.5)	21 (12.5)	
Information on benefits	150 (89.3)	18 (10.7)	
Information on right of refusal	109 (64.9)	59 (35.1)	
<i><u>Probing questions</u></i>			
Do you think the information you provide is sufficient?	121 (72)	27 (16.1)	19 (11.4)
Do you think this amount of time spent is sufficient?	93 (55.4)	66 (39.3)	9 (5.4)
Do you think the hospital consent form is adequate?	105 (62.5)	51 (30.4)	12 (7.1)

Table 3 Major challenges to obtaining informed consent by doctors

Challenges	Median score	P-value
Lack of admin. support e.g. interpreters	4	0.013
Time constraints	2	0.226

Challenges	Median score	P-value
Work load	3	0.110
Lack of education	4	0.915
Cultural barriers	5	0.551
Language barriers	2	0.453
Medical paternalism (doctor knows best)	7	0.300

Notes: (a) Challenges were ranked from 1-7, with 1 being most difficult and 7 being least difficult, median scores are reported here. (b) Tests of statistical significance across all clinical disciplines were done using Kruskal-Wallis test for independent samples, significance level is $P = 0.05$

Information given to patients before obtaining consent

When asked about what types of information was generally disclosed to patients prior to obtaining consent. The majority of doctors provided information on '*diagnosis*' (96.4%), 89.3% provided information on the '*benefits of treatment*', 81% provided information on '*treatment options*', 88.7% recommended a specific treatment. About 83.3% gave information on '*risk of refusing treatment*', while 64.9% advised patients on '*the right of refusal*'. Only 11.9% of doctors provided information on the '*cost of treatment*' (Table 2). When asked specifically whether they explained the benefits of the procedure to a patient, 97% of doctors answered affirmatively, while 95% explained the risk of the procedure to patients (Table 4). When doctors were asked whether they thought the amount of information provided to patients was sufficient for valid informed consent, 72.5% answered 'yes', 16.1% answered 'no'; while 11.4% answered 'don't know'.

Table 4 Nature of risks disclosed to patients

Types of risks disclosed	Yes (%)	No (%)	Don't know (%)
Most serious risks	144 (85.7)	18 (10.7)	2 (1.2)
Most common risks	152 (92.1)	13 (7.9)	-
All material risks	35 (21.2)	117 (70.9)	13 (7.9)
Do you explain risks of the procedure to patients?	158 (94.6)	8 (4.8)	1 (0.6)
Do you explain benefits of the procedure to patients?	162 (97)	4 (2.4)	(0.6)

Hospital consent forms

When asked whether the current consent form used to obtain informed consent from patients is adequate, 62.5% (105) doctors thought it was adequate, while 30.4% (51) answered 'no' and 7.1% (12) answered 'don't know'. When asked to explain why the current universal consent forms used in public hospitals was inadequate, many doctors complained that the current form does not give opportunity to detail specific complications because different clinical conditions may require different mandatory disclosures. Some suggested that the consent forms should contain tick-boxes for more detailed information disclosure. Others complained that the current form does not take into account "privacy, language and cultural values". For example the form is "done briefly in a language not the patients first language (sometimes cannot get an interpreter), so we take for granted the patients understands when he/she says yes to everything". Others complained that the form contains "no binding space that consent was given or alternatives discussed" or that it was "not specific to minors; when guardian

details must be recorded". Others concluded that the current form has not "not kept up with current progress in medico-legal teaching".

Nature of risks disclosed to patients

Information about specific risks of each procedure was provided to patients by about 95% of doctors. When asked what *types of risks* were disclosed to patients? About 92% of doctors said they disclosed the '*most common risks*', 86% disclosed '*the most serious risks*', while only 21% disclosed '*all material risks*' to patients (Table 4). Chi-squared tests were used to test for statistical significance on the types and nature of information disclosed to patients across different clinical specialties. Information on disclosure of 'clinical diagnosis' was statistically significant ($p \leq 0.001$), with radiologists least likely to give patients information on diagnosis. Similarly there was statistical difference in disclosure of information on 'recommended treatment' ($p = 0.002$), with anaesthetists and radiologists least likely to recommend treatment to patients. Finally information disclosure on 'treatment options' was also statistically significant across different specialities ($p = 0.004$), with 60% of radiologists, 50% of anaesthetists and 32.6% of paediatricians least likely to discuss treatment options with their patients. All other categories of information disclosed were not statistically significant across different clinical specialties (Table 2).

Methods used to obtain consent from patients

When asked how patients normally provide consent for clinical procedures. About 6.7% of doctors said 'verbally', 50.9% answered 'written', 34.5% said both verbally and written, while 7.9% answered 'it depends'. Doctors who answered 'it depends' gave various reasons for obtaining consent using different formats. Most stated that it depends on the type of procedure. Others said it depends if it is an 'emergency' or if the patient is unconscious or a minor. Others obtained telephonic consent when parent/guardian was not available, while others said sometimes the hospital superintendent would give the necessary consent in an emergency. Some doctors said it depends if written consent is required by law. There was no statistical difference across specialities or occupational ranks in methods of obtaining consent ($p = 0.587$).

Comprehension/understanding of information disclosed

To examine the extent of patients understanding of informed disclosed by doctors, we asked questions about the language and methods used to obtain informed consent from patients. When communicating with patients, 64.3% (108) doctors used '*English language*', 44.6% (75) used the '*patients' local language*', while 69% (116) doctors said they used '*both English and the patients local language*'. To enhance or facilitate understanding of information disclosed to patients, 96.4% (162) doctors used '*words*' or communicated verbally, 20.2% (34) used '*pictures*', 41.7% (70) used '*diagrams*', while 72% (121) used '*interpreters*' to communicate with patients. When doctors were asked if they think patients understood the information given to them; 76.4% (126) answered 'yes'; 3.6% (6) answered 'no'; 12.7% (21) answered 'don't know', while 7.3% (12) said they 'didn't think so'.

Competence or capacity to give informed consent

When asked whether they generally presumed that patients had the capacity to consent to treatment, 67.3% (113) doctors answered 'yes', 31% (52) answered 'no', while 1.8% (3) answered 'don't know'. When asked whether they routinely assessed a patient's capacity to give consent to treatment, 58.9% (99) doctors answered 'yes', 37.5% (63) answered 'no'; while 3.6% (6) said they 'don't know'. When asked to rank the most important factors in assessing patients' capacity, 73% (123) doctors ranked '*level of consciousness*' first, 74% (125) ranked '*age*' second; 72.6% (122) ranked '*educational level*' third, 65.5% (110) ranked '*appearance*', fourth while 66.67% (112) ranked '*sex*' of the patient last in terms of importance.

Methods used to assess capacity

When asked to rank methods used in assessing patients' capacity when confronted with difficult cases, 72.6% (122) doctors ranked '*mental status examination*' first, 70.8% (119) ranked '*psychiatric consultation*' second, 66.1% (111) and 58.9% (99) doctors ranked

'ethics consultation' and 'use of surrogates' equally third respectively, while 'court adjudication' was ranked fourth by 62.5% (105) doctors. About 28.6% (48) of doctors said they would use 'none of the above' methods. When asked to specify what method they routinely used in assessing patients capacity when dealing with difficult cases, majority of doctors said they used a mini- mental status exam (MMSE), followed by level of consciousness or orientation in time place and person, and the Glasgow coma scale (GCS) in difficult cases. Others said they would involve parents/guardians especially in paediatric cases, while some said they would use other surrogates such as a social worker/psychologist, family members or the hospital superintendent. There was no significant difference across clinical specialties in terms of 'presumption of capacity' ($p = 0.110$) or routine assessment of capacity ($p = 0.698$).

Consent in emergency situations

When doctors were asked whether they obtained consent in emergency cases, 54.2% (90) doctors answered 'yes', 19.9% (33) answered 'no', 24.1% (40), said 'it depends', while 1.8% (3) said they 'don't know'. Doctors who answered 'it depends' gave various reasons for not obtaining consent in emergency cases, including level of consciousness or mental status of the patient, availability of parent or guardian to serve as surrogate. Others said if the patient was in a stable condition and able to comprehend, then they would obtain consent. Others said if patient is incapacitated, then proxy consent is obtained from the consultant or medical superintendent of the hospital. Others indicated that it depends on the procedure and whether it was a life threatening situation.

Voluntariness and consent to treatment

When doctors were asked whether they would 'allow patients to choose a medical procedure or treatment', 53% (88) doctors answered 'yes', 44.6% (74) said 'no', while 2.4% (4) answered 'don't know'. To further explore whether doctors allowed their patients to exercise choice or act on their own free will during clinical encounters, doctors were asked about their understanding and use of implied and presumed consent in practice.

Implied or presumed consent practices

When doctors were asked whether they ever used implied or presumed consent when treating patients, 53% of doctors said 'yes', while 47% answered 'no'. More doctors said they used implied consent in an emergency rather than in the hospital wards or clinics (Table 5). When asked how often they used implied or presumed consent in practice, about 39% of doctors used implied or presumed consent sometimes or occasionally, while 26% used it on rare occasions. Only about 11% used it all of the time, while 24% said they never used it at all (Figure 3). About 66% of doctors also said they obtained specific consent for certain procedures, especially for minor and major surgical procedures or blood transfusions (Table 5). The issues surrounding voluntariness and consent to treatment will be evaluated further from the point of view of patients, when patients' data are analysed.

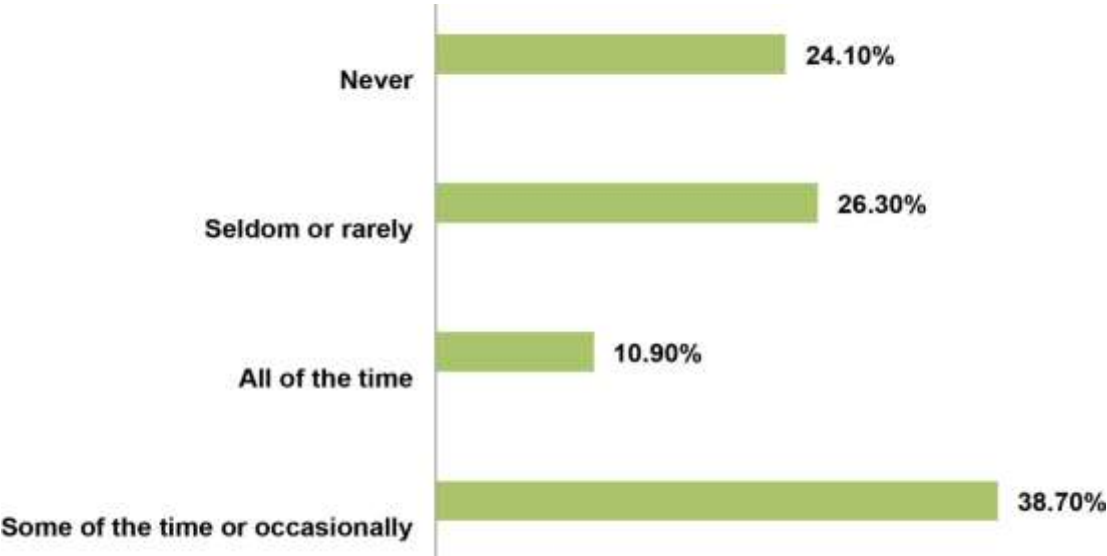


Figure 3 Use of implied or presumed consent by doctors.

Table 5 Use of implied or presumed consent in clinical practice

Implied/presumed consent	Yes (%)	No (%)	Don't know (%)
Do you ever use implied/presumed consent in practice?	80/168 (53)	71/168(47%)	
When do you use implied/presumed consent:			
1. When patients' present at the clinic?	49/168 (34)	95/168 (66)	1/168 (1)
2. When patients are admitted to the ward?	45/168 (31)	98/168 (68)	1/168 (1))
3. In an emergency?	69/168 (48)	73/168 (50)	3/168 (2)
How often do you use implied/presumed consent?			
Some of the time or occasionally	53/168 (38.7)		
Seldom or rarely	36/168(26.3)		
All of the time	15/168 (10.9)		
Never	33/168 (24.1)		
Do you obtain consent for other specific procedures?	95/168 (66)	49/168 (34)	

Major challenges to obtaining informed consent

Doctors were asked to rank a series of potential challenges experienced while obtaining informed consent in practice, on a seven point scale of 1-7, with 1 being most difficult and 7 as least difficult (Table 3). The major challenges identified by doctors in this setting included '*language difficulties*', ranked highest by 87.5% of doctors, '*time constraints*' ranked second by 86.9% doctors, followed by '*work load*' 85%, '*lack of education*' 84.5%, and '*lack of administrative support e.g. interpreters*' 82% of doctors. The least important constraints identified were '*cultural barriers*', by 79.8%, while '*medical paternalism (doctor knows best)*' was ranked last by 78% of doctors (Figure 4). Cultural barriers identified by doctors included religious beliefs such as Jehovah's witnesses or cultural abhorrence of organ transplantation, amputations and blood transfusions. The need to obtain approval from husbands or family members prior to giving consent, preference for traditional healers, cultural taboos, and 'disempowered caregivers' according to one respondent. A test of statistical significance using the Kruskal-Wallis test for independent variables, showed that the '*lack of administrative support e.g. interpreters*' was statistically significant across all clinical specialities ($p = 0.013$) (Table 3).

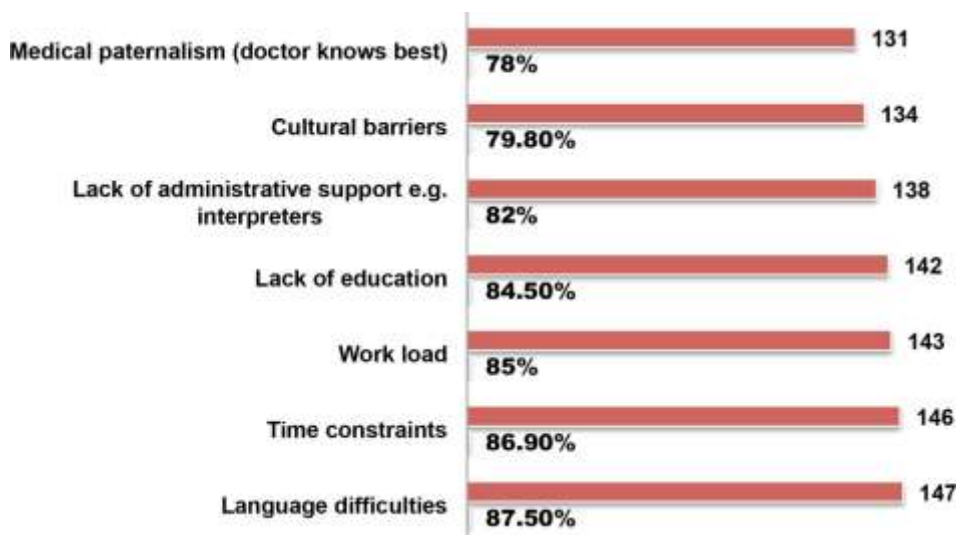


Figure 4 Challenges to obtaining informed consent by doctors.

General knowledge of basic informed consent laws and regulations

To test for general know of informed consent laws and regulations in South Africa, doctors were asked some specific questions. When asked to select the current age of consent to routine treatment in South Africa, only 70.7% of doctors were able to correctly answer '12 years'. This question was answered wrongly by many doctors with 10.8% saying '15 years', 15.3% answered '18 years'; 1.9% answered '21 years', while 1.3% did not know. Further, when asked to select the correct age when women can consent to termination of pregnancy (TOP) in accordance with South African law, only 29.6% of doctors correctly answered 'any age'. Majority gave the wrong answer with 50.9% choosing '12 years', 13.2% chose '15 years', 3.8% chose '18 years', while about 2.5% did not know the correct age. Chi-squared tests were used to test for statistical significance in terms of general knowledge of informed consent laws and regulations across all specialities. There was no statistical significance detected in terms of age of consent, age for women to request for TOP, or standards of information disclosure.

Responsibility for obtaining consent

When asked whose responsibility it was to assure that adequate information was provided before informed consent, only 61.7% (100) doctors thought it was the *'doctor or healthcare professional's responsibility'*. About, 41% (66) answered that *'both the doctor and patient were jointly responsible'*, while 5% (8) thought it was *'the patient's responsibility'*.

Standards for information disclosure

When asked whether the current standards for information disclosure were based on a 'reasonable doctor' or 'prudent patient standard'. Most doctors, 60.2% (97) answered that was based on a *'reasonable doctor standard'*, while 47.8% (76) correctly answered *'prudent patient standard'*. When asked whose duty it was to obtain consent from patients in practice, 66.3% (110) doctors correctly answered that it was responsibility of the *'doctor performing the procedure or treating the patient'*. About 6.1% (10) doctors said *'nurses'*, were responsible, 44.6% (74) said *'junior doctors'* were

responsible, while 10.8% (18) thought it was the responsibility of '*any available healthcare professional*', 3.6% (6) doctors did not know.

Informed consent aggregate scores (ICAS)

To compare informed consent practices across occupational ranks of doctors and nurses, as well as between clinical specialties. I developed an aggregate score using a modified version of the method described by Sugarman and others [51]. While the previous authors used a series of seven questions derived from a brief informed consent evaluation protocol (BICEP) during research studies [51]. Here I have selected a series of questions from the questionnaire which relate to information disclosure, voluntariness, assessment of capacity and understanding or comprehension (Table 6). A total of twelve questions from the questionnaire were adjudged to satisfy these criteria. Each of the selected questions was given a rank score of one (1) and the aggregate score is the sum of the scores (12) (Table 6). ICAS aggregate scores for all doctors by occupational rank ranged from 1 to 12, with a median score of 10 (SD = 2.28). The lowest scores were recorded by interns and registrars with a median score of 9, while medical officers and consultants/specialists recorded a median score of 10 respectively (Figure 5). Tests of statistical significance for ICAS scores by occupational rank of doctors was not statistically significant ($p = 0.174$). However, comparison of ICAS scores by clinical speciality using the Kruskal-Wallis test was statistically significant ($p = 0.005$). In this case anaesthetists and radiologists had the lowest ICAS scores with a median score of 7 and 8, respectively, while the highest scores were obtained by OBGYN, Internal medicine and GP doctors with a median score of 10.50 (Figure 6). Finally when the ICAS scores of doctors was compared with that of professional nurses. Scores by professional nurses was lower than that of doctors with a median score of 8, while the median score for doctors was 10. The difference in scores between doctors and nurses was highly statistically significant ($p \leq 0.001$), using the Mann-Whitney U test for independent samples at a significance level of 0.05.

Table 6 Questions used to calculate ICAS

A. Information disclosure:	ICAS Score	
	Yes	No
What information do you routinely provide to your patients?		
Diagnosis	1	0
Treatment options	1	0
Recommended treatment	1	0
Risks of refusing recommended treatment	1	0
General risks	1	0
Benefits	1	0
Right of refusal	1	0
B. Capacity/Competence		
Do you routinely assess the competence of your patients to consent to treatment?	1	0
Do you generally presume that your patients have the capacity to consent to treatment?	1	0
C. Voluntariness		
Do you allow your patients to choose a procedure or particular treatment?	1	0
D. Understanding		
Do you think your patients understand the explanations given to them?	1	0
E. Consent or agreement		
Do you think the information you provide is sufficient to procure valid informed consent?	1	0
Total: Informed consent aggregate score (ICAS)	12	0

Note: The question about cost of medical treatment is excluded from this ICAS calculation in this cohort because the cost of healthcare services public in hospitals is free

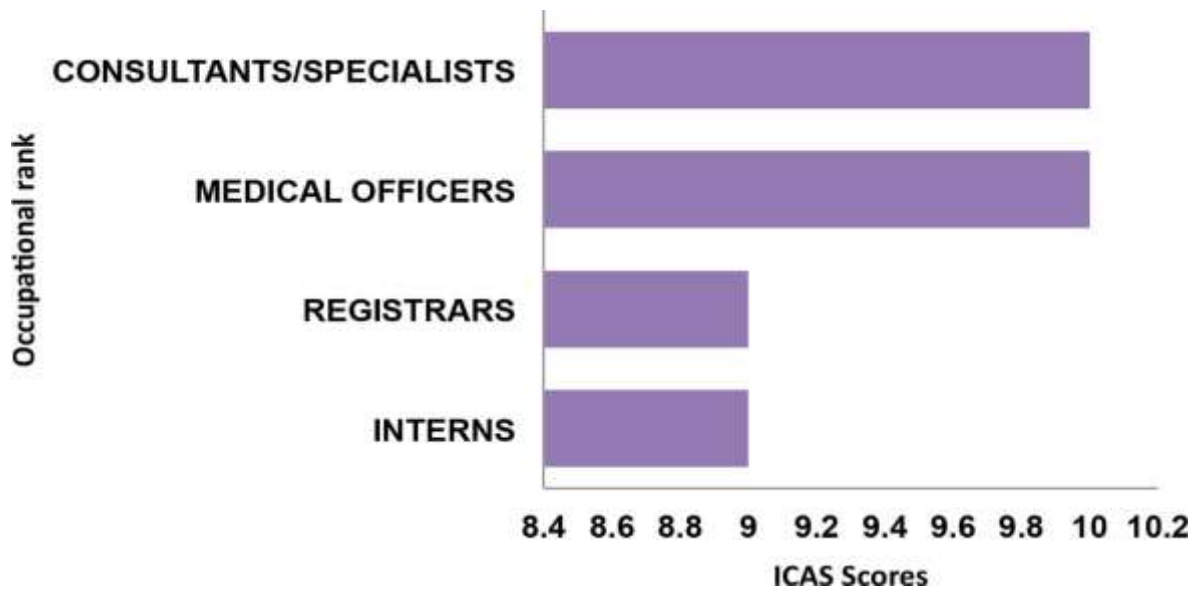


Figure 5 ICAS of doctors by occupational rank.

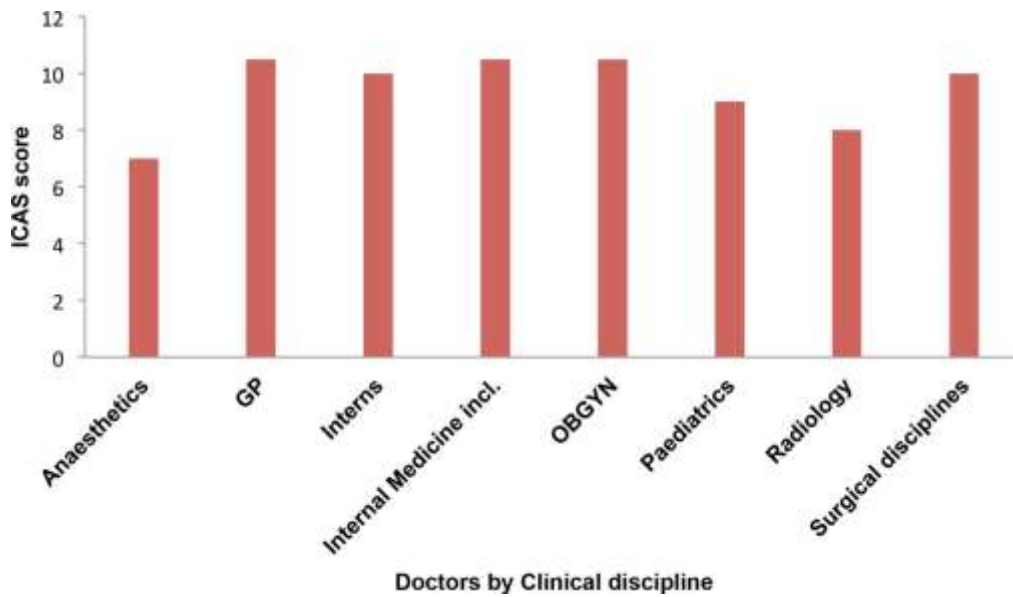


Figure 6 ICAS scores of doctors by clinical sub-discipline or specialty.

Discussion

Most studies evaluating the quality of informed consent especially in developing countries have focused on informed consent practices in clinical research. These include previous studies from Nigeria [52], Uganda [53], South Africa [54] and Mali [55]. Most of these studies reported problems with comprehension and understanding of the informed consent process by patients including the right of withdrawal [52, 53, 54, 55]. Other studies from developed countries have contended with problems of subject's therapeutic misconception, voluntariness and measurement of capacity to consent during biomedical research and clinical trials [51, 56, 57, 58]. While many studies on informed consent have focused on clinical trials and biomedical research, very few studies have actually looked at the quality of informed consent in clinical practice, especially in Africa [59, 60, 61]. The paucity of studies in the area of clinical practice is surprising considering that patients or individuals are more likely to seek treatment for routine medical care than be involved in biomedical research. Nonetheless most of the studies from developing country settings have highlighted the need for more education in biomedical ethics for researchers, healthcare practitioners, as well as patients or human subjects of biomedical research [52, 53, 54, 55]. Some studies have identified the need to improve the quality of informed consent documents, including the need for simplified language to enhance participant understanding [62]. Others have highlighted the different notions of informed consent such as the moral and legal dimensions of consent which have the potential to impact on the quality and practice of informed consent, including information disclosure, understanding and shared decision making [63].

Standards of information disclosure

One of the more controversial areas of informed consent in practice has hovered around the amount of information disclosure required before consent can be considered valid. On this consideration there are two contesting schools of thought. One is the 'reasonable doctor standard' based on English common law as outlined by McNair J in *Bolam v Friern HMC* [64] generally known as the *Bolam test*, which states that: "A doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of men skilled in that particular art...". It has been argued that English courts have opted for a paternalistic approach by following the

reasonable doctor standard which bases disclosure on the clinical judgement or accepted practice or substantial risk/normal/usual risk principles as established in *Bolam* [22, 23] and reaffirmed by the House of Lords in the case of *Sidaway* case where Lord Templeman argued that [65]:

"At the end of the day, the doctor bearing in mind the best interests of the patient and bearing in mind the patients right to information which will enable the patient to make a balanced judgement, must decide what information should be given to the patient, and what terms that information should be couched..."

However, Lord Scarman in the same case suggested the use of a 'prudent patient standard' arguing that: " It was a strange conclusion if our courts should be led to conclude that our law...should permit doctors to determine in what circumstances...a duty arose to warn." [65]. The Courts in North America, have maintained in cases such as *Canterbury v Spence* [17] and *Reibl v Hughes* [66] that a patient must be informed of all material risks, where those 'material risks' would consist of what a reasonable person, in such a patients position, would be likely to attach significance to, in deciding whether to accept or forego a proposed treatment. In South African case law the issue of how much information should be disclosed to patients has been the subject of debate since *Lymburg v Elliot* [67] where the Court was of the opinion that a 'doctor is not obliged to disclose all the conceivable complications that may arise during a medical procedure.' However in *Castell v De Greef* the Court concluded, that a doctor is obliged to warn the patient of all the 'material risks' inherent in the proposed treatment. Where material risks is based on a 'prudent patient standard' [26]. Therefore the current requirements for information disclosure in South Africa are consistent with the practice in North America as outlined in section 6 of the NHA [28]. These requirements reaffirm the need for disclosure of all material risks with few exceptions. In the current study, the results show that while the majority of South African doctors complied substantially with the requirements of the NHA in terms of information disclosure (Table 2), only about 21% of doctors complied with the 'material risks' standard in terms of risk disclosure (Table 4). Further, a majority of doctors (60%) chose the 'reasonable doctor' rather than the 'prudent patient' standard as the required standard for information disclosure in clinical practice. Therefore the current practice by doctors in terms of information

disclosure is inconsistent with ethical guidelines from the HPCSA [68] or current local laws [26, 27, 28].

Comprehension of information disclosed

It has suggested that in developing countries such as South Africa, where education standards and literacy levels are low, knowledge and power asymmetry usually exist between patients and health care professionals [34, 35]. It is also important to recognize the historical backdrop of colonialism and racism, and ongoing challenges of poverty and exploitation [30, 31, 32]. In spite of such considerations however, doctors still have an obligation to adequately explain clinical procedures to patients without turning them or surrogates into students of medicine [69]. The ability to use written information is important to comprehension and understanding [70], as such barriers to communication arising from illiteracy and language differences may prevent a common understanding of medical procedures, thereby putting patients at risk of providing consent without comprehension [71]. It is therefore important that healthcare providers ensure that patients understand the proposed treatment or procedure prior to providing consent. Some authorities have suggested a verbal or written test to ascertain patient capacity, competence or understanding before considering informed consent valid [58].

Language

In the current study one of the major barriers towards obtaining valid consent by doctors has been listed as 'language difficulties', ranked highest by 88% of doctors in this cohort. This was supported by complaints about 'lack of education' (85%) and lack of interpreters by 82% of doctors (Figure 4). Therefore it cannot be overemphasized that one of the major barriers to obtaining valid informed consent in this environment is the issue of language. It has been argued that language barriers can have a deleterious effect on healthcare service delivery, leading to such errors as misdiagnosis, failure of preventive therapy or non-adherence to prescribed medication, which could ultimately lead to charges of medical negligence and award of substantial damages against doctors [72]. The issues of language difficulties and the necessity for appropriately trained interpreters, is not limited to developing countries, but is also a barrier to proper

healthcare services delivery in developed countries such as the USA or any multicultural/multilingual society [72]. Currently South Africa has 11 official languages; therefore language barriers, especially the absence of adequately trained interpreters to assist healthcare professionals in providing care to patients is a major problem. In another study at a South African district hospital, the authors concluded that language barriers in hospitals create significant problems for healthcare professionals and can impact negatively on patients' rights to confidentiality, informed consent and the quality of healthcare service delivery [73]. Other cultural barriers identified by doctors in this study include different cultural beliefs about blood transfusion and amputations. The impact of family members in decision-making, especially husbands within the traditional African cultural ethos. All of these can serve as barriers to the appropriate practice of informed consent in developing country settings [34, 74]. To further improve understanding and comprehension during the informed consent process, the US National Bioethics Advisory Commission (NBAC) has suggested that *community participation* is acceptable, which may include providing written information sheets for discussions with family members and holding community meetings, but cautions that family permission should not replace the requirement for individual informed consent [75, 76].

Capacity

In the common law there is a presumption that any adult person has the capacity to consent or refuse medical treatment unless proven otherwise by acceptable evidence. A lack of capacity cannot be established merely by reference to a person's age, appearance, and intelligence, level of education, or any condition or aspect of behavior, which might lead others to make unjustified assumptions about capacity [2]. According to the Court in *Richmond v. Richmond* [77]:

Capacity is ultimately a legal not a medical decision... it is for the court to decide the question of capacity, although the court must pay attention to the evidence of experts in the medical profession who can indicate the meaning of symptoms and give some idea of the mental deterioration which takes place in cases of this kind....

Thorpe J summarized the common law test for capacity in *Re C* [78] where he said that: the patient must be able to (a) comprehend and retain the information (b) believe it (c) weight it in the balance so as to arrive at a choice. The UK *Mental Capacity Act* [79] further simplified this test, which now states that a person is deemed incapable of making a decision and exercising autonomy rights where that person is unable:

- a) To understand the information relevant to the decision,
- b) To retain that information
- c) To use or weigh that information as part of the process of making the decision, or
- d) To communicate his decision (whether by talking, using sign language or any other means) [2, 78, 79].

In the current study about 67% of doctors said that they would presume that patients have the capacity to consent to treatment, although this low percentage may have been influenced by the large number of pediatricians within our study cohort, who would normally assume that their patients could not provide consent based on their age. Similarly, only 59% of doctors in this cohort routinely tested their patients for capacity to prior to treatment. On the other hand the majority of doctors accurately ranked factors such as level of consciousness, age, educational level, appearance and sex, in descending order, as being factors used in the assessment of capacity. Also, only 71% of doctors accurately identified 12 years as the age of consent to routine medical treatment in South Africa, while only 30% of doctors correctly identified the age of consent to TOP as 'any age', as stipulated in the *Choice on termination of pregnancy Act* [80]. This evidence suggests inadequate knowledge of current local laws and regulations on informed consent in South Africa. When assessing capacity in difficult cases, majority of doctors responding said they would use a MMSE, GCS or orientation in time place and person, to ascertain patient's capacity to give consent to treatment. This is contrary to previous studies on capacity assessment tools for medical treatment which concluded that both the MMSE and GCS should be viewed as blunt instruments when determining patients' capacity [56]. Perhaps more sensitive capacity assessment tools, such as the MacArthur Competence Assessment Tool--Treatment (MacCAT-T) should be evaluated for use in this setting [56, 58].

Voluntariness and consent or agreement to treatment

Voluntariness of consent has been one of the more difficult areas to assess by empirical methods because of the variations in patients' clinical condition and cultural norms associated with the concept of voluntariness [14, 57,63]. In African traditional societies the influence and respect for family, friends and elders is very important in accordance with cultural ethos. Therefore, it is not unusual for individuals to seek the advice of family, friends and relatives before making important decisions related to healthcare [34, 59, 63]. While these types of interference may be considered undue influence in western cultures, with their history of libertarian autonomy and individual rights. African societies are more accepting of collective decision making, based on a different concept of autonomy derived from Ubuntu or "*sumus, ergo sum, (we are, therefore I am)*" [81]. It is generally recognized that voluntariness in informed consent means that the patients' consent must be given voluntarily, devoid of any undue influence or coercion either by fraudulent misrepresentation or trickery from the physician or family or friends [14, 76]. According to Lord Donaldson in *Re T* [82]:

If...his will was overborne; the refusal will not have represented a true decision. In this context the relationship of the persuader to the patient-for example, spouse, parents or religious adviser-will be important, because some relationships more readily lend themselves to overbearing the patient's independent will than others.

In our current study I have tried to study voluntariness by asking some indirect questions from doctors such as whether doctors would allow patients to choose a particular procedure or treatment, only 53% answered affirmatively. Similarly when asked whether doctors ever used implied or presumed consent in practice, 53% answered in the affirmative. When further asked how often they used implied or presumed consent in practice, 39% said occasionally, 26% said rarely, while 11% said all of the time. Only 24% of doctors said they 'never' used implied or presumed consent in practice (Figure 3). This suggests some elements of medical paternalism are still prevalent in clinical practice in this environment. It appears that many doctors resort to implied/presumed consent in lieu of obtaining legally valid consent, contrary to ethical

guidelines from the HPCSA, which advises doctors not to simply presume that patients have given consent when they lay down on the examination table [68], consistent with the injunction of the Court in *Stoffberg v. Elliot* [24] which stated that:

A man by entering a hospital does not submit himself to such surgical operations as the doctors in attendance upon him might think necessary...he retains his rights of control and disposal of his own body; he still has the right to say what operation he will submit to, and unless consent to an operation is expressly obtained, any operation performed on him without his consent is an unlawful interference with his right of security and control of his own body."

Perhaps this unquestioned practice could be explained by the power asymmetry that exists between doctors and patients or special respect shown to doctors by patients in this environment as described in another study from Nigeria [59]. It may also be associated with the many challenges experienced by doctors practicing in this environment including heavy workload and lack of administrative support (Figure 4).

Comparative analysis of ICAS scores

Analysis of ICAS scores showed that interns and registrars scored lower than medical officers and consultant/specialists. This could be explained by the fact that interns and registrars are still trainees and it should be expected that their knowledge of informed requirements would be lower than that of their trainers and supervisors. Across clinical subspecialties radiologists and anaesthetists scored lower than internists and surgeons and GPs. This is somewhat consistent with findings from another study in Croatia where anaesthetists scored lower than internists and surgeons on informed consent [83]. The plausible explanation is that because radiologists and anaesthesiologists are ancillary subspecialties, they may not be required to provide information to patients such as diagnosis treatment options etc. and may also depend on primary care physicians to obtain prior informed consent prior to referral for supplementary services [68]. In the case of nurses and doctors, it should be expected that doctors are more knowledgeable about informed consent regulations, because doctors are generally better trained in the

areas of medical law and ethics and are required to make final decisions regarding patient care, therefore the requisite knowledge about regulations and practice maybe more rigorously enforced by the regulatory authorities.

Conclusions

Previous studies on informed consent in Africa have shown that while doctors are generally knowledgeable about the ethical doctrine of informed consent, the application and adherence to the legal and ethical requirements of informed consent is usually lacking in practice. Analysis of data from this study confirm these observations by showing that doctors practicing in public hospitals in South Africa are generally knowledgeable about some aspects of informed consent, such as information disclosure. However not all adhered to the critical elements as specified in the *NHA*, or the requirements based on international standards of care or local ethical guidelines. The major challenges militating against the proper practice of informed consent as identified in this study were related to issues of language barriers and lack of administrative support, especially interpreters to assist with communicating with patients. Others factors identified include large patient numbers with associated time constraints and workload. These results show that while the majority of doctors spent an average of 5-10 minutes on obtaining informed consent, this amount of time was considered inadequate by many doctors. Knowledge of essential local laws such as the age of consent for routine medical treatment or age of consent for TOP in South Africa was not universally known by doctors. Similarly, the majority of doctors still believed in the paternalistic concept of a 'reasonable doctor standard' rather than more currently accepted 'prudent patient standard' and the disclosure of all material risks. This study suggests that doctors were statistically more knowledgeable about informed consent than professional nurses, however it remains to be seen whether this translates into clinical practice. Finally, there was evidence of overuse of implied and presumed consent by doctors with implications for medical paternalism and lack of voluntariness in consent. This study was limited to public hospitals in an urban setting and the study period was restricted to 3 months. It is possible that future studies in private hospitals or in a more rural setting may provide different results. Based on the findings in this study,

one can recommended the recruitment and training of a 'corps' of interpreters as part of medical teams in South African hospitals, to assist in improving the quality of doctor-patient communications, informed consent, confidentiality, and healthcare service delivery in public hospitals. It would also be useful to modify the current universal hospital consent form to better reflect current teaching in medico-legal practice, by including translations in local languages, or options for specific consent for certain procedures or mandatory disclosures as required by law. It would also be useful for patient information leaflets to be produced in local languages to enhance patient education and understanding prior to providing consent. Finally, continuing education for doctors and other healthcare professionals in ethics and medical law will go a long way towards improving the overall quality of healthcare service delivery in South African hospitals.

List of Abbreviations used

BICEP: brief informed consent evaluation protocol

CEO: Chief executive officer

GCS: Glasgow coma scale

GP: general practitioner

HCW: healthcare workers

HPCSA: Health Professions Council of South Africa

IBC: international bioethics committee

IBM: international business machines

ICAS: informed consent aggregate score

KZN: KwaZulu-Natal

MMSE: mini mental status examination

MacCAT-T: Macarthur competence assessment tool: treatment

MO: Medical Officer

NBAC: National bioethics advisory Commission

NHA: National Health act

NHS: National Health Service

OBGYN: Obstetrics and Gynecology

TOP: termination of pregnancy

SD: standard deviation

SPSS: statistical packages for the social sciences

UK: United Kingdom

USA: United States of America, **US:** United States, **UDHR:** Universal declaration of human rights, **UKZN:** University of KwaZulu-Natal

UNESCO: United Nations Educational Scientific and Cultural organization

UNISA: University of South Africa.

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Electronic supplementary material

[12910_2013_233_MOESM1_ESM.docx](#) Additional file 1: Questionnaire for healthcare professionals (doctors and professional nurses)-Final. (DOCX 21 KB)

Competing interests

This paper is partly derived from a research project entitled "An investigation of informed consent in clinical practice in South Africa", which is being completed as a thesis for the award of the LL.D (Doctor of Laws) degree at the University of South Africa (UNISA).

Authors' contributions

Author conducted the research study and wrote the manuscript

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ANNEXURE 2

ORIGINAL ARTICLE

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"Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa

[S C Chima](#)

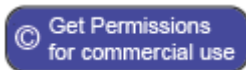
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Abstract

Background: Informed consent (IC) is a legally enforceable right in South Africa based on constitutionally protected rights to bodily integrity and well-being. In terms of the law, patients cannot be involved in medical treatment or research without IC. Healthcare providers must inform patients about diagnosis, risks, benefits, treatment options, and right of refusal in a language patients understand based their literacy level. This study reports an empirical study on patients' perceptions of IC as practiced by doctors and nurses in South Africa.

Materials and Methods: A cross-sectional study, using a bilingual semi-structured questionnaire was conducted among patients attending randomly selected public hospitals in eThekweni Metropolitan Municipality (Durban), KwaZulu-Natal province.

Competent patients or legal surrogates were eligible for inclusion. IC was obtained from all participants.

Results: Four hundred and four participants completed questionnaires of which 68% were female. The median age of participants was 35 years (range 11–91 years). Most respondents spoke IsiZulu (55%), were single (56%), unemployed (66%), and with secondary school education (69%). Patients were generally informed about the diagnosis (81%), risks (57%), and benefits of treatment (61%). Few were informed about treatment options (41%), recommended treatment (28%), and right of refusal (25%). IC was obtained verbally in 73% of cases. Patients favored disclosure of all material risks (78%) and few consulted surrogates before decision-making (76%). There was an association between participant's age and knowledge of the age of consent ($P = 0.005$). Most patients were satisfied with information disclosed (91%) and did not feel coerced. Some were afraid to ask questions for fear of losing free treatment (8%).

Conclusion: This study reveals that South African patients are aware of the right to IC, but many were vulnerable due to indigence. Barriers to IC include poverty, language, and low educational level. South African patients prefer disclosure of all material risks, better communication skills by healthcare workers, and a shift toward informed or shared healthcare decision-making.

Keywords: Africa, doctors, healthcare decision-making, hospitals, informed consent, insights, nurses, patients

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Introduction



The above direct quotation from a patient (because I want to be informed; to be part of the decision-making); desiring full disclosure prior to giving consent to medical treatment, reflects the changing face of modern medical practice from the paternalistic notion of "doctor knows best" to informed or shared decision-making. According to other patients:

"Because I want to know what the options are, and weigh them myself."

"Because I want to know what is going to happen or why; I also look up info on the internet." These statements from knowledgeable and inquisitive patients who approach healthcare professionals imbued with consumer rights, rather than passive recipients of benevolent healthcare, has made contemporary medical practice a more contested and ethically challenging enterprise.

According to the World Medical Association: [\[1\]](#)

Until recently, physicians generally considered themselves accountable only to themselves, to their colleagues in the medical profession and for religious believers, to God. Nowadays, they have additional accountabilities to their patients, to third parties such as hospitals and managed healthcare organizations, to medical licensing and regulatory authorities, and often to courts of law. These different accountabilities can conflict with one another.

Due to recent controversies surrounding the ethics of healthcare decision-making, a central dilemma has arisen in modern medical practice which can be summarized as whether the principle of respect for autonomy should have priority over professional beneficence?^[2] It has been argued that persistence with professional beneficence by doctors creates a culture of medical paternalism which does not fully respect patients' autonomy.^[3] In these situations, the ethical principles of beneficence and respect for autonomy may conflict with one another, thereby creating a tension in the doctor-patient relationship.^{[1],[2],[3]} To promote patients' autonomy it has been advocated by common law cases such as *Canterbury v Spence* ^[4] that:

The patients' right to self-determination can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each... From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.

In view of the above, informed consent (IC) has become the legal and ethical "standard of care" for medical practice since the late 20th century. More recently, others have argued for shared decision-making rather than informed decision-making. Distinguishing informed decision-making as "an individual's overall process of gathering relevant information from both the clinician and other clinical and nonclinical sources with or without independent clarification of values."^[5]

Whereas shared decision-making may be defined as a particular process of decision-making by the patient and clinician in which the patient:

Understands the risk or seriousness of the medical condition

Understands the medical procedure including the risks, benefits, alternatives, and uncertainties

Has weighed his or her personal values regarding the potential benefits and harms associated with the healthcare service

Has engaged in decision-making at a level at which he or she feels comfortable, and finally

Has come to a joint decision in association with the healthcare provider'. Advocates of shared decision-making argue that it promotes patient comprehension and autonomy, reduces unwanted medical procedures and malpractice claims, improves patient compliance, and decreases overall costs of healthcare service delivery.^{[5],[6],[7],[8]}

Informed consent to medical treatment

In its ideal legal and ethical contexts, IC requires five key elements to establish validity. These key elements must include (i) competence, (ii) voluntariness, (iii) information disclosure, (iv) understanding of information disclosed, and (v) authorization or consent to the medical procedure or treatment.^{[9],[10]} In medical practice, IC should ideally involve a conversation between a doctor or healthcare worker (HCW) and the patient, initiated by the healthcare professional. This conversation must involve complete transparency, engagement by both parties, continuity and may require evidence that it occurred, such as eyewitnesses or a signed consent form.^{[2],[9],[10]} IC could be withdrawn at any time by the patient and maybe vitiated by any changes in material facts not previously communicated to, or approved by the patient.^{[2],[9],[10]} In accordance with some state laws, any exculpatory statements intended to deny any claim rights of the individual giving consent in order to protect responsible parties are expressly forbidden and may nullify IC.^[11] Further, valid consent in accordance with certain state regulations^{[10],[11]} and case law, strongly require the absence of coercion, undue influence or deception, as demonstrated in the English case of *Re T*.^{[12],[13],[14]} Here, a patient refusing blood transfusion because of coercion and undue influence by the mother who was a Jehovah's witness was held not to have consented freely because her will was overborne. Therefore, her refusal did not represent an independent choice. It has been

observed that US courts have become increasingly reluctant to dismiss personal injury claims on the grounds that the victims consented to the injury causing risks. Therefore, these courts have disfavored consent-based defenses such as assumption of risk, and product warning as a form of defense against negligence or battery.^[15]

Informed consent and patients' rights

Patient's rights may be defined as a combination of claims, liberties, powers, and immunities that ensure the protection of the patient's dignity and moral autonomy.^[9] This definition forms the core claims which patients may have against clinicians and defines the duties of clinicians to patients. Patient rights ensure access to data and information, protection from most kinds of unconsented activities. It suggests that patients may do no wrong by choosing to accept or refuse any recommended medical intervention.^[9] Wear *et al.* have described patient's rights and IC as enabling and empowering a patient population that has traditionally been largely powerless and mute in the face of medical expertise and authority.^[16] In this way, patient's rights while remaining based on the legal autonomy model also extends beyond the confines of any particular legal system.^{[15],[16]} Patient's rights during medical treatment and research have only risen to prominence in the later part of the 20th century, especially after the reported abuses of human subjects of biomedical research ^{[17],[18],[19]} and the moral conflicts between respect for autonomy and professional beneficence.^{[1],[2]} Further, recent advances in biomedical technology have also led to a constant rethinking of the rights of individuals utilizing the beneficial aspects of modern science.^[20] Prior to these recent evolutions in bioethics and medical practice, with subsequent challenges to the status quo, the rights of patients have previously been based on medical paternalism.^[3] Patient's right was solely dependent on the goodwill of doctors and the presumption that doctors would act in the best interests of the patients.^{[1],[2],[3]} With revelations of physician/researcher abuses; however, and ongoing unethical research,^{[16],[17],[18],[19]} ethicists and legal scholars began to question whether it was still appropriate for a patient to rely entirely on the judgment of doctors, and if not, how patients should be involved in the healthcare decision-making process?^[21] Further, as

medical practice has become more industrialized and sophisticated, patients have become consumers of healthcare services rather than involuntary participants in the healthcare decision-making process, raising the questions about consumer rights.^{[15],[16],[20],[21]} One aspect of the recognition of the moral autonomy of the patient has been the recognition of the need for adequate information disclosure, which would enable the patient to accept, reject or choose between different medical therapies as first recognized in cases such as *Canterbury v Spence*^[4] or as debated by the House of Lords in the English case of *Sidaway*.^[22] Another aspect of this debate has been whether to persist with the "reasonable doctor standard" as established in *Bolam*^[21] or to follow the "prudent patient standard" as suggested by Lord Scarman in *Sidaway*.^[22] Information disclosure is an important aspect of enhancing the patient's moral autonomy and ability to choose. As suggested by Mclean, its potential invasiveness and its social and political potential make it an area ripe for rights discourse.^[23] Debates in this area have, therefore, focused on several issues including whether the doctors' duty to disclose based on the patients' right to receive information can be tested independently of patient understanding.^[23]

However, if the patient is unable to understand, what is the point of disclosure? Therefore is there a duty imposed on clinicians to ensure patient understanding prior to providing IC? There might also be issues with the rationality of patient's decision-making, with regards competence and incapacitated patients, minors, and other vulnerable members of society.^{[3],[23]} In light of the above, questions about competence, information disclosure, understanding, and rights of vulnerable population groups have dominated contemporary debate on patient's rights, respect for autonomy and IC.^{[18],[19],[20],[21],[22],[23]} Some have questioned whether providing information about risks, benefits, and alternatives actually improve patients' decision-making.^[15] Schuck identified two obligations imposed on the doctors by these requirements. First, the fiduciary duty of care, i.e. the duty imposed on doctors to put patients' interests above their own. Second, the problems associated with cost and resource allocation since the obligation on full information disclosure may increase the burden on healthcare resources.^[15] Others have argued that shared decision-making may decrease

healthcare costs for well-informed patients.^{[5],[6],[7],[8]} These observations suggest IC should also be viewed in terms of cost-effectiveness.^[15] Therefore, there may be need to reconceptualize IC to suit the particular geographical or sociocultural environment involved.^[6] For example, there may be a need to reduce consent procedures in "minimal risk" research or treatment while providing more information in "high-risk" situations. Further, not all patients require the same level of information disclosure, either due to personal choice or cultural belief systems.^{[24],[25],[26],[27]} For example, it has been reported that among certain South Asian populations the disclosure of negative information may be considered harmful,^[24] while some Nigerian African population groups are averse to negative information disclosure due to religious beliefs.^{[25],[26]} Consequently, one can argue that IC needs to be viewed as a normative variable, not an empirical constant, due to its cultural plasticity.^{[9],[10],[15]} Therefore, effective implementation of IC should allow for cultural belief systems and differences in regional or geographical medical practice.^{[15],[24],[25],[26],[27]} However, the protections enshrined in the UNESCO Convention on Bioethics and the Universal Declaration of Human Rights among other instruments is emphatic about an acceptable IC.^[28]

Informed consent in South Africa

As previously reported,^[10] IC before treatment is a constitutionally protected right in South Africa.^[10] This has been demonstrated in landmark South African cases such as *Stoffberg v Elliot* 1923,^[29] *Esterhuizen v Administrator Transvaal* 1957,^[30] and more recent cases of *Minister of Safety and Security v Xaba* 2003^[31] and *Castell v De Greef* 1993.^[32] Generally, South African Courts have defended the patients' right to bodily integrity and the need for full information disclosure prior involvement in any medical treatment or procedure. Failure to follow these guidelines may result in offending HCWs being found guilty of assault, battery, or negligence.^{[29],[30],[31],[32]} Following the *De Greef* case, it was suggested that South African Courts appear to have shifted from a "reasonable doctor standard" to the "prudent patient standard" in terms of information disclosure.^{[32],[33]} Further, there was a shift in risk disclosure to the objective "material risks" standard which is based on what a reasonable patient would attach importance to,

in arriving at a decision whether to accept or refuse a recommended treatment.^{[6],[10],[33]} The National Health Act 2003 (NHA)^[34] codified the requirements for IC before treatment by requiring that every healthcare provider before treating a patient must among other requirements disclose the following:

The range of diagnostic procedures and treatment options, generally, available to the user

The benefits, risks, and consequences, generally, associated with each option

The user's right to refuse health services and explain the implications, risks, obligations of such refusal

Finally, healthcare providers must give the user this information in a language that the user understands and in a manner which takes into account the user's level of literacy.^{[10],[33]}

Other factors which may impact on the practice of IC in African communities include sociocultural issues such as language, education and literacy level, and other socioeconomic factors.^{[10],[24],[25],[26],[35],[36],[37],[38]} South Africa is a multicultural middle-income country, with a population of around 54 million people ^[39] who speak eleven official languages.^{[39],[40],[41]} The country has historical, sociocultural inequities resulting from apartheid which left a section of the local population marginalized with a high unemployment rate currently estimated at 25.5%.^{[39],[40],[41]} Because of these inequities there is a dichotomy in the provision of healthcare service delivery with the majority indigent population, about 88% uninsured in KwaZulu-Natal province (KZN) using publicly funded healthcare services, while the minority affluent populace using privately funded healthcare services.^[41] This has led to a situation whereby doctors may be unable to comply with the legal requirements of IC, especially in public hospitals.^{[10],[35],[36],[37]} It has also been reported that there may be geographic and cultural barriers to the practice of IC even in developed countries such as the USA.^{[6],[27],[42],[43]} This has led most international ethical guidelines to recommend that cultural factors and language must be taken into consideration when obtaining IC from

patients, especially those in developing countries during biomedical research or treatment.^{[28],[44],[45],[46]} Previously, I reported on the understanding and practice of IC by medical doctors in South African hospitals.^[10] Here, I analyze and report patient's actual experiences, perceptions, and evaluation of the IC process at local public hospitals in eThekweni Metropolitan Municipality (Durban), South Africa. This study was conducted simultaneously with an interview of doctors and professional nurses practicing in KZN.^[10]

Materials and Methods



Objectives

The general objective of this study was to establish whether IC is obtained from patients prior to medical treatment in South African public hospitals. Specific objectives were to establish whether sufficient information is provided to patients. Whether patients understand the information provided, whether patients providing IC to treatment are generally competent to consent to such treatment, and to establish whether IC is obtained from patients voluntarily. Finally, whether IC provided by patients is truly valid and consistent with the requirements of the NHA.^[34]

Study population and location

The study location and stratified random sampling of selected public hospitals and patient populations were previously described in detail.^[10] Briefly, this study was conducted in the outpatient clinics and inpatient wards of selected public hospitals in eThekweni Metropolitan Municipality (Durban). Inclusion criteria were such that any patient attending the selected hospitals during the period of study (March–June 2012), who was willing to participate voluntarily, was eligible for inclusion in the study. Exclusion criteria were mental incapacity and absence of parent or guardian to provide consent for children below the age of consent in South Africa.

Study instruments

The main study instrument was a semi-structured questionnaire in English language, which was also translated into IsiZulu, the dominant language spoken by about 81% of the population of KZN.^[47] Professional translation was done by the Department of IsiZulu studies, University of KZN. Questionnaires consisted of three sections. The first section collected sociodemographic data; the second part was designed to collect information on patient experiences of IC practices by healthcare providers during clinical encounters. The third part asked questions about patient's general knowledge, understanding, and opinions on IC. Participants were interviewed by three trained bilingual research assistants. Those who preferred were allowed to complete the questionnaire by themselves. Respondents had the option of completing questionnaires either in English or IsiZulu. The study was conducted in various hospital departments shown in [\[Figure 1\]](#).

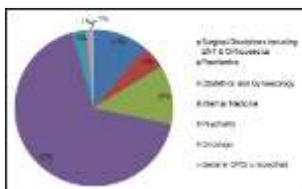


Figure 1: Percentage of participants by clinical departments

[Click here to view](#)

Study design and statistical analysis

Preliminary sample size for this study was calculated using a web-based sample size calculator, Raosoft[®].^[48] Based on the formula for sample size and margin of error from Raosoft, a representative sample size of 385 ± 20 patients was calculated (95% confidence interval; $P = 0.05$). Data from questionnaires were transcribed directly into Statistical Package for Social Sciences (SPSS), IBM Corp. Armonk New York, NY.^[49] The captured data were then checked for completeness and accuracy by both the principal investigator and a qualified biostatistician. Data were later analyzed using SPSS (version 21).^[49] Descriptive statistics such as percentages, proportions, median mode, and interquartile range were used to summarize the data. Scores for

comprehension, understanding, information disclosure, and voluntariness were worked out from the responses. Fisher's exact test was used to test for association between categorical variables and groups of patients. Pearson's Chi-squared test was used to test for differences in responses between patients and HCWs (doctors and nurses). One sample Kolmogorov–Smirnov test was used to test for normal age distribution.

Ethical considerations

Ethical approval was obtained from a local Research Ethics Committee at the University of South Africa (UNISA). The study and biostatistics methodology was also reviewed and approved by the health research and knowledge management subcomponent of the KZN Department of Health. Approval was also obtained from the management of each of the hospitals included in the study. Finally, written IC was obtained from each respondent after full information disclosure prior to participation in the study.

Results



Demographic characteristics

Four hundred and four valid questionnaires were completed by respondents with few missing data. The sociodemographic characteristics of participants are summarized in [\[Table 1\]](#) and [\[Table 2\]](#). The majority of questionnaires were completed by the patients themselves (88.2%, 351/398), while the remainder were completed by surrogates including parents/guardians (8.2%, 33/398). Most participants were female (68.2%; 272/399), single (56%, 225/403), or married (37%, 149/403). The age of participants was not normally distributed ($P < 0.001$, median = 35.5 years; range = 11–91 years). Most of the participants were bilingual, IsiZulu speakers (55%, 222/403), English (49%, 195/403), IsiXhosa (8%, 32/403), and Afrikaans (2%, 9/403). Other minority languages spoken include Hindi, Tamil, Tswana, and Sesotho. The majority of patients had a

secondary education (69%, 278/401), some tertiary education (16%, 65/401), primary education (12%, 49/401), and no education (2%, 9/401). Most respondents were unemployed (66%, 262/398), with (27%, 106/398) employed. The majority of participants reported no monthly income (56%, 227/404). Detailed earnings of participants are shown in [\[Figure 2\]](#).

Table 1: Demographic characteristics of respondents (*n*=404)

[Click here to view](#)

Table 2: Secondary demographic and social stratification data (*n*=404)

[Click here to view](#)

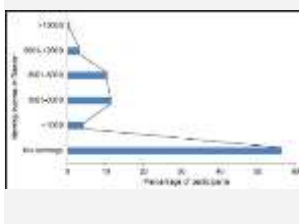


Figure 2: Monthly earnings of participants. *Salaries are shown in South African Rands (ZAR). 1\$ (USD) ≥11.5 ZAR

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Information disclosure

The majority of patients/respondents reported that an HCW (doctor or nurse) explained the treatment or procedure to them (88%, 355/403). Information provided to patients included diagnosis (81%, 326/403), general risks (57%, 229/403), and benefits (61%, 245/403). Less than half were informed about treatment options, (41%, 165/403), recommended treatment (28%, 113/403), and the risks of refusing recommended

treatment (25%, 99/403). Only 28%, (113/403) were given information about their right of refusal [\[Table 3\]](#).

Information provided	No. of patients	Percentage
Written form	100	25%
Verbal form	113	28%
Written and verbal form	100	25%
None	90	22%

Table 3: Information provided to patients by healthcare professionals prior to IC

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Time spent on information disclosure

Time spent by patients with doctors or other HCWs during a clinical encounter, including obtaining IC ranged from <5 min (15%, 58/399); 5–10 min (29%, 115/399); 10–20 min (23%, 91/399); 20–30 min (13%, 51/399) to >30 min (15%, 59/399) [\[Figure 3\]](#).

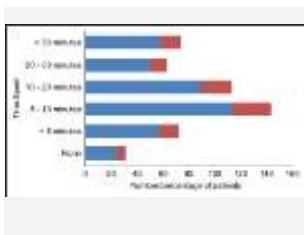


Figure 3: Time spent on informed consent/clinical encounter by healthcare workers

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Patients choice on risk disclosure

The majority of patients reported that they would prefer to receive information on "all the risks" associated with the treatment or procedure (78%, 304/391), while (6%, 22/391) said they would like to know only "some of the risks," another (6%, 22/391) preferred to know "none of the risks," while (11%, 43/391) answered "don't know." Relevant reasons given by patients for requesting full disclosure of material risks are shown in [\[Table 4\]](#). Some respondents wanted to know the side-effects of the drugs because they were allergic to some medications or were concerned about the health effects on their children, pregnancy, or current health status. Those who preferred partial or none disclosure of risks gave varying reasons for their choices as shown in [\[Table 4\]](#).

Table 4: Selected verbatim responses from patient to questions on IC

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Undue pressure or coercion

When patients were asked whether they were advised that they could accept or reject the treatment or procedure, (42%, 153/370) answered "yes." When asked if they felt threatened or were afraid to say "no," (8%, 30/379) answered "yes," while (91%, 343/379) said "no." Patients', who said they were afraid to say "no," gave various reasons as detailed in [\[Table 4\]](#). Some patients complained that they were afraid because the doctor was simply too rude or aggressive or that they would be asked why they were refusing help. When patients were asked if they were given any perverse incentive or persuaded to accept any particular treatment, 9 patients (2.4%, 9/377) answered "yes," while (97%, 365/377) said "no." Some of those who responded affirmatively said they were given some pills and money for bus fare. "They gave me money, and they said it was bus fare?" Another, "there are pills that they say we must take for them to see if they are working and they gave us R120." Another was persuaded by being told it would benefit her in the end.

Methods of obtaining consent

The majority of patients reported that consent was obtained "verbally" (73%, 274/374), "written" (19%, 71/374); while (5%, 19/374) said both methods were used. Information disclosure to patients was rendered using "words" in most cases (89%, 358/401). English language was used in (66%, 255/384) and IsiZulu (32%, 124/384). Methods used to enhance information disclosure included pictures (8%, 32/401); diagrams (5%, 21/401), and interpreters (3.5%, 14/401).

Understanding of information disclosed

The majority of participants said they understood the information provided (91%, 355/392), while about (8%, 31/392) answered "no." When asked if they asked any questions about their treatment (70%, 275/391) said "yes," while (29%, 113/391) said "no." Reasons for not asking questions about treatment elicited responses such as "Doctor knows best" or "I didn't know what to ask." Others said they were already familiar with their medical diagnosis or treatment regimen. Some complained that they did not have time to ask questions because the doctors were in a hurry or too busy. "The doctor was too fast he didn't give me time to ask, he didn't have time at all."

Voluntariness of consent

When patients were asked if the amount of information provided was enough, (74%, 290/391) answered "yes," while (24%, 92/391) said "no." When asked whether they made the treatment decision of their own free will, (95%, 348/366) respondents answered affirmatively. However, some respondents said they only followed orders from the doctor, with one stating: "The doctors tell you what needs to be done and you do it." When asked if they could change their mind if they did not like the recommended treatment, about (87%, 309/356) answered "yes," while (12%, 41/356) said "no." Several patients who stated that they could not change their mind said it was because they could not afford alternative treatment [\[Table 4\]](#). There was no significant association between patients age and knowledge of the right of refusal ($P = 0.334$), educational level and the right of refusal ($P = 0.404$), or income and right of refusal ($P = 0.480$).

Involvement of surrogates in patients' decision-making

When patients were asked whether they sought assistance any other person before deciding to accept or reject recommended treatment. Most patients (76%, 274/363) said "no," while (24%, 86/363) said "yes." Of those who sought help from surrogates, (11%, 42/370) involved parents, (6%, 21/369) from another family member, (3%, 11/369), from

a husband, (2.4%, 9/369) from a friend, about (1%, 4/369) from a wife, and <1% from a child. A few patients sought assistance from a doctor or nurse, the internet, or another patient. Most of those seeking assistance from parents did so because they were minors currently dependent on parents/guardians. Those seeking assistance from doctors or nurses felt that HCWs knew better or were seeking a second opinion.

General knowledge of informed consent regulations by patients

When asked about the age of consent to treatment by children in South Africa, most respondents answered wrongly with (26%, 96/373) choosing, "15 years;" (33%, 122/373) chose "18 years;" (11%, 40/373) "21 years," while (6%, 21/373) did not know. Only (25%, 94/373) participants correctly answered "12 years." There was a statistically significant association between participant's age and knowledge of the age of consent in South Africa ($P < 0.005$). Older age groups were more likely to respond correctly. There was no association between educational level or income and knowledge of the age of consent ($P = 0.080$) and ($P = 0.334$), respectively.

Discussion



This study assesses patients understanding and perceptions on the quality of IC as practiced by healthcare professionals (doctors and nurses) in an urban municipality in South Africa. Patients were generally satisfied with the level of information disclosure during medical treatment with about 74% expressing satisfaction regarding information disclosure. Patients also confirmed that doctors provided most of the information headings required by the NHA 2003,^[34] including diagnosis, general risks, and benefits of treatment. This was consistent with a previous study on doctors practicing in the same region.^[10] However, 25–41% of patients were not given information on the right of refusal, treatment options, recommended treatment, and risks of refusing recommended treatment. With regards to the understanding of information, over 90% of patients stated

that they understood the information provided and about 70% said they were able to ask questions about their treatment. Although about 30% stated they were afraid to ask questions for fear of losing the free treatment provided in public hospitals since they were indigent and did not have any alternatives. This observation is consistent with a similar study in Kenya, where it was reported that patients were too timid or afraid to ask questions because of the fear of losing the benefits of free treatment provided during clinical trials or research.^{[38],[50]} In terms of voluntariness of consent, the majority of patients reported making their decisions of their own free will, while those who sought assistance from surrogates reported the involvement of mostly family members, friends, and occasionally HCWs. Most patients reported the absence of coercion or undue influence with over 90% reporting that they were not afraid to say "no" if they felt uncomfortable with recommended treatment. This is somewhat unusual for developing country, especially in Africa, where cultural and family influences are thought to play a major role in healthcare decision-making as reported from studies in Nigeria ^{[25],[26]} and Kenya.^{[38],[50]} This may indicate that South African patients are more aware of patient's rights and more sophisticated in terms of their understanding of IC when compared to patients from other developing countries in Africa and elsewhere.^{[25],[26],[38],[50]} This may be a complement to the passage and wide publication of the NHA in South Africa and the patients' rights charter displayed by law in all public hospitals in South Africa. This observation may provide a good example to other countries in Africa, such as Nigeria, who are yet to pass or legally enforce healthcare laws in their own jurisdictions. While the Nigerian Health Act was passed into law in late 2014, its active implementation remains a future target.^{[51],[52]} Most patients reported that there was no perverse influence on their decision-making such as financial inducement or threats, except few who reported being given money for "bus fare." The latter were probably patients involved in ongoing clinical trials that were financially compensated for participation, although the amount of 120 ZAR reported is less than the nationally recommended rate of 150 ZAR (≈15 USD) per day.^[53] Time spent on IC as reported by most patients is within the range of 5–20 min as previously reported by doctors.^[10] However, it is not clear from the patients account whether time spent with patients refers to time specifically spent on obtaining IC, or time spent on the entire clinical encounter.

Probably the latter, since most doctors in the public hospitals are very busy with a large case load, thereby militating on time spent on IC as previously observed.^[10] The timeframe of <20 min is also consistent with the entire clinical encounter as reported from other jurisdictions like the USA, where the estimated duration of an average primary care visit is 15 min.^[5] Cultural factors impacting on IC in this population include the unemployment and poverty with over 65% unemployed and 56% reporting no monthly income in this cohort. Other cultural issues identified include language difficulties, with the majority of patients speaking IsiZulu or other African languages, while communication with HCWs on IC was predominantly in English language. Language as a barrier to IC was previously reported in other studies in South Africa ^{[10],[35],[36]} and the USA.^{[42],[43]} However, this barrier did not seem to affect patient understanding with over 90% of respondents claiming they understood the information provided. There was some inconsistency with previous reports where doctors claimed that IC was obtained in writing in 51% of cases,^[1] compared patients in this study who reported that IC was obtained verbally in over 75% of cases. Moreover, doctors reported giving patients information on the right of refusal in 65% of cases, while patients reported only 28%. Further, doctors reported using interpreters in 72% of cases when obtaining IC,^[10] while patients reported that interpreters were involved in only 3.5% of clinical encounters. This inconsistency cannot be readily explained; however, it could be due to the practice of "cultural brokerage," whereby nurses maybe used to "translate, mediate, and negotiate on behalf of patients."^{[36],[54]} In this situation the patient may not readily recognize or relate this to the use of interpreter while a doctor may report otherwise. Finally, patients showed a poor knowledge of the legal age for consent in South Africa, with only 25% identifying the current age of consent to routine treatment. Overall patients were satisfied with their encounter with healthcare professionals in this setting; however, they wanted to be involved in the healthcare decision-making process via informed decision-making.^{[5],[6],[7]} This finding is consistent with reports from other parts of Africa such as Nigeria ^[55] and Kenya,^{[38],[50]} as well as Greece ^[56] where were patients felt that while IC was important, they also wanted to be involved in decisions affecting their healthcare. It has been suggested by some American researchers that informed and shared decision-making are important elements of preventive

medicine.^{[57],[58]} Recommendations by patients on improving IC practices in the environment include improved communication skills by HCWs, with many patients complaining that doctors were too busy, rude, or aggressive while recommending that: "Bit more time spent with each patient will help," and "communicate better with patients." Others said, "doctors need to give all the important information without patients asking." Another, "I think nurses must try to spend more time explaining the treatment because sometimes they just right (write) in your card and you can hardly see what is written." And another, "I think they must be more careful with our documents, and they must also learn how to speak to patients." Finally, "I think they need to manage their time better."

Potential limitations of this study include the fact that it was carried out in an urban metropolitan municipality in South Africa (Durban), with an arguably better educated and more knowledgeable population group by South African standards. It is possible that a similar study in a rural location in KZN may yield a different result as reported elsewhere, although accurate sociodemographic data for proper comparison was not provided another study from rural KZN.^[36] It is also unclear whether a study in a more cosmopolitan South African city such as Cape Town or Johannesburg with different population demographics may or may not produce a different result. It is possible that similar studies on patients utilizing private healthcare services may produce a different result because it has been suggested that doctors in private healthcare setting in Greece are more likely to provide detailed information to patients.^[56]

Conclusion



This study confirms that majority of patients utilizing South African public hospitals are vulnerable because of their indigence and lack of alternative means of obtaining healthcare. This study also shows that despite their evident vulnerability, most patients in Africa are generally aware of their right to information disclosure, human rights, and dignity in healthcare. Patients want to be informed and participate in informed or shared healthcare decision-making. This study supports previous reports by doctors and

patients regarding the IC practices in South Africa, although there were some areas of inconsistency in actual practice with patients and doctors differing on the content and methodology of information disclosure. The major cultural factors militating against IC include language barriers, poverty, and poor communication skills by HCWs. One can conclude that there is a need to further educate patients and HCWs on patients' rights, the legal requirements of IC, with improved communication skills and training CPD of HCWs in ethics and medical law. This will enhance the doctor-patient relationship, patient's rights, and human dignity. Future research should focus on informed and shared healthcare decision-making in order to improve preventive healthcare services in Africa.

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Conflicts of interest

There are no conflicts of interest.

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ANNEXURE 3

Understanding and Practice of Informed Consent by Professional Nurses in South Africa: An Empirical Study-Brief Report

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Abstract

Background: Informed consent (IC) is a legal and ethical doctrine, constitutionally protected in South Africa by rights to bodily integrity, privacy, and self-determination. The *National Health Act 2003* codified requirements for IC; stipulating that healthcare professionals (HCPs) must inform patients about diagnosis, treatment risks, benefits, options, and right of refusal, while taking into consideration patients language and literacy levels. However, multicultural societies are challenged by problems of poverty, education, language, and cultural ethos, which may influence IC practice.

Methods: This was a cross-sectional quantitative study using semi-structured questionnaires at randomly selected public hospitals in Durban city. Data analyzed with SPSS, used descriptive statistics and chi-squared tests to compare results between nurses, doctors, and patients. Local RECs and IC approved the study was obtained from all participants.

Results: Three hundred fifty-five (355) registered nurses completed the study. Majority female (92%), with 1-41years professional experience. Information disclosed by nurses included diagnosis (77%); treatment options (68%); benefits (71%), risks (69%), recommended treatment (65%). Inconsistencies observed between nurses and patients included non-disclosure of right of refusal, treatment options and risks (25-41%). Nurses' knowledge of basic laws like age of consent was deficient, (30%) accuracy.

Conclusions: This study showed that professional nurses in South Africa are deficient in knowledge of local regulations regarding IC, and would benefit from additional training in healthcare law and ethics. Barriers to IC include language, education, and workload. Provision of trained interpreters will minimize language barriers, reduce nurses' workload, and improve overall quality of healthcare service delivery

Keywords: Informed consent, nurses, ethics, law, medical practice, South Africa

Introduction

Informed consent (IC) is a legal and ethical doctrine derived from the principle of respect for autonomy and is constitutionally protected in South Africa through the rights to bodily integrity, privacy and self-determination. (The Constitution of South Africa, 1996). To enhance transparency of consent regulations in South Africa, the *National Health Act* (NHA) (South Africa Government Gazette, 2003) codified requirements for IC by stipulating that healthcare professionals (HCPs) must inform patients about diagnosis, risks, benefits, treatment options, and the right of treatment refusal, while taking into consideration patients' language and literacy levels. Further, a South African High Court decision in the case of (*Castell v De Greef*, 1994) impacted on South African medical jurisprudence; leading to a shift from the paternalistic 'reasonable doctor' to a 'prudent patient' and 'material risks' standards regarding information disclosure. Arguably, a key domain of transparency in healthcare involves the open sharing of information and shared healthcare decision-making between HCPs and patients. It has been suggested that it is very important to understand that transparency in healthcare begins with the process of informed consent whereby a HCP and patient engage in open and transparent conversation regarding IC which should include discussion about the diagnosis, risks, benefits of treatment, alternatives to the recommended treatment if any, costs, risks of refusing treatment, and right of refusal. (Mayer, 2012). This is followed by an opportunity to ask questions prior to 'consent' i.e. acceptance or rejection of recommended treatment by the patient. It has been argued that transparency in medical practice begins with respect for autonomy and IC, although many physicians still view IC as a bureaucratic legalism' which may interfere with patient care (Brody, 1989). Some have suggested that IC should be understood as a fundamental aspect of good healthcare practice whereby any doctor not possessing skills to obtain valid consent, could be considered as lacking essential skills for modern medical practice. To enhance transparency of IC regulations in South Africa, the NHA (South Africa, 2003) codified requirements for IC by stipulating that HCPs must inform patients about diagnosis, risks, benefits, treatment options, and the right of treatment refusal, at a language and literacy

level understandable to the patient. The NHA further requires that the information disclosed must include: (a) The range of diagnostic procedures and treatment options generally available to the user; b) The benefits, risks, and consequences generally associated with each option; and (c) The users' right to refuse health services and explain the implications, risks, and obligations of such refusal. The law further requires that every health care provider must inform a user of: "*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*". Section 7 of the NHA provides some exceptions to IC where it stipulates that health services may not be provided to a healthcare user without the users informed consent unless-

1. The user is unable to give informed consent and such consent is given by a person-
 - (a) Mandated by the user in writing to grant consent on his or her behalf; or
 - (b) Authorized to give such consent in terms of any law or court order; or where
2. The user is unable to give informed consent and no person is mandated or authorized to give such consent.

Historical Background to Informed Consent in South Africa

According to Ferdinand van Oosten, patients consent, as a requirement for all lawful medical interventions, is a well-established principle in South African common law (Van Oosten, 1989). The earliest leading cases in this area were the cases of (Stoffberg v Elliot, 1923) and (Esterhuizen v Administrator Transvaal, 1957). More recently in the case of (Castell v De Greef, 1994), the judgment of Ackerman J seems to have established the doctrine of informed consent within South African medical jurisprudence (Van Oosten, 1995). Further the South African Supreme Court of Appeal (SCA) revisited this judgement and doctrine in (Broude v McIntosh, 1998) but did not overrule this decision despite some technical reservations (Carstens & Pearmain, 2007); thereby reaffirming the doctrine of informed consent as part of South African medical law. I have previously asserted that informed consent before medical procedures is constitutionally protected right in South Africa (Chima, 2013). This was further illustrated in the case of (Minister of Safety and Security v Gaqa, 2002), where the police wanted a court order to

compel an accused person to undergo a surgical procedure to obtain a bullet to be used as evidence in a prosecution. The court asserted that such an order would violate the defendant's constitutional rights to a fair trial, bodily integrity, and privacy. The consequences of the decision of the Court in (*Castell v De Greef*, 1994) on South African medical jurisprudence were that the following principles were generally adopted (Van Oosten, 1995):

1. A shift from medical paternalism to patient autonomy.
2. A shift from the 'reasonable doctor standard' to the 'reasonable patients' standard.
3. A shift in disclosure to the 'material risk' standard, where the level of disclosure required is what a reasonable patient would consider pertinent/important before making a healthcare decision
4. The Court appears to place the patients' informed consent within the framework of *volenti non fit injuria* or voluntary assumption of risk rather than delict (Van Oosten, 1995).

Standards of information disclosure

One of the more contested areas of medico-legal jurisprudence is in standard of information disclosure required for informed consent. In other words, how much information should be disclosed by the treating physician or healthcare professional to the patient for informed consent to be considered valid? On this consideration, there are two contesting schools of thought. On the one hand, there is the 'reasonable doctor standard' based on English common law as outlined by McNair J in (*Bolam v Friern Health Management Committee*, 1957) and generally known as the *Bolam* principle, which states that: A doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of men skilled in that particular art... putting it the other way round, a doctor is not negligent, if he is acting with such a practice, merely because there is a body of opinion that takes a contrary view. It has been argued that English courts have opted for a paternalistic approach by following the reasonable doctor standard which bases disclosure on the clinical judgement/ accepted practice/substantial risk/normal/usual risk principles (Van Oosten, 1991), as established in (*Bolam v Friern Health Management Committee*, 1957) and reaffirmed by the House of

Lords in (*Sidaway v Board of Governors of Royal Bethlem Hospital*, 1985), where Lord Templeman said: At the end of the day the doctor bearing in mind the best interests of the patient and bearing in mind the patients right to information which will enable the patient to make a balanced judgement, must decide what information should be given to the patient, and what terms that information should be couched... (*Sidaway*, 1985)

This idea of abridged information disclosure has since been applied in several court cases such as (*Chatterton v Gerson*, 1981) where Bristow J said that patients should be informed in 'broad terms', thereby implying that not all information is required and the nature and amount of it to be disclosed to a patient would be based on reasonable doctor-standard rather than on the requirements of the patient. Lord Scarman in *Sidaway* argued for a 'prudent patient standard' 'as practiced in other jurisdictions such as Canada, USA, and even Germany when he said: "It was a strange conclusion if our courts should be led to conclude that our law...should permit doctors to determine in what circumstances...a duty arose to warn." (*Sidaway v Board of Governors of Royal Bethlem Hospital*, 1985).

What makes informed consent valid?

- 1. Information disclosure:** provision of adequate information
- 2. Competence:** capacity to understand that information
- 3. Voluntariness:** decision making in the absence of coercion or deception
- 4. Comprehension:** understanding of information provided
- 5. Consent:** agreement to the proposed procedure/treatment or participation in a research study. Therefore, informing the patient must not be simply a ritual recitation of the contents of a written document. Rather the healthcare professional or researcher must convey the information, whether orally or in writing, in language that suits the individual's level of understanding (Tekola et al., 2009).

Socio-cultural Issues Impacting on the Practice of Informed Consent in South Africa

The socio-cultural milieu of South Africa shows that about 25%- 30% of the population is unemployed, with low labour force participation rate of 54% compared to a global average of 69% (Vollgraaff, 2011). Therefore, basic health care is unaffordable for most of the local South African population (Chima, 2015). There are also historical inequities within population groups with some authors asserting that informed consent is light years away from the black South Africans' (Mhlongo & Mdingi, 1997). Further, there is a dichotomy in the organization of the South African healthcare system, which is dual in nature consisting of private hospitals/medical practice which is patronized by the fewer patients (20%) who have health insurance or financial means to pay for private healthcare services, compared with the public health services which accounts for the majority (80%) of indigent patients and citizens (KwaZulu-Natal Department of Health, 2010).

Impact of socio-cultural factors on informed consent practice in South Africa

This evident dichotomy in health services may influence the practice of informed consent in South Africa. Furthermore, most African societies being culturally complex and paternalistic in nature may require that consent or approval be obtained from community elders/extended family members, or men as heads of households before the actual patients/human subjects can provide consent (Irabor & Omonzejele, 2007). The challenge here then is to ensure that informed consent is truly voluntary and that community or surrogate consent is not substituted for individuals' consent, which ideally should be obtained voluntarily in the absence of coercion (Ijsselmuiden & Faden, 1999).

Methods

Study rationale-justifications for using empirical methods to study informed consent

Sulmasy and Sugarman (2001) have described two potential reasons for studying the actual conduct of a group with regards to compliance with moral and ethical dilemmas.

(a) To describe compliance with existing moral norms and

(b) To determine whether policies and procedures designed to operationalize certain moral norms have been successful (Chima, 2013; Sulmasy & Sugarman, 2001). Other empirical studies have shown that people generally have problems in understanding the risks and benefits of medical treatment and decision making, and this could impact on the actual application of the existing law (Musschenga, 1999). For example, a study by means of a questionnaire on Dutch nurses charged with taking care of nursing home resident with due respect for their libertarian rights and respect for autonomy revealed that the nurses were not complying with the existing regulations (van Theil & van Delden, 1997). Based on the above observations, it has been suggested by that to guide action; ethical guidelines must be based on reality and should be formulated in such a way that it is continuous with accepted moral norms (Birnbacher, 1999). Others have suggested that empirical ethics should be used to defend or criticize concrete moral principles or practices rather than make general claims about moral concepts (De Vries & Gordijn, 2009). Consequently, in recent times, applied ethicists have shifted towards combining empirical, especially social scientific research with normative ethical analysis. Proponents of this approach called empirical ethics' have argued that the study of people's actual moral beliefs, behaviour and reasoning should be the starting point of ethics. It has also been acknowledged that the methodologies of the social sciences, especially quantitative and qualitative research, using surveys, interviews and questionnaires is probably the best way to map the reality of people's actual moral norms (Borry, Schotsmans, & Dierickx, 2004). However, complex multicultural societies in Africa and elsewhere are inherently challenged by problems of poverty, poor education, language, and unfamiliarity with libertarian rights-based autonomy, cultural issues, and the power asymmetry between doctors and patients. Some of which could impact on the practice of IC. To evaluate whether the quality of IC practiced by HCPs in South Africa is consistent with current local laws and international standards, I conducted an empirical study to evaluate the clinical practice of IC by HCPs at local hospitals. The general objective of this study was to establish whether informed consent is obtained from patients prior to involvement in clinical procedures in South Africa. Specifically, I wanted to establish whether:

1. Sufficient information is provided to patients in clinical practice before consent is sought.
2. Patients involved in clinical procedures understand the information given.
3. Consent is obtained from patients voluntarily.
4. Whether informed consent provided by patients in clinical practice in South Africa is legally and ethically valid

Research design: The study design was a descriptive cross sectional study in contemporary clinical practice settings. This is because the time between procuring informed consent and treatment is very short and patients are normally in hospital for a limited time. The descriptive approach allowed doctors, nurses, and patients to describe their experience with the informed consent process as it is, thereby bringing out the required information. Further I employed the technique of “triangulation” in this study which has been defined as “the combination of methodologies in the study of the same phenomenon” (Denzin, 1978). The original purpose of triangulation was to seek confirmation of apparent findings- consistency. More recently it has also been used for completeness purposes. In this study, I have applied the method of data triangulation which involves the use of multiple data sources in the study to get diverse views to aid in validating the conclusions, therefore in this study I applied time triangulation, space triangulation, and person triangulation.

Study location: This study was carried out at selected public hospitals within EThekweni metropolitan municipality district in KwaZulu-Natal Province of South Africa, and its environs. EThekweni municipality comprises a major urban city (Durban) and semi-urban areas (townships) with a population of around 3.2 million people (2010 estimate) (Statistics South Africa, 2011). Based on data from KZN department of Health, there are 17 public hospitals in EThekweni district municipality (KZN Department of Health 2011). According to Terre-Blanche (2008) 30% of the population is adequate when conducting a descriptive study (Terre-Blanche, Durkheim & Painter, 2008). Based on these criteria, 6 provincial/public hospitals were finally included in this study.

Target populations: This was a simultaneous study involving patients, medical doctors, and professional nurses at selected provincial hospitals within EThekweni municipality KZN were targeted for the study. All medical doctors and professional nurses within the randomly selected hospitals were given an opportunity to participate in the study.

Sampling procedures: Multi-stage stratified random sampling was used to select participating hospitals. Purposeful sampling was used to include the two central tertiary hospitals within the district because they contain the largest number of medical doctors including specialists as well as professional nurses. The rest of the public hospitals within the municipality district were randomly sampled. A total of 5 hospitals from Durban and one outlying hospital in nearby Pietermaritzburg with rotating surgical registrars from Durban were included in the study. Therefore, a total of 6 provincial/public hospitals were included in the study population.

Sample size: Preliminary sample size for each group of study participants was calculated using a web based sample size calculator by Raosoft®(<http://www.raosoft.com/samplesize.html>), based on the formula for sample size and margin of error. Using this freely available software the estimated sample size for each category of participants was calculated. In this case, an estimate of 373 professional nurses were needed to complete the study at a 95% confidence level.

Inclusion & exclusion criteria for nurses: There are 3 categories of registered nurses in South Africa, professional nurses, staff nurses and nursing auxiliaries (South African Nursing Council (SANC), 2012). A professional nurse sometimes called a nursing sister is an individual who has completed a minimum 4-year degree programme at university or tertiary institution, and are certified competent to practice comprehensive nursing and midwifery. An enrolled or staff nurse is a registered nurse with a minimum of 2-years tertiary nursing education, while an auxiliary nurse has 1 year of nursing education. In this study only nurses in the categories of professional nurse and enrolled nurse were included (SANC, 2012).

Research instruments and data analysis: Data was collected using self-administered questionnaires for healthcare professionals and face-to-face interviews for patients. Two separate open and close-ended questionnaires were applied to patients and healthcare professionals respectively. Doctors and nurses were evaluated using the same questionnaire in English language. The data from questionnaires was captured and subsequently analysed using the Statistical Package for Social Sciences (SPSS v.21 IBM, 2012). Distribution and collection of questionnaires were conducted with the assistance 3 trained research assistants. Preliminary data from the questionnaire was captured into SPSS by a trained research assistant and this was further validated by the principal investigator and a qualified biostatistician. Descriptive statistics such as proportions, median, mode and interquartile range were used to summarize the data. The scores for information disclosure, capacity comprehension, and volition of informed consent were worked out from the responses

Ethical considerations: Ethical approval was obtained from a University of South Africa (UNISA) Research Ethics Committee and the KZN Department of Health Research Ethics committee. Additional approval was obtained from the management of each selected hospital prior to distribution of the questionnaire. Finally, all participants were given a full information disclosure prior to providing signed informed consent.

Main Findings

Demographics: A total of 355 nurses completed this study. Majority of participating nurses were female (92%) with a median age of 39 years, range (22-62). Nurses had between 1 to 41years of professional experience (median = 9). Majority were professional nurses (85%), remainder were enrolled/staff nurses (15%) Figure 1. Professional nurses, a.k.a nursing sisters had a minimum of 4-years University education or degrees in Nursing, while enrolled nurses' a.k.a staff nurses had a minimum of 2 years Diploma. Auxiliary nurses, nursing students, and enrolled nursing assistants (ENAs) were excluded from the study (SANC, 2012). Nurses from all major hospital clinical departments as shown in Figure

Figure 1: Nurses by professional category

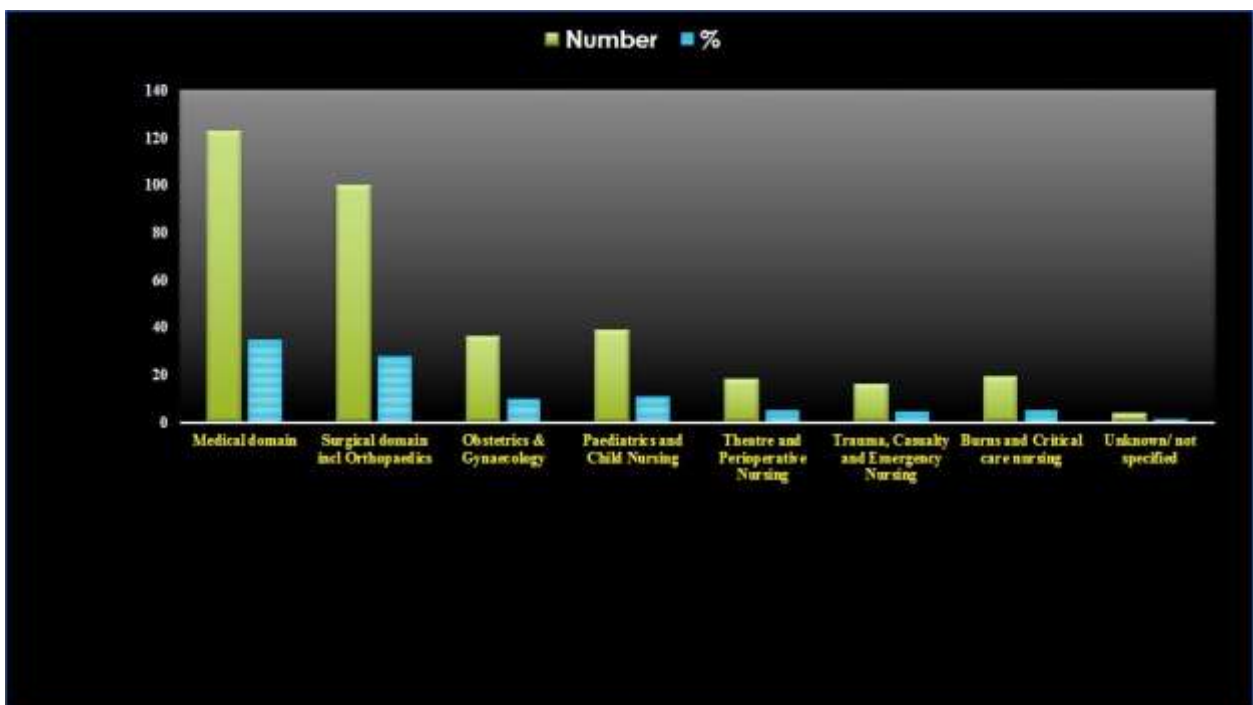
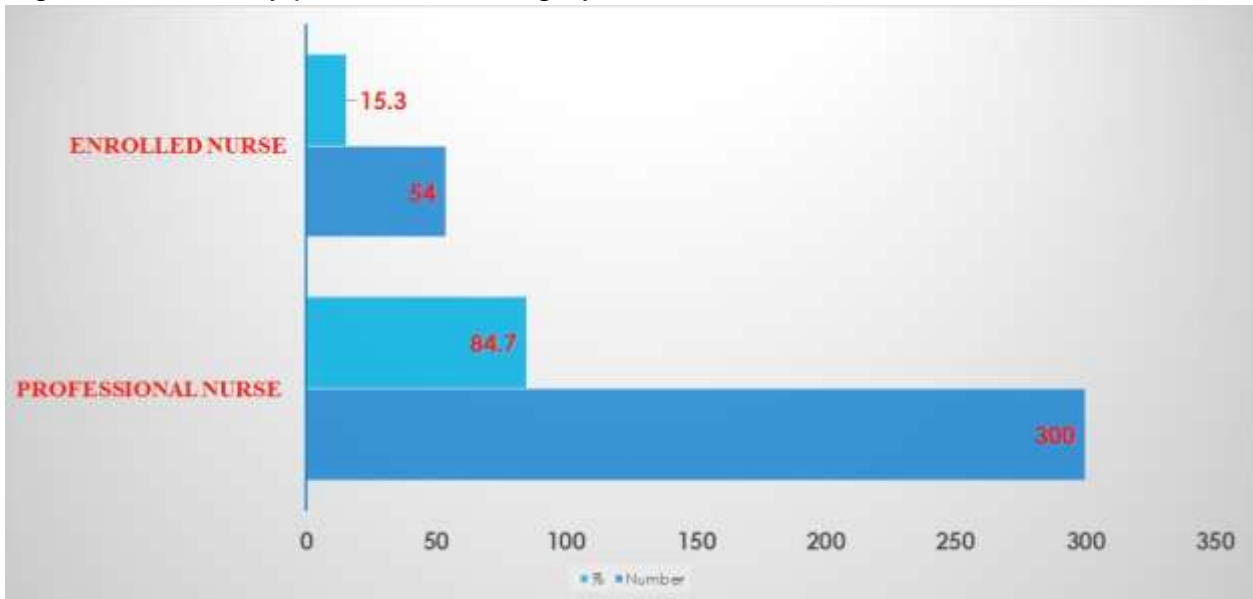


Figure 2: Clinical domains and departments of participating nurses

Information disclosed by nurses to patients: Information reportedly disclosed by nurses included diagnosis (77%); treatment options (68%); recommended treatment (65%); risks of refusing recommended treatment (69%); treatment benefits (71%); and right of refusal (67%). Triangulation of data revealed some inconsistencies between claimed disclosures between nurses and patients as previously reported (Chima, 2015). For example, patients reported that they were informed about diagnosis (81%), risks (57%), and benefits of treatment (61%). However, fewer were informed about treatment options (41%), recommended treatment (28%), and right of refusal (25%). Similarly, patients claimed that informed consent was IC was obtained verbally in 73% of cases while nurses only 8% of nurses reported obtaining consent verbally. Another interesting inconsistent observation involving nurses was the fact previously reported by doctors that interpreters were used in communicating with patients in 72% of cases when obtaining IC (Chima, 2013). On the other hand, patients reported that interpreters were involved in only 3.5% of clinical encounters (Chima, 2015). This inconsistency cannot be readily explained; however, it could be due to the practice of ‘cultural brokerage’, whereby nurses maybe used to ‘translate, mediate and negotiate on behalf of patients (Jezewski, 1990). In this situation, the patient may not readily recognize or relate this to the use of interpreter while a doctor or nurse may report otherwise.

Barriers to informed consent reported by nurses: Major challenges to obtaining IC reported by doctors and nurses included language barriers, time constraints, lack of administrative support e.g. interpreters, and patients’ educational level. Tests of significance using Mann-Whitney U test showed that the ‘lack of administrative support e.g. interpreters’ was statistically significant across different clinical specialities ($p \leq 0.013$). The barriers to informed consent was previously reported for doctors (Chima, 2013). A comparison of doctors and nurses is shown in Table 1.

Table 4: Challenges to informed consent- doctors vs nurses

Challenges	Doctors	Nurses	Median score Doctors/Nurses	P-value (Mann- Whitney U test)
Time Constraints	146	216	2.00/3.00	0.120
Work Load	143	216	3.00/2.00	0.171
Language difficulties	147	259	2.00/1.00	0.002
Lack of administrative support, (E.g. Interpreters)	138	203	4.00/3.00	0.022
Cultural barriers				
	134	207	5.00/3.00	0.000
Lack of education				
	142	220	4.00/3.00	0.002
Medical paternalism (Doctor knows best)	131	183	7.00/6.00	0.000

Note: p-values calculated using Independent samples Mann-Whitney U test; significance level = 0.05

Time Spent on Informed Consent: Majority of nurses (41%) reported spending about 5-10 minutes on the IC process, consistent 53% of doctors as previously reported (Chima, 2013). This Another 24% of nurses spent 10-20 minutes, while 16% spent less than 5 minutes on IC as shown in Figure 3. When asked if this amount of time was sufficient, majority of nurses 52% answered affirmatively, while 41% responded negatively.

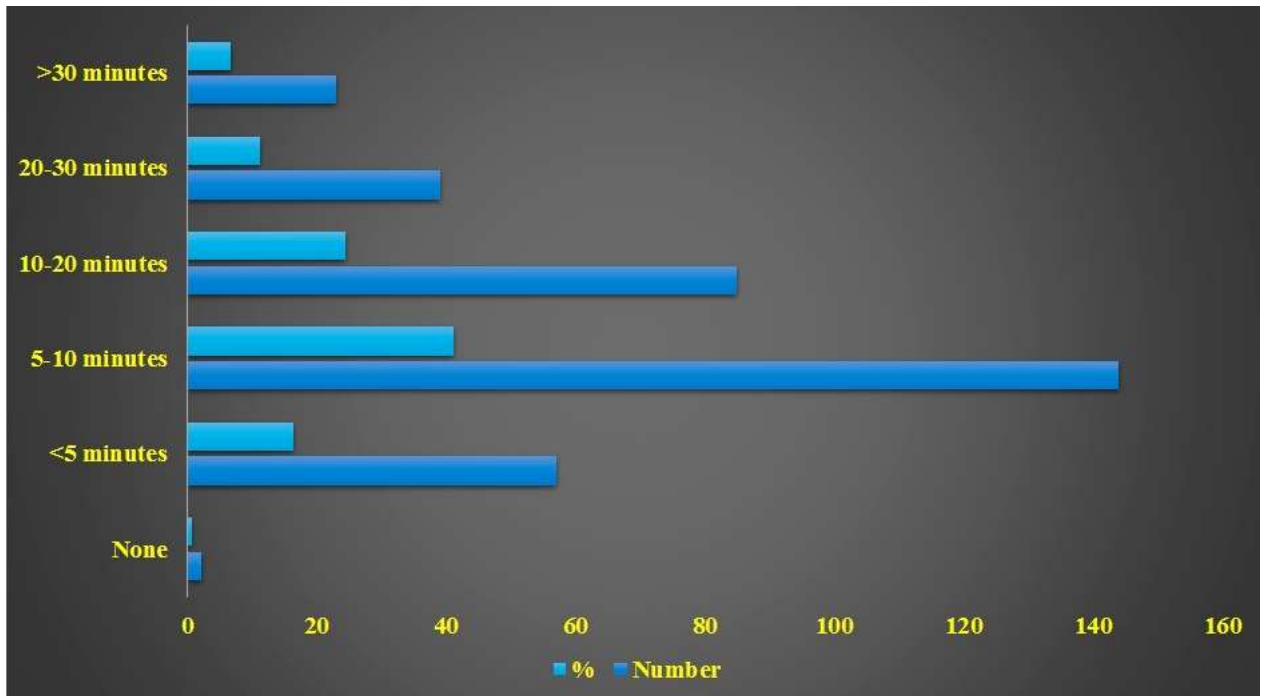


Figure 3: Time spent on informed consent by nurses

General knowledge of IC by healthcare professionals: Questions pertaining to general knowledge of IC regulations in South Africa such as age of consent to treatment' and 'legal age of eligibility for termination of pregnancy' in terms of (Choice on termination of pregnancy Act, 1996) were inserted into the questionnaires for to gauge the level of general knowledge of HCPs regarding local laws. Results showed that only 71% of doctors and 30% of nurses could correctly identify the age of consent for routine medical treatment. Similarly, only 30% of doctors and 8% of nurses knew age of consent for termination of pregnancy. Further, to compare IC knowledge across occupational ranks of doctors and nurses using quantitative means, I developed an Informed Consent Aggregate Score (ICAS) (Chima, 2013). Comparison of ICAS scores between doctors and nurses ICAS showed that nurses scored lower than doctors with a median score of 8 versus 10. This difference was statistically significant ($p \leq 0.001$). However, there was no significant difference in knowledge level between professional nurses with 4 years' degree or more, and enrolled nurses with a minimum of 2 years nursing diploma.

Implications of these findings

This study shows that nurses practicing in South Africa are generally aware of the importance of informed consent in clinical practice, although not all adhered to the key elements as specified in the (NHA, 2003), or are familiar with the requirements based on international standards. Generally South African nurses understand the basic elements of informed consent such as comprehension, capacity, information disclosure and volition. However large percentages of professional nurses are still unaware of general changes in South African law, such as the age of consent to treatment or the age at which a woman can request for termination of pregnancy. This study also confirmed that majority of patients utilizing South African public hospitals are vulnerable because of their indigence and lack of alternative means of obtaining healthcare. However, the study also indicated that despite their evident vulnerability, most patients in Africa are generally aware of their right to information disclosure, human rights and dignity in healthcare as previously reported (Chima, 2015).

Limitations of the study

Potential limitations to this study include the fact that it was carried out in an urban metropolitan municipality in South Africa (Durban), with an arguably better educated and more knowledgeable population group by South African standards. It is possible that a similar study in a rural location in South Africa may yield a different result. It is also unclear whether a study in a more cosmopolitan South African city such as Cape Town or Johannesburg with different population demographics may or may not produce a different result. Finally, it is also possible that similar studies on patients utilizing private healthcare services may produce a different result because it has been suggested that doctors in private healthcare setting in Greece are more likely to provide detailed information to patients (Falagas et al. 2009).

Conclusion and recommendations

This study identified the major cultural factors militating against IC practice in this setting as language barriers, poverty, and poor communication skills by HCWs, consistent with findings from studies from other multicultural and multilingual settings South Africa (Schlemmer & Mash 2006) and USA (Flores, 2006). One can conclude that there is

need to further educate patients and HCWs on patients' rights and the legal requirements of IC. There is a need for further training of nurses on improved communication skills and ethics and healthcare law. This will enhance the healthcare professional-patient relationship, patient's rights, and human dignity. Future research should focus on informed and shared healthcare decision-making to improve preventive healthcare services in Africa. Finally, more continuing education programmes should be initiated to further educate South African healthcare workers on the key elements of informed consent to meet required international standards and local laws. There is also a need for an interpreter 'corps to aid local language translation and improve patient understanding, improve informed consent practices amongst local populations, reduce the burden on nurses who have to play the dual role of interpreters and caregivers. This will help to minimize nurses' workload and reduce HCP attrition and improve the overall quality of healthcare service delivery.

Acknowledgements

This paper is derived in part from a research project entitled "An investigation of IC in clinical practice in South Africa," which is being completed as a thesis for the award of the LLD (Doctor of Laws) degree at the University of South Africa (UNISA).

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5 April 2011

Prof S Chima
6 Sunset View
449 Queen Elizabeth Avenue
Manor Gardens
DURBAN
4001

Dear Prof Chima

**REQUEST FOR ETHICAL CLEARANCE: AN INVESTIGATION OF
INFORMED CONSENT IN CLINICAL PRACTICE IN SOUTH AFRICA**

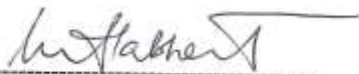
Your application for ethical clearance of the above study was considered by the College of Law Sub-Ethics Review Committee on 1 April 2011. The Committee is pleased to inform you that ethical clearance has been granted for this study as set out in your application.

We trust that sampling and processing of the relevant data will be undertaken in a manner that is respectful of the rights and integrity of participants, as stipulated in the Unisa Research Ethics Policy, which can be found at the following website:

http://www.unisa.ac.za/contents/research/docs/ResearchEthicsPolicy_apprvCounc_21Sept07.pdf

Congratulations on an interesting and very relevant study. We would like to wish you well in this research undertaking.

Kind regards



PROF MN SLABBERT
CHAIR: COLLEGE OF LAW SUB-ETHICS REVIEW COMMITTEE





health

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www.kznhealth.gov.za

Reference : HRKM180/11
Enquiries : Mrs G Khumalo
Telephone : 033 – 3953189

17 January 2012

Dear Prof S C Chima

Subject: Approval of a Research Proposal

1. The research proposal titled '**An investigation of informed consent in clinical practice in South Africa**' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at selected public facilities at eThekweni district.

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mrs G Khumalo on 033-3953189.

Yours Sincerely



Dr E Lutge



Department:
Health
PROVINCE OF KWAZULU-NATAL

Inkosi Albert Luthuli Central Hospital
Ethekwini Health District
Office of the Medical Manager
Private Bag X 03, Mayville, 4058
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Email: ursulanun@ialch.co.za
www.kznhealth.gov.za

Reference: Unisa Study
Enquiries: Dr M E L Joshua

22 February 2012

Prof S Chima
UKZN
Durban

Dear Prof Chima

RE: PERMISSION TO CONDUCT RESEARCH AT IALCH

I have pleasure in informing you that permission has been granted to you by the Medical Manager to conduct research on: **An investigation of informed consent in Clinical Practice in SA**

Kindly take note of the following information before you continue:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Kindly ensure that this office is informed before you commence your research.
4. The hospital will not provide any resources for this research.
5. You will be expected to provide feedback once your research is complete to the Medical Manager.

Yours faithfully


.....
Dr M E L Joshua
Medical Manager

uMnyango Wezempilo . Department van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope



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ENQUIRIES: DR P.S. SUBBAN

27 February 2012

Prof S. Chima
6 Sunset View
449 Queen Elizabeth Avenue
Manor Gardens
DURBAN
4001

Dear Prof Chima

**PERMISSION TO CONDUCT RESEARCH : AN INVESTIGATION OF INFORMED
CONSENT IN CLINICAL PRACTICE IN SOUTH AFRICA**

Permission is granted to conduct your research at this institution provided:-

- Confidentiality is maintained at all times.
- Your research does not interfere with the smooth running of the hospital
- Proper consent is obtained from patients/staff participating in your study
- Research is conducted during normal working hours
- The hospital receives a copy of your research on completion.

Yours faithfully

HOSPITAL CEO

Sylvester Chima - FW: Request for Permission to conduct a Questionnaire based research study at Clairwood Hospital

From: "Dorasamy Dayalan" <dayalan.dorasamy@kznhealth.gov.za>
To: <Chima@ukzn.ac.za>
Date: 2012/02/27 12:31 PM
Subject: FW: Request for Permission to conduct a Questionnaire based research study at Clairwood Hospital
CC: "Naidoo Cookie" <Naidoo.Cookie@kznhealth.gov.za>

From: Dorasamy Dayalan
Sent: 27 February 2012 12:29 PM
To: Naidoo Cookie
Subject: RE: Request for Permission to conduct a Questionnaire based research study at Clairwood Hospital

[Faint, illegible text]

From: Naidoo Cookie
Sent: 27 February 2012 11:31 AM
To: Dorasamy Dayalan
Subject: FW: Request for Permission to conduct a Questionnaire based research study at Clairwood Hospital

From: Sylvester Chima <mailto:Sylvester.Chima@ukzn.ac.za>
Sent: 21 February 2012 11:27 AM
To: Gwala Njabulo
Cc: Naidoo Cookie
Subject: Re: Request for Permission to conduct a Questionnaire based research study at Clairwood Hospital

Dear Dr Gwala:
I would like to obtain your permission/ approval to conduct a Questionnaire based research study amongst Doctors, Professional nurses and some patients at Clairwood Hospital Durban. This is part of a doctoral qualification in Medical Jurisprudence from UNISA. The title of this study is **"An investigation of informed Consent in Clinical Practice in South Africa."**

We are conducting the study in 14 randomly selected private and public hospitals in Ethekwini Municipality (Durban). The project has been approved by the Research Ethics Committee at UNISA, KZN-DOH and is supported Ethekwini DOH District Manager's office

Please find attached supporting documents for the proposed research study at your institution.
Enclosed:

1. Research Proposal and Protocol
2. Approval letter from UNISA Research Ethics Committee
3. Letter of support from Ethekwini Hospitals District Manager
4. Letter of Approval from KZN-DOH
5. Informed consent document with IsiZulu translation for patients.
6. Sample questionnaires with IsiZulu translation for patients



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

OFFICE OF THE HOSPITAL CEO

KING EDWARD VIII REGIONAL HOSPITAL
Private Bag X02, CONGELLA, 4013
Corner of Rick Turner & Sydney Road
Tel.031-3603853/3015; Fax.031-2061457:
Email.rejoice.khuzwayo@kznhealth.gov.za:
www.kznhealth.gov.za

Ref.: KE 2/7/1/ (01/2012)
Enq.: Mrs. R. Sibiya
Research Programming

7 February 2012

Prof. S. Chima
6 Sunset View
449 Queen Elizabeth Avenue
Manor Gardens
DURBAN
4001

Dear Prof. Chima

Protocol : " An Investigation of Informed Consent in Clinical Practice in South Africa"

Permission to conduct research at King Edward VIII Hospital has been approved.

Kindly note the following:-

- Signing of an indemnity form at Room 8, CEO Complex before commencement with your study.
- King Edward VIII Hospital received full acknowledgment in the study on all Publications and reports and also kindly present a copy of the publication or report on completion.

The Management of King Edward VIII Hospital reserves the right to terminate the permission for the study should circumstances so dictate.

Yours faithfully

SUPPORTED / NOT SUPPORTED



DR. O.S.B. BALOYI
ACTING CEO & SENIOR MEDICAL MANAGER



DATE

uMnyango Wezempilo , Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope



Department
Health
PROVINCE OF KWAZULU-NATAL

OFFICE OF THE CHIEF EXECUTIVE OFFICER
OSINDISWENI HOSPITAL
Private Bag X15, Verulam, 4340

Tel: 032-5419201 Fax: 032-5410340
Email: Ntomphele.Ngcobo@kznhealth.gov.za
website: www.kznhealth.gov.za/osindiswenihospital.htm

ENQUIRIES: MRS NP NGCOBO

DATE: 20 April 2012

Sylvester C Chima
MD LL.M
Associate Professor and Head
Programme of BioResearch Ethics and Medical Law
College of Health Sciences
University of KZN

RE: REQUEST FOR PERMISSION TO CONDUCT A QUESTIONNAIRE BASED RESEARCH STUDY AT
OSINDISWENI HOSPITAL

The above matter and your correspondence dated 18/04/2012 bears reference.

Permission is hereby granted for you to conduct a questionnaire based research study at this institution.

Thank you

Mrs NP Ngcobo
Chief Executive Officer
/npr



ADDINGTON HOSPITAL
OFFICE OF THE HOSPITAL MANAGER
Postal Address: P.O. Box 977, DURBAN, 4000
Physical Address: 18 Erskine Terrace, South Beach
Tel.: (031) 327-2970, Fax.: (031) 368-3300
Email: addington.management@kznhealth.gov.za
www.kznhealth.gov.za

AD/9/2/3/R

Enquiries: Dr R N Mokoena
Extension: 2970/2568

27th February 2012

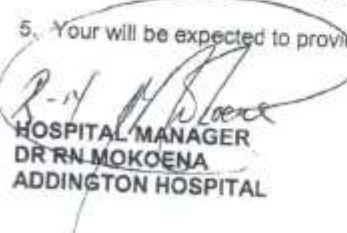
Principal Investigators:
> Prof. S C Chima

PERMISSION TO CONDUCT RESEARCH AT ADDINGTON HOSPITAL: "AN INVESTIGATION OF INFORMED CONSENT IN CLINICAL PRACTICE IN SOUTH AFRICA"

I have pleasure in informing you that permission has been granted to you by Addington Management to conduct research on "An investigation of informed consent in clinical practice in South Africa"

Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Please ensure this office is informed before you commence your research.
4. Addington Hospital will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to Addington Hospital.


HOSPITAL MANAGER
DR RN MOKOENA
ADDINGTON HOSPITAL

uMnyango Wazempilo . Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope

Appendices

Appendix 1

Questionnaire for Healthcare professionals (doctors and professional nurses)

SECTION A DEMOGRAPHICS

1. Age of the Respondent: _____
2. Gender
 Male Female
3. Are you a doctor or a professional nurse? _____
4. Years of professional experience or rank _____
5. Area of specialization, please state _____
6. Department in the hospital _____
7. Public or Private Practice _____

SECTION B

8. How many patients do you see on average in a day?

9. How much time do you spend giving information about a treatment or procedure in to a patient during a professional encounter?
 < 5 minutes 5-10 mins
 10-20 mins 20-30 mins
 > 30 mins None
10. Do you think this amount of time is sufficient?
 Yes No Don't know
11. If No, Please explain why? _____

12. Do you think the information you provide is sufficient to procure valid informed consent?
 Yes No Don't know
13. Do you think the consent form currently used in your hospital is adequate to obtain valid informed consent from patients?
 Yes No Don't know
If No, please explain why _____

14. What information do you routinely provide to your patients? Please tick or circle all that apply

- Diagnosis Y or N
- Treatment Options Y or N
- Recommended Treatment Y or N
- Risks of refusing recommended treatment Y or N
- Costs of medical treatment or each option Y or N
- Risks Y or N
- Benefits Y or N
- Right of refusal Y or N

Any additional information? (Please specify) _____

15. Do you allow your patients to choose a procedure or particular treatment?
 Yes No Don't know

16. Do you explain the benefits of the procedure to the patient?
 Yes No Don't know

17. Do you explain the risks of the procedure to the patient?
 Yes No Don't know

18. If yes, what types of risks do you routinely explain to the patient?

- A. Most common risks Yes No Don't Know
- B. Most serious risks Yes No Don't Know
- C. All material risks Yes No Don't Know

19. What language do you use to explain/obtain informed consent from your patients?

- A. English Yes No Don't know
- B. The patients local language Yes No Don't know
- C. Both English and local language Yes No Don't know

20. Which of the following methods do you use to explain/obtain consent from patients? Please tick all that apply.

- Words Diagrams
- Pictures Interpreter
- None

21. Do you think your patients understand the explanations given to them?
 Yes No Don't know Don't think so

22. Do you routinely obtain consent in emergency cases?

Yes No Don't know It depends

If you choose it depends, please explain_____

23. How do the patients normally provide consent?

Verbally Written Both It depends

If you choose it depends, please explain_____

24. Who obtains informed consent from patients in your practice or clinic?

- A. Nurses
- B. Junior doctors
- C. The doctor performing the procedure/treating the patient
- D. Any available healthcare professional
- E. Don't know

25. What are the challenges you face in the process of obtaining informed consent from a patients in clinical practice?

Please rank in order of importance (where 1 is most important and 7 is least important):

- A. Time constraints ()
- B. Work load ()
- C. Language difficulties ()
- D. Lack of administrative support e. g. interpreters ()
- E. Cultural barriers (). Please specify_____
- F. Lack of education ()
- G. Medical paternalism (Doctor knows best) ()

26. Do you routinely assess the competence of your patients to consent to treatment?

Yes No Don't know

27. If Yes please rank the following criteria in terms of importance in assessing patient capacity or competence to consent to treatment (where 1 is most important and 5 is least important):

- A. Age ()
- B. Sex ()
- C. Appearance ()
- D. Educational level ()
- E. Level of consciousness ()

28. Do you generally presume that your patients have the capacity to consent to medical treatment?

Yes No Don't Know

29. In difficult cases, which of the following methods do you/ would you use determine if a patient has the capacity to consent to treatment (Please rank in order of importance where 1 is most important and 6 is least important)

- A. Mental Status Exam () Please specify which one _____
- B. Psychiatric consultation ()
- C. Ethics consultation ()
- D. Court adjudication ()
- E. Surrogates () Please specify _____
- F. None of the above ()

Section C- Generic questions on informed consent

30. Do you have any suggestions or recommendations regarding informed consent?

31. At what age can a minor consent to routine medical treatment in South Africa?
(Please choose one)

- 12 years () 15 years () 18 years () 21 years () Don't know ()

32. At what age can a woman request for termination of pregnancy in South Africa?
(Please choose one)

- 12 years () 15 years () 18 years () Any age () Don't know ()

33. In your opinion, which standard do you think should be used for information disclosure before obtaining consent from patients?

- A. Based on a reasonable doctor standard () Yes () No () Don't know
- B. Based a reasonable/prudent patient standard () Yes () No () Don't know

34. Whose responsibility is it to ensure adequate information disclosure before informed consent?

- A. () Doctor or healthcare professionals responsibility
- B. () The patients responsibility
- C. () The patient and healthcare professional are jointly responsible

Section D:

35. Do you ever use implied or presumed consent when treating patients? () Yes or () No

If yes, when do you usually use implied or presumed consent?

- A. When the patient present themselves at the Clinic () Yes () No () I don't know
 B. When the patient is admitted to the Ward () Yes () No () I don't know
 C. In an emergency () Yes () No () I don't know

36. What do understand by the term implied or presumed consent?

Implied consent:

Presumed consent:

37. How often do you use implied or presumed consent when treating patients?

- A. Some of the time or Occasionally ()
 B. All of the time ()
 C. Seldom or Rarely ()
 D. Never ()

38. Do obtain any additional or specific consent for certain procedures? () Yes () No
 If yes, please list all or any procedures for which you would obtain specific consent from the patient:

Thank you for your assistance

11. How much do you earn in a month:

- No earnings
- Less than ZAR 1000
- Between ZAR1001- 3000
- Between ZAR 3001- 5000
- between ZAR 5001- ZAR 10,000
- Over ZAR 10000
- Don't know/Refuse to disclose

Section B – Questions on Consent to treatment

12. Name of the Department in which you are admitted or receiving treatment:

- Surgical
- Paediatric
- Obstetrics & Gynaecology
- Medical (Internal Medicine)
- Psychiatry

13. Did the doctor or nurse explain the treatment/ medical procedure to you?

- Yes
- No
- I do not remember

14. Please tell us the information that was provided to you?

- Diagnosis Y or N
- Treatment Options Y or N
- Recommended Treatment Y or N
- Risks of refusing recommended treatment Y or N
- Risks Y or N
- Benefits Y or N
- Right of refusal Y or N

Any additional information (please specify) _____

15. How much time did the doctor or nurse take to explain the procedure or treatment?

- < 5 minutes
- 5-10 minutes
- 10-20 minutes
- 20-30 minutes
- > 30 minutes
- None

16. In what language was information on the treatment or procedure provided?

- English
- IsiZulu
- IsiXhosa
- Afrikaans
- More than one language. Please specify _____
- Other, specify _____

17. Did the doctor or nurse explain the treatment that he/she would provide?

- Yes
- No
- I do not remember

18. Which of the following methods did the doctor use to explain the treatment? Please tick.

- Words Diagrams
 Pictures Interpreter
 None

19. Did you understand the information provided?

- Yes No I do not remember

20. Did you ask any questions concerning the treatment or procedure?

- Yes No I do not remember

If No, Why not? _____

21. If you had had a choice would you like to know all the risks or some of the risks involved in the treatment or procedure?

- Yes, I would like to know all the risks, No, I would not like to know the risks
 I would like to know only some of the risks Don't know

22. Please explain your choice _____

23. Were you advised that you could accept or reject the treatment or procedure?

- Yes No Don't remember

24. Did you seek assistance in reaching a decision whether to accept or reject the treatment or procedure?

- Yes No Don't remember

25. If yes, why did you seek assistance?

26. Please specify from whom you sought assistance from

- Parent Child
 Husband Wife
 Family member Friend
 Other, specify _____

27. Did you make your choice of your own free will?

- Yes No Don't Remember

28. If **No**, Please explain _____

29. Do you think the amount of information provided to you was enough to enable you to make an informed choice?

Yes No Don't know

30. Did you feel threatened or afraid to say no?

Yes No Don't Remember

If yes, please explain _____

31. Were you offered an incentive or persuaded to accept any particular treatment?

Yes No Don't remember

If yes, please explain _____

32. How did you give consent?

Verbally Written Don't remember

Section C- Generic questions on informed consent

33. Do you have any suggestions or recommendations regarding informed consent?

34. At what age can a minor (young person) consent to routine medical treatment in South Africa? (Please choose one)

12 years () 15 years () 18 years () 21 years () Don't know ()

35. Finally, if you do not like the treatment that a doctor or nurse is providing to you or your child, or if you think it is not working for you. Can you change your mind or refuse the treatment at any time?

Yes No Don't know

If **No**, Please tell us why? _____

Appendix 3 – Questionnaire for patients as translated into IsiZulu

Uhlu lwemibuzo lweziguli

1. Amagama obuzayo: _____

Usuku Lwengxoxo: _____

Isigaba A- Imininingwane ngezakhamizi emphakathini

2. Ubudala balona obuzwayo: _____

3. Ubudlelwane nesiguli:

Wena uqobo

Okugadile

Umzali

Okunye, Sicela uchaze.....

4. Ubulili

Owesilisa

Owesifazane

5. Isimo somshado/songashadile

Ushadile

Awushadile

Udivosile

Wehlukanisile

Umfelokazi

6. Isimo sezingane:

Uyintandane

Uhlala nabazali

Uhlala wedwa

7. Izilimi ozikhulumayo:

ISingisi

IsiZulu

IsiXhosa

ISibhunu

Okunye, Sicela uchaze _____

9. Izinga lemfundo

Ayikho

Eyamabanga aphansi

Eyamabanga aphezulu

Eyesikhungo semfundo ephakeme

10. Umsebenzi

Awusebenzi

Uyazisebenza

Uqashiwe

Okunye– Sicela uchaze _____

11. Uhola malini ngenyanga:

- Angiholi lutho
- Ngaphansi kwa ZAR 1000
- Phakathi kwa ZAR1001- 3000
- Phakathi kwa ZAR 3001- 5000
- Phakathi kwa ZAR 5001- ZAR 10,000
- Ngaphezu kuka ZAR 10000
- Angazi/Angifuni ukukuveza

Section B – Imibuzo mayelana ngokuvumelana ngokulashwa

12. Igama loMnyango lapho ulaliswe khona noma lapho uthola khona ukwelashwa:

- Egunjini lokuhlinza/lokuhlinzwa
- E-Paediatic
- E-Obstetrics & Gynaecology
- E-Medical (Internal Medicine)
- E-Psychiatry (Egunjini labagula ngokwengqondo)

13. Kungabe udokotela noma unesi uluchazile uhlobo lokwelashwa/okuzokwenzeka kuwena?

- Yebo Cha Angisakhumbuli

14. Sicela usitshela ulwazi onikezwe lona?

- Ukuhlolwa Yebo noma Cha Izingozi Yebo noma Cha
- Ukwelashwa ongakhetha kuko Yebo noma Cha Imihlomulo Yebo noma Cha
- Ukwelashwa okuphakanyiswayo Yebo noma Cha Ilungelo lokunqaba Yebo noma Cha
- Izingozi zokwenqaba ukwelashwa okuphakanyisiwe Yebo noma Cha

Olunye ulwazi (Sicela uchaze) _____

36. Uthathe isikhathi esingakanani udokotela noma unesi ukuchaza okuzokwenzeka noma ukwelashwa?

- ngaphansi kwa 5wamaminithi phakathi kwa 5-10wamaminithi
- phakathi kwa 10-20wamaminithi phakathi kwa 20-30 wamaminithi
- ngaphezu kuka 30wamaminithi Lutho

37. Kungabe ulwazi ngokwelashwa noma okuzokwenzeka kudluliswe ngaluphi ulimi?

- ISingisi
- IsiZulu

- () IsiXhosa
() ISibhunu
() Ngaphezu kolimi olulodwa. Sicela uchaze_____

38. Kungabe udokotela noma unesi uchazile ukwelashwa azokunika kona ?
() Yebo () Cha () Angikhumbuli

39. Eyiphi kulezi ezingezansi izindlela esetshenziswe udokotela ukuchaza ukwelashwa.? Beka uphawu.

- () Amagama () Imidwebo
() Izithombe () Utolika
() akukho lutho

40. Bewuluqonda ulwazi onikezwa lona?

- () Yebo () Cha () Angisakhumbuli

41. Kungabe uyibuzile imibuzo mayelana nokwelashwa noma okuzokwenzeka?

- () Yebo () Cha () Angikhumbuli

Uma uphika, kungani ungabuzanga?

42. Uma bewungakhetha, bewungathanda ukwazi ngazo zonke izingozi noma ezinye zezingozi ezikhona ekulashweni kwakho noma kokuzokwenzeka?

() Yebo, ngingathanda ukwazi zonke izingozi, () Cha, ngeke ngathanda ukwazi ngezingozi

- () Ngingathanda ukwazi ngezinye zezingozi () Angazi

43. Chaza ngempendulo oyikhethile

44. Kungabe welulekiwe ngokuthi ungakuvuma noma ukwenqabe ukwelashwa noma okuzokwenzeka?

- () Yebo () Cha () Angikhumbuli

45. Kungabe ulucelile usizo ekuthatheni isinqumo ukuthi kufanele uvume noma wenqabe ukwelashwa noma okuzokwenzeka ?

- () Yebo () Cha () Angikhumbuli

46. Uma uvuma, uluceleleni usizo?

12weminyaka () 15weminyaka () 18 weminyaka () 21 weminyaka ()
Angazi ()

35. Okokugcina, uma ungakuthandi ukwelashwa okunikwa wudokotela noma unesi elapha ingane yakho, noma ucabanga ukuthi akukusebenzeli. Ungawushintsha umqondo noma wenqabe ukwelashwa noma yinini?

() Yebo

() Cha

() Angazi

Chaza ukuthi kungani uma uphika?

**APPLICATION FOR ETHICS APPROVAL
For research with human participants (Biomedical)**

INFORMED CONSENT DOCUMENT

Information Sheet and Consent to participate in a Research Study entitled:

“An Investigation of Informed Consent in Clinical Practice in South Africa”

Date: 24 March 2011

My name is Prof Sylvester Chima from the Programme of Bio & Research Ethics and Medical Law, Nelson R Mandela School of Medicine, University of KwaZulu-Natal (UKZN) (chima@ukzn.ac.za, 031 2604604). I am also an LLD (Doctor of Laws) candidate at the School of Law, University of South Africa (UNISA).

You are being invited to consider participating in a study that involves assessing whether patients and healthcare professionals (doctors and nurses) understand and apply the ethical principles of informed consent, and comply with the requirements of the law on informed consent during medical practice in South Africa. The study is expected to enrol a maximum of 1118 participants in total (360 doctors, 373 nurses and 385 patients). The study will be conducted amongst doctors, nurses and patients at randomly selected provincial and private hospitals in eThekweni metropolitan municipality (Durban), Kwazulu-Natal province (KZN). The study will involve self-completion of a questionnaire by doctors and professional nurses and interview of patients based on a questionnaire. It is anticipated that the duration of your participation if you choose to participate will not exceed 30 minutes to 1 hour.

There will be no risk or discomfort to you from participating except perhaps the time taken to complete the questionnaire. If you choose to participate in this study, the data from the questionnaire will be analyzed and reported anonymously so that there will be no individually identifiable information included in the final report or publications.

Ethical clearance, Authorization from KZN Department of Health, and Informed consent

This study has been ethically reviewed and approved by the UNISA Research Ethics Review Committee (URERC) (approval number_____). Authorization has been obtained from KZN Department of Health (DOH) to conduct the study and permission has been obtained from the Hospital Management to conduct the study at this hospital. Each respondent will be asked to provide written informed consent. The documents describing the study and requesting the patient's participation have also been translated into isiZulu, in order to obtain written informed consent from each patient.

In the event of any problems or concerns/questions you may contact the researcher at chima@ukzn.ac.za or by telephone at 031-260-4604. You may also contact the URERC at UNISA through Professor MN Slabbert, Chair of URERC at UNISA as follows:

UNISA RESEARCH ETHICS REVIEW COMMITTEE (URERC)

C/O Professor MN Slabbert

Contact Info

Tel: + 27 12 429-8305

Fax: + 27 12 429-3442

Email: slabbn@unisa.ac.za

Department of Jurisprudence

School of Law

University of South Africa

P.O. Box 392

UNISA

0003

South Africa

Participation in this research is voluntary and you may withdraw at any point. In the event of refusal/withdrawal of participation you will not incur penalty or loss of treatment or other benefit to which they are normally entitled. There are no potential consequences to you for withdrawal from the study.

No costs will be incurred by you as a result of participation in this study. There is no incentive or direct benefit to you for participating in the study. However indirect benefits may occur in that the findings of the study may be used to improve the quality of informed consent and medical practice in South Africa. The researcher may derive a benefit in the award of an academic qualification from UNISA through completion of a thesis and the results will be published in scientific journals or a book. However, your confidentiality will be protected as any publications will not include any individually identifiable information.

CONSENT

If you agree to voluntarily participate in this research project as described, please indicate your agreement by signing this consent form. Please retain this consent cover form for your reference.

_____ (Name) have been informed about the study entitled: "*An Investigation of Informed consent in Clinical Practice in South Africa*" by Sylvester Chidi Chima

I understand the purpose and procedures of the study.

I have been given an opportunity to ask questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any treatment or care that I would usually be entitled to.

I have been informed about the risks and benefits of the study.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at chima@ukzn.ac.za or by phone at 031-260-4604

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

UNISA URERC

C/ O Professor MN Slabbert

Contact Info

Tel: + 27 12 429-8305

Fax: + 27 12 429-3442

Email: slabbn@unisa.ac.za

Department of Jurisprudence

School of Law

University of South Africa

P.O. Box 392

UNISA

0003

South Africa

Signature of Participant

Date

Appendix 5- Informed consent document for surrogates

**APPLICATION FOR ETHICS APPROVAL
For research with human participants (Biomedical)**

INFORMED CONSENT DOCUMENT

**Protocol for Parental/Guardian Informed Consent
Form for Minor Child or Dependent**

Information Sheet and Consent to participate in a Research Study entitled:

“An Investigation of Informed Consent in Clinical Practice in South Africa”

Date: 24 March 2011

My name is Prof Sylvester Chima from the Programme of Bio & Research Ethics and Medical Law, Nelson R Mandela School of Medicine, University of KwaZulu-Natal (UKZN) (chima@ukzn.ac.za, 031 2604604). I am also an LLD (Doctor of Laws) candidate at the School of Law, University of South Africa (UNISA).

Your child/children is/are being invited to consider participating in a study that involves assessing whether patients and healthcare professionals (doctors and nurses) understand and apply the ethical principles of informed consent, and comply with the requirements of the law on informed consent during medical practice in South Africa. The study is expected to enrol a minimum of 1118 participants in total (360 doctors, 373 nurses and 385 patients). The study will be conducted amongst doctors, nurses and patients at randomly selected provincial and private hospitals in eThekweni metropolitan municipality (Durban), Kwazulu-Natal province (KZN). The study will involve self-completion of a questionnaire by doctors and professional nurses and interview of patients based on a questionnaire. It is anticipated that the duration of you and your child/children's participation will not exceed 30 minutes to 1 hour.

There will be no risk or discomfort to you or your child/children from participating except perhaps the time taken to complete the questionnaire. If you choose to participate in this study, the data from the questionnaire will be analyzed and reported anonymously so that there will be no individually identifiable information included in the final report or publications.

Ethical clearance, Authorization from KZN Department of Health, and Informed consent

This study has been ethically reviewed and approved by the UNISA Research Ethics Review Committee (URERC) (approval number_____). Authorization has been obtained from KZN Department of Health (DOH) to conduct the study, and permission has also been obtained from the Hospital Management to conduct the study at this hospital. Each respondent/participant will be asked to provide written informed consent. The documents

describing the study and requesting the patient's participation have also been translated into isiZulu, in order to obtain written informed consent from each patient.

In the event of any problems or concerns/questions you may contact the researcher at chima@ukzn.ac.za or by telephone at 031-260-4604. You may also contact the URERC at UNISA through Professor MN Slabbert, Chair of URERC at UNISA as follows:

UNISA RESEARCH ETHICS REVIEW COMMITTEE (URERC)
UNISA URERC

C/ O Professor MN Slabbert

Contact Info

Contact Info

Tel: + 27 12 429-8305

Fax: + 27 12 429-3442

Email: slabbn@unisa.ac.za

Department of Jurisprudence

School of Law

University of South Africa

P.O. Box 392

UNISA

0003

South Africa

Signature of Parent/Guardian

Date

Signature/Assent of minor child

Date

Participation in this research is voluntary and your child/children may withdraw at any point. In the event of refusal/withdrawal of participation you will not incur penalty or loss of treatment or other benefit to which they are normally entitled. There are no potential consequences to you for withdrawal from the study.

No costs will be incurred by you as a result of participation in this study. There is no incentive or direct benefit to you for participating in the study. However indirect benefits may occur in that the findings of the study may be used to improve the quality of informed consent and medical practice in South Africa. The researcher may derive a benefit in the award of an academic qualification from UNISA through completion of a thesis and the results will be published in scientific journals or a book. However, your confidentiality will be protected as any publications will not include any individually identifiable information.

CONSENT

If you agree for your child/children to voluntarily participate in this research project as described, please indicate your agreement by signing this consent form. Please retain this consent cover form for your reference.

_____ (Name) have been informed about the study entitled: "*An Investigation of Informed consent in Clinical Practice in South Africa*" by Sylvester Chidi Chima

I understand the purpose and procedures of the study.

I have been given an opportunity to ask questions about the study and have had answers to my satisfaction.

I declare that my child/children's participation in this study is entirely voluntary and that they may withdraw at any time without affecting any treatment or care that they would usually be entitled to.

I have been informed about the risks and benefits of the study.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at chima@ukzn.ac.za or by phone at 031-260-4604

If I have any questions or concerns about my child/children's rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

UNISA URERC
UNISA URERC

C/ O Professor MN Slabbert

Contact Info

Tel: + 27 12 429-8305

Fax: + 27 12 429-3442

Email: slabbmn@unisa.ac.za

Department of Jurisprudence

School of Law

University of South Africa

P.O. Box 392

UNISA

0003

South Africa

Signature of Parent/Guardian

Date

Signature/Assent of minor child

Date

Appendix 6

Appendix 6

List of Provincial and Private Hospitals in eThekweni Metropolitan Municipality
KwaZulu-Natal Province, South Africa

Provincial Hospitals-eThekweni (Durban)

A

- Addington Hospital

C

- Charles James Hospital
- Clairwood Hospital

D

- Don McKenzie Hospital

E

- Ekuhlengeni Psychiatric Hospital

F

- FOSA TB Hospital

H

- Hillcrest Hospital

I

- Inkosi Albert Luthuli Central Hospital

K

- King Edward VIII Hospital

- King George V Hospital

M

- Mahatma Gandhi Hospital

O

- Osindisweni Hospital

P

- Prince Mshiyeni Memorial Hospital

R

- R K Khan Hospital

S

- St Mary's Mission Hospital

W

- Wentworth Hospital

**COLLEGE OF LAW
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5 April 2011

Prof S Chima
6 Sunset View
449 Queen Elizabeth Avenue
Manor Gardens
DURBAN
4001

Dear Prof Chima

**REQUEST FOR ETHICAL CLEARANCE: AN INVESTIGATION OF
INFORMED CONSENT IN CLINICAL PRACTICE IN SOUTH AFRICA**

Your application for ethical clearance of the above study was considered by the College of Law Sub-Ethics Review Committee on 1 April 2011. The Committee is pleased to inform you that ethical clearance has been granted for this study as set out in your application.

We trust that sampling and processing of the relevant data will be undertaken in a manner that is respectful of the rights and integrity of participants, as stipulated in the Unisa Research Ethics Policy, which can be found at the following website:

http://www.unisa.ac.za/contents/research/docs/ResearchEthicsPolicy_apprvCounc_21Sept07.pdf

Congratulations on an interesting and very relevant study. We would like to wish you well in this research undertaking.

Kind regards



**PROF MN SLABBERT
CHAIR: COLLEGE OF LAW SUB-ETHICS REVIEW COMMITTEE**

