CAN INFORMED CONSENT EVER BE FULLY INFORMED?

A REVIEW OF KNOWLEDGE AS AN INTEGRAL PREREQUISITE OF LAWFUL CONSENT

by

EUGENE BALESENG MALEFAHLO

u10059025

Submitted in partial fulfilment of the requirements for the degree of

MPhil in Medical Law and Ethics

In the

FACULTY OF LAW

UNIVERSITY OF PRETORIA

Prepared under the supervision of

PROF A NIENABER

OCTOBER 2018

Dedications

To Malefahlo, Mareketle Sophinah

At every moment, I am loving you.

Acknowledgments

I extend my greatest gratitude to Professor A Nienaber, for your invaluable guidance throughout the processes of this study.

Declaration

1. I understand what plagiarism is and am aware of the University's policy in this regard.

2. I declare that this dissertation is my own original work. Where other people's work has been used (either from a printed source, internet or any other source), this has been properly acknowledged and referenced in accordance with the departmental requirements.

3. I have not used work previously produced by another student or any other person to hand in as my own.

4. I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.

SIGNATURE:

Abstract

This study explores the doctrine of informed consent and its application in South African medical law. The advent of the Constitution of the Republic of South Africa, 1996, introduced democracy and human rights, specifically the rights to human dignity, privacy, and freedom and security of the person, amongst others. As a result of a recognition of these rights, together with corresponding changes in the doctor-patient relationship which increasingly leans towards the patient as a consumer of medical services, consent has become a significant part of the doctor-patient relationship.

It is unequivocally stated in South African legislation that consent is a prerequisite for the provision of health care services; however, the application of this is not clear, specifically the extent of the disclosure of information that is needed and the duty placed on the doctor to provide information.

The study, therefore, explores relevant authority concerning informed consent and the standards of disclosure in South African law and reviews, in particular court precedent on knowledge as a prerequisite to lawful consent. The study aims to discuss the question whether consent can ever be fully informed, and if the foregoing is possible, whether this is possible in a South African context.

Key words: Informed consent; knowledge requirement; doctor-patient relationship

Table of Contents

CHAPTER ONE

INTRODUCTION

1. Chapter overview

The premier chapter of this study contains the introductory notes to the study. The chapter outlines the purpose, aims and objects of the study. In addition, the concept of the doctrine of informed consent is introduced, noting the particular attention that the doctrine has received in the past half-century. The interest and the resultant discussions on the doctrine followed, in particular, the developments after World War II, which included a renewed focus on individual human rights, personal rights, and the promotion of autonomy and self-determination in as far as the provision of health care is concerned. The shift in approach from medical paternalism to patient autonomy is referenced in the chapter. Informed consent (in particular, the aspects of knowledge and the provision of information) as a requirement of lawful consent prior to the provision of surgical and medical treatments became, and continues to be (as we shall see in the study) a topic of lengthy discussion.

The study assumes the form of a desk-top literature review, focusing specifically on knowledge as a prerequisite of lawful consent. The study explores aspects of this prerequisite, including the concepts of disclosure and its standards and the concept of material risk. In addition, it explores informed consent with specific reference to South African law, including available primary sources of authority (inclusive of legislation and case law) as well as the opinions and writings by South African law commentators.

The purpose relates to the study title, that is, to answer the question whether informed consent can ever be fully informed. In an attempt to arrive at a comprehensive answer to the question above, the study reviews the ethical and legal bases for the doctrine of informed consent, including the duty placed on health-care practitioners to disclose information. The study correspondingly explores the nature, content and the extent of the information to be disclosed and deliberates on the

repercussions for failing to disclose pertinent risks and benefits in the prescribed manner. Therefore, the purpose of the study is achieved through the proposed aims and objects as listed at paragraph 4 below. Furthermore, in chapter 1 the study outlines the methods, limitations and the sources of literature at paragraph 5 below.

2. Background

Over the past fifty years, the doctrine of informed consent has received increased attention globally in medical ethics and medical law. Professor F Van Oosten[1] notes that informed consent has received specific attention only in recent years. However, Professor further adds that there exists ample Roman and Roman-Dutch law authority on consent to medical intervention as such and, in particular, the aspects of information and knowledge as requisites for consent. Van Oosten therefore advances the idea that informed consent as a prerequisite for lawful medical intervention is by no means a new phenomenon.[2]

The increased attention paid to the doctrine of informed consent has followed in particular international declarations after World War II, including the Universal Declaration of Human Rights[3] and the Nuremberg Code,[4] amongst others.[5] It also

---

1 Van Oosten F *The doctrine of informed consent in medical law* 11.

2 Van Oosten (n 1 above) 11. Van Oosten writes that informed consent had made its official entry into the German-medical scene as early as a century ago, he further adds the following regarding the history of informed consent: "The earliest case that could be traced in which the matter [informed consent] was touched upon, dates back to 1899 and the first case that specifically turned upon the issue, dates back to 1912."

3 A declaration adopted by the United Nations on 10 December 1945. As per the preamble, the Declaration recognises inherent dignity and equal and inalienable rights of all humans as the foundation of freedom, justice and world peace. The Declaration constitutes of 30 articles which articulate the rights and freedoms to which every human being is equally and inalienably entitled. Universal Declaration of Human Rights at http://www.un.org/en/universal-declaration-human-rights/ (accessed 1 October 2018).

4 The Nuremburg Medical Trials were a wide-ranging review into the atrocities by Nazi Germany during the Second World War, where humans were abused in the name of scientific research. The trials ran for the period December 1946 to August 1947 in the city of Nuremberg in Germany. See Weindling PJ *Nazi medicine and the Nuremberg trials, from medical war crimes to informed consent* 1. These developments include also the Declaration of Helsinki.

followed the general recognition and promotion of individual rights, including the right to human dignity, and human dignity as a value.[6] In addition to human dignity, the period after World War II brought about a renewed interest in individual autonomy in particular.[7] Another aspect that bore a close relationship to human dignity was the appreciation of other personality rights, including the right to freedom, which in turn includes the right to *self-determination,* that is, the 'exercising of one's will and the living out of oneself'.[8] These developments preceded the discussion on the doctrine of informed consent.

In the medical field, a shift occurred from the traditional Hippocratic belief in medical paternalism to the promotion of the autonomous person.[9] The new approach regarded the person as a rational agent, capable of deliberating and making informed choices, which would accord with their own beliefs and their own ideas of what is in their best interest.[10] The shift gave way to patient autonomy, in which the patient became 'the master of his own body and health' and could exercise their human right to choose whether to undergo or forfeit a medical intervention.[11] It is on this renewed approach and on the aforementioned regard that the basis for the doctrine of informed consent lies. A number of legal scholars propose that in addition to its promotion of respect for patient dignity and autonomy, informed consent engenders a fertile, fiduciary relationship between the patient and the health-care

---

5 Dhai A "An introduction to Informed consent: Ethico-legal requirements" (2008) *SADJ* 18-20 and Van Oosten (n 1 above) 12, both attribute the recent attention on the doctrine of informed consent to the Universal Declaration of Human Rights and the Nuremberg Trials.

6 Ackermann L *Human dignity: Lodestar for equality in South Africa* 86-113. Ackermann proposes that the human dignity of each and every individual should be viewed as both the capacity for and the right to respect as a human being, and ascribes human dignity as being the aspect that personalises human beings, as contrasted to the impersonality of nature. Ackermann J further adds at 86 that: "[human dignity] enables them [human beings] to exercise their own judgement, to have self-awareness and a sense of self-worth, to exercise self-determination, to shape themselves and nature, to develop their personalities and to strive for self-fulfilment in their lives…"

7 Van Oosten F *The doctrine of informed consent in medical law* 11.

8 Ackermann (n 6 above) 86-113.

9 Dhai (n 5 above) 18-20.

10 Dhai (n 5 above) 18-20.

11 Van Oosten (n 1 above) 13.

practitioner.[12] More authors, including van Oosten and Carstens and Pearmain, note a similar opinion that, generally-speaking, informed consent is essential to establish a proper doctor-patient relationship.[13]

Van Oosten ascribes additional developments to this shift in approach from traditional medical paternalism, to the favouring of the patient-autonomy-centred approach. He includes advances in modern technology and organisational developments in medical care, and a 'distinct psychological change' in the doctor-patient relationship as contributors.[14] Current discussions on the doctrine of informed consent have also been exacerbated by the currently increasing pandemic of medical litigation cases around the world and, in particular, in developed countries. Linked once again to legislative provisions in the past two decades, which were prompted by the rising recognition and protection of human rights, patients were entitled to institute claims against health-care practitioners and health-care service providers. Law suits are instituted against health-care practitioners for a number of reasons, including a lack of communication between patients and health-care practitioners.[15]

---

12 Dhai (n 5 above) 20.

13 See van Oosten (n 1 above) 31. See also Carstens P and Pearmain D *Foundational principles of South African medical law* (2007) 877. Carstens and Pearmain write that informed consent forms the core of the patient-doctor relationship. They further write that: "It [informed consent] represents, as it were, the beginning of either an amicable and harmonious encounter between patient and doctor…or an acrimonious relationship with the potential for litigation…"

14 Van Oosten (n 1 above) 12, writes about the distinct psychological change in the doctor-patient relationship, and states that it has: "…to a large extent, brought an end to the old-world mysticism and magic of doctors and medicine, with their inevitable authoritarian aura, and came forth with a far more professionalised and consumer-orientated medical-care dispensation in terms of which doctor and patient have become equal partners." His assessment is shared by Kennedy and Grubb, who also note the contemporary trends, including the recent changes in health-care practices and broader societal changes to "contemporary American life," as well as the technological approach to medicine (noted by the writers to be perhaps the most significant factor) as developments that promoted the change in approach to medicine. See also Kennedy I and Grubb A *Medical law: Text and materials* United Kingdom (1989) 230.

15 Pienaar L "Investigating the reasons behind the increase in medical negligence claims" (2006) *PER/ PELJ* 1.

Pertaining to South Africa, van Oosten writes that generally ample authority exits for the statement that a patient's consent is needed prior to medical intervention.[16] His assessment proves to be a matter of fact, as is supported by the numerous available sources of law in South African law.[17] These sources include previous court judgements on informed consent and matters relating to this doctrine.[18] In addition to knowledge as a prerequisite of consent, authority also exists for the statement that it is legally expected of the health-care practitioner to provide information to the patient as part of the consent process.

The duty to obtain informed consent is not limited to medical procedures, but also extends to medical experimentation and study. I do wish to state from the outset however, that the study focuses particularly on informed consent in a clinical-medicine setting, and deliberately excludes medical study. Medical study will only be referenced in short where applicable.

A study into informed consent as a doctrine forms the entirety of this study. While the aim is ultimately to review knowledge as a prerequisite of informed consent, the study contextualizes the subject.

3. Purpose

The purpose of the study is ultimately to answer the study question whether informed consent can ever be fully informed. The question relates ultimately to only one specific aspect of informed consent, that is, knowledge and information-sharing (one entity). However, the pursuit of this answer depends on a discussion of some core principles and concepts applicable to the doctrine of informed consent. To that end, the added purpose of the study is to review the ethical and legal bases of informed consent, the ethical and legal duties placed on health-care practitioners to disclose information, including repercussions for a failure to fulfil these duties (particularly in

16 Van Oosten (n 1 above) 31.

17 The position of informed consent in South African law is discussed in detail later in the study at chap 2 para 6, headed 'Informed consent in South African law.' The available authoritative sources range from the Constitution to 'soft law' (also discussed below).

18 See discussion of South African case law at chap 2 para 6.3, headed "Case law."

South African law), and a review on the nature, content and extent of the information to be disclosed.

4. Aims and objectives

The study sets out to review the literature on informed consent, particularly the component of knowledge as an integral part of the consent process. The discussion of this component can, for multiple reasons, not be isolated from the generalized understanding of the doctrine of informed consent as a whole, including its ethical and legal bases, and the nature of the information and the information-sharing process. The study culminates in a discussion on the first part of the research question, as it appears in the research proposal: "*Can informed consent ever be fully informed?*" The latter part of the question "*Is the doctrine of informed consent possible and adequate in a healthcare setting in the South African context?"* is tackled by reviewing the South African law on informed consent, including particularly judicial precedents. The objects of the study, therefore, are:

a) To outline the doctrine of informed consent, including the history thereof, and the legal and ethical bases;

b) To explore what it is to be informed prior to consenting to a medical procedure;

c) To study arguments for and against knowledge (on the part of the patient) as a legal prerequisite of the doctrine of informed consent;

d) To review alternative manners of imparting knowledge unto patients; and

e) To propose alternative methods for the practical application of the doctrine of informed consent.

5. Methods, limitations and sources of literature

The method that is used in this study includes a review on current authority in respect of the doctrine of informed consent in South African law. This includes primary sources of law in South Africa, particularly legislation and court precedent. In

addition to the primary sources of law, the study investigates available interpretations, assessments and opinions by law commentators on the topic. To this end, the design of the study is that of a literature review. Relevant and available literature is extracted from both electronic and hardcopy sources.

A wide range of medical, philosophical and law databases were searched for available literature on the doctrine of informed consent. Various internet search engines were used to search for web pages that provided relevant and reliable references. Search engines included Google Scholar, Jutastat, Sabinet, LexisNexis database, Westlaw UK, Medline and PhilPapers. Search words included ‘consent,’ ‘informed consent,’ ‘valid consent,’ ‘limitations,’ ‘shortfalls,’ ‘knowledge,’ ‘disclosure,’ ‘material risks’ and ‘negligence’ amongst others. The resultant references were examined for relevance and credibility.

The electronic search was augmented by manual searching in academic books and journals, and references described in some online sources. The formulated study questions and the literature selection criteria described the acceptable standards of material to be studied. The findings from the relevant literature were evaluated and interpreted. The interpretation and summary was carried out in a descriptive fashion, in order to allow for observations, descriptions, and classification of data in order to evaluate available literature on the topic. The descriptive manner of interpreting the findings allowed for inclusion of diverse concepts proposed by different writers. The literature review is of a theoretical nature, and allows for the definition of concepts and the review of theories and evidence.

6. Ethical considerations

In following the structure of a literature review, the study relies considerably on previous works and opinions by other law and bioethics authors. The study reviews the opinions of previous authors and considers theories promoted by them. The study acknowledges this reference to works by others, and credits the authors appropriately: the accreditations include in-text references and footnotes and a formal bibliography at the end of the study. By this, the study aims to maintain good ethical standards, and a status of utmost academic integrity. In addition, the study will be handed in to the supervisor for ethical clearance prior to submission for

assessment and a signed document of plagiarism declaration will be attached to the final copy. Ethical considerations as they appear in the study proposal include the consideration of, and the accurate acknowledgement of other authors' work cited throughout the paper. It will be ensured that the work is of utmost academic integrity and the infringement of the intellectual property rights of others will be shied away from. To this end, a bibliography will be included, crediting the authors whose work will be referenced. Additionally, footnotes will be included to rightfully acknowledge sources. A declaration of own work document (plagiarism declaration) will be signed and attached to the final draft that will be handed in for assessment.

Chapter two, below, offers an introduction to the concept of informed consent.

CHAPTER TWO

INTRODUCTION TO INFORMED CONSENT

1. Chapter overview

Chapter 2 provides a detailed discussion on informed consent. The discussion begins with an overview of consent and the history thereof. The study notes first, the ancient Roman-law references to the requirement of consent prior to a surgical procedure, then discusses the development of the doctrine, in particular, the post-World War II developments, and how these developments have facilitated the discussions on the doctrine. The biggest proponent of informed consent, with regard to medical ethics, is the principle of autonomy. This principle is one of the four that are described as Beauchamp's and Childress's *principlism*. This principle of autonomy affords a person the opportunity to self-rule and to self-govern, and to conduct their lives in a manner which accords with their own opinions on life. Based on this principle and the corresponding spotlight put on human rights and, in particular, personal rights, the approach to medicine and the practices thereof have shifted in favour of patient autonomy, and moved away from medical paternalism. The shift towards patient autonomy allows the patient to partake in decisions on matters regarding their health, and affords the patient their well-deserving right to decide what is to happen with their body. Other components of informed consent include the ethical theory of utility and the common law right to security of the person.

South African law has made similar transitions towards the promotion of individual autonomy, and the adoption of views that promote human rights and the protection thereof. This revised view on consent is evident in the Constitutional[1] provisions and numerous judicial decisions. Chapter 2 explores these provisions in detail, and further highlights the different definitions of the term 'consent' in South African law. For an assessment of the position of informed consent in South African law, the

[1] The Constitution of the Republic of South Africa, 1996; referred to as 'the Constitution.'

study employs the multi-layered approach.[2] This approach allows for a comprehensive assessment of the available authoritative pronouncements on informed consent.

2. Introduction to informed consent

'Consent' has become a ubiquitous term in the medical field. Generally-speaking, it is accepted in medicine (on the ethico-legal bases discussed below) that for a health-care practitioner to provide health services to a patient, the practitioner first needs to secure consent from the patient. By consenting, the patient is agreeing to the proposed treatment and granting permission to the health-care practitioner to carry out the treatment. Furthermore, for the consent to be lawful, it is subject to the patient fully comprehending and appreciating what he or she is consenting to. From the ethico-legal point of view, informed consent has intricate details that need closer consideration. These intricate details, including the issue of information disclosure, and the standards thereof, have been the subject matter in many local and foreign court rulings. A considerable amount of comments and literature by authors on this topic also exist.

In his evaluation of the doctrine, Brock cites three arguments in favour of informed consent: Firstly, he points out that health is not 'objective,' but rather invariant between persons.[3] Secondly, he notes that medical criteria often do not fully settle which treatment is correct or even best for certain conditions. Lastly, he advances the view that health is only part of a person's well-being. It remains only one of many values of the person, viewed in light of other values and goals in their life. Other aspects in their life exist, which are specific and subjective to their life. Different

---

[2] The multi-layered approach aims to find solutions to ethico-legal problems on an integrative level. As South African law remains uncodified, a comprehensive assessment of the legal status of certain matters necessitates an integrative approach to the multiple authoritative sources of law. This approach is utilised in this study to evaluate the multiple sources, including the Constitution, legislation, case law, principles of common law, related foreign law, and considerations of medical ethics. See Carstens P and Pearmain D *Foundational principles of South African medical law* (2007) 1.

[3] Brock DW *Life and death: philosophical essays in biomedical ethics* (1993) 25.

individuals place varying weight in importance on health. Health alone in such instances does not define entirely what a person regards as being good for their life. Thus, respect for patient autonomy remains pivotal for these reasons enumerated above.[4] Following the favour in respect for individual autonomy, Carstens and Pearmain argue that the traditional paternalistic arguments of 'doctor-knows best' and 'patient's best interest' fail, as they undermine patient's autonomy.[5]

The practice of medicine remained paternalistic prior to the shift in approach to the endorsement of the patient-centred approach, which accorded with respect for patient autonomy. The transition allowed for patient participation. Brock explains that input is inevitably required from the patient, in order to promote health decisions that are in accordance with their holistic well-being.[6] Respect for the autonomy of the individual, remains the most significant ethical principle from which informed consent is argued. The shift in approach from medical paternalism had an influence on the legal justifications of medical interventions. It ruled out a professional right to heal and rendered the patient's consent the appropriate justification. Strauss SA in *Doctor, patient and the law – A selection of practical issues,* makes the following remarks regarding the doctor-patient relationship and the provision of health—care services:

> There being no legal duty in general upon a doctor to accept a patient, it is also true that the doctor has no general right to treat any person. Legally, the doctor's right to operate or treat is based entirely on patient's consent – apart from emergency cases where a patient is brought to a doctor in an unconscious or semi—conscious state, and apart from instances where the patient in under a statutory duty to submit to [e.g.] vaccination, medical examination or treatment in his own interest or for the purposes of public health.[7] (Footnotes omitted).

From a legal perspective, informed consent is argued on the basis of the common-law right to security of the person.[8] Furthermore, van Oosten advances the opinion

---

4 Brock (n 3 above) 25.

5 Carstens and Pearmain (n 2 above) 882-883.

6 Brock (n 3 above) 25.

7 Strauss SA *Doctor, patient and the law – A selection of practical issues* (1991) 3.

8 Carstens & Pearmain discuss (with reference to the comments of Judge Watermeyer J in *Stoffberg v Elliot*), both the common-law right to absolute security of the person and the Constitutional right to freedom and security of the person of bodily and psychological integrity,

that the patient's consent is at the least, generally-speaking, essential for the establishment of a fruitful relationship between the health-care practitioner and the patient.[9] Due to the aforementioned ethical and legal justifications, it remains the generally-accepted view in both local and foreign law that consent is needed prior to medical intervention. This point is not of contention. What remains unclear and of continued discussion and adjudication is the scope of the doctrine and its application in medical law. These were the views of Scott J in *Castell v de Gree*f, who upheld that consent is, without contention, required prior to provision of health-care services, and that the health-care practitioner is duty-bound to disclose information and warn the patient of the risks involved, but that (at 517) '…the difficulty is to determine when that duty arises and what the nature and extent of the warning must be.'[10]

In addition to respect for patient autonomy, informed consent can serve as a valid defence in medical litigation cases, provided that the treatment (or procedure) is not contrary to public policy of good morals.[11] As such, informed consent can serve as a ground of justification. South African law approaches the issue of consent from the Roman law maxim of *volenti non fit injuria,* that is, no harm done to someone who consents thereto,[12] and treats the issue of consent by patients to medical procedures as falling under the defence of this maxim. The patient's right to privacy and personal integrity is waivered when there exists informed consent from them authorising the proposed procedure or treatment.[13] The presence of such consent validates the procedure and legalizes what would otherwise be an unlawful act. Van

---

as provisioned at s12 of the Constitution. They promote the opinion that the two should not be differentiated from each other, and that the "non-absolutism" of rights as provided for at s36 of the Constitution should similarly apply to the common-law right in question. See Carstens and Pearmain (n 2 above) 880ff.

9 Van Oosten F *The doctrine of informed consent in medical law* 31.

10 *Castell v de Greef* 1994 (4) SA 408 (C); referred to as *Castell*.

11 Poonitha N "Informed consent in South Africa" *SAR* 41 (2003) 8-10.

12 Van Oosten (n 9 above) 14 fn 4. See also Carstens and Pearmain (n 2 above) 875. See also the judgement of Ackermann J in *Castell* (n 28 above) 420: "It is important, in my view, to bear in mind that in South African law (which would seem to differ in this regard from English law) consent by a patient to medical treatment is regarded as falling under the defence of *volenti non fit injuria,* which would justify an otherwise delictual act."

13 Van Loggerenberg A "An alternative approach to informed consent" *SALJ* 135 (2018) 55-73.

Loggerenberg quotes on informed consent, as summarised in *Christian Lawyers' Association v National Minister of Health*[14] as follows:

> [I]nvasive medical treatment, which would otherwise have constituted a violation of a patient's right to 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.[15] (Footnotes omitted).

Regarding this approach by the South African law, the enquiry into the defence of *volenti non fit injuria* is then whether the said defence has been established and, in particular, whether the patient's consent has been a properly informed consent.[16] As part of the requirements to establish the defence of *volenti non fit injuria*, the patient needs to have been furnished with adequate information to allow for full appreciation of the risks he or she is consenting to. On this requirement, Bekker J in *Esterhuizen v Administrator Transvaal* mentioned inter alia that:

> …the plaintiff must have shown not only to have perceived the danger, for this alone would not be sufficient, but also that he fully appreciated it and consented to incur it…[17]

Scott J in *Castell* (n 10 above), held a similar view to that of Bekker J above. This view on informed consent as a lawful defence, particularly the aspect of information disclosure, was similarly adopted by Ackermann J in the appeal case of *Castell*. Ackermann J quoted inter alia the judgement of Scott J in *Castell* as follows: 'The doctrine [informed consent] holds that a patient's consent to medical treatment is vitiated if he is given inadequate information concerning the proposed treatment…'[18]

---

14 *Christian Lawyers' Association v National Minister of Health* 2004 (10) BCLR 1086 (T).

15 Van Loggerenberg (n 13 above) 55-73.

16 *Castell* (n 10 above) 408. In South African law, the patient's consent constitutes a justification that excludes the wrongfulness of medical treatment and its consequences, the inquiry of this justification being whether the said defence has been established and, in particular, whether the patient's consent has been a properly informed consent. This approach by the South African courts is contrasted to other foreign law, spotlighting in particular Australian law, where the issue of informed consent is approached on the basis of the doctor's duty of care to the patient, a breach of which constitutes negligence on the doctor's part.

17 *Esterhuizen v Administrator, Transvaal* 1957 (3) SA 710 (T); referred to as *Esterhuizen*.

18 See *Castell* (n 10 above) 420.

After discussing the South African law approach of *volenti non fit injuria*, van Oosten provides an expansive list of conditions to be met for consent to serve as a defence, including the requirements of capacity, voluntariness and the appreciation of the nature and extent of the harm and risk. He writes:

> …a) It [consent] must be recognised by law, that is it must not be *contra bonos mores*. b) It must be given by a person capable in law of consenting, that is by someone who is capable of forming an intention (wilsbevoeg) or of understanding what he consents to. c) It must be free and voluntary, that is not induced by fear, force or fraud. d) The consenting party must have had knowledge and been aware of the nature and extent of the harm or risk. e) The consenting party must have appreciated and understood the nature and extent of the harm or risk f) The consenting party must have consented to the harm or assumed the risk.[18] g) It must be comprehensive, that is extent 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 (regshandeling). k) It must, as a rule, be granted by the plaintiff or complainant himself. l) The conduct in question must fall within the limits of the consent given, that is it must not exceed the bounds of the consent give.[19] (Footnotes omitted).

In the summary above, van Oosten suggests at point d) that knowledge on the part of the patient presents itself as a pertinent prerequisite. In fact, it is widely-accepted that for consent to be lawful, and indeed informed, there needs to be knowledge and appreciation on the part of the patient consenting. Kennedy and Grubb propose that respect for personal autonomy (a proponent of informed consent) includes the prevention of ignorance from hindering autonomous choices and as thus, requires comprehension and disclosure. [20] To the end of knowledge (encompassing comprehension and appreciation), there had to be a shift from the traditional duty to obtain consent to a duty to disclose certain forms of information and only then obtain consent. This has led to judicial pronouncements placing an ethical and legal duty on the health-care practitioner to disclose information to the patient. For a lay person (which the patient often is), the provision of information is a prerequisite of knowledge and therefore also of lawful consent. Following, as Carstens and Pearmain explain, this prerequisite implicates a legal duty on the health-care

---

19 Van Oosten (n 9 above) 17-19.

20 Kennedy I and Grubb A *Medical law: Text and materials* United Kingdom (1989) 233.

practitioner to provide information to the patient.[21] Neser J in his judgement in *Rompel v Botha*,[22] after reserving judgement on emergency situations, renounced consent without disclosure of inherent risks to the patient with the following comments:

> There is no doubt that a surgeon who intends operating on a patient must obtain the consent of the patient…but in the case of this nature, which may have serious results to which I have referred, in order to effect a possible cure for a neurotic condition, I have no doubt that a patient should be informed of the serious risks he run. If such dangers are not pointed out to him then, in my opinion, the consent to the treatment is not in reality consent – it is consent without knowledge of the possible injuries. On the evidence defendant did not notify plaintiff of the possible dangers, and even if plaintiff did consent to shock treatment he consented without knowledge of injuries which might be caused to him. I find accordingly that plaintiff did not consent to the shock treatment. (Footnotes omitted).

As a result of the duty to disclose information to the patient, there has been on-going world-wide discussions and court adjudications on the standards of disclosure, characteristics of information to disclose, general rules of disclosure and the different forms of liability for a failure to disclose. The requirements for lawful consent are capacity, knowledge and voluntariness.[23]

At common law, the relationship between the doctor and the patient can be that of contract or of delict. A contractual relationship when exists when the patient presents to the health-care practitioner for health care services. The contract normally expects of the health-care practitioner to provide the medical services to the patient with reasonable skill and care. The health-care practitioner is normally not expected by the contract to guarantee success of the treatment, and neither is he liable for the failure.[24] A contractual duty to disclose information on the treatment proposed may

---

21 Carstens and Pearmain (n 2 above) 879.

22 *Rompel v Botha* (1953, Transvaal Provincial Division, unreported).

23 See Brock (n 3 above) 36.

24 Giesen D *Medical malpractice law. A comparative law study of civil responsibility arising from medical care* Gieseking (1981) 158.

also be placed on the health-care practitioner. Kennedy and Grubb discuss this duty to disclose in detail.[25]

Concurrently, a civil relationship exists between the two parties. This includes a delictual duty of care placed on the health-care practitioner. Strauss highlights the delictual relationship that is referenced above, and states that a duty of care exists, irrespective of contract or consent. The health-care practitioner is under a duty to act with reasonable skill and care when providing health-care services to the patient. Failure to act in this manner, so that incorrect treatment is given or the correct treatment is omitted, constitutes negligence, and the health-care practitioner may be liable in civil claims. Strauss states therefore that the liability of the doctor is not dependent on the existence of a contract or on the patient having granted consent to the proposed procedure, if the procedure was carried out with skill less than that which is expected of a reasonable doctor in the same condition.[26] The grounds of the liability may be in damages in malpractice (medical treatment not according to the expected standards of the reasonable doctor), and damages arising in the course of providing medical treatment without the patient's informed consent.[27]

Failure to obtain informed consent remains, in itself, a liability of the doctor, irrespective of the outcomes of the procedure or the treatment instituted. Even though the form of this liability differs between different countries' jurisdictions, the view that failure to obtain consent amounts to ground for liability has become a well-established law in some foreign jurisprudences. This is also in line with various prescriptions in the South African law, including the Constitution, various legislation and available judicial precedents. Treatment without valid patient consent may arise both in situations where consent was wholly omitted and those where the consent obtained was not valid.[28] I infer with correction from the above opinion by Strauss that, similarly, the liability of the doctor for failing to obtain informed consent is independent of the existence of contract.[29] In South African jurisdiction, failure to obtain informed consent may amount to violation of bodily integrity (criminal charge

---

25 Kennedy and Grubb (n 20 above)

26 Strauss (n 7 above) 3.

27 Giesen (n 24 above) 161.

28 Giesen (n 24 above) 171.

29 Discussed in detail below at para 6.

of assault) or violation of one's dignity and their personal right to privacy (*crimen injuria*).[30]

Situations where medical treatment can be lawfully provided without *valid* patient consent include situations of emergency,[31] where the act can be argued on the common-law doctrine of necessity.[32] Other legal grounds of justification, which can be lawfully invoked to excuse provision of medical treatment without valid consent, are discussed in detail by Carstens and Pearmain,[33] and include statutory authority, court order and *boni mores* (that is the development of the common law that would accord with the legal convictions of the society).

In concluding this section, I wish to highlight a couple of important considerations on autonomy and informed consent. Firstly, it is important to note that, as pointed out by Kennedy and Grubb, informed consent seeks to protect the autonomy of the patient, and not to protect the patient from harm. It is this consideration that, in my opinion,

---

30 See van Loggerenberg (n 13 above) 56; Naidoo P "Informed consent in South Africa" *SAR* 41 (2003) 9-10; Thomas R "Where to from Castell v de Greef? Lessons from recent developments in South Africa and abroad regarding consent to treatment and the standard of disclosure" *SALJ* (2007) 193, who summarizes the pleadings in cases of lack of disclosure in both assault and crimen injuria. Thomas references the case of *Broude v McIntosh* and the writings of Van der Walt and Midgley, who found the idea of filing a case of undisclosed risks as assault 'bizarre.' The courts argued that it was odd that a case can be bought on grounds of assault where the health-care practitioner failed to disclose certain risks, even if the risk did not materialize and the procedure was a success. The remedy proposed by Van der Walt and Midgley is that the case should rather be pleaded on "intentional or negligent infringement of the right to bodily integrity (corpus)," and point out that it should be clearly understood that physical injury is not a requirement in South African law.

31 Kennedy and Grubb (n 20 above) 215, write on the distinction between valid and informed consent, noting that they are not synonymous; 'informed' is only one part of valid consent. Giesen (n 24 above) 176: "As *volenti non fit iniuria*, the patient, before his giving consent, must receive such information as to enable him to appreciate and to realise the nature and significance of the medical treatment to be provided). A valid consent now is an informed consent freely given. An informed consent is that which is based on a physician's fulfilment of his duty to give a fair and reasonable explanation of the proposed procedure including the probable affect and any special or unusual risks." (Footnotes omitted).

32 Strauss (n 7 above) 3.

33 Carstens and Pearmain (n 2 above) 917ff.

rightly affords the principle of autonomy some superiority to its counterparts. Respect for autonomy remains the most important proponent of informed consent, and should always be used as a point of departure when considering matters related to informed consent. This stance is applied specifically to an adult patient, who meets all the requirements of valid informed consent. I am of the view that what a doctor is called upon, in such an instance, is to provide comprehensive professional advice, and to promote adequate comprehension on the part of the patient, and to then accept whatever informed choice the patient makes. This is in keeping with the respect for patient autonomy, and the right to decide what is to happen to their body. This respect for patient autonomy includes in it, informed refusal, which is recognized as having merit, regardless of expert medical opinion on the patient's informed choice. It allows the person who is in the best position to determine what would be in the best interest of the patient (that is, the patient himself) to make that decision. It would seem rather arrogant of the doctor and the medical fraternity as a whole to decide what is in the best interest of the patient, while disregarding their human right to freedom and security of the body. Regarding the functions and justifications for obtaining informed consent, Kennedy and Grubb reference the two historic and contemporary positions that have dominated literature. They note the following:

> One maintains that the purpose of and justification for obtaining informed consent is to protect persons from various risks of harm. Those who subscribe to a justification based on *protection from harm* are inclined to protect patients whether or not it is the patient's choice that leads to an 'unwise' assumption of a risk. The other position sees the purpose and justification for obtaining informed consent as respect for the autonomy of patients, by recognizing their rights to know and choose. Those who subscribe to a justification based on *protection of autonomy* are not inclined to protect patients against their choices, on grounds that such constraints would violate their autonomy.[34]

As alluded to above, I find the former justification not appropriate in this circumstance. It is in contrast to the respect for patient autonomy, by denying the patient their right to choose. In fact, it leans towards the now discredited paternalistic approach. Patient autonomy is the more appropriate approach.

---

[34] Kennedy and Grubb (n 22 above) 233.

The second point I wish to highlight is this: After discussing the legal stance on informed consent, Beauchamp and Childress stress that from a moral point of view, informed consent is less to do with the professional and his liability, but is rather about the patient as an autonomous being, and his autonomous choices.[35] Brock makes similar remarks, that informed consent aims at maximising patient understanding and comprehension, not to protect against legal liability on the part of the doctor.[36]

3. History of the doctrine of informed consent

Kennedy and Grubb write of records of daily medical practice that found 'indigenous medical traditions' of truth-telling and consent seeking, 'grounded on the theory that such knowledge had demonstrably beneficial effects on most patient's health…'.[37] They also note, however, that little evidence exists to suggest that such traditions amounted to the modern day doctrine of informed consent, nor were they derived from any undertakings and commitments by the medical professions to patient autonomy.[38] The current form of informed consent as a doctrine is a relatively new development in medical practice. For decades prior, the approach to the practice of medicine was heavily paternalistic, in which the doctor assumed a fatherly role within the patient-doctor relationship, thus constructing a distinct power discrepancy within the relationship in favour of the latter. The doctor, with his impressive knowledge of medicine and his impressive skill in the practice thereof, was deemed to know what was in his patient's best interest and was entrusted with making medical decisions on behalf of the patient, whose participation was in turn retained at minimum. Murray[39] notes that in ancient Greece, patient participation in medical treatment was in fact frowned upon. During the 1800's, stances on the question whether to disclose a dire diagnosis to a patient were contested, with physicians of the time holding

35 Beauchamp TL and Childress JF *Principles of biomedical ethics* (2001) 77.

36 Brock (n 3 above) 48.

37 Kennedy and Grubb (n 20 above) 229.

38 Kennedy and Grubb (n 20 above) 229.

39 Murray PM "The history of informed consent" *IOJ* (1990) 104.

closely a view in favour of non-disclosure.[40] Van Oosten notes that informed consent had made its way into the German medico-legal scene as early aback as the 1910's, and he resultantly submits that the general form of consent as an entity is not by any means a new phenomenon.[41] In addition, Murray cites the doctrine of assault and battery in the English Common Law, noting that this doctrine forms the basis for the possible injury or liability that may be incurred from surgery without proper consent.[42]

The concept of informed consent in the medical practice gained popularity in the twentieth century. The gain in popularity was occurring alongside landmark cases that were making progressive pronouncements on informed consent. The discussions on informed consent were following the developments after World War II, which have influenced in great part the current status of the doctrine. The developments included, as put by Beauchamp and Childress, the '…widespread social developments'[43] of the twentieth century and the Nuremberg Trials of 1940, among others. However, it was only a decade later that the term 'informed consent' started appearing,[44] and only in subsequent years, particularly in the early 1970's, that informed consent started receiving detailed examination.[45] The foreign law court cases of that era included *Salgo v Leland 1957* (USA), the landmark case of *Natanson v Kline 1960* (USA)*, Counterbury v Spence 1972* (USA), *Reibl v Hughes 1981* (Canada), and *Rogers v Whitaker 1992 (*Australia) among others. The coinciding South African cases included, amongst others, *Castell* (n 10 above), where the courts had the opportunity to provide judgement, and make *obiter* remarks, on informed consent and the standard of disclosure. Further discussions in South African law were facilitated by the advent of the Constitution of the country

40 Murray (n 39 above) 104.

41 In addition to noting the general form of consent as being more prehistoric than the recent attention it has received, van Oosten notes also the lack of authority on consent to medical interventions as such. Van Oosten (n 9 above) 11 writes: "Although ample Roman and Roman-Dutch authority exists on…consent generally, no Roman and Roman-Dutch authority on consent to medical interventions as such and, more particularly, information as a requisite of consent in the medical context could be traced."

42 Murray (n 39 above) 104.

43 Examples include various consumer and civil rights movements and constitutional developments…" See Beauchamp and Childress (n 35 above) 875.

44 Beauchamp and Childress (n 35 above) 77.

45 Beauchamp and Childress (n 35 above) 77.

which has, and continues to influence South African law. With the history and the development of the doctrine of informed consent considered, it remains to date controversial and hotly debated in international medico-legal arena.[46]

4. Informed consent in bioethics

Informed consent can be justified on multiple ethical principles. However, the one principle that greatly supports informed consent is that of respect for autonomy. Other principles on which informed consent is underscored include the principles of beneficence and non-maleficence and the ethical theory of utility.

4.1. Principlism

The doctrine of informed consent has its bioethical basis in the ethical principle of respect for individual autonomy. This principle is one of four principles that were introduced and proposed by Tom Beauchamp and James Childress in their book *Principles of biomedical ethics,*[47] first published in 1979. The four principles have therefore come to be referred to as Beauchamp's and Childress's principlism, and they aim at providing a model with which moral and ethical questions can be approached. Principlism has since attained significant status in bioethics and has been generally-accepted as one of the important approaches to moral reasoning and to ethical dilemmas in bioethics. It can be utilized as a framework to solve some of the bioethical challenges. The principles are beneficence, non-maleficence, respect for autonomy and justice. It is acknowledged that principlism is not infallible and is not a complete moral system on its own.[48] In fact, the different principles may in

---

46 Van Oosten qualifies this assessment by making reference to the abundance of numerous court reports and literature on the subject on informed consent. See van Oosten (n 9 above) 11.

47 Beauchamp and Childress (n 35 above) 12 and 57ff.

48 Moodley K *Medical ethics, law and human rights, a South African perspective* (2017) 53. Moodley also discusses the controversies and the different practical arguments charged at principlism 38. Moodley cites Beauchamp and Childress, who explain the rationale for the favour of principlism. Moodley writes "Beauchamp and Childress make the point that, while it is nigh impossible to consistently and coherently defend one single moral theory, it is remarkable

some instances conflict with each other. However, they provide at the least an approach to moral problems, by application of one or more of the four basic ethical principles to moral problems. Moodley further briefly describes principlism as 'action guides' operating at a rather advanced level of abstraction.[49] From these broad action guides, specific action guidelines can further be specified. The level of abstraction (particularly in comparison to other ethical theories) remains a topic of contention, and regarding this, Moodley writes as follows:

> There is significant controversy in the debate about principlism about the question of exactly at what level of abstraction the principles in fact operate. Up to the fourth edition of their book, Beauchamp and Childress stuck with a scheme of deductivist reasoning in terms of which ethics theory (e.g. utilitarianism or social contract theory) was regarded as the highest level of abstraction, followed by principles, then rules and, lastly, particular moral judgements.[50]

Moodley further qualifies the aforementioned statement with an example.[51]

4.1.1. Principle of respect for autonomy

Autonomy is a Greek-derived term that translates to 'self-law.' In modern-day literature, the term has become synonymous with 'self-rule'.[52] Beauchamp and

---

that almost all the known theories yield insight into the general validity of the four principles. Therefore, while we can agree to disagree about the possibility of consistently upholding one single moral theory, we can agree that the "common morality" compels us to embrace the four principles. The implication of principlism is the outright rejection of the need for an overarching moral theory that definitely grounds moral convictions and judgements. Principlism much rather, as we have seen, draws on the idea of a *common morality.*"

49 Moodley (n 48 above) 37.

50 Moodley (n 48 above) 38.

51 Moodley writes: "For example: suppose that utilitarianism as an overarching moral theory proclaims utility as the ultimate moral value, as we have seen. From that the principle of beneficence is then derived, it is stated that to benefit a fellow human being is fundamental to the moral life. From this principle a specific rule for moral action is in turn deduced: "Always try to maximise the net aggregate of good and to minimise suffering." Lastly, on the basis of this rule a particular judgement is then made: "It is better (i.e. morally preferable) to let Terri Schiavo die than to keep her alive."" See Moodley (n 48 above) 38. (Footnotes omitted).

52 Moodley (n 48 above) 55.

Childress describe personal autonomy as '…at minimum self-rule…free from both controlling interference by others and from limitation such as inadequate understanding that prevent meaningful choice,' and regarding respect for an autonomous agent, they write that it is: '… at a minimum, to acknowledge that person's right to hold views, to make choices, and to take actions based on personal values and beliefs'.[53] Respect for personal autonomy remains the biggest proponent for informed consent. Regarding autonomy, Kennedy and Grubb write as follows:

> Autonomy can be defined as the individual's freedom to decide her or his goals and to act according to those goals. Inherent in this principle is the notion of personal responsibility. Because we believe human beings to be rational we regard them as persons rather than objects or things. A person is a self-determining individual who is able to think about ends, and decide on the means by which she or he intends to fulfil those ends.[54]

Kennedy and Grubb further write that informed consent endorses the right to self-determination and the respect for the autonomy of an individual with 'inherent dignity and value'.[55] Beauchamp and Childress advance the following rules as justified by the principle of respect for autonomy:[56]

1. *Tell the truth.*
2. *Respect for the privacy of others.*
3. *Protecting confidential information.*
4. *Obtaining consent for interventions with patients, and*
5. *When asked, help others make important decisions.*

In their discussion on autonomy, Beauchamp and Childress refer to autonomy as a matter of having capacity to reflectively control and identify with one's basic desires through higher—level desires.[57] They refer to two conditions for autonomy, that is, liberty (independence) and agency (capacity).[58] Beauchamp and Childress analyse respect for autonomy as facilitating one to act intentionally, with understanding and

---

53 Beauchamp and Childress (n 35 above) 63.

54 Kennedy and Grubb (n 20 above) 236.

55 Kennedy and Grubb (n 20 above) 232.

56 Beauchamp and Childress (n 35 above) 65.

57 Beauchamp and Childress (n 35 above) 58.

58 Beauchamp and Childress (n 35 above) 58.

without controlling influences that determine one's action. The preceding statement describes the requisites of informed consent viz capacity, voluntariness and knowledge. Beauchamp and Childress further highlight distinctions between the 'substantially autonomous' and the 'fully autonomous' persons,[59] and argue in favour of 'substantially autonomous,' by stating that for action to be autonomous there needs to be only a substantial degree of understanding, not a full or comprehensive understanding. This statement is revisited later in chapter 3 of the study, under disclosure.

Some authors, including Beauchamp and Childress articulate the position that respect for autonomy does not supersede other principles. It is also important to note that even though the respect for one's autonomy seems absolute, Beauchamp and Childress note that it can be overridden by other competing moral considerations, including endangerment to public health, threat to others, and a limitation in resources needed to promote respect for autonomy.[60]

I am of the opinion that in a competent adult patient, respect for individual autonomy should be promoted above the principles of beneficence and non-maleficence. What is in 'the best interest of the patient' should be determined by the patient himself, after being afforded adequate relevant information to make that determination in an autonomous and informed manner. Not only does this approach respect patient autonomy, but it also solves in the simplest manner the problem of determining what is in the best interest of the patient. By allowing the patient to determine the answer to this question themselves, it relieves the doctor of the potentially difficult task of determining this answer each time he interacts with the individual patient. I am of the opinion that it would appear rather arrogant of a doctor to argue on the principle of beneficence in an act to which the patient declined to provide informed consent, irrespective of the outcomes of that act. Failure to obtain informed consent prior to a medical procedure, without any other lawful justification, is rightfully regarded as a breach of patient's autonomy and an unlawful act (or rather omission), irrespective of whether the patient is content with the outcomes of the procedure or not. The patient can then claim for such an omission if they wish. If they do not wish to claim, for various reasons they may have, including being content with the results of the

59 Beauchamp and Childress (n 35 above) 60.

60 Beauchamp and Childress (n 35 above) 65.

procedure, that is well too. Either way, their autonomy is respected. A laparotomy that has been successful (as per expert medical opinion) should not be judged as such if the patient had not wanted to undergo such a procedure. This line of thinking should, in my opinion, be extended to consent that was not valid, but still obtained. Outcomes of the procedure should remain null and void if the original aim is to afford the competent patient the opportunity to make their own informed medical decisions regarding what happens to their body, and if the original aim is to afford the patient such an opportunity, this aim should be upheld consistently. I extend, that outcomes of the procedure should not be considered, as the charge against the doctor is not regarding the procedure and how it was carried out, but rather, his liability is regarding his failure to secure valid consent. In such instances, respect for patient's right to autonomy should be used as the point of departure. Giesen, in my opinion, rightly promotes the view that the patient's right to decide what happens to their body must be guaranteed, even in instances where the patient's decisions are contrary to what the expert medical opinion regards as a 'reasonable' patient.[61] Propositions that are contrary to this point of departure should therefore be avoided.

4.1.2. Principles of beneficence and non-maleficence

The two principles of beneficence and non-maleficence refer to acting in the manner that is in the best interest of the patient and protecting the patient from harm respectively.[62] With regard to beneficence, two different interpretations exist: a positive act being to produce benefits, and the negative act being to prevent from harm.[63] Beauchamp and Childress highlight the implied duty on the doctor, embedded in the principle of beneficence, to act in the best interest of the patient.[64] Regarding beneficence, however, the question of what exactly is in the best interest of the patient, and whose decision it is what is in the best interest of the patient is discussed above, acknowledging the fact that patients remain individuals and not cases, with varied individual opinions of what is 'in their good.' In the instance of a

61 Giesen (n 24 above) 171ff.

62 Kennedy and Grubb (n 20 above) 234.

63 Kennedy and Grubb (n 20 above) 238.

64 Kennedy and Grubb (n 20 above) 238.

competent adult, respect for autonomy seems preferable over the principle of beneficence.

4.2. Theory of utility

This theory seeks to maximally protect and benefit everyone in society.[65] Kennedy and Grubb note that, after recognizing the justifications of utility and non-maleficence as being appropriate for some consent requirements, the justification of autonomy is somewhat superior to its two counterparts.[66]

5. Forms of consent

Informed consent can be either tacit or expressed. Tacit includes implied consent, as in cases where the competent patient, after being fully informed of the proposed procedure, and without duress, voluntarily submits himself for the treatment, or fails to object to such treatment by behaving passively. With regards to the former example, consider a patient who acts actively by extending his arm in anticipation of a phlebotomy procedure to obtain a blood sample. The latter is exampled by a situation where the said patient, anticipating the same procedure, does not object or draw back. Expressed consent refers to consent expressly given. It can be either verbalized, or written. There exist neither a prescribed format, nor positive law

---

65 Kennedy and Grubb (n 20 above) 234, write on the principle of utility that: "Informed consent requirements will maximally protect and benefit everyone in society, including health professionals, patients, and the institutions of medical practice and research themselves. Rules of consent serve to protect and benefit patients and professionals, to allay public fears (especially about research), to encourage self-scrutiny by physicians and investigators, and to maintain a relation of trust between them."

66 Kennedy and Grubb (n 20 above) 234 argue as follows: "…the justification based on autonomy recognise consent as *valid* because the consenting party is an autonomous person, with all the entitlements that status confers. Neither utility nor nonmaleficence leads to this strong conclusion, for both would justify not seeking consent in some circumstances- utility when it would not maximise the social welfare and nonmaleficence when no apparent harm would result."

prescribing that consent should be written.[67] In South African law, both formats are recognized as lawful forms of consent, save for a few exceptions where written consent is specifically required for legal consent.[68] Both are of equal merit, the only added benefit of written consent being that it is easier to produce as evidence.[69]

6. Informed consent in South African law

Insofar as South African law is concerned, there are ample legal prescriptions for the requirement of valid informed consent prior to provision of medical procedure and treatment. The laws governing informed consent in South Africa includes the Constitution,[70] which has greatly influenced the South African jurisprudence in general, and the National Health Act.[71] The South African jurisdiction has made strides in a direction that promotes individual autonomy, a shift that is similar to international trends. Therefore, the general stance in South African law, as we shall see below, is a consistent provision that informed consent is required prior to provision of treatment and that a doctor is under a legal and ethical duty to obtain valid consent from his patients. Other legal prescriptions for informed consent include various other legislation and their regulations, case law, common law, and soft law from various statutory bodies governing the medical fraternity, including the HPCSA[72] and the SAMRC.[73] For a comprehensive assessment of the sources of law

---

67 Kennedy and Grubb (n 20 above) 175. See also Giesen (n 24 above) 174: "The legal validity of consent does *not* require consent in any specific *form*." Strauss (n 7 above) 13 notes also that generally there exists no law that makes a requirement for written consent, over verbal consent, save for the few exception, see fn 68 below.

68 Example of exceptions include specific procedures, leucotomy (MHA), sterilization (Abortion and Sterilization Act) and treatment of a mental health care user (MHA). See Strauss (n 7 above) 13.

69 Kennedy and Grubb (n 20 above).

70 The Constitution (n 1 above).

71 National Health Act 61 of 2003; abbreviated NHA.

72 Health Professions Council of South Africa.

73 South African Medical Research Council.

on informed consent, the multi-layered[74] approach is adopted in the discussion below.

6.1 The Constitution

The Constitution holds the status of supremacy in South African law. Following, it has significantly influenced other sources of law, and the South African jurisprudence as a whole, since it came into effect in February 1997. It is founded on some ethical principles and theories, including value ethics.[75] It is also drafted on foundational principles of justice; values of human dignity, equality, and freedom; and the recognition, promulgation and respect for human rights.[76] In addition to embracing human rights, the Constitution places a duty on the state to protect and fulfil the rights in the Bill of Rights.[77]

One such right flows directly from the ethical principle of respect for individual autonomy, and is prescribed at section 12 of the Constitution. In this section, the Constitution makes provisions for the human right to freedom and security of the person, which includes the human rights to bodily and psychological integrity and, specifically, security and control over one's own body. The section further singles out the requirement for informed consent in medical and scientific experiments. The respect for this right (and all other rights in the Bill of Rights)[78] is promoted by pronouncements of section 1(a) of the Constitution, that is, the advancement of human rights as one of the founding values of democratic South Africa.

---

74 The application of the multi-layered approach draws on multiple sources, including The Constitution of the Republic, relevant legislative law, applicable precedents in case law, applicable principles of common law, related foreign law (where relevant local law is deficient) and guidelines for health professions. It also considers relevant medical ethics and applicable ethical theories. See Carstens and Pearmain (n 2 above) 1 on the discussion of the multi-layered approach.

75 An ethical theory that focuses on the characteristic traits of an individual, rather than the nature or character of the action. Moodley (n 48 above) 29.

76 The Constitution (n 1 above) ch 1, 'founding provisions.'

77 The Constitution s 7(2).

78 The Constitution ch 2 s 9–35.

The theme in the provisions of section 12(2) of the Constitution is further emulated in other sources of law. They promote informed consent, a stance that is endorsed by the Constitution. This consistency validates section 2 of the Constitution – which requires that any other law be consistent with the Constitution, and invalidates any other law and conduct that contradicts the purport of and provisions in the Constitution.[79] Some of the sources make provisions for generalized broad principles, while in some of the sources, the doctrine of informed consent is expanded to specific detail.

6.2 Legislation

Various legislation on health-care matters make provisions for the requirement of informed consent. The NHA deals with the requirement of informed consent in general terms, and it discusses general proposed procedures/ treatments for which informed consent is sought. The relevant legislation can be broadly classified into two 'groups:' one group relates to considerations of capacity of the individual from whom consent is being sought, and hence include the competent and incompetent elderly, the mentally ill persons and the minors. The other group is based on specific procedures, viz the sterilization and termination of pregnancy procedures. Let's consider first the NHA, then followed by the Health Profession's Act,[80] Children's Act,[81] MHCA,[82] Sterilization Act,[83] Choice on termination of pregnancy act,[84] and POIA.[85]

(i) National Health Act

---

79 The Constitution s 2*:* "This Constitution is the supreme law of the Republic; law or conduct inconsistent with it is invalid, and the obligations imposed by it must be fulfilled."

80 Health Professions Act, 56 of 1974: referred as HPA.

81 Children's Act, 38 of 2005.

82 Mental Health Care Act, 17 of 2002: abbreviated MHCA.

83 Sterilization Act, 44 of 1998.

84 Choice on Termination of Pregnancy Act, 92 of 1998.

85 Promotion of Access to Information Act, 2 of 2000.

Section 6 of the NHA makes provisions for the user's right (refers to users receiving treatment in a health establishment…) to have full knowledge on matters relating to their health. At section 6(1), the Act further imposes a duty upon the health-care provider to inform; recognizes the concepts of *therapeutic privilege*, *best interest of the user* and of *informed refusal*; and lists in broad terms the components of the information that is required for knowledge on the part of the user. At section 6(2), the Act also places a duty on the health-care provider to, where possible, inform the user in a manner that would maximise their chance of understanding, including the language the user finds most comfortable. The NHA provides a definition of informed consent, and appears at section 7(3), for the purposes of this specific section, and reads:

> [I]nformed 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.[86]

My criticism levelled against section 6 of the Act is the use of the word 'generally'[87] in subsections 1(b) and (c). The word is vulnerable to varied interpretations and is thus, at risk of inconsistent application. I do acknowledge however that it is perhaps this word that is at the epicentre of the informed consent debate, that is, what is the nature and the extent of the information that is included in or represented by the word 'generally'?

Section 7 prohibits the health-care provider from providing services to the user without the set user's informed consent. It qualifies with exceptions to this prohibition, which include situations where consent is granted by other individuals on behalf of the user should the user be unable to (for whatever reason), and situations where consent is granted by other institutions, including the courts through a court order. In addition, the section lists in specific order the individuals who may grant

---

86 S 6 of the NHA relates to the user having full knowledge on health matters relating to him, and enumerates the categories of information to be provided to the user. For discussion of s 6 refer to the discussion on the NHA below.

87 NHA (n 71 above) s 7.1(b) "the range of diagnostic procedures and treatment options generally available to the user;" and 1(c) "the benefits, risks, costs and consequences generally associated with each option."

consent on behalf of the user. Section 7 also makes an exception for situations where failure to treat may result in adverse effects to either public health or the patient's own health. At section 7(3), the NHA provides, for the purposes of this section, the definition of informed consent. It reads:

> …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.

Section 8 pertains to the participation of users in decision-making. It makes provisions which regard to users who are capable of understanding but lacking legal capacity to provide consent, and further provides for users who are unable to participate in decisions affecting their personal health at a particular moment. Section 9 provides orders that need to be taken when health services are provided to the user, subject to any applicable law, without informed consent of the user. These include notifying the head of the provincial department within 24 hours following admission of the user into the health care facility.

Section 11 makes provision for the requirement of 'authorisation' form, amongst others, the relevant health research committee, when health services are provided to the user for experimental or research purposes. The question that arises here is whether the word *authorisation,* as used in this context, shares a meaning with informed consent. Are they synonymous? In a model of informed consent proposed by Beauchamp and Childress, *authorisation* is only one component of informed consent.[88] *Authorisation* follows ultimately, in the list of seven elements of informed consent that include *competence, voluntariness, disclosure, recommendation, understanding* and *deciding.* The term then, as considered in reference to the model proposed by Beauchamp and Childress, is not synonymous with informed consent. For authorisation without knowledge and voluntariness, is not informed consent. The NHA fails to define or elaborate on this term. Another similar criticism I level at the section is the use of the term *'prescribed manner'*[89] at section 11(1). The meaning of this term is not accounted for in the act. It remains unclear what the manners referenced are.

---

88 Beauchamp and Childress (n 35 above) 80.

89 NHA (n 71 above) s 11(1) reads: "Before a health establishment provides a health service for experimental or research purposes…the health establishment must inform the user in the prescribed manner…"

The requirement for informed consent is further prescribed for at section 55 of the NHA, which relates to removal of tissue, blood, blood products or gametes from living users. It provides that these tissues and organs may not be removed without written consent from the user from whom they are being removed.

(ii) Mental Health Care Act

The MHCA, at section 9.1(a), provides for consent as a legal requirement to provision of care, treatment and rehabilitation services to a mental health care user or the admission thereof to a health-care facility. The section further acknowledges, at (c) the concept of '*best interest of the patient'* and the ground of justification of *'emergency:'* It provides that treatment can be provided to such a patient without their consent only in situations where (i) adverse effects to their health or death is inevitable if treatment is delayed or even totally forfeited; (ii) there is a threat of the user causing harm to himself or others; and (iii) it is for the protection of the property of the user and of others.'

At section 17, a provision is made for what could be regarded as part of the information that needs to be disclosed to the user before treatment is administered to them. It states that:

> Every health care provider must…inform a mental health care user in an appropriate manner of his or her rights, unless the user has been admitted under the circumstances referred to in section 9 (1) (c).[90]

Sections 26 and 32 continue the theme of the prerequisite of consent prior to treatment being given. They make provisions for exceptions where set treatment can be provided without the consent of the user – that is, when the opinion is that the user suffers significant mental illness to require treatment, and at the time of application, the user is incapable of making informed decisions on the need for care, treatment and rehabilitation services. The sections allude to one component of informed consent, that is, capacity. It recognizes that in some instances the mental illness may be debilitating enough to impede the user's insight and judgement, and compromise their ability to make informed and well-considered decisions, and thus to provide valid consent. Based on this acknowledgement of the concept of capacity,

[90] S 9.1(c) of the MHCA discussed above.

and the ability of the user to make informed decisions at a set time, sections 25, 27 and 33 of the legislation prescribe for three types of admissions into the mental health-care facility, two of which relate to admission without valid consent from the patient. The types of admissions are namely: voluntary care, assisted care and involuntary care.[91]

(iii) The Children's Act

The Children's Act makes provisions for informed consent insofar as it relates to children (a child is defined in this act as persons under the age of 18 years). At section 10, the Act makes provisions for a child's right to participate (in an appropriate manner) in decisions concerning them (that is, a child who is of such an age, maturity and stage of development as to be able to participate in matters involving them). Section 13 relates to children and health information and highlights, among others, the child's rights to have access to information regarding their health and to have access to information regarding the cause and treatment of their health status. These rights, once again, imply a duty of disclosure upon the health-care practitioner.

The Act provides that a child may not be subjected to medical or surgical treatment without valid consent. The child can lawfully consent to his own medical treatment or surgery if he is over the age of 12, provided he is of adequate maturity and mental capacity to appreciate well the natures and consequences of such treatments, while parents or guardians may provide consent for the minors under the age of 12, and those with insufficient maturity to comprehend the nature and the risks inherent

91 See the MHCA s 25. Voluntary admission refers to a user presenting himself voluntarily to a mental health care facility and requesting their services. This section also provides that users presenting voluntarily are entitled to care, treatment and rehabilitation services. S 26–31 of the MHCA relate to matters concerning assisted care. Assisted admissions refer to the application by a third party to have the user admitted into a health care facility. The user in this instance is incapable of making informed decisions by themselves on the need for care, and are willing to receive care. At s 32–38 the MHCA regards matters of involuntary care and admission of mental health-care users. The user in this instance is both incompetent to make informed decisions on the need for care, and is unwilling to receive such care.

within the treatment. Other entities who may lawfully provide valid consent on behalf of the child include the superintendents of the health-care facility, the Minister of health, and the courts, each in certain specific situations.[92]

(iv) Sterilization Act

Section 1 of this legislation includes a definition of consent as it appears in this specific Act.[93] The definition provides some of the characteristics of the information that needs to be imparted unto the patient in order to obtain consent to the proposed procedure, that is, the information must be clear, adequately describe the proposed plan of the procedure, and include the risks and consequences of the proposed treatment. It is perhaps worth noting however, that the Act never refers to the term 'informed consent', but only 'consent'. However, the former term is probably implied as the Act, similar to other legislation, implies a legal duty upon the health-care practitioner to provide such information.

(v) Choice on Termination of Pregnancy Act

The provisions for the requirement of informed consent are made at section 5(1) of the Act. The section further provides that, in spite of any other law or the common law, no other consent, than that of the pregnant woman in question is required. The section makes provisions at section 5(3) for pregnant minors;[94] and at section 5(4) for a severely mentally disabled and unconscious woman who requires termination of pregnancy. In the couple of sections above, the legislation references one of the components of informed consent: mental capacity. The Act fails however, to define the term 'informed consent' as appearing in this legislation, and similarly fails to

92 The Children's Act s 129.

93 Sterilization Act (n 83 above) s 4 provides a definition of informed consent: "…'consent' means consent given freely and voluntarily without any inducement and may only be given if the person giving it has – (a) been given a clear explanation and adequate description of the – (i) proposed plan of the procedure; and (ii) consequences, risk and the reversible or irreversible nature of the sterilization procedure…"

94 "[M]inor means any female person under the age of 18 years."

make pronouncements on knowledge and information sharing, including the duty implied on the doctor to impart such knowledge: it does not describe the content of the information, including information on the actual procedure. The best the Act provides on the component of knowledge is at section 7, which states that the pregnant woman must be informed of her rights as they are provided for in the Act.[95]

My criticism levelled at all the legislation discussed above remains this: they fail to provide a comprehensive and consistent definition of informed consent. Definitions often guard against different interpretations, including misinterpretations. However, I acknowledge the following two considerations: a) The Constitution and legislation usually provide a broad framework and refer to broad concepts, and thus it is not inconceivable that a lengthy discussion of the term would be omitted. Regulations can then be used to include expanded details. b) I also consider the fact that the topic is vast, has multiple components and has different ethical theories levelled for and against it. In fact, this specific fact about informed consent forms a considerable part of this writing.

7. Case Law

Previously, informed consent had received little attention in South Africa medical-malpractice law and,[96] precedence on the duty placed on the doctor to disclose information was scant. However, there has since been cases where the issue of consent to medical procedures has come to the fore, which allowed the courts the opportunity to make remarks on the doctrine of informed consent and its applicability in South African medical law. Leading cases include *Stoffberg v Elliot* (1923),[97] *Esterhuizen v Administrator Transvaal* (1957),[98] *Castell* (1994),[99] and the relatively

---

95 Contrast this to the NHA (n 71 above) which lists the following at s 6(1): "(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."

96 Van Oosten (n 9 above) 31.

97 *Stoffberg v Elliot* (1923) CPD 148.

98 *Esterhuizen* (n 17 above).

99 See *Castell* (n 10 above) 420. Facts of the case are summarized from the judgement of Scott J as follows: In this 1994 case, the plaintiff (patient) underwent a surgical called subcutaneous

recent Supreme Court of Appeal case of *Louwrens v Oldwage* (2005),[100] among others. In his thesis, van Oosten discusses in length the relevant cases according to their pronouncements on the different aspects of informed consent. The first group of cases, relate to informed consent as a requirement for medical intervention, and includes *Stoffberg*, *Esterhuizen*, and *Phillip v De Klerk* (1983).[101] The general standpoint regarding informed consent in South African case law, is the adjudication that, from both ethical and legal considerations, valid consent is required prior surgical procedures and medical treatment, with the three cases referenced above consistently upholding this pronouncement. The pronouncement accords with provisions of the Constitution, including in particular the respect and elevation of human rights. This standpoint also accords with international standards, and evidently reflects international strides towards respecting and embracing patient autonomy, largely by allowing patients to partake in matters and decisions regarding their health. The South African courts were also consistent, particularly in *Phillip*, in rejecting the notion of doctor-knows-best and the principle of professional medical judgement. They instead affirmed the principle of self-determination, individual autonomy and the right to security of the body of the person. In *Stoffberg*, Watermeyer J noted that:

> [A] man, entering a hospital, does not submit himself to such surgical treatment as the doctors in attendance upon him may think necessary…[102]

Relating somewhat to the above quotation, Strauss highlights the fact that, notwithstanding cases of emergency, in which the doctor is then constitutionally obligated to provide emergency treatment, the doctor is in general under no legal duty to provide medical treatment to a patient. A doctor, when not willing, can

---

mastectomy performed by the defendant (a plastic surgeon). Some 36 hours post the operation, the plaintiff noticed a discolouration of the left nipple, and an area below the right areolar appearing pale and ischaemic. Day 7 after the operation, the plaintiff, while changing her wound dressings at home, noticed a discharge, with a foul smell on both the right and left breasts. As a result of the worsening necrosis, the plaintiff had to undergo multiple further surgeries, both debridements and reconstructions, procedures which needed further financing by the patient. Resultantly, the plaintiff claimed for damages against the defendant to the sum of R94 952, 12.

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

101 *Phillip v De Klerk* 1983 (T) – unreported.

102 *Stoffberg* (n 97 above).

lawfully refuse to provide treatment to a patient. Strauss further adds that, save for other grounds of justification, including a court order and instances where there exists a statutory order necessitating the doctor to treat, no doctor holds a right to provide treatment to a patient: His right to treat is based on the patient's consent.[103] Watermeyer J qualified his point quoted above by referencing the patient's right to security of the body, and stated the following about the patient and consent:

> ...he [the patient] remains a human being, and he retains his right [the patient] to remain human being, and 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 his consent to an operation is expressly[7] obtained, any operation performed upon him without his consent is an unlawful interference with his right of security and control of his own body, and is a wrong entitling him to damages if he suffers any.[104] (Footnotes omitted).

This stance was upheld by the court in *Esterhuizen*. Bekker J at 721B/C-E said the following regarding consent to medical procedures:

> I do not pretend to lay down any such general rule; but it seems to me, and this is as far as I need go for purposes of a decision in the present case, that a therapist, not called upon to act in an emergency involving a matter of life or death, who decides to administer a dosage of such an order and to employ a particular technique for that purpose, which he knows beforehand will cause disfigurement, cosmetic changes and result in severe irradiation of the tissues to an extent that the possibility of necrosis and a risk of amputation of the limbs cannot be excluded, must explain the situation and resultant dangers to the patient - no matter how laudable his motives might be - and should he act without having done so and without having secured the patient's consent, he does so at his own peril.[105]

It has thus become a well-established principle in local case law that informed consent is essential for lawful medical interventions.

In addition to consistently upholding that consent is needed prior to provision of certain health-care services, the courts noted comprehension as a prerequisite for

---

103 Strauss (n 7 above) 3.

104 *Stoffber*g (n 97 above).

105 *Esterhuizen* (n 17 above) 721.

valid consent, and how this implies a legal duty on the doctor to provide the patient with information prior to consenting. The courts have thus established and upheld consistently that disclosure of information that is relevant to the proposed procedure is in fact a prerequisite for valid consent. The second group of cases discusses by van Oosten involve the duty placed on the doctor to inform the patient of risks involved in a proposed treatment. Court rulings on the doctrine of informed consent generally impose a duty upon the health-care practitioner to disclose information for lawful consent. In one of the first cases to deal with the duty of disclosure, *Lymbery v Jefferies* (1925),[106] the court accepted the notion that the health-care practitioner is duty-bound to provide the general information to the patient as part of the consenting process. In *Lymbery*, the plaintiff sustained burn wounds from radiation treatment for her uterine fibrosis. In their action for claim, the plaintiff's counsel argued that the doctor acted negligently in omitting to inform the plaintiff of the risks and consequences involved in a proposed treatment. The court noted as follows at 240:

> It may well be that it is the duty of the surgeon before operating to tell the patient that the operation is dangerous and may end in death, or that it will be accompanied with great pain.[107]

Similarly in *Rompel* (1953),[108] it was ruled that a health-care practitioner is duty—bound to disclose to the patient serious risks the latter voluntarily accepts in consenting to certain medical procedures. Neser J, in *Rompel* held the opinion that a patient should be informed of risks he agrees to incur by undergoing the proposed treatment and renounced consent without comprehension of such risks. Neser J, stated:

> 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, in order to effect a possible cure for a neurotic condition, I have no doubt that a patient should be informed of the serious risks he does run. If such

106 *Lymbery v Jefferies* 1925 AD 236.

107 *Lymbery* (n 106 above) 240.

108 *Rompel* (n 22 above).

> dangers are not pointed out to him then, in my opinion, the consent to the treatment is not in reality consent - it is consent without knowledge of the possible injuries. On the evidence defendant did not notify plaintiff of the possible dangers, and even if plaintiff did consent to shock treatment he consented without knowledge of injuries which might be caused to him. I find accordingly that plaintiff did not consent to the shock treatment.[109]

These were also the views of Scott J, in *Castell*.[110] In the plaintiff's particulars of claim, the plaintiff's counsel averred that the doctor was under a legal duty to warn the plaintiff of material risks and complications prior to the operation. The counsel charged that the defendant breached this duty to disclose that he owed to his patient, and suggested that the plaintiff would have forfeited the operation had the defendant not breached his duty to disclose material risks and complications. Scott J, articulated that a doctor needs to obtain informed consent from his patient prior to any medical intervention and that as part of the consenting process, the doctor has a duty in certain instances to disclose certain risks involved in a procedure (or treatment) on the patient. Scott J, remarked that 'a medical practitioner undoubtedly has a duty in certain circumstances to warn his patient of the risks involved in surgery or other medical treatment.' Regarding the duty to disclose however, Scott J further noted that: '… the difficulty is to determine when that duty arises and what the nature and extent of the warning must be'.[111]

Neser J, in *Rompel* commented further on the duty to disclose. In addition to highlighting the existence of the duty placed on the doctor to disclose, Neser J discussed the standard of measurement regarding the information to be disclosed. He proposes and upholds that this duty to disclose, and subsequently the conduct of the health-care professional in this regard, is to be tested against the standard of the reasonable doctor faced with a similar situation. Notwithstanding his stance on the medical expert test, Neser J further disclaims that the final adjudication should still remain that of the court, and that the court should still make up its own mind, with the assistance of medical expert opinion.[112]

---

109 *Rompel* (n 22 above).

110 *Castell* (n 10 above).

111 *Castell* (n 10 above).

112 *Rompel* (n 22 above).

In *Richter and Another v Estate Hammann*,[113] the courts acquitted the defendant (a neurosurgeon) of charges brought against him by the plaintiff, and found that the defendant had not acted negligently in failing to warm the patient of those complications of the proposed surgery that have been proved on evidence to be remote. What constitutes a remote complication was discussed, *inter alia*, in the case of *Louwrens v Oldwage*. The issue of consent and the standard of disclosure came once again to the fore in *Louwrens*, a case that was heard at the Supreme Court of Appeal of South Africa. The plaintiff suffered from peripheral arterial disease and a disc prolapse in the lumbar vertebrae, for which he consulted the defendant, and a neurosurgeon respectively. The court dismissed the plaintiff's claim that she had not consented to the surgical procedure performed by the defendant. This claim was based on the discrepancy in terminology between the procedure documented on the consent form (femoro-femoral bypass) and the procedure performed by the defendant (iliac bi-femoral bypass). The court, after consideration of expert medical advice, held that the procedures were the same, and that highlighting the discrepancy in terminology was a matter of semantic interest only. Mthiyane JA, once again after considering expert medical testimony, dismissed also the patient's claim that he was not informed of the risks involved with the surgical procedure, particularly the risk of claudication post-surgery. Mthiyane JA, held that, regarding the duty to disclose, the doctor's failure to disclose a risk worth a 2% chance of occurrence did not constitute negligence. The Judge articulated as follows:

> In my view of the evidence, the likelihood of steal occurring, with the resultant claudication, was so negligible that no duty arose on the defendant to mention it and his omission to do so did not constitute negligence.[114]

The court, in this case, attached a numerical value to what would define whether a complication or risk is negligible, and thus not requiring disclosure, or conversely significant, and so enough to warrant disclosure. The court 'determined' the materiality of a risk based on a number percentage. I consider the fact that the numerical value was determined with assistance from expert medical testimony and that they have been proved on evidence. The court did not elaborate however, on what the maximally negligible percentage would be, and subsequently, at what

---

113 *Richter & Another v Estate Hamman* 1976 (3) SA 226 (C).

114 *Louwrens* (n 100 above) 27.

minimum percentage a risk becomes material enough to warrant disclosure. The determination of this percentage speaks directly to the standard of disclosure, and the approach thereto, which has been rather inconsistent in different countries' jurisdictions. However, two particular standards are widely recognized, that is, 'the patient-oriented,' and the 'doctor-oriented' standards. Insomuch as it relates to the component of knowledge for informed consent, and also to the study question (can informed consent ever be fully informed?), the topic of disclosure is discussed in detail in the following chapter.

Van Oosten comprehensively summarizes the stance on informed consent in South African case law with the following points:[115] (Paraphrased).

- South African case law affirms informed consent,
- it acknowledges the grounds of justification of emergency,
- it highlights patient's rights to knowledge, informed consent and informed refusal,
- it invalidates consent without genuine knowledge and understanding on the part of the patient,
- it places a duty upon the health-care professional to disclose information,

---

115 Van Oosten (n 9 above) 48 – 53.

"d) Moreover, in the absence of awareness, knowledge, perception and appreciation of the risks and dangers inherent in the treatment in question, there can be no question of real consent to it by the patient" and

At e) he writes: "Consequently, the doctor is under a corresponding obligation not only to procure his patient's consent to the proposed treatment, but also to inform him of its attended risks and dangers.

And at f) However, the doctor's duty to inform is confined to providing the patient with a general idea of the serious or dangerous risks attached to the proposed treatment, there being no obligation incumbent upon him to disclose in detail all the complications that may arise or to disclose rare, idiosyncratic, unforeseeable, uncommon, unusual or remote adverse consequences that may result from the proposed treatment. In this regard, however, it must be pointed out that since, on the one hand, rare, uncommon, unusual or remote risks or dangers may be of a serious nature, and since, on the other hand, slight risks or dangers may be usual and common, the simultaneous application of these criteria to determine the scope of disclosure can easily lead to diametrically opposing results. (Footnotes omitted).

- it provides the extent to which the health-care practitioner is required to disclose, quoting the general idea of serious or dangerous risks attached to the proposed treatment,
- it acknowledges the concept of therapeutic privilege and the standard of 'best interest of the patient,'
- it states that failure to procure informed consent can result in civil liability and criminal assault, while failure to disclose information material to the proposed procedure is typically dealt with in the law of negligence delict, and
- it acknowledges *conditio sin qua non test* and the *expert medical advice test*.

8. Common law

Informed consent is also based on the common law right to absolute security of the person. This right is discussed above.

9. 'Soft' law

Let us now consider other sources of law, particularly *soft law.* These encompass sources that prescribe authoritative rules of conduct and guidelines for matters regarding the health-care fraternity in South Africa. Although they are not always legally binding, they do still warrant at the least a brief discussion and assessment for a few reasons: (i) some documents include booklets issued by the HPCSA, which is a statutory body, as per provisions of the Health Professions Act; (ii) some of the documents are dedicated entirely to the topic of informed consent and as such provide a more detailed discussion on the application of the doctrine in a health-care setting, and the components of this doctrine. They provide practical dos and don'ts to obtaining informed consent. They also provide discussions of, and in most instances make reference to, ethical theories and concepts that are applicable in informed consent. For this reason, some concepts and principles can be referenced from provisions in these documents; and (iii) although contravention of provisions of these sources may not result in a law suit and a course in legal action (neither civil nor criminal) they do possess authoritative power and contravention thereof may result in disciplinary repercussions from authoritative bodies like the HPCSA. Let's consider the series of booklets issued by the HPCSA:

HPCSA's booklet 1, at paragraph 2 deals with core ethical values and standard grounds for maintaining good professional practice. Specifically at paragraph 2.3, the booklet enumerates the applicable core values including respect for persons and their dignity, principles of non-maleficence and beneficence, and principles of autonomy and truthfulness, amongst others. At paragraph 5.3, the booklet provides, regarding informed consent, for the manner in which the health-care practitioner should act.[116] Furthermore, paragraph 5.5 of the booklet relates to patient participation in their own health-care: It places a duty on the health care practitioner to respect the patient's right to full involvement in his health-care including the right to give informed consent, to respect patient's right to refusal of treatment, and to inform patients of their right to seek alternative medical opinion should they wish.[117]

HPCSA's booklet 3, on the National Patient's Right Charter,[118] states that, at paragraph 2.8, everyone has a right to informed consent and to full and accurate information regarding their health and health-care, and also that, at paragraph 2.9, everyone possess a right to refuse medical treatment.

---

116 HPCSA's booklet 1, General ethical guidelines for the health care professions, at para 5.3 states that:

"Health care practitioners should:

5.3.1 Give their patients information they ask for and need about their condition, its treatment and prognosis.

5.3.2 Give information to their patients in the way they can understand it. The information must be given in a language that the patient understands and in a manner that takes into account the patient's level of literacy, understanding, values and belief systems.

5.3.3 Refrain from withholding from their patients any information, investigation, treatment or procedure the health care practitioner knows would be in the patient's best interest.

5.3.4 Apply any principle of informed consent as an on-going process.

5.3.4 Allow patients access to their medical records."

117 HPCSA's booklet 1 (n 116 above) at para 5.5 states that:

"Health care practitioners should:

5.5.1 Respect the right of patients to be fully involved in decisions about their treatment and care even if they are not legally competent to give the necessary consent.

5.5.2 Respect the right of patients to refuse treatment or to take part in teaching or research.

5.5.3 Inform their patients that they have a right to seek a second opinion without prejudicing their future treatment."

118 HPCSA's booklet 3 "Guidelines for good practice in the health care professions. National Patents' Rights Charter."

Booklet 6 of the HPCSA's guidelines for good practice deals with the general ethical guidelines for health researchers. [119] It is worth having a closer look at the provisions of this booklet as it provides advanced details on informed consent, as compared to the legislative documents. The booklet refers first to ethical values governing medical research, particularly the theory of *principlism.*[120] The booklet further prescribes at paragraph 4.1(2) for the requirement of participants to be afforded the opportunity to make informed decisions regarding their participation in research.

Paragraph 6.3 of the HPCSA's booklet 6 deals specifically with the issue of consent in medical research. It makes a provision for the requirement of *informed consent*. It further details the kind of information needing to be disclosed, including the nature and effect of the research, particularly the effects of the research on the participants, including its consequences, risks and benefits. The section also requires that information be provided when the participants ask about the research. In a similar breath, the section further disallows the act of purposefully withholding information from a participant. Paragraph 6.3 further makes provisions for participants who are unable to legally consent for themselves, for example, children, the mentally challenged, the elderly and the unconscious persons. The section also states that consent should be viewed as an ongoing process and participants be allowed to change their mind at any point in the research regarding their voluntary participation. A further provision is made at paragraph 6.3(10) to inform participants of the above-referenced right to abstain from participation or to withdraw at any point from participating in the research. The section further reinforces the need for ongoing disclosure of information and transparency.

At paragraph 9.2(6), the booklet further prescribes that failure to obtain informed consent amounts to scientific misconduct, which is reportable to the HPCSA. The scientific misconduct is not elaborated on further, omitting also prospects of repercussions for the misconduct.

---

119 HPCSA's booklet 6 "Guidelines for good practice in the health care professions. General ethical guidelines for health researchers."

120 See principlism discussed above.

The provisions of booklet 6 on the general ethical guidelines for health researchers give a rather expanded idea of the character of information that need to be provided to the participant. This abundance of detail is overlooked in statutes.

Another booklet worth discussing briefly is booklet 9[121] which relates specifically to seeking informed consent from patients. The considerable points in the booklet include one in the preamble, which regards the health-care profession as a moral enterprise. The first argument the booklet advances, in favour of respect for patients' autonomy, is that it cultivates mutual trust between health-care practitioners and patients.[122] It further explains respect for patient autonomy as encompassing patient's rights to both informed consent and informed refusal, even in situations where the latter may lead to adverse effects concerning their health. The booklet defines informed consent as encompassing the patient's right to informed consent and refusal, together with the provision of sufficient information, in a way that the patient can understand, so as to enable the patient to exercise their right to make informed decisions about their care.

At paragraph 2.3 the booklet makes provisions for effective communication between the health-care practitioner and the patient by noting that the health-care practitioners must take appropriate steps to find out what the patient wants to know and ought to know about their condition and its treatment. In addition to the prescribed minimum information disclosure requirements for consent, the booklet also makes reference to the so-called patient-oriented standard of disclosure. While the minimum requirements for information disclosure provide an objective model of disclosure, further specific information disclosed to the specific individual patient is in keeping with the more 'subjective' approach. Regarding the minimum requirements for information disclosure, the booklet makes reference to provisions of the NHA and, a list characterising the type of information that needs to be disclosed to a patient is provided at paragraph 3.1(3). The 'subjective test' of disclosure is further

---

121 Booklet 9 "Guidelines for good practice in the health care professions. Seeking patients' informed consent: The ethical considerations;" referred as booklet 9.

122 Booklet 9 (n 121 above) paragraph 2.1.

acknowledged at paragraph 3.1(1) of the booklet.[123] Regarding the subjective test, the booklet notes the following:

> It provides that the amount of information that must be given to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patients may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects, or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.

At paragraph 3.1(4), the booklet further makes a requirement that health-care practitioners should take steps to find out about the patient's individual needs. At paragraph 3.1(5), the booklet discusses the scope of the consent and the extension of procedures: It prohibits health-care practitioners from exceeding the scope of the provisions in the consent agreement, save for emergency situations. At paragraph 3.1(7), it provides for prior discussion of, and consent to, health issues that may result during the course of a treatment, when the patient would be unable to give consent, for example, under general anaesthesia during surgery.

At paragraph 3.2, the booklet requires that should the patient specifically ask about his health, questions be responded to truthfully and as fully as the patient wishes. The concept of *therapeutic privilege* is recognized at paragraph 3.3 of the booklet, a section which further references the South African courts in their view that patients must be informed of all 'material' risks in order to provide proper informed consent. 'Material' is discussed to be:

> 3.3.2.1 A reasonable person in the position of the patient, if warned of the risk, would attach significance to it; and 3.3.2.2 the health care practitioner should reasonably be aware that the patient, if warned of the risk, would attach significance to it.

These two definitions of material risk are discussed in details below at chapter 3.[124] Paragraph 3.4 of the booklet discusses the manner in which information is to be disclosed, including the consideration of informed consent as an on-going process,

---

123 Booklet 9 (n 121 above) paragraph 3.1.1.

124 See discussion on material risk below at Chap 3.

the use of language that the patient is comfortable with and allowing for sufficient time for questions and reflections on the information.

Paragraph 4 provides the meaning of informed consent as adjudicated in South African courts.[125] Another important point made in the booklet is at paragraph 7.1 which states that: 'It is for the patient, not the health care practitioner, to determine what is in the patient's own best interests.'

Section 8 of the booklet makes reference to the ground of justification of emergency. It provides that treatment may be given without patient's consent in situations of emergency where consent cannot be obtained timeously. In addition, the section addresses situations where advance refusal to treatment on the part of the patient may be available, stating that where such exists, the health-care practitioner should respect the patient's wishes contained therein.

The booklet further discusses another requirement of informed consent viz capacity. It discusses children insofar as their ability to give informed consent is concerned. At paragraph 10, the booklet recognizes the ethical theory of *'best interest of the patient'* and its application to situations where the patient lacks capacity for whatever reason there may be, while at paragraph 13, the booklet outlines the different forms of consent, that is, verbal or scribed; and further outlines situations where written consent is specifically required.

10. Conclusion

This chapter has placed the doctrine of informed consent into perspective in terms of the history, the broader ethical theories underscoring this doctrine and the legal prescriptions for informed consent in South African law. After a detailed review on principlism and the ethical theory of utility, and how they relate to informed consent, this chapter focused on available local authority on consent. This included the review

---

[125] Booklet 9 (n 121 above) paragraph 4 states: "4.1 The South African courts have held that legally for a proper informed consent the patient must have:

4.1.1 Knowledge of the nature or extend of the harm or risk;

4.1.2 Appreciated and understood the nature of the harm or risk;

4.1.3 Consented to the hard or assumed the risk; and

4.1.4 The consent must have been comprehensive, (i.e. extended to the entire transaction, including of its consequences)."

of the different provisions in sources that included the Constitution, other legislation and case law. The discussions have thus far yielded the following assessments: Firstly, that informed consent plays a critical part of the lawfulness of the doctor-patient relationship and, that no medical or surgical procedures may be provided to the patient without their valid consent. This remains subject to lawful grounds of justifications that the doctor can evoke as defence for absent or invalid consent. Informed consent ousted medical paternalism as the standard of approach to health-care and the provision thereof to patients. In addition to cultivating a fertile doctor-patient relationship, informed consent embraces the respect for individual autonomy, a principle on which it is largely grounded. Particular to South African Law, informed consent is emulated through the Constitutional right not to be subjected to medical or research procedures without one's consent.[126] This is also the general judgement in our case law, a stance that corresponds with the assenting trend in foreign case law on informed consent.

Secondly, both local and foreign case law similarly consistently uphold the view that there exists a duty upon the doctor to inform the patient of the proposed treatment, including its nature, and the risks inherent therein. Thirdly, as we have seen in this chapter, it is upheld in local case law and legislation, particularly the NHA, that the doctor is expected to disclose only the diagnostic procedures and treatments 'generally' available to the patient, and the benefits, risks, and consequences 'generally' associated with each option.[127] The questions that logically follow are regarding the exact information encompassed by the term 'generally,' and the amount of information the doctor is legally constrained to disclose, for the consent in question to be informed, and therefore, valid. The answers to these questions are discussed in detail in the subsequent chapter.

---

126 The Constitution (n 1 above) s 12.

127 NHA (n 71 above) s 6 prescribes the following, regarding the kind of information to be disclosed:

"…(b) the range of diagnostic procedures and treatment options generally available to the user [patient];

(c) the benefits, risks, costs and consequences generally associated with each option…"

CHAPTER THREE

KNOWLEDGE AND DISCLOSURE

1. Chapter overview

The preceding two chapters provided the foundation or introductory notes to this study, as well as an introduction to informed consent. Particularly in chapter 2, the history and the development of informed consent were discussed. The discussion on the doctrine of informed consent was further narrowed, in chapter 2, to a review of South African law and the application of the doctrine therein. The previous discussions have yielded the following three assertions: a) that valid consent is a legal requirement prior to provision of health-care services, b) that the doctor is under a legal obligation to provide certain information and disclose certain risks to the patient, and that c) it is not expected of the doctor to provide all the information and to disclose all the risks inherent in a procedure. Instead, only the provision of the general information regarding the procedure is expected of him, while disclosure of risks considered by medical expert to be remote, is not legally required.

While both local and foreign medical laws have made similar strides towards a more patient-orientated approach to the provision of medicine and health-care, there are discrepancies between different countries' jurisprudence regarding the standards of disclosure. These different standards, together with the concept of materiality of risks, form the brunt of the discussion in this chapter. The standards are discussed in this chapter, and the South African law approach to these standards is compared to that of foreign jurisdictions. Whereas in English and Australian law, the issue of informed consent is viewed as a delictual duty placed on the doctor, a transgression of which is regarded as negligence, the approach in South African law differs. It approaches the issue as falling under the defence of *volenti non fit unjuria*, the inquiry of which would be whether the defence has been established, and whether the patient's consent has been properly informed consent. In both approaches, the patient must be furnished with information to allow for adequate understanding. This requirement is particularly important in the latter approach adopted in the South African jurisdiction, as it is a requirement for the defence of *volenti non fit injuria*. The

patient so consenting therefore admits to have perceived and understood the risks, and consents to incur such risks. The requirements for consent to operate as a valid defence were discussed earlier in chapter 2.

For a true realisation of patient autonomy, the manner in which information is provided to the patient needs to take cognisance of this principle of respect for autonomy. Therefore, more patient-orientated approaches are being adopted in court judgements. The professional community standard leaves the decision whether to disclose certain information and certain risks at the discretion of the doctor and the medical fraternity. As we shall see in this chapter, this standard has been criticised in recent court judgements on the matter, and similarly by law authors, because this standard exhibits remnants of the old-fashioned medical paternalism. Instead, the patient-orientated standards are preferred, as they approach the matter of disclosure of information and risks with consideration of the patient: The one standard judges the patient's informational needs with reference to a 'reasonable' patient in the same situation, while the other standard, which is the more appropriate one in my opinion, focuses on the particular informational needs of that particular patient in question. These different standards, together with the arguments for and against them, are examined in detail in this chapter.

2. Components on informed consent

This third chapter hones in on the component of knowledge. Brief references to other components are made where necessary for contextualization. As alluded to above, the courts, as well as writers and commentators on the doctrine of informed consent, have been consistent on the components of informed consent. These components have been proposed through different models by different writers on the topic.[1] However, notwithstanding the numerous forms in which they appear, the different models boil down to the same principles. The components have been generally

[1] Brock DW *Life and death: philosophical essays in biomedical ethics* (1993), who lists the more-widely accepted 3-component model, that is, knowledge, capacity and voluntaries. Kennedy I and Grubb A *Medical law: Text and materials* United Kingdom (1989), list similar 3 components, while Beauchamp TL and Childress JF *Principles of biomedical ethics* (2001), lists 5 elements of informed consent, viz competence, disclosure, understanding, voluntariness and consent.

accepted as follows: knowledge, capacity and voluntariness. Knowledge, as alluded to extensively in the preceding chapters, includes both comprehension and the appreciation of the information the patient is provided with. The application of this component (prerequisite for informed consent) in the medico-legal sphere introduces some rather expected questions regarding the extent of disclosure and materiality of risks that are inherent in medical treatments and surgical procedures. Capacity, requires that the consenting patient have both medical and legal competency to provide the consent. This component regards maturity of the patient as a matter of age, and also the patient's mental state at the time of consenting, that is, they must be *compos mentis*. Regarding voluntariness, it is upheld that for consent to be valid, it should be given without duress and coercion from external influences.

At the outset of this chapter, I wish to make a few disclaimers: a) this chapter focuses particularly on the one component of informed consent, that is, knowledge. This is in accordance with the study question.[2] b) The discussion relates particularly to individuals who are ethically and legally competent to provide consent. Therefore, for the purposes of this discussion, it can be assumed that the patient in question is one who fulfils the other components of informed consent, that is, competent to consent and acting freely. And c) The study focuses particularly on consent in a clinical setting, as opposed to research circumstances. Therefore the discussion can be assumed to be referring to consenting to medical procedures, unless stated specifically otherwise in the text.

3. Knowledge

For consent to be valid, and for true realisation of patient autonomy, the patient so consenting, should be furnished with adequate information to provide them with knowledge. This view holds similarly true in the South African law context where, if it is to be held that the patient's consent insinuates assumption of risks and consequences inherent in the procedure, and thus acquits the doctor of

[2] "Can informed consent ever be fully informed? Is the doctrine of informed consent possible and adequate in a healthcare setting in the South African context?" – As stated in the study proposal.

wrongfulness, it is to be presumed that the patient so consenting, must have knowledge of those risks and consequences. Not only should they be informed, but they need to have adequately comprehended the knowledge on the proposed treatment so as to allow them to make informed decisions. This was the judgement regarding knowledge in *Esterhuizen*, in which Bekker J mentioned *inter alia* that:

> … the plaintiff must have shown not only to have perceived the danger, for this alone would not be sufficient, but also that he fully appreciated it and consented to incur it …[3]

Consent provided by a misinformed patient, or a patient failing to comprehend fully the particulars of the procedure, is further regarded as invalid. Speaking directly to this view, Scott J, in *Castell* made the following remarks regarding informed consent as a lawful defence, in particular, the aspect of information disclosure:

> The doctrine [informed consent] holds that a patient's consent to medical treatment is vitiated if he is given inadequate information concerning the proposed treatment …[4]

Furthermore, it is a generally-accepted view that the doctor is under a legal obligation to provide information to the patient before the patient consents. Pertaining to the duty to inform, van Oosten notes the following, in his assessment of the doctrine of informed consent in South African law:

> … Consequently, the doctor is under a corresponding obligation not only to procure his patient's consent to the proposed treatment, but also to inform him of its attended risks and dangers.[5]

3.1. Disclosure

South African courts have upheld that knowledge is a requirement for valid consent, this necessitating a legal duty on the doctor to disclose information unto the patient (see discussion under knowledge above). As suggested above, the next matter that follows in the discussion on knowledge is the amount of information that the doctor is

---

3 *Esterhuizen v Administrator, Transvaal* 1957 (3) SA 710 (T); referred to as *Esterhuizen*.

4 See *Castell v de Greef* 1994 (4) SA 408 (C); referred to as *Castell,* 420.

5 Van Oosten F *The doctrine of informed consent in medical law* 48-53.

obligated to disclose. This amount of information, together with the kind of information to be disclosed and the standard of disclosure remain contentious, and the standards differ between various foreign jurisdictions. With particular reference to South African law, the uncertainty on this issue is aggravated by the facts that legislation fails to shed better light on the issue, while precedent judgements in South African law on this matter are scarce.[6] One thing remains clear however, and that is, as in accordance with the general move towards embracing patient autonomy, the standard of disclosure has also evolved from the 'professional community standards' to the 'reasonable patient'.[7]

When considering disclosure of information to the patient, two extreme points exist: On the one extreme, lies total non-disclosure. We have seen in the preceding discussions how this is unfavourable, as it undermines patient autonomy, denies the patient the opportunity to make informed medical decisions in terms of what is to happen to their body, and disallows the patient their right to express themselves in a manner that accords with their particular views on life. Patients would likely leave the decisions to the well-learned doctor, a situation which would clearly mimic the obsolete paternalistic approach to medicine. The other extreme is the view that the doctor should disclose all the information regarding the proposed treatment or procedure. This view, however, has never found favour as the applicable standard of disclosure. Arguments against such a stance include the valid concern (and to some extent, a fear) that it would render the medical profession intolerable if it was expected of the doctor to disclose all information, including all possible risks and consequences.[8] Another criticism charged at this view is that the patient, if told all the information and warned of all risks of a procedure, could never completely apprehend the vast medical knowledge and terminology. This would render the exercise futile, as valid consent requires knowledge, comprehension and

---

6 *Castell* (n 4 above) 408. Ackermaan J, in Castell noted that even though case law on informed consent has been previously deliberated on in South African courts, there has not been ample discussion on disclosure and the standards thereof. He referenced the 'reasonable doctor' standard of disclosure by commenting on the scarcity of firm judicial pronouncement to the effect that disclosure was deemed unnecessary because a reasonable doctor finding himself in the same situation would similarly not have disclosed.

7 Dhai A. "An introduction to informed consent: Ethico-legal requirements" SADJ (2008) 63.

8 *Esterhuizen* (n 3 above) 417.

appreciation by the patient of the risks involved. Further critique regards the possibility of overwhelming the patient with information, which could present undesirable consequences, including difficulty in processing even the relevant information, and the risk of the patient refusing necessary procedures based on remote risks. Strauss,[9] warns of over-informing, and promotes that it may be tantamount to not informed at all, and that the consent may not be real if the patient is over-burdened with massive technical and medical information.

Perhaps the best-stated response to the criticism on total-disclosure is by Brock,[10] who advances that for consent to be valid, the patient is not expected to gain expert knowledge on all the scientific information regarding the procedure. Instead, the patient needs only to understand how the relevant information and how various options will affect their 'capacity to pursue their various plans of life.' This strikes a fair balance between complete non-disclosure and total-disclosure. It appears to be a good point of departure in the argument on disclosure, as it aims not to furnish the patient with all information, but only the information which would be material in the patient's decision making-process. This approach remains appropriate as it still upholds the respect for individual autonomy, and affords the patient the opportunity to make informed decisions and to exercise their inherent and fundamental right to self-determination, including the chance to decide what is to happen to their body. This stance takes cognisance of the well-acknowledged view that if the patient specifically asks for information, such information should be provided candidly and fully.[11]

Therefore in South African law, the doctor remains under no duty to inform the patient of all aspects of the procedure, including remotely possible consequences. Instead, he is called upon to provide only the 'general' idea of the treatment and risks. The general information required for disclosure in South African law is summarised by Carstens and Pearmain,[12] and also by Strauss,[13] and include the following:

---

9 Strauss SA *Doctor, patient and the law – A selection of practical issues* (1991).

10 Brock (n 1 above).

11 Kennedy and Grubb (n 1 above).

12 Carstens P and Pearmain D *Foundational principles of South African medical law* (2007).

13 Strauss (n 9 above) 3-13.

- the general idea of the procedure in broad terms,
- the importance of the procedure,
- the nature, scope, consequences, risks, dangers, complications, and benefits,
- the disadvantages and the prognosis,
- alternative treatment available,
- the patient's right to refusal of treatment, and
- the information should be provided in lay language.

This list is comparable to the provisions of the NHA, which requires disclosure of, among others, the benefits, risks, costs, and consequences generally associated with the proposed procedure.[14]

Regarding disclosure, and with particular reference to the risks and consequences inherent in a procedure, it is upheld that the doctor is not obliged to disclose them all. These were the utterances of Wessels JA, in Lymbery,[15] where he (Wessels JA), in concord with other foreign law, pronounced that the legal duty of the health-care practitioner to disclose information extends only to 'some general idea' of the consequences. Wessels JA, made the following statement:

> [A]ll that the surgeon is called upon to do is to give some general idea of the consequences. There is no necessity to point out meticulously all the complications that may arise.[16] (Footnotes omitted).

In the foregoing statement, Wessels JA, implies a differentiation of the kind of information he considers a necessity to disclose. By his pronunciation on the 'general' information, Wessels JA insinuates that there exists another kind, that is, information that is not encompassed by the word 'general,' and thus, not necessary to disclose. The exact nature of this 'general' information is not specifically

---

14 National Health Act 61 of 2003, referred NHA, s 6 prescribes the following, regarding the kind of information to be disclosed:

"…(b) the range of diagnostic procedures and treatment options generally available to the user [patient];

(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."

15 *Lymbery v Jefferies* 1925 AD 236.

16 Van Oosten (n 5 above) 46.

expounded on. However, he (Wessels JA), elaborated further by referring to risks that are rare (in cases where treatment is administered with relevant skill and considerable precision) and those risks that are often due to idiosyncrasy and could not be foretold. Wessels JA pronounced that the duty to disclose such risks is not to be imposed upon the doctor. A similar judgement was upheld in the appeal case of *Louwrens*, where the plaintiff's allegations of medical negligence by the doctor, based on the alleged lack of informed consent, were dismissed. It was stated in the judgement that the chance of the resultant risk occurring was, based on evidence, negligible enough not to warrant disclosure.

In the *Lymbery* and *Louwrens* cases above, the determination of the 'general' information is considered with reference to chance of occurrence, which is in turn based on expert medical evidence. I am of the view however, that the nature of the information also plays a considerable role in determining which risks are to be disclosed. If the risk is significant to the particular patient's life, regardless of the chance of the risk actually materializing, I opine that the risk warrants disclosure. I am of the view that Wessels JA's statement above should be augmented with the clause that information relevant to the patient's decision-making process of the patient should be disclosed, that is, in instances where it is reasonably known that certain risks play *any* (emphasised) role in assisting the patient to make informed choices, including those risks whose possibility of occurrence are regarded as minute. Consider for example a Jehovah's Witness patient who, as per their religious beliefs is against donor blood transfusion. In a situation where such a patient is consenting to a procedure, with minimum likelihood of significant blood loss, but nevertheless still a possibility, and where treatment to this risk is only blood transfusion, I am of the opinion that such a risk should be disclosed.

3.1.1. Test of disclosure

Granted, on the one hand, that the courts favour patient autonomy and uphold the view that the health-care practitioner is duty-bound to furnish the patient with information and, granted on the other hand, that the courts acknowledge the fact that it would be an unreasonable expectation of the doctor to disclose all information regarding a procedure, it would seem what remains at the heart of the debate is the

difficulty in striking a balance between the attempt to adequately inform the patient and, not rendering the medical profession unbearable due to difficult expectations of disclosure.

3.1.1.1. Doctor-orientated standard

Considering that the doctor is obliged to disclose risks inherent in a procedure, but noting also that it is not expected of him to disclose those risks considered rare, the question remains how these risks are judged and by whom. There remains contention regarding these tests of disclosure, in particular as to who sets this standard, that is, the patient or the medical profession. Two standards of disclosure exist, one doctor-orientated, and the other, patient-orientated. The former leaves the decision whether or not to disclose certain information at the discretion of the doctor and the medical fraternity. It tests the actions, or the lack thereof, of the doctor against that of a 'reasonable' doctor. It judges the doctor's conduct regarding consent against that of a 'reasonable' doctor in a similar situation. This was the viewpoint adopted by Watermeyer J in *Richter*, in his discussion on therapeutic privilege. Granted that the judge (Watermeyer J) was discussing specifically therapeutic privilege, his comments are similarly applicable in the discussion on the test of disclosure, as therapeutic privilege invokes an argument regarding the balance between patient autonomy and allowing the medical profession to determine the standard of disclosure. Watermeyer J held as follows:

> 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.
>
> It may well be that in certain circumstances a doctor in 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 circumstances of the

> particular case, should or should not do. The Court must, of cos, make up its own mind, but will be assisted in doing so by medical evidence.[17]

The approach was also adopted by Scott J in *Castell* who, while referencing English law, noted the following:

> The 'reasonable doctor' test is one which is well-established in our law and it applied in relation to both medical diagnosis and treatment. It affords necessary flexibility and if properly applied does not, in my view, 'leave the determination of a legal duty to the judgement of doctors', as suggested by Lord Scarmann in *Sidaway v Governors of Bethlehem Royal Hospital and others* [1985] 2 WLR 480 (HL) ([1985] 1 All ER 643) at 488 (in WLR, and 649e in All ER) in relation to the so-called 'Bolam principle' (*Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 QB).[18]

The 'reasonable' doctor standard is comparable to the one adopted in the English law, and similarly in Australian law, where the issue of consent is regarded as falling under the doctor's duty of care, the transgression of which constitutes negligence, which is judged as per the 'reasonable' doctor test.

I am of the view that the 'reasonable doctor' test, as applied to medical diagnosis and treatment, should not be similarly applied in the case of consent and disclosure. My view is that the three issues are not similar, and are not underscored by similar principles. While medical diagnosis and treatment are largely underscored by the principles of beneficence and non-maleficence, leaving the learned doctor at the best position to decide what constitutes 'doing good' and 'eliminating' or 'avoiding' harm, consent, as already learned, is underscored primarily by the principle of respect for individual autonomy. While the doctor is expected to act in the best interest of the patient and to reduce harm in matters concerning diagnosis and treatment, actions which are appropriately measured using the 'reasonable doctor' standard, the primary concern regarding consent relates to the patient's opportunity to self-rule. The recognition of patient autonomy serves as the primary point of departure in the debate on consent. It should not be the discretion of the doctor to decide which information to disclose, and which to withhold, based on the principles of beneficence and non-maleficence. It seems inconsistent of the law to afford

---

17 *Richter & Another v Estate Hamman* 1976 (3) SA 226 (C).

18 *Castell* (n 4 above) 517-518.

recognition to informed refusal, but not to recognize appropriate disclosure on the argument that the patient may not choose those options regarded by the medical profession to be the best. In accordance with the principle of respect for individual autonomy, the person in the best position to calculate what information and what risks would impact on their various plans of life is the patient himself. To this effect, Ackermann J,[19] in the appeal case of *Castell*, respectfully argued against the 'reasonable' doctor test, and proposed that the patient-orientated approach to disclosure is not only justified, but is indeed necessary. He agreed with the view held by Scott J, which included the renouncement of the Bolam test that was reaffirmed by the House of Lords in *Sidaway v Board of Governors of the Bethlem Royal Hospital* (1985).[20] Ackermann J argued that just as it is generally-accepted that patient autonomy affords the patient the right to make informed choices regarding their health, including informed refusal and, disregarding the view held by the medical fraternity on the said matter, it is similarly irrelevant that the medical profession would hold the expert opinion that it is the doctor's duty to inform, or to refrain from bringing certain risk to the patient's attention. Ackermann J argues that the formulation laid out in the Australian case of *Rogers v Whitaker* ought to be adopted and adapted suitably to the needs of South African jurisprudence.[21]

3.1.1.2. Patient-orientated standard

While critiquing the standard of disclosure adopted in the English law, Ackermann J referred considerably to the work of Giesen. Giesen similarly criticises the doctor-orientated standard, which applies the 'reasonable doctor' test in a similar situation, and he argues that this standard leaves the decision of the scope of disclosure to the medical fraternity. Giesen rightfully notes that this approach is against patient autonomy. It denies the patient the opportunity to exercise their right to self-rule by deciding for themselves what information they should be informed of, in order to make informed decisions regarding their treatment options. Giesen further qualifies his view with the assertion that it remains the decision of the patient whether to

19 *Castell* (n 4 above) 408.

20 *Sidaway v Board of Governors of the Bethlem Royal Hospital* (1985) AC 871.

21 *Rogers v Whitaker* (1993) 67 ALJR.

undergo medical treatment or not.[22] Their rights to security of the body, personal dignity and integrity and to informed consent allow the patient the right to decide what is to happen to their body. The patient retains this right, irrespective of the acceptable medical expert standards. The patient is also afforded the right to be different and the right to be wrong. This remains in my opinion the favourable view as it accords with the founding principles of informed consent, that is, respect for patient autonomy and a shift away from medical paternalism.

Giesen references the increasing favour for the more 'patient-based' standards in foreign jurisprudence, and notes the two patient-orientated standards that could be applied in this regard: the first is the more objective standard, which references a 'prudent patient'. It determines the information to be disclosed by reference to a hypothetical reasonable patient in a similar situation. Giesen refers to it as the 'objective' standard, and writes regarding this standard that it is 'posited on the informational requirements of the hypothetical 'reasonable' patient in what the physician knows or should know to be the patient's situation. The other is the more subjective test, which focuses on the individual patient's specific needs. This standard holds that the physician ought to disclose 'information which he knows, or ought to know, that his particular patient in his particular situation requires'.[23]

The two standards referenced above can also be applied to 'material' risks. For consent to constitute valid justification that excludes the wrongfulness of medical treatment and its consequences, the obligation upon the doctor is to warn of material risks inherent in the proposed treatment. A risk is regarded to be 'material' if: (a) 'a

---

22 Giesen D *Medical malpractice law. A comparative law study of civil responsibility arising from medical care* Gieseking (1981) 158. Giesen also comments on German and Swiss law regarding the duty of disclosure. He writes: "the fundamental principle of self-determination put the decision to undergo or refuse a medical intervention squarely where it belongs, namely with the patient. It is, after all, the patient's life or health that is at stake and important though his life and health as such may be, only the patient is in a position to determine where they rank in his order of priorities, in which the medical factor is but one of a number of considerations that influence his decision whether or not to submit to the proposed intervention. But even where medical considerations are they only ones that come into play, the cardinal principle of self-determination still demands that the ultimate and informed decision to undergo or refuse the proposed intervention should be that if the patient and not that of the doctor.

23 Giesen (n 22 above) 297.

reasonable person in the patient's position, if warned of the risk, would be likely to attach a significance to it,' or (b) 'the medical practitioner is or should be aware that the particular patient, if warned of the risk, would be likely to attach significance to it'.[24]

A different test was adopted in *Castell* and subsequently applied by the Supreme Court of Appeal in *Broude v McIntosh*.[25] The enquiry in this test is whether the particular patient would have chosen a different option had the risks been disclosed to them. Thomas summarizes it as follows: 'Thus it would appear that the actual test for materiality in terms of the common law is in fact that [c] 'a risk is material if the person who consented would not have done so had the risk been known to him' '.[26] This test appears to be a certain form of the 'subjective' test. In both tests the subject of reference is the individual patient. What differentiates them are the 'outcomes.' In the test noted at (b) above, the outcome of consideration is whether the specific patient would have attached significance to the risk, while the outcome in the test at (c) above, is whether the significance that is attached to the risk would have actually resulted in the patient choosing a different course of action. The second test appears also to be narrowing the scope of the outcomes.

I am of the opinion that none of these standards remain infallible. On the face of it, the objective test appears to be the safer approach for the medical profession. It considers the patient in relation to the 'prudent' patient in a similar situation (situation that the health-care practitioner knows or ought to know to be that of the patient). It would seem to be an easier task for the courts to determine the informational needs of a reasonable man than it would be to determine specific informational needs and specific interests of a particular patient. However, even though the concept of the 'reasonable' man is not a new one to the courts, the courts can never know, with complete certainty in every case, how even a 'reasonable' patient in a similar situation would have reacted. The other drawback of the objective test remains that it is less individualistic than its counterpart, subjective test.

---

24 *Castell* (n 4 above) 426.

25 *Broude v McIntosh* 1998 (3) SA 60 (SCA),

26 Thomas R "Where to from Castell v de Greef? Lessons from recent developments in South Africa and abroad regarding consent to treatment and the standard of disclosure" *SALJ* (2007) 192.

Thus, the subjective standard seems, also on the face of it, the more favourable one, in a sense that it comes closer to the ideal target of packaging the information in a manner that is most suitable to the individual patient. However, it is more difficult to know with certainty the individual needs of each patient. Similarly, it will be difficult for the courts to determine with better precision what an individual patient would have done had certain information and risks been disclosed to them. This approach is also scrutinized by Thomas, who also note that on the face of it, the subjective standard seems to be affording the most considerations to the patient. He further notes, however, that on closer scrutiny, the use of the word 'reasonably' swings the subject in this standard to a 'reasonable' doctor (that is, what a reasonable doctor ought to have known to be the patient's condition), while the term 'likely' makes the 'reasonable' patient the 'standard' to be judged against.

Giesen proposes the 'blending' model, which would incorporate the 'objective' standard of disclosure, and thus set a standard 'minimum' set of information that needs to be disclosed, based on considerations of a 'reasonable' patient, and compounded by the more individual-patient-based standard. The former sets a uniform standard across the medical fraternity, and thus offers protection to the patient, while the latter aims at the possible maximum individuality, in accordance with the principle of respect for patient autonomy. I am constrained to agree with the propositions of Giesen in this regard. These propositions by Giesen, and in particular his arguments therefor, were quoted by Ackermann J in his judgement in the appeal case of *Castell*. Regarding the objective test, Ackermann J quoted the work of Giesen as follows:

> It will normally lead the physician to a correct assessment of the average patient's *minimum* informational needs. His right to self-determination does not require more if in fact the individual patient is a member of that community of reasonable (or 'model') patients with average informational needs.[27]

And that the additional 'subjective' test would be:

---

[27] *Castell* (n 4 above) 421.

> … better attuned to the values of each person and his or her inalienable right of self-determination, and better able to manage situations beyond the limitations of the objective test.[28]

The application of such proposal by Giesen recognizes the patient's right to choose not to be informed, and their right to transfer all the proxy to the doctor. Other traditional restrictions would include, as noted previously by Carstens and Pearmain,[29] instances where the patient is already in possession of the information, 'therapeutic privilege' and instances where disclosure is impossible.

The South African courts have not yet made a firm pronouncement in favour of any particular one of these tests. With the exceptions of *Richter*[30] and, in passing, in *SA Medical & Dental Council v Mcloughlin*, the issue regarding the standards of disclosure has not been discussed in other cases. Should an opportunity arise, the courts should use to develop positive law on this doctrine, and pronounce on the approach which seems most appropriate. It remains clear, however, that the courts are leaning towards the more patient-orientated standards of disclosure. For consent to constitute valid justification that excludes the wrongfulness of medical treatment and its consequences, the obligation upon the doctor is to warn of material risks inherent in the proposed treatment, and the materiality of the risks should be adjudicated with considerations of the patient, and not the doctor.

Thomas in his assessment of the standard of disclosure in South African law, makes the following observation and proposes the following opinion respectively: (i) he notes that neither the Constitutional Court nor the Supreme Court of Appeal have been called upon to make an evaluation on the common law relating to consent to medical treatment; and (ii) he concludes that the standard of disclosure is too vague and must be rendered more precise by the addition of specific criteria regarding what ought to be disclosed and what qualifies as a material risk.[31]

---

28 *Castell* (n 4 above) 421.

29 Carstens and Pearmain (n 12 above) 888.

30 *Richter* (n 17 above).

31 Thomas (n 26 above) 188-215.

Irrespective of the approach adopted by the law, the courts should, in my opinion, remain the final adjudicators. The particular merits of each individual case should be granted appropriate recognition and consideration. The expert medical opinion should also be granted due consideration. It should guide the courts and provide opinions for the courts to consider, and should not be the final word on the matter.

3.1.2. Restrictions on disclosure.

Traditional restrictions on providing information include, as noted by Carstens and Pearmain,[32] instances where the patient already has the information, where the patient has expressly indicated his wish not to be told the information, 'therapeutic privilege' and instances where disclosure is impossible.

[32] Carstens and Pearmain (n 12 above) 888.

CHAPTER FOUR

CONCLUSION

It remains clear that informed consent is required prior to the provision of medical procedures or treatments. Consent forms a pertinent part of the doctor-patient relationship, and allows it to be a fruitful relationship. From an ethical point of view, informed consent is underscored particularly by the ethical principle of respect for individual autonomy. This principle forms the basis of the argument for informed consent and therefore, in my opinion, should be used as the point of departure in discussions around consent. The principle allows for self-determination, and aims at allowing a competent individual to make informed decisions regarding their life – decisions which would accord with their own views on life, and their personal plans for such life.

For the true realisation of patient autonomy, consent ultimately requires knowledge and comprehension on the part of the patient so consenting. The study asks whether this knowledge can ever be fully attained, and thus, whether consent can ever be fully informed (particular reference to the South African jurisprudence). An affirmative answer would be impractical. It could only be feasible in procedures or treatments that are minor, with little and easily comprehensible information, which the doctor can quickly rattle out each time he seeks to obtain consent for the procedure from the patient. However, this is often not the case. Inherent in some procedures are multiple and complex risks and consequences. Most procedures and treatments remain foreign knowledge to the lay person, which requires a complex process of receiving knowledge from the doctor, and having to make sense of it. As we have seen in the discussions, expecting the patient to be fully informed of all risks and possible consequences inherent in a procedure would be an enormous imposition on the medical fraternity who would be faced with that difficult task of having to inform the patient fully.

I agree with the popularly-held view that respect for patient autonomy does not require the full disclosure of all information. Instead, only the general information, including the material risks and consequences that are inherent to the proposed procedure, forms part of the obligation to disclose. Consent needs not be fully informed, but rather *adequately* informed. The true realization of the foregoing ethical principle does not aim to make a medical expert out of the patient, but aims only to provide them with that information which is relevant to their decision-making.

The doctor-orientated standards of disclosure should be avoided, and South African law is rightly leaning towards patient-orientated standards. The 'blending' model as proposed by Giesen, appears to be a possible option. His view that both the objective and the subjective approaches to disclosure should be concurrently adopted seems to be a possible solution. The objective standard judges the patient against a 'prudent' patient. This can then be augmented with the subjective test. The final adjudication of the case should remain (as it is currently), that of the court.

As the stance of the South African courts on the standards of disclosure remains obscured, the courts should revise this aspect and make a clear adoption of one standard over the other, for a better understanding.

Bibliography

Books

1. Ackermann L. *Human dignity: Lodestar for equality in South Africa.* Cape Town (2012).
2. Beauchamp TL. and Childress JF. *Principles of biomedical ethics.* New York (2001).
3. Brock DW. *Life and death: philosophical essays in biomedical ethics,* Cambridge (1993).
4. Carstens PA. and Pearmain D. *Foundational principles of South African medical law* (2007) Lexis Nexis, South Africa.
5. Giesen D. *Medical malpractice law. A comparative law study of civil responsibility arising from medical care,* Gieseking (1981).
6. Kennedy I. and Grubb A. *Medical law: Text and materials,* United Kingdom (1989).
7. Moodley K. *Medical ethics, law and human rights. A South African perspective,* Pretoria (2017).
8. Strauss SA. *Doctor, patient and the law. A selection of practical issues,* Pretoria (1991).
9. Van Oosten F. *The doctrine of informed consent in medical law.* Frankfurt (1991).
10. Weindling PJ. *Nazi medicine and the Nuremberg Trials. From medical war crimes to informed consent.* United Kingdom (2004).

Journals

1. Dhai A. “An introduction to informed consent: Ethico-legal requirements” *SADJ* 63 (2008).
2. Murray PM. “The history of informed consent” *IOJ* 104 (1990).
3. Naidoo P. “Informed consent in South Africa” *SAR* 41 (2003).

4. Pienaar L. “Investigating the reasons behind the increase in medical negligence claims” *PELJ*, 19 (2016).
5. Thomas R. “Where to from Castell v de Greef? Lessons from recent developments in South Africa and abroad regarding consent to treatment and the standard of disclosure” *SALJ* 2007.
6. Van Loggerenberg A. “An alternative approach to informed consent” *SALJ* 135 (2018).

Case Law

South Africa:

1. *Castell v de Greef* 1994 (4) SA 408 (C).
2. *Christian Lawyers' Association v National Minister of Health 2004 (10) BCLR 1086 (T).*
3. *Esterhuizen v Administrator, Transvaal* 1957 (3) SA 710 (T).
4. *Louwrens v Oldwage* 2006 (2) SA 161 (SCA).
5. *Lymbery v Jefferies* 1925 AD 236.
6. *Phillip v De Klerk* 1983 (T) – unreported.
7. *Richter & Another v Estate Hamman 1976 (3) SA 226 (C).*
8. *Rompel v Botha* (1953, Transvaal Provincial Division, unreported).
9. *Stoffberg v Elliot (1923) CPD 148.*

Australia:

Rogers v Whitaker (1993) 67 ALJR.

England:

Sidaway v Board of Governors of the Bethlem Royal Hospital (1985) AC 871.

Legislation and other related documents

1. Children's Act 38 of 2005.
2. Choice on Termination of Pregnancy Act 92 of 1998.
3. Health Professions Act 56 of 1974.
4. HPCSA's booklet 1, General ethical guidelines for the health care professions (2008).
5. HPCSA's booklet 3, National Patients' Rights Charter (2008).
6. HPCSA's booklet 6, General ethical guidelines for health researchers (2008).
7. HPCSA's booklet 9, Seeking patients' informed consent: the ethical consideration (2008).
8. Mental Health Care Act 17 of 2002.
9. National Health Act 61 of 2003.
10. Promotion of Access to Information Act 2 of 2000.
11. Sterilization Act 44 of 1998.
12. The Constitution of the Republic of South Africa 1996.

Websites

1. http://www.un.org/en/universal-declaration-human-rights/ (accessed 1 October 2018).