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Informed consent: A review of the ethical and legal framework for medical practitioners and nurses

By

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Philippians 4:13 – 'I Can Do All Things Through Christ Who Strengthens Me.'

ABSTRACT

The purpose of this dissertation is to review legislation and ethical guidelines that help to inform the practice of healthcare workers on the undertaking of informed consent.

The standard management of the healthcare worker and patient presides over open and voluntary consent, underpinned by ethical and legal foundations.[1] The legal requirements of informed consent and the obligation to recognise the constitutional rights to privacy is laid out in chapter two of the National Health Act.[2] A meaningful discussion must include the material risks and provided in a manner that the patient has full understanding and is able to reflect on the options of the undertakings on his /her own health.[3] Globally, the bioethical principle of respect for patient autonomy, forms the guiding indicator for ethical practice of healthcare workers, defining the requirement for the establishment of trust through ongoing information discussion in the absence of coercion.[4]

Ethically, morally, and legally, informed consent remains the fiduciary responsibility of the physician.[5] In *Pandie v Isaacs*,[6] a case based on delictual negligence, as a result of the surgeon placing reliance on the nurse to undertake the task of informed consent, the responsibility of informed consent for surgery is explored and exposed.[7] The principal conclusions of this study is to emphasise that informed consent practices among healthcare workers fall below the legal requirements, and to highlight the need to know the relevant legislative requirements and ethical guidelines in medical law for health care practitioners.

Integration of ethics and legislative requirements into medical law and into doctor and nurse education are required to accomplish a meaningful patient relationship.

[1] De Roubaix M 'Dare we rethink informed consent?' *South African Journal of Bioethics and Law* (2017) June 10(1) 25–28.
[2] CL Jack, Y Singh and BP Ncama 'A South African perspective to medical law and ethics in nursing: getting basic principles right' *African Journal of Nursing and Midwifery* (2015) 17(2) 118.
[3] Ibid.
[4] Jack, Singh and Ncama (note 2 above) 118.
[5] Ibid.
[6] *Pandie v Isaacs* (A135/2013, 1221/2007) [2013] ZA WCHC123.
[7] CJ Badul, A Strode and PP Singh 'Obtaining informed consent for a sterilisation in the light of recent case law' *South African Medical Journal* (2018) 108 (7) 557–558. 1.

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CHAPTER 1: INFORMED CONSENT AND ITS RATIONALE

1 INTRODUCTION AND BACKGROUND

Currently, both the medical practitioners and nurses practise within an environment that is regulated through ethical guidelines and the law. Through the courts, it has been brought into evidence that this has, however, not always been the case. Over the centuries, the practice of medicine was paternalistic in nature, in that it left little room for the patient to make decisions or express an opinion on matters related to their medical treatment.[1] The understanding was that the medical practitioner, being an expert in the field, knew and understood what was best for his or her patients. As someone who possessed information and the requisite expertise, the medical practitioner was empowered to make decisions on behalf of the patient, even when those decisions were not in keeping with the wishes of the patients. The practice of medicine, particularly in the last seven decades, has seen a move away from the paternalistic approach of relating to patients and research participants towards an approach that puts the patient and the research participant at the centre.

2 HIPPOCRATIC OATH AND PATERNALISM

Historically, the traditional Hippocratic oath allowed for the medical practitioner to perform treatment and to proceed in what only he considered as the best interests of his or her patient.[2] Ahmed Dhai asserts that this form of paternalism was practised provided that the two bioethical principles of beneficence and non-maleficence were supported.[3] Subsequent to the Nuremburg Trials, in terms of the Universal Declaration of Human Rights and guidelines from the World Medical Association, this paternalistic approach had far-reaching changes, as autonomy and self-determination were put into place as the foundational principles in healthcare practice.[4] Beauchamp and Childress further submitted that the ethical theory of Principlism formed the foundational principles in medical ethics, forming the criterion for the administration of medical services and adopted globally.[5]

[1] A Dhai 'Informed consent' (2008) 1 *South African Journal of Bioethics and Law* 27.
[2] Ibid.
[3] Ibid.
[4] Ibid.
[5] CL Jack, Y Singh and BP Ncama 'A South African perspective to medical law and ethics in nursing: getting basic principles right' *African Journal of Nursing and Midwifery* (2015) 17(2) 120–131.

The Second World War marked a turning point in sensitising the world to the need to protect and respect human rights. For medical researchers, particularly for research that involves human participants, the Nuremburg trials that followed the war marked a turning point in medical and research ethics. In light of the fact that the focus of the trials was mainly on medical practitioners who had committed atrocities in the name of medical research and experimentations, the focus of the Nuremburg Code of ethics that was drafted in 1947 was mainly on medical research and not necessarily on medical practice.[6] This notwithstanding, the Nuremburg Code had implications for the practice of medicine. In general, the Nuremburg Code marked a clear departure from the paternalistic approach to medical practice and research, and by so doing placed the individual at the centre. The Nuremburg Code consists of ten principles which, when read together, are about ensuring that the human rights of research participants are respected and protected. The first of these principles is about informed consent.[7]

3 UNDERSTANDING INFORMED CONSENT

Given the information that the medical practitioner possesses, it is inevitable that the doctor–patient relationship will in most likelihood be an uneven one. The medical practitioner will in most cases possess information of a technical nature which the patient does not have. A paternalistic approach to medical practice has no regard to what the views and wishes of the patent are, as critical decisions are taken on behalf of the patient. The requirement for informed consent marks a radical shift from a paternalistic approach, in that it places the patient at the centre of all the medical decisions that need to be taken. In this regard, decisions must not be made *for* the patient but should be made *with* the patient. This approach requires the patient to be included in all the critical decisions that are taken regarding their well-being and health. As Dhai points out, the requirement for informed consent is based on 'a process of information sharing and decision making based on mutual respect and participation.'[8]

McQuoid-Mason points out that legally and ethically, a patient making a decision must be informed, independent and respected.[9] This forms a systematic exposition of respect for autonomy as a founding principle for patient decision making.[10] In terms of section 12 of the

[6] JD Moreno 'The Nuremberg Code 70 Years Later' *Journal of American Medical Association* (2017) 318 795.
[7] RB Ghooi 'The Nuremberg Code – A critique' *Perspectives in Clinical Research* (2011) 2 (2) 72–76 74.
[8] Dhai (note 1) 127.
[9] D McQuoid-Mason 'Michael Jackson and the limits of patient autonomy' *SAJBL* (2012) 5 11 Available at http://www.sajbl.org.za/index.php/sajbl/article/view/191/176, Accessed on 15 July 2019.
[10] Ibid.

Bill of Rights, everyone has the right to bodily and psychological integrity. This right includes, among others, the right to have control over their body.[11]

The National Health Act,[12] which is one of the principal pieces of legislation dealing with health-related matters in South Africa, lays out provisions to enable respect for the autonomy of patients and to move from a medical practitioner's paternalistic approach to a more patient-centred approach when seeking a patient's informed consent.[13] In this way, the patient, empowered by the information at his/her disposal, will be in a position to participate meaningfully in decisions related to their health. This, is in line with what is required by the National Health Act, which provides that the patient be informed of, among others, their health status,[14] the diagnostic procedures and treatment options generally available to them, the benefits, risks, and consequences generally associated with each option, and the right of the patient to refuse health services and have the implications, risks and obligations of such refusal explained to them.[15] Upon receiving the information that has been provided, the patient is able to consent freely to be admitted to a medical facility for treatment or to undergo medical interventions outlined to them. Further, the patient may refuse to be admitted to a medical facility, and this will be within his/her rights as a patient, as per the provisions of the Act.[16]

On the strength of the information received, the patient can refuse to receive medical treatment, even where it is clear to those with medical expertise that medical intervention would be beneficial to the patient. As is well known, in the case of *Castell v De Greeff*, [17] an important development to informed consent was laid down when the 'reasonable patient' standard for disclosure was established by the courts as conforming to right of self-determination and individual autonomy.[18] The case made it imperative for the medical practitioner to inform the patient of the nature and extent of the harm and/or risk and consents to the harm or risk as well as its consequences.[19]

The Health Professions Act of 1974 established the Health Professions Council of South Africa (HPCSA) and professional boards, in order to regulate, monitor and enforce standards of

[11] Constitution of the Republic of South Africa, 1996 (hereafter 'Constitution').
[12] National Health Act 61 of 2003.
[13] D McQuoid-Mason 'The National Health Act: Some implications for family practice' (2006) *CME* 24(1).
[14] The Act makes an exception in circumstances where there is substantial evidence that the disclosure of the patient's status would be contrary to their best interests.
[15] National Health Act (note 12) section 6(1)(a)–(e).
[16] Ibid. section 7(1).
[17] *Castell v De Greeff* 1994 (4) SA 408 (C).
[18] South Africa. Supreme Court, Cape Provincial Division. *Castell v De Greeff* SALR 1994(2) 17; *Castell v De Greeff* (note 17).
[19] MA Dada & DJ McQuoid-Mason *Introduction to Medico-Legal Practice* (2001) 8.

education, training and registration, and the practice of all these health professionals.[20] The HPCSA Guidelines for Good Practice sets out ethical rules and legal provisions that the medical practitioner is required to practise when seeking patients' informed consent to investigations, treatment, screening or research, so much so, that failure to obtain consent unlawfully and intentionally constitutes assault.[21]

It is public knowledge that in the healthcare setting, procedures are performed daily and that the challenge in obtaining informed consent is often taken for granted as ensuring a patient's signature on a form, instead of an opportunity for a deliberative dialogue between the patient and surgeon.[22] When a person is ill or believes that he/she is ill, their first response is to seek medical attention from a doctor. This person then becomes the patient of the doctor. The patient enters into a contractual relationship with the doctor wherein an agreement is established allowing the doctor to take on the responsibility to diagnose and direct care and treatment, while exhibiting a professional and ethical approach.[23]

This is a unique relationship where bonding is planned with the ultimate objective of assisting the patient to achieve treatment outcomes.[24] The National Patients' Rights Charter affirms that

> *'[e]everyone has a right to be given full information about the nature of one's illness, diagnostic procedures, the proposed treatment and risks associated therewith, and the costs involved'.*[25]

Dhai and McQuoid-Mason describe an autonomous person as someone who 'has the ability to deliberate about personal goals and to act under the direction of such liberation'.[26] The duty of the medical practitioners to obtain written consent before any procedure is mandatory and this task cannot be assigned to a nurse.[27] Failure by the medical practitioner to obtain the informed consent is tantamount to a violation of the patient's rights.

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[20] Health Professions Act 56 of 1974.
[21] Health Professions Council of South Africa (HPCSA) *Guidelines for Good Practice in the Health Care Professions: The Ethical Considerations Booklet* 9 (2007). Available at https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf. Accessed 15 July 2020
[22] S Naidoo 'Obtaining informed consent for surgery' *Current Allergy & Clinical Immunology* (2014) June 27 (2) 112–114.
[23] Dhai (note 1).
[24] Ibid.
[25] HPCSA *Guidelines for Good Practice in the Health Care Professions: National Patient's Rights Charter Booklet 3* (2008). Available at https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf. Accessed 15 July 2020
[26] A Dhai & D McQuoid-Mason *Bioethics, Human Rights and Health Law* (2011) 70.
[27] Dhai (note 1).

(1) The Doctor-Patient Relationship

We have discussed that traditionally the medical practitioner mainly engaged a paternalistic patient approach, in that their actions and decisions were based on beneficence projected for the benefit of the patient.[28] Following the Universal Declaration of Human Rights in 1948, this culture of human rights gained huge ground in South Africa with the abolition of the apartheid regime and the drafting of the new Constitution of South Africa containing the Bill of Rights in 1994.[29] The relationship between the doctor and the patient is therefore a fiduciary and clinical connection between the doctor and a patient, and requires that the doctor in his professional capacity owes the patient a duty of care.[30] Signing a form should not be a routine and expected requirement; but should be an acknowledgement that the patient's autonomy for decision-making with regard to proposed treatment is accommodated and respected by the medical practitioner.[31] Withholding information from a patient is therefore a violation of the doctor's legal obligation in ensuring that the patient makes an autonomous decision regarding his/her care.[32] Many patients have reported that information about the procedures in respect of which the consent is obtained is adequate but that the risks associated with the procedure often lack detail.[33]

It is the patient, not the doctor, who decides whether a procedure will be performed, where it will be done, when it will be done and by whom it will be done.[34]

(2) The Nurse-Patient Relationship

Nursing is a caring profession and concerns the needs of human beings.[35] The nursing profession has evolved over a number of years. According to Mellish, nursing is unique in that it is not about just the care component, but also the promotion and maintenance of health, prevention of illness and rehabilitation to contribute to the health of the patients so that they achieve optimal health potential.[36] In pursuing this process, the nurse forms part of the multidisciplinary team and shares the responsibility in the execution of prescribed treatment to

[28] K Rowe and K Moodley 'Patients as consumers of health care in South Africa: The ethical and legal implications' *BMC Med Ethics* (2013) 14 15.
[29] Ibid.
[30] Dada & McQuoid-Mason (note 19).
[31] Ibid.
[32] Dhai (note 1).
[33] Naidoo (note 22).
[34] *Allan v New Mount Sinai Hospital* (1980) 11 CCLT 299.
[35] JM Mellish, A Oosthuizen and F Paton *An Introduction to the Ethos of Nursing* 3rd ed (2010) 3.
[36] Ibid.

assist the patient in the improvement in their health status.[37] The advocacy role of the nurse requires patients' rights to be protected; and that they should be adequately informed by the medical practitioner before they commit to making an autonomous decision about their care.[38] Nursing practice incorporates the Patients' Rights Charter, which speaks directly to the patients' rights to informed consent. To ensure that these rights are upheld, the nurse is required to ensure that the patient is knowledgeable about the significance of diagnostic procedures and proposed treatment, the probable and reasonable side-effects and risks related to this interaction, and alternative procedures or treatments that are available.[39]

Like all professions, the nursing profession is guided by a statutory body, which in this case is the South African Nursing Council (SANC). SANC sets out rules that govern the profession and prescribes that the nursing profession is regulated to practise within the ethical rules that govern the profession and scope of practice.[40]

In a healthcare setting, one of the many tasks of nursing practice is to make real the rights of patients in decision making, prior to formally consenting on a written form. The International Council of Nurses Code of ethics for nurses prescribes that 'the nurse ensures that the individual receives sufficient information on which to base consent for care and related treatment'.[41] The nurse needs to be aware of this requirement and assess and confirm that the patient understands the material risks and is knowledgeable about the procedure to be performed prior to witnessing the signing of the IC form.[42] This task will fulfil the duty of the nurse as a patient advocate and ensures that the patient makes a knowledge-based decision about the patient's care.

Surgical and medical procedures are performed daily, yet shared decision making between patients and health care providers is not achieved. Obtaining confirmation of a patients' informed consent (IC) is part of a nurse's daily routine during admissions and before a procedure. It is noteworthy that the IC form is a legal document, but it forms a colossal

[37] JC Bruce, HC Klopper and JM Mellish '*Teaching and Learning the Practice of Nursing'* 5th ed (Johannesburg: Heinemann 2011).
[38] JB Menendez 'Informed consent: essential legal and ethical principles for nurses' *JONA Healthcare Law Ethics and Regulation* (2013) Oct-Dec 15 (4) 140–144; quiz 145–146.
[39] M Muller *Nursing Dynamics* 4th ed (Johannesburg: Heinemann 2009 16).
[40] SANC *Policy on Nurses' Rights.* Available at https://www.sanc.co.za/nurses-rights/. Accessed 9 August 2021.
[41] International Council for Nurses *The ICN Code of Ethics for Nurses* (2012). Available at https://www.icn.ch/sites/default/files/inline-files/2012_ICN_Codeofethicsfornurses_%20eng.pdf. Accessed 19 September 2020.
[42] Law Teacher *Nurses Roles and Duties to the Patient* (2013) November. Available at https://www.lawteacher.net/free-law-essays/medical-law/nurses-roles-and-duties-to-the-patient-medical-law-essay.php?vref=1. Accessed 7 June 2020.

proceeding of the IC process.[43] In the caring for patients of a diverse culture, different ethnic group and of all ages, there is also a requirement for the nurse practitioner to have knowledge of the requirements as well as the exceptions to informed consent. [44]

To ensure a defensible legal nursing practice, nurses spend an abundance of time documenting the care planned for a patient. Unfortunately, they are very rarely able to follow through with it.[45] An aspect of delict where nurses tend to assume liability is in respect of obtaining the consent from a patient, prior to execution of care and in having to witness an informed consent before a procedure is performed.[46] The type of delict involved can be classified as negligence (which is unintentional).[47] It therefore follows that there remains a gap in certain understanding of the changes in legislation and risks pertaining to modified medicine.[48]

The foundation of nursing ethics lies in the SANC code of ethics which provides for ethical decision making and binds the nurse practitioner to the applicable ethical and moral principles that guards his/her practice:

> *'Identifying ethical values and principles that form the foundation for professional conduct;*
>
> *Providing the framework for reflection on the influence of ethical values on the behaviour and interaction between nurses and the public, stakeholders and healthcare users;*
>
> *Providing the framework for ethical decision-making for practice;*
>
> *Indicating to the public, stakeholders and healthcare users the standards and ethical values they can expect nurses to uphold; and*
>
> *Providing guidance to professional conduct or ethical committees regarding decisions relating to unethical behaviour.'*[49]

The code further postulates that the nurse practitioner provides the role of an advocate to the patient in her care and has to work amicably within the multidisciplinary team.[50] In chapter 3, we will discuss the exceptions to informed consent which also apply to the nurse practitioner, whose core function is to assess a patient, so much so, that where the situation requires non-

[43] Menendez (note 38).
[44] SC Chima An Investigation of Informed Consent in Clinical Practice in South Africa 9 (unpublished Doctor of Law thesis University of South Africa 2018).
[45] Law Teacher (note 42).
[46] Ibid.
[47] Ibid.
[48] Chima (note 44).
[49] SANC Code of Ethics for Nursing in South Africa.
[50] Ibid.

disclosure of risks and hazards that may have an adverse effect on the co-ordination of prescribed treatment, such information will be withheld to ensure a positive clinical outcome.[51]

4 RESEARCH OBJECTIVES AND METHODOLOGY

Since the events of the Second World War outlined above, informed consent has become an important requirement for medical practice in South Africa and the world over. [52] Ethically and legally, failure to obtain informed consent from patients constitutes unethical conduct on the part of the medical practitioner and as such the medical practitioner can be held legally liable.[53] This study is conducted within the backdrop of the escalating incidence of medical malpractice.[54]

Professionally, medical practitioners and nurses play clear and distinct roles. The requirement for informed consent provides a point of convergence for the two professionals in that, medically or surgically, no intervention can be performed without obtaining the patient's informed consent. The study seeks to conduct a review of the ethical and legal framework for both medical practitioners and nurses. In the event that there are gaps or loopholes identified, the study will propose measures to strengthen the protection of patient's rights.

This is a desktop research that will draw from available literature, case law, reports, journal articles and newspaper reports. The information relied upon is all in the public domain.

5 RESEARCH QUESTION

The international human rights framework is constructed, among others, around the need to respect the autonomy of human beings and their right to self-determination. The requirement for informed consent constitutes an important part of both the legal and ethical framework. This study seeks to conduct a review of the ethical and legal framework for both medical practitioners and nurses. In this context the research question that the study seeks to address is:

- Are there further measures that can be put in place to enhance the processes and procedures for both medical practitioners and nurses to obtain informed consent from patients?

[51] Law Teacher (note 42).
[52] And research involving human participants. This study will, however, focus on patients within the context of medical practice.
[53] McQuoid-Mason (note 9).
[54] K Child 'Hospital horrors costing SA plenty' *Sunday Times* (2014) 14 January.

This research question will be answered following the structure below.

6 OVERVIEW OF CHAPTERS

Chapter 1 provides an overview and background of the main focus and purpose of the research topic.

In Chapter 2, the ethical aspects of informed consent from an international perspective.

Chapter 3 focuses on the legal aspects of informed consent from a South African perspective. A discussion of the legal bodies that regulate the practice of the medical and nurse practitioner are discussed to accentuate the specific roles and the consequences of not adhering to the rules of practice.

Chapter 4 is the concluding chapter, which completes the discussion on the topic and provides a summary of the study. The main arguments will be summarised and will reiterate the importance and significance of the study. Recommendations are made for provisions and strategies to improve the working partnership of the medical and nurse practitioner in the care of the patient and informed consent.

CHAPTER 2: LEGAL ASPECTS OF INFORMED CONSENT

1 INTRODUCTION

This chapter aims to examine the legal aspects of informed consent by understanding the meaning of informed consent which is the cornerstone to the topic of this dissertation. There are certain rules of law that are mandatory and requires healthcare providers to assert when obtaining informed consent. Informed consent is set out in South African law such as provisions of the Constitution of South Africa, National Health Act and the Consumer Protection Act. In South Africa, in consideration to common law; informed consent is based on the doctrine of 'volenti non fit injuria',[55] meaning 'no injury is done against someone who consents/agrees' which emphasises the doctor-patient relationship. This chapter concludes with the challenges experienced in ensuring compliance within the healthcare team in their specific roles and the consequences of not adhering to the rules of practice.

2 INFORMED CONSENT AND THE LAW

(1) The Constitution of 1996

The Constitution of the Republic of South Africa, 1996 ('the Constitution)', as the supreme law of South Africa), makes provision for informed consent in Chapter 2, in the Bill of Rights. Section 12 of the Constitution expresses the right to freedom and security of a person and affirms that every person has the right to bodily and psychological integrity, which includes the right to security and control over his or her body as well as the right not to be subjected to medical or scientific experimentation without his or her informed consent.[56] The Constitution is a jurisprudential document advocating the applicable laws and underpins the patient's rights to autonomy and self-determination when receiving medical care or treatment.[57] Therefore, the significance in the understanding of the right to informed consent in terms of section 12(2) of the Constitution extends beyond what is normally referred to as consent. Specifically, it has to do with the practice that delineates between right and wrong,[58] which can be instituted by

[55] A Barit *The Doctrine of Informed Consent in South African Medical Law* (2017).
[56] Constitution (note 11) s 12(2)(b) & (c).
[57] Ibid. chapter 2.
[58] RR Faden, TL Beauchamp & NMP King *A History and Theory of Informed Consent* 4–5.

examining the degree of skill and care that is reasonably applied in a particular set of conditions.[59]

The rule in section 12(2) provides that every person has the principle right to be make autonomous decisions on health and procedural interventions and treatment on their health, which undoubtedly includes that no treatment should be forced onto their person or intrusions made on their bodily integrity.[60] The 'Bill of Rights' concedes the patient's rights to autonomy and self-determination in decisions pertaining to his/her health. Dhai and McQuoid-Mason describes an autonomous person as someone who 'has the ability to deliberate about personal goals and to act under the direction of such liberation',[61] However, on justifiable grounds, rights may be limited. Section 36 of the Constitution provides for the limitation of constitutional rights in so far as it is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom[62] and incorporates factors such as the nature and extent of the limitation as well as its importance.[63] According to the South African Constitution, all health care users may expect a certain level of health service when they visit a public or private health institution. This is also part of the patient's right charter[64] and Batho Pele principles. Moreover, the National Health Act 61 of 2003 contains clear provisions for emergency treatment (section 5), consent (sections 7 and 9), and participation in decisions of a medical nature (section 8).[65] It is notable that the patient's autonomy and the right to self-determination are upheld and enforced with clear, enforceable national and international legislation.[66]

The consideration of the right to human dignity, in informed consent, which embodies interests and integrity, is enshrined in both international and South African law and must be respected.[67] Kirchoffer argues that human dignity refers to the worth of a person, is multi-dimensional and is to be considered to be of value in ethical and legal discourse.[68] Giesen confirms that for human beings, the rights of the patient are entrenched in the South African Bill of Rights as

[59] *Van Wyk v Lewis* 1924 AD 438 444; *Mitchell v Dixon* 1914 AD 519 525.
[60] Ibid.
[61] Dhai & McQuoid-Mason (note 26) 60.
[62] Constitution (note 11) section 36.
[63] Ibid.
[64] *Patients' Rights Charter.*
[65] National Health Act (note 12) sections 5–9.
[66] D Schroeder 'Informed consent: From medical research to traditional knowledge' in R Wynberg, D Schroeder and R Chennells (eds) *Indigenous Peoples, Consent and Benefit Sharing* (2009) (Springer: Dordrecht). Available at https://doi.org/10.1007/978-90-481-3123-5_3. Date of access 20 August 2021.
[67] DG Kirchoffer & K Dierickx 'Human dignity and consent in research biobanking' *South African Journal of Bioethics and Law* 2012 5 (2) 74, 77.
[68] Ibid.

well as the Constitution, accentuating the individual right to privacy, self-determination, autonomy and physical and psychological integrity.[69]

The Constitution[70] provides that every person has the right to privacy, which includes the right to have their communications protected from intrusion.[71] Section 14 protects the right to privacy, which is further protected by common law.[72] Privacy deals with access to confidential information, and the protection of such information from any intrusion.[73] JA Singh discusses that there are legal implications for breach of confidentiality to include violation of privacy and/or defamation.[74] In the case of *Jansen Van Vuuren and Another v Kruger*,[75] during a game of golf, a practitioner disclosed the HIV status of a patient to one of his colleagues. The court held that the practitioner had no legal or ethical duty to make such a disclosure and therefore the disclosure was unwarranted and unlawful.[76]

(2) National Health Act 61 of 2003

The right to bodily integrity and security as well as the right to IC are constitutionally protected rights which have been enacted in the Constitution and conveyed in the Patients' Rights Charter. The charter serves as a guideline to make people aware of their rights to receive care and treatment and the responsibilities of healthcare providers. Specific to informed consent, the charter put forward the requirements for everyone to be afforded the right to correct and full disclosure on the nature of their illness, and the associated risks to proposed procedures. The National Health Act, aligned to the obligations set out in the Constitution and other laws of the government, provides a framework for the health care system of the country.[77] Section 6(1) in chapter 2 of the National Health Act, states that:

[69] D Giesen 'From paternalism to self-determination to shared decision making' (1988) *Acta Juridica* 107–127. Available at http://heinonline.org. Accessed 18/01/2022.
[70] Constitution, 1996 (note 11).
[71] National Health Act (note 12) section 14(d).
[72] LC Coetzee & SA Strauss Department of Criminal and Procedural Law *Study Guide* 2008 University of South Africa.
[73] Dhai & McQuoid-Mason (note 26) 86.
[74] JA Singh 'Law and the health professional in South Africa' in K Moodley (ed) *Medical Ethics, Law and Human Rights: A South African Perspective*. 2nd ed. Van Schaik Press (2017) 153.
[75] *Jansen van Vuuren and Another NNO v Kruger* [1993] ZASCA 145.
[76] Ibid.
[77] D McQuoid-Mason (note 13) 12.

'Every healthcare provider must inform a user of:

- *the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user:*[78]
- *the range of diagnostic procedures and treatment options generally available to the user;*
- *the benefits, risks, and consequences generally associated with each option; and*
- *the user's right to refuse health services and explain the implications, risks and obligation of refusal.'*

The National Health Act further states that a healthcare practitioner is required to inform patients of the provisions of various diagnostic procedures and the treatment options and to include the associated risks, benefits and costs.[79] In supplement to this, the National Health Act states that '[a] health service may not be provided to a user without the user's informed consent', except when a user is unable to give informed consent, where failure to treat the user will result in a serious risk to public health, or if delays in treating the user may result in death or irreversible damage and further provides for the specific health service given by a person with legal capacity to do so and who has been informed according to the provisions of section 6.[80]

Section 7(2) of the Act stipulates that a health care provider must ensure that all reasonable steps are taken to obtain the patient's informed consent; and also allows for certain exceptions.[81] The Act further requires the language and level of literacy to be considered when obtaining an informed consent. Therapeutic privilege provides that the health care provider is allowed to deviate from the rules of informed consent in instances where disclosure of the patient's health status would not be in his or her best interests.[82] The legal and ethical discipline involving the patient and the doctor contract, Professor Singh postulated that an understanding of informed consent, confidentiality and the legal implications of malpractice is applicable to

[78] Ibid.
[79] National Health Act (note 12).
[80] Ibid. s 6.
[81] Ibid. s 7((2).
[82] Barit (note 1).

all age groups and patient types.[83] Therapeutic privilege is enforced only as an exception to the general rule of the informed consent process and only applies to certain diagnosis that may have a negative or detrimental effect to the patient's own health.[84]

The NHA is explicit in the requirements for the medical practitioners to fully disclose and explain procedures prior to obtaining an informed consent. Moreover, the provisions map out the requirement for respect for autonomy of persons by embracing a patient centred approach in obtaining informed consent.[85]

(3) Informed Consent and the Common Law

Castell v De Greeff[86] remains the leading authority in terms of 'informed consent' and asserts that the doctor or practitioner is compelled to warn 'a patient [who is] consenting of a material risk inherent in the proposed treatment' [87] Having established that the medical practitioner and a patient enter into a contractual relationship in agreement to decisions addressing the health needs of the patient, this allows for the informed consent process to be a point of convergence in the doctor-patient relationship. Common law imposes a duty on healthcare professionals to act positively. In the case of the historical conduct of behaviour, where the creation of an under-threat situation, by somewhat forcing their thoughts on the patient's decision; a statute now compels them to act in a caring and respectful approach, a special relationship ought to exist between the doctor and the patient; and society would deem this relationship as important.[88]

In *Castell v De Greeff*, the court held that doctors are obliged to warn patients of 'material risks' inherent in the proposed forms of treatment or procedure.[89] The court defined 'material risk' as follows:

> *'A risk is material if, in the circumstances of a particular case: (1) a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it, or (2) the doctor is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.'*[90]

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[83] Singh (note 74) 129–156.
[84] Ibid.
[85] McQuoid-Mason (note 13).
[86] *Castell v De Greeff* (note 17).
[87] Ibid. 426F-H.
[88] D McQuoid-Mason 'Introduction to aspects of health law: Bioethical principles, human rights and the law' *SAJBL* (2008) June 1 (1) 7–10.
[89] *Castell v De Greeff* (note 17).
[90] Ibid.

(4) Informed Consent and Its Elements

Informed consent is valid if certain elements are present. According to Strauss, the two basic elements of consent are knowledge and appreciation, and he goes on to state that unless a patient knows what they are consenting to, consent is not legal.[91] For an individual to give valid informed consent, three elements must be present: disclosure, capacity and voluntariness.[92]

- *Disclosure* requires that, in order for the patient to make an autonomous decision, the medical practitioner or nurse must provide the necessary information and ensure that the patient understands the information received. This would entail that the level of understanding of the patient would be assessed. In this regard, the National Health Act states that the medical practitioner must, where possible, communicate the information in a language that the patient understands and in a manner which takes into account the user's level of literacy.[93]
- *Capacity* pertains to the ability of the subject to understand the information provided and its relevance to the decision that he/she wants to make. Further, the patient is required to have the ability to make a reasonable judgment based on the potential consequences of his/her decision.
- *Voluntariness* refers to the subject's right to make a choice of his/her own free will without being subjected to any pressure or coercion.

3 INFORMED CONSENT AND LEGISLATION

Owing to the importance of IC in modern medicine, the criteria for IC are expounded upon in the Constitution, legislation and case law.

(1) The National Patients' Rights Charter

The constitutionally protected rights to bodily integrity and security as well as the right to IC as codified in the Constitution has been put into effect by official proclamation in the Patients' Rights Charter.[94] The set provisions and regulations guide the right of access to healthcare for all South African citizens. In *Stoffberg v Elliot* 1923 CPD 148, the judge instructed the jury in the following terms:

[91] SA Strauss *Doctor, Patient and the Law* 3rd ed (1991) 8.
[92] Dada and McQuoid-Mason (note 19).
[93] National Health Act (note 12) section 6(2).
[94] HPCSA (note 25).

> *'In the eyes of the law every person has certain absolute rights which the law protects. They are not dependent on statute or upon contract, but they are rights to be respected, and one of the rights is absolute security to the person ...* '[95]

Any bodily interference with or restraint of a man's person which is not justified in law, or excused or consented to, is a wrong. The Patients' Rights Charter formally recognises patients' right to IC during medical treatment. Everyone has the right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and the costs involved for one to make a decision that affects any one of these elements.[96] According to the Patients' Rights Charter, '[e]veryone has a right to be given full information about the nature of one's illness, diagnostic procedures, the proposed treatment and risks associated therewith, and the costs involved'.[97]

Dhai and McQuoid-Mason define an autonomous person as someone who 'has the ability to deliberate about personal goals and to act under the direction of such liberation'.[98] Autonomy is observed when the patient is informed, independent and respected.[99] The right to human dignity, the right to bodily and psychological integrity and the right not to be subjected to medical or scientific experimentation without their informed consent is enshrined in section 12 of the Constitution.[100] It is noteworthy that medical practitioners are required to provide full and complete disclosure of medical treatment in a context that is understood by the patient; hence a reasonable standard of practice, from a legal and ethical perspective, will ensure respect for the patient's autonomy.[101]

(2) Duty of Care

A duty of care is the legal responsibility of a person or organisation to avoid any behaviour or omissions that could reasonably be foreseen to cause harm to others. A person who violates his or her duty of care by acting in a negligent or reckless matter is then liable for any harm that another person suffers as a result of such behaviour. The medical duty of care refers to a doctor's duty of care to his patient. According to the law, there must be a 'special' relationship between the doctor and his patient for the

[95] *Stoffberg v Elliot* 1923 CPD 148.
[96] *Patients' Rights Charter.*
[97] Ibid.
[98] A Dhai & D McQuoid-Mason (note 26) 70.
[99] McQuoid-Mason (note 9).
[100] Constitution (note 11) s 12.
[101] lbid.

doctor to be liable for any injuries that can result from his conduct. *Pandie v Isaacs*[102] is a case based on delictual negligence which was result of the surgeon not obtaining the consent of the patient but placing reliance on the nurse to undertake this task.[103] It was argued that common law recognises any form of intrusion on a patient's body as prima facie wrongful.[104]

Doctors must exercise a duty of care and ensure that they have confirmed understanding when treating patients who have consented to the prescribed treatment.[105] The obligation and accountability remains with the medical practitioner to discuss all proposed procedures with the patient and the patient's informed consent to treatment must be obtained.[106] The patient remains accountable for his/her own health and has to ensure that he/she is available to receive the prescribed treatment, failing which the patient remains accountable for incurred medical fees.[107]

(3) Nursing Act, 2005 (Act 33 of 2005)

The Nursing Act 33 of 2005 created the legislative framework for the review of the scope of practice for different categories of nurses to ensure that nursing practice in South Africa is aligned to the needs of the healthcare system. Subsequently, the new qualifications framework and the revised scopes of practice were developed. The fundamental purpose of the nursing act is to regulate the nursing profession, protect the public from unsafe practitioners, and ensure that quality care is provided by competent, qualified nurse practitioners. The Nursing Act bestows certain powers on the South African Nursing Council (SANC) to regulate nursing practice professionally and ethically. Such regulations take place by means of registration of the practitioner, creating and applying regulations, professional discipline, and the application of educational standards. The Nursing Act makes provisions for the South African Nursing Council (SANC) to manage the regulatory processes in South Africa.[108]

[102] *Pandie v Isaacs* (A135/2013, 1221/2007) [2013] ZA WCHC123.
[103] CJ Badul, A Strode & PP Singh 'Obtaining informed consent for a sterilisation in the light of recent case law' *S Afr Med J* (2018) 108 (7) 557–558. DOI:10.7196/SAMJ. 2018.v108i7.13141
[104] Ibid.
[105] Strauss (note 91) 3.
[106] Dada & McQuoid-Mason (note 19) 5.
[107] Ibid 6.
[108] C Searle, S Human and SM Mogotlane *Professional Practice: A Southern African Nursing Perspective* 5th ed (2009) 49.

(4) South African Nursing Council (SANC)

South Africa boasts that it was one of the leading countries to achieve state registration for nurses and, thereafter, in 1944, the SANC was established.[109] The SANC as a statutory body for the nursing profession was initially established by the Nursing Act, 1944 (Act 45 of 1944), and is currently enacted under the Nursing Act, 2005 (Act 33 of 2005). Section 3 of the Nursing Act, 2005 provides for the SANC as the professional body to set and maintain standards of nursing education and professional conduct in South Africa.[110] The SANC as a statutory organisation is responsible for the professional-ethical regulation of nursing in South Africa, to provide a service to, and protection of, the community; ensures that the position of the patient within the healthcare system is safeguarded in accordance to the prescribed standard for nursing practice; and has the function of setting the standard for performance within the nursing practice.[111] The Nursing Act[112] provides for the specific functions of the SANC, one of which is to ensure that nurses respect the human rights of the healthcare users they are treating, and to regulate and perform inspections to monitor compliance, as provided for by the Nursing Act, and to institute disciplinary action where necessary.

The objectives of SANC as stated in the Nursing Act 33 of 2005 are

> *'to serve and protect the public in matters involving health services generally and nursing services in particular; perform its functions in the best interests of the public and in accordance with national health policy as determined by the Minister; promote the provision of nursing services to the inhabitants of the Republic that comply with universal norms and values; establish, improve, control conditions, standards and quality of nursing education and training within the ambit of this Act and any other applicable law; promote and maintain liaison and communication with all stakeholders regarding nursing standards, and in particular standards of nursing education and training and professional conduct and practice in and outside the Republic; advice the Minister on the amendment or adaptation of this Act regarding matters pertaining to nursing; be transparent and accountable to the public in achieving its objectives and in performing its functions; uphold and maintain professional and ethical standards within nursing'.*[113]

[109] A Singh and M Mathuray 'The nursing profession in South Africa - Are nurses adequately informed about the law and their legal responsibilities when administering health care?' *De Jure Law Journal* (2018) 51 (1) 122–139.
[110] South African Nursing Council.
[111] SW Booyens (ed) *Introduction to Health Services Management*. Juta and Company Ltd. (2008) 45.
[112] Nursing Act 33 of 2005 section 4*(f)*.
[113] Ibid. section 3.

The aforementioned measures serve to perpetuate safe standards of professional and ethical conduct, which are fundamental in the trust relationship of the medical team.[114] Regulation 767 sets out the acts and omissions of the nurse practitioner and Regulation 2598 sets out the scope of practice for nurses and midwives; these regulations were promulgated by the Nursing Act to ensure safe and ethical nursing practice within the nursing profession.

(5) Regulation relating to Scope of Practice (Regulation 2589)

Nursing practice is based on scientific evidence and critical thinking, grounded in values, moral codes and ethical principles, and remains dynamic in meeting changing legislation and regulations. The scope of practice allows the nurse practitioner to work within a specific framework related to the level of training and skill.[115] While Scribante, Muller and Lipman[116] assert that this regulation is not specialisation-specific and should be interpreted for the different nursing specialisations, Regulation 2598 remains the standing regulatory requirement. The nurse, acting in her professional capacity, participates in creating and maintaining safe, equitable nursing care for all patients. The nursing pledge states that the patient will be a nurse's first consideration, clearly defining that the interest of the patient is the nurse's first obligation[117]. Having regard to the context in which the nurse functions, the roles and responsibilities of the nurse in any healthcare setting are to perform safe, competent and ethical care while having respect for the patient.[118] When the duty of obtaining consent has been delegated to a nurse, the nurse has an obligation to ensure that the patient, parents and legal guardians have been informed of and understand the extent and implications of the proposed operation before signing the consent form. The nurse adopts a facilitation of the informed consent process approach; whereby she assesses the patient's level of comprehension and clarifies any misunderstandings that the patient may have.[119] Cultural preferences and barriers pose a significant challenge in the IC process, and requires that the nurse has inert knowledge and takes this into consideration to ensure a streamlined process to complete understanding of the prescribed procedures.[120] In her advocacy role, the nurse sustains a co-operative and

[114] B Bhengu, S Armstrong and C Geyer *A New Approach to Professional Practice* (Juta & Co Ltd 2013 74).
[115] Regulations relating to the Scope of Practice of Nurses Registered or Enrolled Nurses under the Nursing Act 50 of 1978 (Government Notice R2598 of 1985, as amended). Pretoria: Government Printer.
[116] J Scribante, ME Muller and J Lipman 'Interpretation of the scope of practice of the South African critical care nurse' *SAMJ* (1995) May 85 (5) 437–441.
[117] *Nurses` Pledge*. Available at https://www.sanc.co.za/nurses-pledge. Accessed 9 August 2021.
[118] Ibid.
[119] JG Ngwenya An investigation into the knowledge and practice of securting informed consent for surgery by healthcare workers in a selected institution in KwaZulu-Natal (unpublished Masters in Nursing University of KwaZulu Natal South Africa) (2016).
[120] Ibid.

trusting relationship with patients. It is not the duty of the nurse to attempt explanations for the planned treatment; that is the doctor's responsibility.[121]

(6) Implications for the South African Nursing Council (SANC)

Legal and ethical frameworks guide the nursing professional practice and shape the nurse's ability to advocate for patient safety. A much-needed intervention by the South African Nursing Council (SANC), as the statutory and regulatory body of nursing practice, into the improvement of the nursing curriculum will positively impact on the improvement of nurses to deliver holistic patient care competently, ethically and legally.[122] The quality of nursing education contributes to the recognition of the nursing profession, which is characterised by commitment to upholding patients' rights through excellence in nursing care that is impressed by the instilled values underpinned by ethical consideration.[123] Having consideration to the increased focus on patients' rights, the SANC should seek to implement a structured content approach to ethical and legal aspects of nursing pertaining to informed consent, such as principles of ethical practice and legal perspectives related to overall health care.

In summary, Regulation 2598 addresses the obligations of categories of nurse practitioners to engage judgement, critical thinking and skill in providing safe, competent and quality patient care within their scope of practice.[124]

(7) National Core Standards

The need for improving the standard and quality of healthcare delivery was realised by the National Department of Health (DoH), and in its commitments to ensuring effective healthcare provision, it introduced the National Core Standards (NCS) in April 2008.[125] The aim and purpose of the NCS is to achieve compliance to initiating systems that set out requirements for

[121] South African Nursing Council Government Notice R2598 of 1985, as amended.
[122] A McCallin & C Frankson 'The role of the charge nursing unit manager: A descriptive exploratory study' *Journal of Nursing Management* (2010) 18 319–325.
[123] R Farkiya *Role of Regulatory Bodies in Improving Quality Education* (2012). Available at https://www.google.com/. Accessed 18 January 2022.
[124] SANC *Relationship between SOPs – Practice-Standards and Competencies* 2020. Available at https://www.sanc.co.za/wp-content/uploads/2020/06/SANC-Relationship-between-SOPs-Practice-Standards-and-Competencies.pdf. Accessed 9 August 2021.
[125] S Whittaker, C Shaw, N Spieker and A Linegari 'Quality Standards for Healthcare Establishments in South Africa' *South African Health Review* (2011) 59–67.

quality and safe care, incorporating current policies and guidelines,[126] and to prevent poor quality care and/or reduce the impact of such care on patients. [127]

Section 30 of the NHA provides for district health systems to have regard to the principles enshrined in sections 27 and 195 of the Constitution, which speaks to the district health system having regard to quality, effectiveness and efficiency.[128, 129, 130]

The NCS and its assessment tools were revised and benchmarked against other accreditation systems and structured into seven domains.[131] The nursing profession has adopted the NCS into practice, with reference to Domain 1 – Patient Rights and Domain 2 – Patient Safety / Clinical Governance wherein:

(a) Domain 1, Sub-domain 1.1 refers to respect and dignity in that staff must treat patients with care and respect, with consideration for patient privacy and choice.[132]

(b) Domain 2, Sub-domain 2.1 refers to patient care, in that patients will receive care and treatment that follows nursing protocols, meets basic needs and contributes to their recovery.[133]

Every nurse has to ensure that the patients' rights are taken into consideration and are specific as to informed consent and respect for patient autonomy, which forms form the core of the nursing function.

4 CHALLENGES

Culture, religion and psychology are common values that plague a patient's choice in relation to healthcare treatment. Namibia and South Africa share the same legal ancestry. Both legal systems have aspects of Roman-Dutch law and English common law. In *ES v AC* (SA 57/2012) [2015] NASC 11,[134] the right to self-determination on religious grounds or the autonomy of the mother of three minor children was afforded more weight by the majority of the judges than were the best interests of the children. This case concerns Ms. Semente, a Jehovah's Witness

[126] Ibid.
[127] National Department of Health *Towards Quality Care for Patients: National Core Standards for Health Establishments in South Africa* (2011). Available at: https://static.pmg.org.za/docs/120215abridge_0.pdf. Accessed 9 August 2021.
[128] National Health Act (note 12) section 30(2).
[129] Constitution (note 11) ss 27, 195.
[130] Whittaker et al (note 125).
[131] Ibid.
[132] National Department of Health (note 38).
[133] Ibid.
[134] *ES v AC* (SA 57/2012) [2015] NASC 11 (24 June 2015).

with two minor children. With the delivery of the third child, she had to undergo an emergency caesarean section and the removal of her uterus and had lost a lot of blood, but refused a blood transfusion. Her brother argued that she should be given blood in order to allow her to survive as it would be in the interests of the children to have their mother remain alive. While succeeding with the High Court, he was, however, unsuccessful in convincing the Appeal Court, which placed his sister's autonomy above the best interests of the children. The judgment indicates that patient autonomy enjoys a preferred position in Namibian law over that of children's rights.[135]

Healthcare workers face a number of challenges when managing the informed consent process. In a country that is rich in diversity and cultures, language, beliefs; educational competencies affect the delivering of information relating to obtaining informed consent for procedures. This forms an added paternalistic discord between medical practitioner and the nurse practitioner, in such a case the quality of a valid informed consent is not obtained.

5 CONCLUSION

Legally, if medical practitioners so much as touch a patient without their consent, they are likely to face criminal or civil litigation on grounds of assault or *crimen injuria*.[136] Disclosure of material risks associated with procedures is mandatory and should be viewed as both an ethical and a legal obligation.[137]As mentioned previously, there is joint accountability of the medical practitioner and the nurse practitioner in ensuring the engagement of legislation that guides their practice in the contractual relationship with the patient. While nurse practitioners must remember their duty to keep themselves informed of legal implications, the medical practitioners' obligations in taking the informed consent remain mandatory before a procedure, failing which professional misconduct of practice may result. It is within this role that nurses can determine whether patients have received sufficient information to make an informed decision. We can derive that it is necessary that education on and training on informed consent processes forms the cornerstone to safe healthcare delivery. The legal and ethical foundations require that the customary interaction and relationships, which are medically related, should be governed by the patient's explicit informed consent.

[135] F Mnyongani and M Slabbert 'A Jehovah's witness's autonomy versus the interests of her children' *THRHR* (2018) 81 316–325.
[136] M De Roubaix 'Dare we rethink informed consent?' *SAJBL* 2017 June 10 (1) 25–28.
[137] R Lemaire 'Informed consent – a contemporary myth?' *J Bone Joint Surg* [Br] 2006 88 2–7.

CHAPTER 3: INFORMED CONSENT AND ETHICAL CONSIDERATIONS

1 INTRODUCTION

The health and well-being of patients is dependent on the decision-making of the healthcare professionals who are in charge of their care.[138] The objective of the Bill of Rights, entrenched in the Constitution, is to advocate freedom of choice, and protect patients' rights such as the rights to human dignity[139] and bodily integrity,[140] which allows for a person to make autonomous decisions regarding his/her body. The foundation of ethical health care and treatment underpins the respecting of these rights.[141] Thomas discusses the fact that we make decisions daily, not all of which may be good; in the same way, a patient making a decision on the basis of all the required information must be respected, regardless of whether the decision does or does not match the medical practitioner's own decision.[142]

We may ask, then, what happens in the case when a patient is deemed to be incompetent? Giesen asserts that in cases where incompetency is ascertained, consent must be obtained by either a guardian, a curator or a family member who has legal power.[143] Ethics are the principles that should guide doctors and other health care professionals in their work and decision making. While they are not laws, they are guiding principles that apply to medical care all over the world.[144] Nursing practice is firmly grounded in ethical principles. However, the principles of informed consent prior to medical intervention remain the ultimate responsibility of the medical practitioner.[145] In the case of *Minister of Safety and Security v Xaba*,[146] it was alleged that the accused, who was involved in a robbery, had sustained a gunshot to his leg and the bullet was needed as evidence to link the accused to the crime. A court order was requested by the police for the removal for the bullet. The court held that this would be an infringement to the defendant's constitutional right to bodily integrity and privacy. Codified in sections 10 and

[138] E-Jun Park 'An integrated ethical decision-making model for nurses' *Nursing Ethics* 2012 Jan 19 (1) 139–159,
[139] Section 10.
[140] Section 12(2).
[141] Rowe & Moodley (note 28) 1–9. Available at https://doi.org/10.1186/1472-6939-14-15. Accessed 11 August 2020.
[142] R Thomas 'Where to from Castell v De Greeff? Lessons from recent developments in South Africa and abroad regarding consent to treatment and the standard of disclosure' *South African Law Journal* (2007) 124 (1) 188–215.
[143] Giesen (note 69).
[144] TL Beauchamp & JF Childress. 5th ed. New York: Oxford University Press, 2001.
[145] Menendez (note 38). doi: 10.1097/NHL.0000000000000015. PMID: 24263229.
[146] *Minister of Safety and Security v Xaba* 2003 (2) SA 703 (D).

12(2) of the Constitution,[147] the rights to human dignity and bodily integrity declare that everyone has a right to bodily and psychological integrity; this is fleshed out to include the right not to be subjected to medical or scientific experimentation without informed consent.[148]

2 DECLARATION OF HELSINKI AND THE NUREMBURG CODE

The Declaration of Helsinki, which sets out the principles for medical research, was developed by the World Medical Association and is intended for medical practitioners. These principles provided guidance to both the researcher and participants in the research process, to include being adequately informed of the anticipated benefits and potential risks and the right to refuse to participate or to withdraw consent to participate in a study at any time without counterattack.[149] In August 1947, following the atrocious and torturous human experiments conducted by the Nazi doctors, the code was formulated to expose the transgression of the Hippocratic oath, to shape the ethical framework for medical practitioners and to underscore the principles of patients' rights.[150] Although the code has not been officially adopted, its influence on international human-rights law and medical ethics in informed consent has been universally accepted and expressed in international law.[151] Today, the benefaction of the Nuremburg code enables the enforcing of application to world-wide human rights.[152]

3 THE HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA'S GUIDELINES

The standards of good practice set out by the Health Professions Council of South Africa (HPCSA) require health practitioners to treat personal or private information as confidential. They should not disclose the information communicated during their professional relationship, unless compelled by a moral or legal duty to make a disclosure.[153] Rule 13 of the Ethical and Professional Rules of the HPCSA provide instances when a practitioner may divulge a patient's

[147] Constitution (note 11).
[148] SC Chima 'Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study' *BMC Medical Ethics* (2013) 14 (Suppl 1) S3 1–17.
[149] World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects 2004. Available at https://www.who.int/bulletin/archives/79(4)373.pdf. Accessed 11 July 2020.
[150] E Schuster 'Fifty years later: The significance of the Nuremberg Code' *New England Journal of Medicine* (1997) 337 1436–1440.
[151] Ibid.
[152] Ibid.
[153] HPCSA *Guidelines for Good Practice in the Healthcare Professions. Booklet 1: General Ethical Guidelines for Health Professions* (2016). Available at https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf. Accessed 15 July 2020

information.[154] Further, the HPCSA guidelines: 'Confidentiality: Protecting and Providing Information',[155] set out the requirements of health practitioners' duty of confidentiality in the retention,[156] protection[157], and disclosure of patient information to other health practitioners for treatment purposes[158]. In *Jansen van Vuuren and Another v Kruger*,[159] during a game of golf, the HIV status of a patient was disclosed between a medical practitioner and his colleague. The court held this disclosure as unlawful, stating that the medical practitioner had no legal or ethical duty to disclose this patient information.[160] It is noteworthy that the standards as set out in these guidelines are of particular significance to the ethical considerations which underpin the medical practitioner's obligation in respecting the patients' rights of autonomy and self-determination when obtaining informed consent.[161] Njotini argues that the National Health Act was unable to provide a clear definition of informed consent, and refers to the HPSCA as a lateral source to understanding of informed consent.[162] Endorsing the HPCSA Guidelines of 2008, he states that:

> *'Successful relationships between health care practitioners and patients depend upon mutual trust. To establish that trust practitioners must respect patients' autonomy – their right to decide whether or not to undergo any medical intervention, even where a refusal may result in harm to themselves or in their own death. Patients must be given sufficient information in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. This is what is meant by an informed consent.'*[163]

[154] HPCSA *Guidelines for Good Practice in the Healthcare Professions. Booklet 2: Ethical and Professional Rules of The Health Professions Council of South Africa as promulgated in Government Gazette* (2007), rule 13. Available at https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf. Accessed 15 July 2020

[155] HPCSA *Guidelines for Good Practice in the Healthcare Professions Booklet 5: Confidentiality Protecting and Providing Information* (2016). Available at https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf. Accessed 15 July 2020

[156] Health Professions Council of South Africa.

[157] Ibid.

[158] Ibid.

[159] *Jansen van Vuuren and Another NNO v Kruger* [1993] ZASCA 145.

[160] Ibid.

[161] Health Professions Council of South Africa (note 21).

[162] Njotini MN 'Preserving the Integrity of Medical-Related Information – How "Informed" is Consent?' P*ER/PELJ* 2018 (21)

[163] Ibid.

4 INTERNATIONAL COUNCIL OF NURSES (ICN)

Ethics and ethical frameworks provide nurse practitioners with a guide or code of conduct of what is wrong and right within the nursing profession. The ICN Code of Ethics for Nurses of the International Council of Nurses was adopted in 1953 and revised and reaffirmed in 2012.[164] The code serves to oversee four fundamental responsibilities that form the umbrella of the nursing professions and include the promotion of health, prevention of disease, restoration of health and alleviation of suffering.[165] The mission of the ICN is to be a universal representative of the nursing profession, advance the nursing profession, promote the wellbeing of nurses, and advocate for health in all policies,[166] Further, the ICN seeks to align and integrate the nursing model with international health priorities and works with the World Health Organization to facilitate inclusion of nurses to form part of the decision-making, policy-setting and implementation of national and international policies and strategies. This affords the nursing profession a voice for advocating for re-enforcing nursing rights as well as those of the patients; these rights are aligned to the ethical and legal framework.[167]

As a profession, nursing is guided by this code, which serves to keep the nursing practitioners in line with professional conduct in the delivery of nursing care to patients. Included in the categorisation of every nurse practitioner lies the declaration for respect of human rights as set out in the Nurses' Pledge:

> *'... to include cultural rights, the right to life, choice and dignity without consideration of age, colour, creed, culture, disability or illness, gender, sexual orientation, nationality, politics, race or social statuses.*[168]

The nursing profession in South Africa endorses the ICN code as part of the essential supporting regulatory guidelines in any nursing curriculum and it forms part of the ethical and legal framework for professional practice. This stresses the importance of the role of moral obligation and questions moral values, norms and obligations. The nurse practitioner is required to determine what is best for the patient, and in deciding what will be right and what

[164] International Council for Nurses (note 41).
[165] Ibid.
[166] Ibid.
[167] Ibid.
[168] South African Nursing Council *Code of Ethics for Nursing Practitioners in South Africa* (2013). Available at https://www.sanc.co.za/wp-content/uploads/2021/04/Code-of-Ethics-for-Nursing-in-South-Africa.pdf. Accessed 15 September 2019.

will be wrong is where her skills and knowledge in decision making are applied. The code of ethics of the profession serves as a set of principles to guide or direct behaviour.

5 CONCLUSION

The doctrine of informed consent is well entrenched in the ethical framework that governs the practice of both the medical and nurse practitioner and places the healthcare team in a safe enclave, provided that the ethical principles form the cornerstone of their practice. We have progressively moved from an era of overt paternalism to a patient-centred approach affording the patient autonomy and allowing him/her to be the voice for medical decisions on his/her body. The next chapter will draw conclusions as to how both the professions can work together to focus on an integrated approach to the rule of law and ethics to improve the informed consent process.

CHAPTER 4: RECOMMENDATIONS AND CONCLUSION

1 INTRODUCTION

Historically and to date, legislation and societal changes have seen a renewed appreciation for patient autonomy and the significance of informed consent. The practical application of the doctrine of informed consent is anchored on the healthcare workers ethical and medico-legal knowledge. The human rights discourse is constructed around respect for autonomy, thus placing a high premium on self-determination. If any procedure were to be conducted on an individual without their consent, that conduct would constitute an infringement of their rights. Obtaining informed consent is of paramount importance, particularly within the context of the ethical legal system; not doing so would be a violation of patients' rights. Facing challenges forms part of the normal day-to-day activities in a healthcare setting. The knowledge and understanding of the ethical and legal framework will provide new impetus to the informed consent process to ensure optimal care of patients.

2 RECOMMENDATIONS

(1) Responsibility for the Obtaining of Informed Consent

While nurses have a role in the IC process, clause 1.4 of the American Nurses Association's (ANA) Code of Ethics provides that the patient's decision-making process is to be supported by the nurse, and that the nurse understands the moral and legal rights of the patient.[169] Full disclosure of all risks and the associate complications as well as alternative treatments is required for the patient to have complete understanding of a procedure.[170, 171] The qualified and experienced medical practitioner assumes responsibility for the discussion and sharing of significant information that will prevent a patient from arriving at a decision based on wrong beliefs.[172] The nurse's responsibility is to ensure that the patient understands what the doctor has discussed.

[169] American Nurses Association, 2015.
[170] National Health Act (note 12) section 6.
[171] Dhai (note 1) 27.
[172] Agard A 'Informed consent: theory versus practice'. *Nature Clinical Practice Cardiovascular Medicine* (2005) 2 (6) 270–271.

(2) Recommendation

In consideration of the dual role of the medical and nurse practitioner, a checklist as an addendum to the informed consent form must be compiled, to include the discussion of the procedure, potential and material risks. This document must be ratified by a panel of representatives of the healthcare workers and agreed upon with regard to implementation. Further, as with newly appointed nurses, new doctor recruits must attend a specific orientation programme based on the importance of their role and responsibility in the informed consent to form the pinnacle of the orientation programme.

3 KNOWLEDGE OF THE ETHICAL AND LEGAL FRAMEWORK

Chima, in his suggestion, expounded the requirement of bio-ethics and the law to form part of a training requirement for all healthcare workers.[173]

(1) Recommendation

In addition to the completion of the Bioethics and the Law course, should follow through on as a Continuous Professional Development (CPD) programme. This would ensure that the knowledge is continuously updated in keeping with changing legislation and its application to the Bill of Rights and informed consent of the patient. The knowledge acquired will not only empower nurses and medical practitioners but will also improve healthcare by elevating the role of nursing as nurses take their place in facing health challenges. This will remain as an extension of their advocacy role to maximise their contribution towards achieving ethical and legal patient care and guiding medical practitioners to safe patient practice.

4 CHALLENGE OF THE GERIATRIC PATIENT AND CULTURAL BELIEFS

A diversified nation comes with cultural and language barriers.[174] While we respect the religious beliefs of our patients, the ethical dilemma becomes apparent when facing an emergency and a life-threatening scenario.

[173] SC Chima An Investigation of Informed Consent in Clinical Practice in South Africa (unpublished Doctor of Law thesis, University of South Africa) (2018).
[174] Ibid.

(1) Recommendation

To safeguard patient safety, healthcare facilities should enforce revision of existing procedures. Contractual documentation between the facility and the patient must include religious considerations and options for the refusal of and consent to procedures that may be affected by culture and beliefs. In addition, very often elderly patients arrive from frail care and old-age homes, and their own family are not aware of their admission to a healthcare facility. The Department of Health should develop a national database of all patients entering a health facility for clinical care. This system should obtain and link data from all hospitals in the country for ease of traceability of contacts and to be able to identify immediately all medical intervention and records of the patient. While this may seem to be a task which is extremely challenging, the Sisonke vaccination and electronic vaccination data system (EVDS) proves that this can be successful.[175] Apart from the diversity in South African cultural languages, with South Africa being an international tourist-rich country, foreign language interpreters should be sourced and included on a national database for services when required. This database should include availability of sign language interpreters. Obtaining the correct information relating to the requirements of informed consent will ensure a smooth process that allays fears, doubts and anxieties.

5 DISCLOSURE OF INFORMATION

(1) Recommendation

Agard argues that the ethical standard of disclosure to patients must be specific and modified to meet the metacognitive needs of the patient, and that having regard for health and cultural beliefs forms a salient point of the discussion,[176] as failure to do so constitutes negligence. Through the findings of Chima, the challenge of a high doctor-patient ratio results in doctors not having sufficient time to discuss all risks.[177] It would be advantageous for medical practitioners to consider using the EIDO Healthcare solutions[178] to improve doctor-patient communication and relationships when obtaining informed consent. The information is

[175] Covid-19 '*South African Coronavirus News and Information'* Available at https://sacoronavirus.co.za/. Accessed 21 August 2021.
[176] Agard (note 172).
[177] Chima (note 173).
[178] EIDO Healthcare *The Experts in Informed Consent for Over 20 Years*. Available at https://www.eidohealthcare.com/about/about-eido/. Accessed 11 May 2021.

developed by clinicians in a pamphlet format and is available electronically or can be printed out. It assists in supporting patients in making an autonomous decision about their health.[179]

6 CONCLUSION

The medical practitioner is required to adopt the standards and the rule of law when soliciting the informed consent process and to maintain a continuous dialogue to establish trust and respect for the patient's autonomy.[180] The quality and transparency of information are becoming increasingly important, as patients hold healthcare practitioners to account on adverse service delivery. It is therefore vital to link legal principles and ethics to every aspect of patient care to ensure the provision of the best clinical care for optimal recovery. Medical practitioners should be gearing towards becoming a medical professional led by a bioethical and legal structure, thereby making provision for all members of the multidisciplinary teams to work together to deliver quality and risk-free healthcare in order to ensure the best clinical outcomes for patients. Mark Crane informs us that physicians in Pennsylvania delegated the informed consent process to lower categories of healthcare workers, including nurse practitioners; however, the courts have ruled that such a delegation causes a risk as the personnel lack the understanding of complications of a procedure and are therefore not qualified to discuss material risks and alternatives.[181]

As one of the most trusted professions, nurses provide effective and quality care for patients of all ages and are central in addressing the increasing burden of disease. Every day nurses step up to the plate and take responsibility for being the champions of evidence-based practice while nurturing, comforting and building relationships. Pursuant to a bioethical and law training, nurses would be further empowered to align patient information according to the core values and to remind medical practitioners of those patients requiring more information on their diagnosis and procedures. While the nurse's core role is to be the patient advocate, clinical assessment and judgement are aligned to legal and ethical requirements incorporated into the scope of practice.[182] All too often, ethical dilemmas faced by the nurse arise when there are conflicting moral judgements by the nurse and medical practitioner regarding the point of care and what is in the best interest of patient.[183] A tighter alignment between the hospital and the

[179] Ibid.
[180] JA Singh 'Ethical decision-making' in Dada & McQuoid-Mason (note 19).
[181] Crane M Legal Risks of Delegating Informed Consent to an NP or PA Medscape. Available at www.medscape.com/viewarticle/887074 Nov 30 (2017). Accessed 24 February 2022.
[182] Ibid.
[183] Ibid.

medical practitioners is required to ensure that the informed consent process is ethically, legally and morally accepted and practiced. According to HASA (Hospital Associations of South Africa), hospitals must obtain informed consent for health services, where the written consent will be in the form of a signed document consenting to health services performed. This must form part of the admission documentation to be completed by the patient, prior to admission.[184]

[184] *HASA Recommended Policy: Internal Hospital Policy for Informed Consent and Related Matters*. Available at https://hasa.co.za/. Accessed 20 June 2020.

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