Authenticity of Informed Consent in Anaesthesia:

Ethical Reflection on the Dilemma of Informed Consent in Anaesthesia

By

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Thesis presented in fulfilment of the requirements of the degree of Master of Philosophy (Applied Ethics) in the Faculty of Arts at the Stellenbosch University

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March 2020

DECLARATION

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ABSTRACT

Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment (Appelbaum 2007: 1834).

Health Care Professionals should obtain informed consent from the patient before proceeding with the proposed treatment. Therefore, the anaesthesiologist should obtain informed consent from the patient before proceeding with the anaesthetic.

The requirement of informed consent implies that certain pre-requisites should be met. The patient should be competent to understand the information given to him/her. The patient should be adequately informed and thereby be able to decide, without being influenced, and should also have the right to refuse the treatment. These requirements of obtaining informed consent prompted this investigation into the authenticity of informed consent in anaesthesia and the ethical dilemma faced by the anaesthesiologist.

In order to examine this dilemma in anaesthesia the thesis firstly investigates the origin and establishment of informed consent, both in biomedical ethics and in the law. It starts by investigating the concept of autonomy and the development of respect for autonomy as the basic premise for the development of the informed consent process and elucidates the move away from the paternalistic approach in medicine to the current patient centred approach.

To expound the unique nature of informed consent consultation in the peri-operative environment, anaesthesia as a speciality is examined. This investigation into the history and origin of anaesthesia leads to an acknowledgment of the unique moral status of the anaesthetised patient. The patient transits from the patient-as-person to the-patient-as-body while undergoing anaesthesia, as was alluded to by the first users of anaesthesia who experienced this transition firsthand. This unique moral status questions the validity of consent in this exceptional environment. The unique ethical dilemma the anaesthetists faces in the peri-operative setting is further

investigated, keeping in mind the requirements for informed consent as stipulated in bioethical literature as well as in legal and regulatory guidelines. The guidance of current thought leaders in informed consent, as well as bioethical principles as published in bioethical literature are used as tools to examine the dilemma of informed consent in anaesthesia.

In an attempt to find ethical solutions to this dilemma, ethical alternatives to informed consent in anaesthesiology are investigated. Phronesis and the ethics of responsibility, virtue ethics as well as medical professionalism offers some solutions to the ethical dilemma, and if promulgated could alter the construct of informed consent in anaesthesiology as it currently exists. The unique moral status that being anaesthetised infers upon a patient also has interesting potential implications for altering the construct of anaesthetic informed consent.

Lastly practical solutions to satisfy the responsibilities that current legal, regulatory and bioethical guidelines place on the anaesthesiologist are investigated. Ultimately the reality of the difficulties in obtaining authentic informed consent in anaesthesia remains a dilemma in its current form and one looks forward to future development in the bioethical and legal fields to be able to develop an authentic anaesthetic informed consent consultation.

ABSTRAK

"Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment "(Appelbaum 2007: 1834).

Dokters en ander mediese terapeute behoort ingeligte toestemming te verkry van pasiente voordat hulle voortgaan met behandeling. Dit impliseer dan ook dat 'n narkotiseur ingeligte toestemming van 'n patient moet verkry voordat die pasient narkose ondergaan. Dié vereistes vir ingeligte toestemming impliseer dat daar aan sekere voorvereistes voldoen moet word: Die pasient moet in staat wees om die inligting wat aan hom/haar verskaf word te verstaan. Die pasient behoort voldoende inligting te ontvang sodat hy of sy bevoeg sal wees om 'n besluit te neem, sonder om beïnvloed te word in terme van sy/haar keuse, en die pasient moet ook behandeling mag weier. Hierdie voorvereistes vir ingeligte toestemming, en die dilemmas wat dit bring vir 'n narkotiseur het dié ondersoek geïnisieer, met die uiteindelike doel om die outentisiteit van ingeligte toestemming vir narkose te ondersoek.

Om hierdie dilemma in narkose te ondersoek, word die oorsprong en vestiging van ingeligte toestemming ondersoek, beide uit 'n bioetiese en 'n wetlike oogpunt. Eerstens word die konsep van outonomie en die ontwikkeling van die beginsel van respek vir outonomie ondersoek. Dit is die basiese boublokke wat die ontwikkeling van die ingeligte toestemming proses beïnvloed het.

Om die uniekheid van die ingeligte toestemming konsultasie vir narkose te ondersoek, word toepaslike aspekte van die spesialiteit van narkose bepreek. Die geskiedenis en oorsprong van narkose word ondersoek en dit lei na 'n herkenning van die unieke morele status van die pasiënt onder narkose. Die pasiënt verskuif van 'n pasiënt-as-persoon, na 'n pasiënt-as-liggaam tydens narkose, soos wat die eerste gebruikers van narkose eerstehands ondervind het. Die unieke morele status van die pasiënt onder narkose bevraagteken die geldigheid van kontemporêre toestemming in hierdie unieke peri-operatiewe omgewing. Die unieke etiese dilemma wat die narkotiseur ondervind word verder bepsreek, terwyl die vereistes vir voldoende

ingeligte toestemming, soos voorgeskryf in etiese literatuur en wetgewing verder ondersoek word. Die huidige denke oor ingeligte toestemming, asook die bioetiese beginsels soos gepubliseer in die bioetiese literatuur, word ingespan in ‘n poging om die dilemma van ingeligte toestemming in narkose op te los.

In ‘n poging om etiese oplossings vir dié dilemma te vind, is etiese alternatiewe ondersoek. Fronese en die etiek van verantwoordelikheid, deugde etiek en mediese professionalisme bied sekere oplossings vir die etiese dilemma en kan potensieel die struktuur van ingeligte toestemming vir narkose totaal verander. Die unieke morele status waarin die pasiënt onder narkose hom/haar bevind het ook interessante potensiële implikasies vir die verandering van die struktuur van ingeligte toestemming vir narkose.

Laastens word praktiese oplossings, om aan die vereistes van voldoende ingeligte toestemming vir narkose, soos dit huidiglik verwag word, te voldoen, ondersoek. Ten slotte word die realiteit van die dilemma om opregte, outentieke ingeligte toestemming te verkry vir narkose beklemtoon, en word daar uitgesien na verdere ontwikkelinge in die bioetiese en wetlike vakgebiede om outentieke ingeligte toestemming te bevorder.

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CHAPTER 1: ORIENTATION OF THE STUDY

1.1. Informed Consent And The Anaesthesiologist

The anaesthesiologist, who is under legal and ethical obligation to obtain informed consent[1] from a patient, finds him/herself in various peri-operative settings in which to perform this consultation. The following scenario is a typical but critical setting:

> *The patient is in severe pain. The patient has an inflamed appendix which has to be removed as soon as possible. Surgery is imminent. An anaesthesiologist, whom the patient has not met before, wearing surgical scrubs enters the room, and should now obtain informed consent for the anaesthetic that is about to be administered. The anaesthesiologist has a consultation with the patient, both a clinical consultation and a consultation to obtain informed consent for the anaesthetic.*

This type of scenario, with some variations on the level of urgency of the medical procedure or the discomfort of the patient, whether physical or emotional, is common in clinical practice. The authenticity of that informed consent conversation, however brief or extended, is questionable. The peri-operative setting may be emergency or elective surgery but the authenticity of truly informed consent in any peri-operative setting comes into question due to multiple factors that will be discussed.

Biomedical ethicists Beauchamp and Childress have outlined seven elements in order to best obtain informed consent. These elements are:

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[1] *Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment* (Appelbaum 2007: 1834)

> I: Preconditions or threshold elements, namely **Competence** of the patient to understand and decide and his/her **Voluntariness** (in deciding for or against the procedure)
> II: Information elements, namely **Disclosure** (of the relevant information), **Recommendations** for the treatment and **Understanding** (of the information and recommendations)
> III: Consent elements: The **Decision** (in favour of the plan) and **Authorisation** (of the plan) by the patient (Beauchamp and Childress 2013: 124 [emphasis mine]).

In the peri-operative setting, each of these seven elements is relevant, but compromised. The patient is often distressed by being admitted to hospital. A hospital admission will compromise even a usually calm and cognitively competent patient's understanding, because of emotional factors such as anxiety and fear. The patient's cognitive and emotional functioning may also be negatively affected due to physical factors as part of the underlying disease and medication. The fact that the anaesthetic is vital, and not a real choice for the patient, compromises the voluntariness of the consent. Disclosure of information can be compromised by the lack of time to adequately discuss the details of the anaesthetic. The information in itself poses a problem. Complications that can be discussed are numerous and the seriousness of such complication may be extreme. The concept that the patient is not really being put to 'sleep', but actually is put into a state of unconsciousness is usually not discussed with patients. All these factors impair the patient's true understanding of the information, thus making true decision-making and authorisation of the anaesthetic procedure questionable.

This concerns me deeply and should be of greater interest to the profession of anaesthesiology in general. I wish to practise as an authentic medical professional, which implies that I practise in accordance with both professional practice and legal guidelines as set out by the Department of Health and the Health Professions Council of South Africa (HPCSA). I also want to practise in accordance with fundamental ethical precepts, which are becoming increasingly important in biomedical ethical literature.

Beauchamp and Childress influentially argued that there are four fundamental biomedical ethical principles which form a backdrop to ethical medical practice. These are respect for autonomy, beneficence, non-maleficence and justice (Beauchamp and Childress 2013). Obtaining authentic informed consent, out of respect for autonomy of the patient, has become fundamental to all spheres of contemporary medical practice. However, the question arises: *Is this practice possible in anaesthesiology?* To what purpose is it necessary in the clinical scenario sketched above? Anaesthesia is essential for surgery, yet legal and ethical guidelines mandate that informed consent be obtained. These difficult questions prompted this thesis; my aim is to *investigate the authenticity of informed consent in the everyday practice of anaesthesiology.*

Informed consent is the subject of much deliberation and increasing importance. It has become a foundational precept, both in medical ethics and the law (Siegal, Bonnie and Appelbaum 2012). Informed consent came about and was initially driven by legal cases in American civil litigation that compelled doctors, who in the past would treat patients with limited consent, to now obtain proper consent from their patients. Before this, physicians would act in an all-knowing paternalistic manner and 'protect' patients from bad news. This behaviour was put to stop by legal cases that compelled physicians to not only obtain consent, but to also provide all relevant clinical information to their patients. The requirement for informed consent was also reinforced by the increasing importance of bioethical principles, as espoused by Beauchamp and Childress. (Beauchamp and Childress 2013)

The growth and developments of the field of bioethics has had a significant impact on all spheres of medicine and research. The principle of respect for autonomy, a cornerstone of biomedical ethics, has hugely influenced the swing from a paternalistic approach in medical practice to that of respect for the autonomy of the patient. The word autonomy means 'self-rule'. Therefore, respecting the autonomy of the patient emphasises the right of the patient to make decisions, affecting himself/herself, based on the relevant information.

Respect for autonomy of the patient implies that **informed consent** be obtained for any medical examination, procedure or treatment. In fact, the HPCSA guidelines on

informed consent (HPCSA 2017b) clearly state that consent in medical practice always means informed consent. In the unique peri-operative setting in which the anaesthesiologist finds him/herself, the important concept of informed consent becomes less clear as the clinician attempts to act both ethically and legally soundly. The literature on this abounds with cries of 'unrealistic, unethical and untenable' with regards to the extensive guidelines for informed consent for anaesthesia (Kumar 2006; Cyna and Simmons 2017:1). This sentiment is reflected by many clinical anaesthesiologists for whom obtaining informed consent remains a conundrum.

"We are discussing no small matter, but how we ought to live" is an often-quoted phrase from Socrates in Plato's *Republic* (ca. 390 BC) with regards to moral philosophy (Rachels and Rachels 2015). The fundamental questions upon which I wish to reflect philosophically are these: *how ought anaesthesiologists to 'behave' in the perioperative setting, and how authentic is anaesthesiological informed consent?*

1.2.Aim Of Thesis

This thesis has two overarching aims. The first is investigative in nature, while the second is an attempt to deliberate on both ethical and practicable solutions for the dilemma of informed consent as faced by the anaesthesiologist.

The thesis firstly aims to interrogate a number of fundamental ethical questions regarding the informed consent obtained from the patient by the anaesthesiologist in the pre-operative setting. The following issues will be addressed:

- *Informed consent*
    - *The concept of informed consent*
    - *The origin of informed consent, both form a legal and bioethical viewpoint*
    - *The legal and regulatory requirements for informed consent*
    - *Impediments to informed consent*

- *Anaesthesia*
    - *Anaesthesia in the past and present*
    - *The unique moral status of the anaesthetised patient*

- *Informed consent and its validity in the peri-operative setting*
- *The ethical dilemma of anaesthetic-specific informed consent*

The second aim of the thesis is to find and deliberate possible answers to the ethical dilemmas in anaesthetic informed consent, employing insights gained through literature based research and the reflection of professional bioethicists. The thesis will discuss:

- *Ethical alternatives to informed consent*
- *Practical alternatives to informed consent*

The question the thesis ultimately attempts to answer is: Can truly authentic informed consent for anaesthesia ever be obtained in the peri-operative setting?

1.3.Thesis Structure

The thesis begins in chapter 1, which outlines the introduction and the scope of the thesis.

In chapter two, the origin of the construct of “informed consent” is explored, with a particular discussion of autonomy as it plays a pivotal role in the development of informed consent. Thereafter, the origin of informed consent and the history of the development of informed consent, in terms of philosophical, bioethical and legal precepts, are discussed. The different standards of disclosure, as they were developed and informed by legal rulings are presented.

In chapter three, we will look at the law and the anaesthesiologist, and at both the legal requirements and regulatory guidelines that are placed on the anaesthesiologist by the South African regulators, and also by professional societies, such as the South African Society of Anaesthesiologists (SASA).

Chapter four discusses the impediments to obtaining authentic informed consent as prescribed in the previous chapter. Patient competence to and the ability to understand and deliberate upon the information given to them will be investigated

and patient recall of information will be looked at. This chapter will also discuss the relevance problem of informed consent, namely, which information is appropriate for which patient in which situation. The problem of exhaustive or 'over' information will be investigated and discussed as well as challenges from the clinician's side, namely the practicalities of lack of time and the lack of motivation to provide information. The practice of defensive medicine and intentional non-disclosure will be deliberated. The transfer of information is paramount during the informed consent process and the thesis will investigate this important concept. Lastly, the concept of patient responsibility, as well as the role of the patient and the responsibility he/she takes in the informed consent process, will be considered.

The following chapter takes a close look at the unique field of anaesthesia, starting with the history of anaesthesia and its development through the ages. It will look at anaesthesia as it is practised currently and also briefly look to the future and the advances that will inevitable bring new ethical challenges relating to informed consent.

Chapter six will examine the unique moral and ethical status of anaesthetised patients. The anaesthetised patient enters a moral status that is unique in its induction and reversibility and confers a different moral status on the patient, namely patient-as-body versus patient-as-person.

The next chapter will investigate the unique peri-operative settings anaesthesiologists find themselves in. It will look at how this setting is different from those of other clinicians, and how that impacts on the transfer of information, as well on the validity of the consent as obtained. It will also investigate how the peri-operative environment may alter the physician–patient relationship and attempt to identify the aspects of informed consent that will be the most important in this unique setting, focusing on risk versus benefit discussions, and specific disclosure of anaesthetic risks.

In chapter eight, the ethical dilemma that presents itself to the anaesthesiologist in the peri-operative setting will be addressed. The numerous challenges that comprise this ethical dilemma will be described, and the impact of the unique moral status of

the anaesthetised patient will be touched on.

Chapter nine investigates different theories and ethical alternatives to informed consent and chapter ten will propose practical solutions to obtaining or attempting to obtain true authentic informed consent in anaesthesia. The final chapter concludes the thesis with a discussion of conclusions made and challenges discovered.

1.4.Conclusion

The aim of the thesis is to determine the authenticity of informed consent in anaesthesiology by means of the investigation of applicable bioethical literature and ethical reflection on the dilemma of informed consent in anaesthesia.

The important differences between customary clinical consultation and treatment and that of the anaesthetic clinical consultation highlighted the difficulty in obtaining true authentic informed consent, as traditionally stipulated by legal and regulatory guidelines, as well as by the bioethical requirements placed on health care professionals.

The ethical dilemma of obtaining authentic informed consent in anaesthesia has been unpacked and reflected on, and important ethical considerations elaborated on. Ultimately the anaesthesiologist strives for the ethical ideal to obtain authentic informed consent, but has to accept the inherent dilemmas of this unique informed consent process.

The unique moral status of the anaesthetised patient opens up an exciting field of research that may impact informed consent as it is currently perceived in anaesthesia and change its essence.

CHAPTER 2: CONSTRUCT OF INFORMED CONSENT

2.1. Introduction

Chapter 2 presents the development of the construct of informed consent from its roots in early philosophical-ethical contemplations. It follows its development to a modern bioethical construct which is central to the practice of medicine. It looks at important historical events that influenced the practice of the informed consent process and then examines the influence of law and important legal cases that changed the current-day informed consent construct. Informed consent has become an integral part of the ethics of current medical practice (Appelbaum 2007).

Examining informed consent involves researching the history of its development within medicine and also in the realm of the law. By means of metacognition and critical thinking, the basic tenets of modern-day bioethics were shaped through decades to the point where it is today. The inception of the modern bioethical principle of respect for patient autonomy defines the current status and substance of informed consent in both clinical and research practice. The important influence of medical law on the development of the modern informed consent will be investigated (Van Niekerk 2017).

This analysis of the origin and establishment of informed consent and all aspects thereof in medical ethics pertains also to the specialty of anaesthetics.

Appelbaum provides a general definition of informed consent :

> *Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment* (Appelbaum 2007: 1834)

Berg et al. allude to the challenging interwovenness of the ethical and legal aspects of informed consent.

> *Informed consent refers to the legal rules that prescribe behaviour for physicians and other health care professionals in their interactions with patients and provide for penalties, under certain circumstances, if the physician deviates from those expectations; to an ethical doctrine, rooted in our society's cherished value of autonomy, that promotes patients' rights to self-determination regarding medical treatment; and to interpersonal processes whereby the parties interact with each other to select an appropriate course of medical care. Informed consent is each of these things, yet none of these alone* (Berg et al. 2001: 3).

2.2.The History Of Biomedical Ethics

Biomedical ethics as it exists today has grown from the field of ethics as a relatively new sub-discipline of ethics. Ethics itself is a sub-discipline of philosophy (Van Niekerk 2017) Ethics, the study of what is *right* and what is *wrong*, is as old as humanity itself. Judging if an action is *right* or *wrong*, or investigating the concepts of *good* and *bad* can be traced back to some of the oldest philosophical documents (Van Niekerk 2017).

The origin and development of the construct of informed concept therefore has its roots in philosophy. Van Niekerk (2017) states that philosophy is the study of the human process of thinking and reflecting on concepts and ideas. This thinking activity evolves to the process of metacognition (thinking about thinking) which is a higher-order thinking skill and it is safe to say that metacognition lies at the root of ever-advancing reasoning and development of human awareness, perception and knowledge and therefore philosophy. Metacognition is imbedded in critical thinking which was described by Scriven and Paul and as follows:

> *Critical thinking is the intellectually disciplined process of actively and skilfully conceptualizing, applying, analysing, synthesizing, and/or evaluating information gathered from, or generated by, observation,*

> *experience, reflection, reasoning, or communication, as a guide to belief and action* (Scriven and Paul 1987)

The Hippocratic oath formulated in 500 BC contained the first prescription of ethical conduct for the medical profession in the Western world. (Faden, Beauchamp and King 1986) The roots to the paternalistic approach to consent can be found here, the idea behind this approach being the wellbeing of the patient. The philosopher Plato stated that if a doctor forced a patient to comply with a medical procedure it was not wrong if the procedure was in the best interest of the patient (Kumar 2006). Kumar also states that the early Grecian philosophers such as Socrates, Plato and Aristotle endorsed the concept of "fundamental human rights" which contained the element of benevolence in their thinking (Kumar 2013).

The paternalistic approach was maintained in medical philosophic thinking for a very long time as a reflection of the morality of the time.. An example of the paternalistic approach in practice in the nineteenth century is found in the first booklet on medical ethics which was published in 1847 by the American Medical Association called "Code of Medical Ethics" (Haslam 2004).

This booklet is a far cry from contemporary biomedical ethics. Initially, medical ethics only implied the ethics of medical professionals and their behaviour towards their patients and towards each other. This booklet on ethics actually preached the paternalistic approach to medicine, stating that "The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions to their fitness" (Code of Ethics of the American Medical Association 1848, 12)

It is only much later that biomedical ethics evolved to its current standard. The model of informed consent as applied today underwent many transitions due to philosophical contemplation, modernisations in the medical profession and historical events that will be discussed below.. The crux of the current construct of informed consent lies within the concept of *autonomy*, and the bioethical principle of respect for patient autonomy.

2.2.1. Events That Transformed The Construct Of Informed Consent

2.2.1.1. Historical events

The paternalistic approach to bioethics continued to be an ethical and moral guideline through the ages. However, bioethics was propelled into the consciousness of medical professionals after the atrocities that occurred during the Second World War with human experimentation.

The horrors of the Holocaust also played a big role in this shift leading to the Nuremberg Code in 1947 to guide research ethics. The Declaration of Helsinki in 1964 reinforced the autonomy of the patient in a research setting. It reinforces respect for human rights, with specific emphasis on autonomy and informed consent. The Declaration of Helsinki states: “It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects” (World Medical Association 2013). Furthermore, regarding informed consent the declarion states: “Participation by individuals capable of giving informed consent as subjects in medical research should be voluntary” (World Medical Association 2013).

This reinforcement of respect for human rights and autonomy did not only influence research ethics, but also spilled over to the medical treatment sphere where respect for the autonomy and obtaining the informed consent of the patient has become an important requirement inherent to medical treatment.

2.2.1.2. Modernisation of medicine

Biomedical ethics has evolved in line with the development of new technologies such as increasingly sophisticated artificial life support as well as futuristic technologies such as nanotechnology and transhumanism. These developments in modern-day medicine to a great extent directed the philosophical probes into the ethics and morals of contextual informed consent.

Clinicians are faced with decisions about right and wrong in various aspects of their practice on a daily basis. Some of these decisions may be classified as micro-ethics, referring to the small ethical decisions which constantly face us (Truog 2015). It can also be decisions with complex ethical challenges such as end-of-life withdrawal of treatment or termination of pregnancy.

Whether medical decisions are quotidian or life-changing, the ethics and morality of underlying informed consent deserve investigation.

2.3.Informed Consent And The Four Bioethical Principles

The principle of respect for autonomy plays an enormously important role in biomedical ethics, and is heavily defended by biomedical ethicists. The opening sentence of Beauchamp and Childress in their chapter on autonomy reads: “The principle of respect for autonomous choices of persons runs as deep in the common morality as any principle” (Beauchamp and Childress 2013: 101).

In their seminal textbook, Beauchamp and Childress base their biomedical ethical approach on the four principles born from the theory of common morality. The concept of common morality is what guides us in deciding what is right and wrong in life in general. According to Beauchamp and Childress, it is so common (shared, mutual, collective) that it is the principle that guides society as a whole as “the set of norms shared by all persons committed to morality” (Beauchamp and Childress 2013: 417).

It is this common morality that provides us with certain sets of norms, which are applicable to all persons: “The common morality is applicable to all persons in all places and we rightly judge all human conduct by its standard” (Beauchamp and Childress 2013: 3).
Beauchamp and Childress justify their concept of a universal common morality by using three types of claims. Firstly they feel that if an investigation is done, universal consent will be found in moral belief; they call this an *empirical justification* of the existence of common morality. Furthermore, they call upon the work of Bernard Gert

in his books *Morality: It's Nature* and *Justification and Common Morality: Deciding What to Do* to show that common morality can be seen as an ethical theory and that common norms can be drawn form that theory. Beauchamp and Childress see this as a *normative theoretical justification* of their common morality theory. Lastly, Beauchamp and Childress defend their common morality theory by *conceptual justification* by emphasising how the principles of their biomedical ethics are drawn from common morality (Beauchamp and Childress 2013: 421).

The four pillars of biomedical ethics, as espoused by Beauchamp and Childress are:

- Respect for autonomy,
- Beneficence
- Non-maleficence and
- Justice

These principles are hugely important within the bioethical framework. In practice, when faced with an ethical matter, the biomedical ethicist will consider and weigh up these four principles, and be guided by the principle that is deemed to be the most important to guide them towards a sound and ethical decision. The principle of respect for autonomy is the guiding principle in any discussion about informed consent, but the other three are as important. I'd like to look at the other three in some detail here.

- Non-maleficence: This principle is as old as ethics itself – 'Primum non nocere'. This is a principle that specifies above all (literally 'firstly') to not do any harm. It is seen as a passive principle, as opposed to beneficence that requires one to act in a positive manner.
- Beneficence: This principle requires us to act benevolently (to do only good) and contribute to the welfare of the people around us. Beneficence is born from the virtue of benevolence. This is a principle that is paramount in the medical fraternity and plays an important role in considering bioethical challenges.
- Justice: This principle refers to the equitable distribution of benefits (and burdens) within society, and in the medical sphere specifically to the equitable distribution of healthcare resources *(Beauchamp and Childress 2013)*

Acting only in accordance with patients' expressed wishes is a departure from the paternalistic way of conducting medicine of decades before. The development of ethics and consequent ethical behaviour has hugely influenced the shift from paternalistic medicine to that of *respect for the autonomy* of the patient. The ethical principle on which informed consent rests, namely *autonomy* embodies the idea that we as humans should be in command of decisions that relate to our bodies and our lives (Siegal, Bonnie and Appelbaum 2012:359).

From a bioethical perspective the principle of respect for autonomy is the basis on which the discussion of informed consent rests. In this discussion there are complexities to consider because there are multiplicities of autonomous consent. Consent may be implied, tacit or presumed.

- Implied (or implicit) consent may be evident from the actions of the patient.
- Tacit consent may be obtained when there is no objection to a suggestion, therefore a 'silent' consent.
- Presumed consent is when consent is presumed since one knows the particular preferences of a patient (Beauchamp and Childress 2013).

Despite the existence of these different types of consent, it should be clarified that the only authentic form of consent acceptable in medical practice is contextual and direct informed consent.

Due to the exceptional circumstances of the anaesthetic setting, there are certain exclusions and exceptions to the usual requirements for informed consent, which are presented to the anaesthesiologist in daily practice, which then mandate further examination later in this thesis.

2.4. Autonomy

> *The goal of informed consent is to respect patient autonomy and enable him to make decisions regarding his medical care, of his free will, without*

> *coercion, after understanding fully what he is consenting for* (Harish, Kumar and Singh 2015: 410).

2.4.1.The concept of autonomy

In order to investigate informed consent in its current status, one should investigate autonomy as a concept and as a principle. The word autonomy is derived from Greek with *Autos* meaning self and *Nomos* meaning rule. It means to rule yourself (Beauchamp and Childress 2013). Although it was historically used in reference to provinces or states, and their ability to rule themselves, it has been extended to become a term that describes individuals' ability to rule and decide for themselves, without the influence of others. To rule the self means to live one's own life, according to personal desires and values (Rachels and Rachels 2015).

Isaiah Berlin is often quoted when discussing autonomy. In *Two Concepts on Liberty*, he says:

> *I wish my life and decision to depend on myself, not on external forces of whatever kind. I wish to be the instrument of my own, not of other men's act or will…. I wish above all to be conscious of myself as a thinking, willing, active being, bearing responsibility for my choices and able to explain them by reference to my own ideas and purposes* (Berlin 1969: 131).

Berlin did not use the term 'autonomy', but used 'liberty' instead. He had two concepts of liberty, namely positive liberty and negative liberty. Both these concepts are important in the context of autonomy. Positive liberty is to act on your own free will and negative liberty is to have freedom from outside interference.
Gerald Dworkin's work on autonomy equates autonomy to varying concepts such as liberty, independence, self-assertion and knowledge of one's own interests (Dworkin 1988).

Philosophically autonomy is understood under different categories, namely, personal autonomy, moral autonomy and political autonomy. Personal autonomy is the capacity to decide for yourself, regardless of the morality of your decision. Moral autonomy is seen as decisions strictly guided by morality. Political autonomy can be seen as having a capacity to decide for yourself, and also have your decisions respected in a political context.

2.4.2. Different perspectives on autonomy within the sphere of informed consent

Deliberations regarding autonomy as an element of informed consent continue. Varying opinions and arguments are offered by professionals in all spheres. Divergent understandings, awareness and perceptions indicate just how problematic the functions and acts of medical professionals and the anaesthesiologist in particular have become.

Autonomy is a concept that is criticised extensively. Some of the criticism is that it is not possible to separate an individual's personal autonomy from that of society's. The autonomy of the person is tied in with the community within which a person resides, as well as the close relations persons have within their communities. A person may have the freedom to decide for him/herself, but ultimately there will be societal limits to this freedom. Many ethicists question whether true autonomy exists at all, or even if it exists, if it has any value (O'Neil 2002). The mere fact that so many different words and concepts are used to describe autonomy points to the difficulty in understanding its true meaning, if any.

In his chapter titled 'The place of autonomy in bioethics' in *Arguing about Bioethics,* James Childress states*: "*I come not to bury autonomy, but to praise it. Yet my praise is somewhat muted; for autonomy merits only two cheers, not three*"* (Childress 2013: 309). He goes on to stress the importance of recognising the complexity of autonomy: firstly, to recognise the difference between *first order* (a person's basic instinct and desire) and *second order* (higher-level desires made through deliberation) choices; and secondly by recognising that all persons are temporal by

nature. This implies that their opinions and choices may and will most probably change over time.

The authenticity of a patient's decision at a certain point in time can also be called into question. Childress (2013: 310) uses the example of a blind young man who is in renal failure, and since he is suffering from incurable diabetes requires renal dialysis for his remaining life. This man, while lucid, asks for the renal dialysis to be discontinued, and to be allowed to pass away. This is agreed to and the dialysis is stopped. When the patient is in pain hours after the dialysis is stopped, he now asks to be put back on dialysis. Which request is the physician now to follow? The original request, while the patient was lucid, or the new request, despite the fact that his autonomy is impaired by the uraemia and a morphine infusion that sedates him? The question is: Was the first decision really made out a fully autonomous choice with a full realisation of the consequences? The authenticity of this patient's autonomy is in question.

Childress goes on to say that "the principle of respect for autonomy is more than a maxim. Yet it is not absolutely binding and does not outweigh all other principles" (Childress 2013:313). Childress nevertheless acknowledges that despite the many shortcomings of the principle of respect for autonomy, and its complexity in application, it plays a very important part in biomedical ethics. "But that role requires a sense of limits; and we should not overextend or overweight respect for autonomy" (2013, 315).

The above discussion by Childress, and the difficulty in defending autonomy, especially when patients may be in compromised positions of medical wellbeing, enhance one's understanding of the difficulty that is faced if a patient is in a situation of distress, and it draws into question the authenticity, not only of the autonomy of the patients, but also of the authenticity of the consent to the procedure as given by the patient under duress. This is of paramount significance in anaesthesiological informed consent.

For Bruce Miller, authenticity means that "an action is consistent with the attitudes, values and disposition of life plans of the person" (Miller 1981). This stresses that the

anaesthesiologist should be mindful of the individual person, and their own personal beliefs, traits and the society they exist in.

Investigating autonomy as a biomedical ethicist and anaesthesiologist makes one question whether true autonomy can exists within biomedicine. The requirements that autonomy and liberty demand, namely for the patient to truly have freedom from interference and to be able to make his own choices is a contradiction to the very reason for consulting with the medical practitioner. The consultation takes place to obtain advice and to investigate a medical problem. This complicates the notion of authenticity in informed consent which I will address later.

Viewing autonomy from a purely bioethical view, in order for a person to have autonomy, they should have two essential components:

- Liberty (independence from the influence of anyone else)
- Agency (the capacity to act intentionally).

Beauchamp and Childress prefer to use a *three-condition theory* (Beauchamp and Childress 2013: 104). For them to satisfy the true meaning of autonomy, a person should *act intentionally*, therefore not out of accident. They should have an *understanding* that is comprehensive, as deficiencies in comprehension, for whatever reason, e.g. language or terminology, will influence the validity of their autonomy. To have full autonomy a person should also be *free from the influence of any external controls.*

Although Beauchamp and Childress are very specific about their requirements for autonomy, they do also immediately agree that acts can be "*autonomous by degrees"* (Beauchamp and Childress 2013: 105). It is evident that not all the requirements of intentionality, understanding and non-control can be satisfied in all conditions, and if not all requirements are satisfied, a person can still be autonomous, but only to a certain degree. However, the question is whether a line can be drawn between substantial and non-substantial autonomy. The only way in which one can decide about these important distinctions is to see each individual case in context.

How do these important considerations impact on anaesthesiology? In an anaesthetic setting, it is readily apparent that these requirements for autonomy are difficult to meet. A patient is often acting on advice of the physician, so the intention is not fully the patient's own. The patient's understanding may be limited, depending on his/her education and insight into the situation. The patient can also not be said to be acting without outside influence, as the physician, and possibly the family, will be hugely influential in making the decision. Carl Schneider feels that one should be more concerned with what a patient *should* want, than with what a patient *actually* wants. He emphasises therefore another principle: that of beneficence. The health practitioner, while keeping the autonomy of the patient paramount, should nevertheless act out of beneficence, and do what is in the best interest of the patient (Schneider 1998). Schneider also feels that the duty of respect for autonomy also gives a patient the *right to choose* how much information he/she requires. but it doesn't make it their *duty* to choose how much information they want (Beauchamp and Childress 2013).

Schneider quotes William James from his seminal work entitled, *The Varieties of Religious Experience – A Study in Human Nature*:

> *"Experience shows that there are times in everyone's life when one can be better counselled by others than by one's self. Inability to decide is one of the commonest symptoms of fatigued nerves; friends who see our troubles more broadly often see them more wisely than we do; so it is frequently an act of excellent virtue to consult and obey a doctor, a partner or a wife*."(Schneider 1998,p xi).

Schneider draws strongly on the principle of beneficence and much less on the principle of autonomy.

Schneider (1998) points to the dichotomous nature of authoritarianism, which inherently contains the element of paternalism, thus undermining the autonomy of the patient, and the **respect** for this autonomy as proposed by Beauchamp and Childress (Beauchamp and Childress 2013: 108). However *respect for autonomy* is integral to contemporary bioethics, and the guidelines regarding the requirements for

informed consent are constantly being updated, thus placing more requirements on health care professionals.

2.5. Moral Theories

Deliberations and critical thinking in biomedical ethics are guided by moral principles and moral theories. This thesis has thus far focused on the moral principles in biomedical ethics (see 2.3), and particularly the principle of respect for autonomy as that is the guiding principle in informing the construct of informed consent.

Moral theories are important in the field of biomedical ethics as guidelines on how to think, in decision-making processes and in determining how we ought to behave. I shortly describe some of the more important moral theories that guide our contextual considerations.

Virtue ethics, originally argued by Aristotle more than two thousand years ago, is currently resurfacing as a popular moral theory in biomedical ethics (Holland 2011). According to Beauchamp and Childress,

> *A virtue is a dispositional trait of character that is socially valuable and reliable present in a person, and a moral virtue is a dispositional trait of character that is morally valuable and reliably present* (2013: 377).

Virtue ethics doesn't concern itself with the action or the consequences of the action, but rather with the person that is performing the action. It judges the character of the person, and the person can be inherently virtuous. Certain virtues may be appropriate for health care professionals to have, such as benevolence, compassion, integrity, trustworthiness, discernment and diligence to name a few. If the inherent character of the health care professionals is virtuous, then inevitable the actions of the clinicians will be thoughtful and appropriate.

Utilitarianism is the theory that makes us always consider the greater good. Our actions are judged on whether they have good consequences, and on whether it is a

good action on its own. *Deontology* is a theory where our actions are judged as such, irrespective of outcomes. Deontology can also be called 'rule morality' because it urges us to behave according to strict moral rules. Deontology also gives us the *categorical imperative*, which Kant formulated as follows: "Act only according to that maxim by which you can at the same time will that it should become a universal law "(Rachel and Rachel 2015:130) In this way Deontology gives us a test to apply to our action to judge its moral worth. In many ways, utilitarianism and deontology are at opposite ends of a spectrum.

Other theories of importance include the *social contract theory*. In this theory it is seen that all human beings in a society are in a contract with each other. All persons owe to one another a certain amount of indebtedness, and this will guide their behaviour towards each other. In this theory all persons are seen as equal to each other, with equal rights and equal liberty. Although the *ethics of responsibility* is not seen as a full moral theory, phronesis (practical wisdom) and the ethics of responsibility is a practical ethical guide, particularly when obtaining informed consent (see 9.2).

These theories all play a pivotal role in the moral thinking and ethical behaviour of health care professionals and guide their ethical decision making.

2.6. Informed Consent In The Legal Setting

Berg et al (2001) in their book titled *Informed Consent* allude to the challenging interwovenness of the ethical and legal aspects of informed consent (see 2.1). They emphasise that informed consent as ethical doctrine cannot stand alone and is integrally part of the legal doctrine of informed consent.

2.6.1. The history of the legal development of informed consent

Informed consent as it exists today in a legal form has been largely influenced by numerous (American) civil court cases. These court cases were brought by patients initially because of the lack of any form of consent and later because they had not been fully informed. Even if they had consented to the procedure, they did not have

all the information they needed. These precedent setting court cases have shaped and continuously shape informed consent to what it is today. Therefore, informed consent as it stands today cannot be discussed without discussing the history of its legal development.

The modern concept of informed consent has not always been around. From the time of Hippocrates until the nineteenth century, the idea of informing patients was approached in a completely different manner. Doctors where actually advised to avoid giving patients any information that may upset them, with critically ill patients in fact being 'protected' from this information (Beauchamp 2011).

Before the development of informed consent to its current status, the concept of consent first had to be developed and this development is closely connected to the legal cases that influenced it. In this sense the court's rulings preceded the ethical obligations of consent (Katz 1977).

2.6.2. Precedent setting legal cases

2.6.2.1.*Schloendorff v. Society of New York Hospital* (1914)

In 1914 Mary Schloendorff consented to an examination under anaesthesia for an abdominal problem. She did not consent specifically to any surgical intervention. She was anaesthetised and the surgeons found fibroids, which they proceeded to removed surgically. This resulted in Schloendorff taking the Society of New York Hospital to court. The result of the court case was the following, with Judge Cardozo declared:

> *Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages* (Katz 1977: 145).

Although there were other legal cases, both English and American court cases, that stated that performing a procedure without consent is tantamount to battery (or tort, the legal term), the Schloendorff case stood out as the legal case that influenced the clinical practice of obtaining consent from patients (Green and MacKenzie 2007). This important legal case established the importance of consent as an entity. The law now stipulated that the health care professional should obtain consent from the patient for any medical procedure or treatment.

2.6.2.2. *Bolam v. Friern Hospital Management Committee* (1957)

Another court case that played an important role in the development and expanding of the importance of the legal concept of informed consent (this time in the British legal environment) was the 1957 case of Bolam. Bolam received electroconvulsive therapy without the use of muscle relaxants. During the therapy his muscles went into spasm and fractured both femurs. At the time, the use of muscle relaxants during electroconvulsive therapy (ECT) was not ubiquitous, with only around 50% of health care professionals using relaxants during ECT. During the trial the defendant used a panel of doctors to testify to that regard. The health care professional was found not guilty of not informing the patient adequately. – “A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art” (Oxford Reference 2018). This came to be known as the Bolam Test from then on.

From this case onwards, cases where often ‘Bolamised’ and courts often referred back to the Bolam case. This implied that the opinion of a body of health care professionals was sufficient to testify to the aid of the physician defendant. This type of defence utilised the professional practice standard as the measure of the appropriate disclosure of information to the patient. This professional practice standard is a measure of disclosure of information that a medical professional would judge as adequate disclosure to a patient. The problem with this standard of disclosure is that it does not take into account what an average patient may want to know.

2.6.2.3. *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957)

The next important case (back to the USA) was of *Salgo v. Leland Stanford Jr. University Board of Trustees* in 1957, where a patient underwent an aortography from which he awoke paralysed. Justice Bray coined the term *informed consent* at this juncture because Mr Salgo was not informed of the possible complication of paralysis after aortography. This type of invasive and dangerous investigation has subsequently been abandoned in in favour of less invasive methods of examination. It was with this case that the term *informed consent* was introduced into medical and legal nomenclature.

2.6.2.4.*Canterbury v. Spence* (1972)

In 1972 Jerry Canterbury, a young man of 19 years, was having thoracic spine surgery done. After the surgery he had weakness in his legs. The *Canterbury v. Spence* court case revolved around the fact that he was not informed of the possibility of numbness and weakness or paralysis after the surgery.

This case changed the amount of information to be disclosed to the patient to not only that which is common, but also that which is of a serious nature. Consent was now to be more patient-centric. It was to focus on what the patient would want to know and not only on what the health professional thinks the patient ought to want to know. This introduced the concept of material risk, which are the risks that a reasonable patient would want to know about. It is not only the risks the health care professional thinks that the patients would want to know, i.e. important medical risks, but also smaller inconveniences and side effects. These may not have real morbidity, but would be things that a patient may want to know (for example, inserting a urinary catheter when undergoing a spinal anaesthetic).

These cases illustrate that the information given to patients should satisfy what a patient would want to know and started to introduce the *reasonable person standard* as the measure of what information needs to be disclosed to a patient.

From 1972 to 1978 there was now a distinct change in the view of both physicians and biomedical researchers, whose duty to obtain prior informed consent became mandatory (Beauchamp 2011). At this time obtaining both ethically and legally sound informed consent started to become more common, but consent was still a long way from being adequate.

2.6.2.5. *Castell v. De Greef* (1994)

In the South African context an important court case was *Castell v. De Greef* in 1994. A patient underwent a mastectomy and immediate reconstruction for breast cancer. She developed complications after the surgery and subsequently went to court. Her case was that the fact that the risk of infection and skin necrosis doubles when doing immediate reconstructive surgery, was not explained to her. The patient sued for non-disclosure. During the hearings, it was revealed that the risk of these complications do double: from 3–6%, but the court found the surgeon not guilty of non-disclosure. The court upheld that even though the risks doubles, the risk was still small, and therefore not a *material risk*, and therefore not a risk that would have altered the decision-making process.

The significance of this case in the South African context is multi-fold. It was the first court case in South African law that signified that the doctrine of informed consent was to be upheld. The doctrine of informed consent was previously introduced in South Africa in 1976 (*Richter v. Estate Hammann 1976*) but it was not introduced into law at that time.

The *Castell v. De Greef case* reinforced the importance of respect for patient autonomy. It also emphasised that any treatment can be seen as assault, breach of contract, crimen injuria and/or negligence, depending on circumstances, if authentic informed consent is not obtained. It reinforced the standard of disclosure of information that the law will attach importance to being the reasonable person standard of disclosure, in other words, that information that a reasonable patient would want to be informed of prior to surgery or other treatment.

2.7. Standards Of Disclosure In Informed Consent

Disclosure is the aspect of informed consent that determines the amount, type and detail of information that should be given to a patient. Different standards of disclosure influence that which is disclosed to the patient.

Disclosure is one of the seven elements of informed consent, according to Beauchamp and Childress (2013). Informed consent can be categorised into threshold elements, information elements and consent elements.

I. Threshold elements:

1. Competence (to understand and decide)
2. Voluntariness (in deciding)

II. Information elements:

3. Disclosure:
   - Professional practice standard
   - Reasonable patient standard
   - Subjective standard
4. Recommendation
5. Understanding

III. Consent elements

6. Decision (for or against plan)
7. Authorisation (of the plan)

(Beauchamp and Childress 2013, 124)

Disclosure is one of the *information elements* and plays a very important role in informed consent, not only from an ethical viewpoint, but also from a legal viewpoint. In most court cases disclosure gets placed under legal scrutiny. Due to this challenging aspect, the courts have often commented on disclosure and hence the standards of disclosure have become very important.

There are currently three standards of disclosure:

1. The Professional Practice Standard
2. The Reasonable Person Standard
3. The Subjective Standard

A fourth standard of disclosure is the standard of disclosure that is prescribed by specific regulatory bodies, such as the HPCSA, with regards to obtaining informed consent. (These guidelines will be elaborated on in chapter 3.)

The Professional Practice Standard is the standard of disclosure that a health care professional would perceive as adequate information from a clinical viewpoint. This has been the standard of disclosure that most physicians used for many years. This standard would usually demand that all the most common complications be discussed, as well as the most severe complications.

Although this standard is widely used it has obvious caveats, and information that a patient may want to know, but doesn't fall into the categories discussed, may be omitted. Therefore, the more popular standard of disclosure now used is The Reasonable Person (specifically, the reasonable patient) Standard (Beauchamp and Childress 2013).

The Reasonable Person Standard implies that the standard of information disclosed should be according to what a reasonable patient would want to know. It could include information that a Health care professional may not usually disclose, but what a patient may want to know. The health care professional should put him/herself in the patient's shoes and deliver information appropriately. Here the concept of *material information* comes into play. Material information is information that would make a material difference to the patient's decision, information that would make a patient change their mind. This includes discussing the option of opting out of the treatment and alternative treatment options (Beauchamp and Childress 2013).

To improve the delivery of information the third standard of disclosure namely the subjective standard is most appropriate. In this model the health professional that delivers information has to attempt to personalise the information and deliver

information that that specific patients would want to know. This standard will attempt to take into account each specific patient's personal requirements for information. In this standard the ideal is a detailed discussion, taking into account nuances of the patient's need, that can only be obtained by asking details of the patient's daily life, as opposed to in the medical sense. By way of example of the subjective standard of disclosure discussion: During the informed consent consultation with a professional piano player about to have surgery on his arm, the option of a regional block with a low, but real chance of nerve damage, would probably not be a patient preference considered even if deemed superior by the anaesthesiologist. Even if small the risk of nerve damage affecting the patient's career may in his/her opinion outweigh any advantage of superior pain relief for the procedure.

Beauchamp says in his discussion of informed consent: "If one uses overly demanding criteria for informed consent – such as full disclosure and complete understanding then informed consent can hardly ever be obtained" (Beauchamp 2011: 517). He adds that if the criteria are under-demanding and the health care professional just follows the routine of obtaining a signature on an informed consent form, then the term loses its moral significance.

"Although truthful disclosure to a patient is coined as the essence of informed consent, mere disclosure is seldom evidence of informed consent" (Beauchamp 2011, 517). In his attempt to answer the question, What is informed consent?, Beauchamp points out that two senses of the meaning of informed consent can be investigated:

1. Informed consent as *autonomous authorisation*: In this scenario, informed consent is given by a person in the absence of influence or control of another, for the health professional to proceed with a treatment of procedure. This is the part of informed consent that has moral value and enables a patient to make an appropriate choice from a moral perspective.

2. Informed consent as an *institutional and policy rule*: This is the legal aspect of informed consent. It is the part of informed consent that makes the consent valid in society. It is also this part of consent that is regulated and promulgated by the

authorities such as in the National Health Act and the Health Professions Council of South Africa.

In Beauchamp's opinion, as a bioethicist, the former meaning, where informed consent is rooted in autonomous choice is the more important of the two. For the practising health care professional this is not necessarily the case. For an anaesthesiologist, both senses of informed consent, as an autonomous authorisation and informed consent as a policy rule, are of equal importance because he/she always want to act both ethically sound and adhere to regulatory guidelines.

2.8. The Paradigm Of Informed Consent

The most popular model of informed consent can be described in three sequential steps, where one step follows on the other (De Roubaix 2005):

1. *Competence* of the patient: The patient should be competent to understand the information that is supplied to them, and should have the ability to process the information, and come to a decision.

2. *Information supplied*: The patient should be adequately informed of all the appropriate information that is relevant to the specific clinical scenario. The patient cannot be expected to make appropriate decisions if all the information is not supplied.

3. *Decision-making:* When the competent patient has received all the appropriate information, he can now, without undue outside influence, make a decision. This decision making includes the right to refuse treatment.

2.9. Conclusion

The construct of informed consent as it stands currently is an integral and important part of the treatment of all patients. The leap from paternalism in medical practice to

the practice of informed consent has been particularly important during the last 30 years and respect for the patients' autonomy is now paramount in the bioethical field.

The leap in bioethics was precipitated by the atrocities that were committed during the Second World War. The Declaration of Helsinki in 1974 reinforced the importance of patient rights and the autonomy of the patient. The increasing importance of autonomy and human rights in bioethical and philosophical thinking has changed the concept of respect for autonomy. The development of informed consent to its current status in legal and regulatory guidelines for anaesthesiologists was influenced by legal cases, where specific court cases led to its refinement. It was further developed by the biomedical ethical field. Along with the developments in biomedical ethics, the legal requirements for informed consent have been clarified through the years and are continuously being updated as ground-breaking court cases are changing the face of the requirement for respect for autonomy and informed consent, and consequent to ethical reflection. These court cases have influenced the standards of disclosure of information during the informed consent process. The following chapter will look at the current legal and regulatory guidelines, as they have been established by both the influence of the law as well as the bioethical environment.

CHAPTER 3: REQUIREMENTS FOR INFORMED CONSENT: LEGAL AND REGULATORY GUIDELINES

3.1.Introduction

In this chapter the legal and regulatory requirements for informed consent as stipulated by law and prescribed by different regulating bodies will be investigated. It will also look at the patient requirements for informed consent to be considered valid. The anaesthetic regulatory guidelines of Great Britain, whose informed consent guidelines play an important role in influencing the guidelines of countries such as South Africa and Australia, will also be reviewed.

The guidelines, as set by the law and regulatory bodies, are aimed at the clinical consultation environment, including anaesthetics. When one interrogates the moral status of the anaesthetised patient, it questions whether these guidelines are really relevant to the unique anaesthetic consultation environment, in the peri-operative setting. Nonetheless, as it stands, these guidelines are required to be followed by anaesthesiologists.

3.2. Legal Requirements And Regulatory Guidelines

The legal requirements and regulatory guidelines are stipulated by various SA bodies, namely:

- The Department of Health legal framework as promulgated in the National Health Act *(Goverment Gazette 2003)*
- The National Patient's Rights Charter (HPCSA Guidelines for good Practice in the Healthcare Professions, Booklet 3)
- Regulatory guidelines as published by the Health Professions Council of South Africa (HPCSA). The importance of the HPCSA general guidelines lies in the fact that these are the regulations and principles upon which an

anaesthesiologist's conduct will be judged in the event of a complaint. The South African Society of Anaesthesiologists (SASA) have also published guidelines for the obtaining of informed consent before anaesthesia.

3.2.1. The Department of Health: The National Health Act (2003)

In the National Health Act, chapter 2 is called 'Rights and Duties of Users and Health Care Personnel'. This chapter guides the health care provider in detail as to what the health care user should be informed about. In section 7 of chapter 2, the consent of the user is discussed in detail:

> *Consent of user. (1) Subject to section 8, a health service may not be provided to a user* ***without the user's informed consent*** *[emphasis mine], unless*
> *(a) the user is unable to give informed consent and such consent is given by a person*
> *(i) mandated by the user in writing to grant consent on his or her behalf; or*
> *(ii) authorised to give such consent in terms of any law or court order;*
> *(b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;*
> *(c) the provision of a health service without informed consent is authorised in terms of any law or a court order;*
> *(d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or*
> *(e) any delay in the provision of the health service to the user may result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.*

> *(2) A health care provider should take all reasonable steps to obtain the user's informed consent.*
>
> *(3) For the purposes of this section "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6* (Goverment Gazette 2003).

It is clear that the National Health Act is very demanding of the health care professional to adhere to obtaining informed consent prior to treatment and it stipulates the exceptions to this rule clearly. This section of the Act reinforces the importance of informed consent and that it is a legal requirement. In practice the health care professional should take this into account with every action whilst treating the patient.

In section 8 of chapter 2 of the Act, patient participation is discussed as follows:

> ***8. Participation in decisions***
>
> *(1) A user has the right to participate in any decision affecting his or her personal health and treatment.*
>
> *(2) (a) If the informed consent required by section 7 is given by a person other than the user, such person should, if possible, consult the user before giving the required consent.*
>
> *(b) A user who is capable of understanding should be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7.*
>
> *(3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she should be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest* (Goverment Gazette 2003).

Section 8, therefore, stresses the rights of the user of the health service to participate in the decision-making as the decisions have a direct influence on their own well-being. This places the onus on the health care professional to actively

endeavour to enable the heath care user to truly understand and participate in the decision-making process. This section is therefore stressing the importance of obtaining authentic informed consent from the patient.

3.2.2. The National Patients' Rights Charter

The National Patients' Rights Charter was developed to empower all persons living in South Africa, who are constitutionally guaranteed access to health care (Constitution of the Republic of South Africa, 1996, Act No. 109 of 1996). The Department of Health, with the help of other various other bodies, developed it as a common standard for bringing about this right.

With regards to informed consent, it states:

> *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* (HPCSA 2017a).

3.2.3. Health Professions Council of South Africa (HPCSA)

The HPCSA booklet 4 stipulates the need for informed consent from patients (HPCSA 2017b). This booklet stresses the importance of informed consent and the impact it may have on the success of the patient/health care professional relationship. It specifies that the patient has the *right* to be informed. It requires of the health care professional to explain procedures in a language that the patient can understand. It stresses the need for communication between health care professional and patient to be optimal to achieve its goal of true informed consent. It also stresses the importance of elucidating from patients the amount/extent of information they require to make informed decisions. The HCPSA thus urges the health care professional to strive for the subjective standard of disclosure: What does the individual patient want to know? HPCSA Booklet 4, guided by the National

Health Act, gives really comprehensive guidelines as to how much information needs to be disclosed:

> *3.1.1 Patients have **a right to information** about their condition and the treatment options available to them. The amount of information that should 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.*
>
> *3.1.2 The National Health Act requires patients to be given information about:*
>
> > *3.1.2.1 Their patient's health status except in circumstances where there is substantial evidence that the disclosure of the patient's health status would be contrary to the best interests of the patient;*
> >
> > *3.1.2.2 The range of diagnostic procedures and **treatment options** generally available to the patient;*
> >
> > *3.1.2.3 The benefits, risks costs and consequences generally associated with each option; and*
> >
> > *3.1.2.4 The **patient's right to refuse** health services and explain the implications, risks and obligations of such refusal.*
>
> *3.1.3 Patients have a right to information about any condition or disease from which they are suffering. This information should be presented in a **language that the patient understands**. The information which patients*

want or ought to know, before deciding whether to consent to treatment or an investigation, includes:

3.1.3.1 Details of the diagnosis and prognosis, and the likely prognosis if the condition is left untreated;

3.1.3.2 Uncertainties about the diagnosis, including options for further investigation prior to treatment;

3.1.3.3 Options for treatment or management of the condition, including the option not to treat;

3.1.3.4 The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient may experience during or after the procedure including common and serious side effects;

3.1.3.5 For each option, explanations of ***the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks*** *and of any lifestyle changes which may be caused or necessitated by the treatment;*

3.1.3.6 Advice about whether a proposed treatment is experimental;

3.1.3.7 How and when the patient's condition and any side effects will be monitored or re-assessed;

3.1.3.8 The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;

3.1.3.9. Whether students will be involved, and the extent to which students may be involved in an investigation or treatment;

> *3.1.3.10 A reminder* ***that patients can change their minds*** *about a decision at any time;*
>
> *3.1.3.11 A reminder that patients have a right to seek a second opinion;*
>
> *3.1.3.12 Where applicable,* ***details of costs or charges*** *which the patient may have to meet* (HPCSA 2017b: 2–3 [emphasis mine]).

The important point that needs to be stressed is that a patient has the right to be informed of their own health status, as it could influence their choices with regards to anaesthesia. The patient should know the various available treatment options and should be informed of benefits, risks and cost consequences that are associated with the different treatment options. This means that a risk versus benefit assessment of each available option should be discussed. The booklet also stresses that the patient should realise that they have a *right to refuse treatment*.

The booklet goes on to discuss the importance of not withholding any information that could change the choice the patient makes in their decision regarding health care. It therefore stipulates the needs for disclosure of material risks. Material risks are the *risks that matter* to a patient, those that will influence making a decision for or against the procedure. In the anaesthetic setting, material risks can include common risks such as nausea, vomiting or a sore throat, or a rare but serious risk such as an anaphylactic reaction to the anaesthetic.

The fact that the HPCSA stresses the disclosure of material risks is of particular importance in anaesthesia as it emphasises the importance that will be placed on disclosure of information that will alter the decision making of the patient. This will guide the health care professional as to the relevant information that needs to be disclosed.

The HPCSA also places great emphasis on effective communication and advises the use of visual aids and written material to explain procedures. This may be more valid in other medical disciplines but may be of less use in anaesthesia where concepts like ‘loss of consciousness’ may be less tangible.

Regarding the documentation of informed consent in anaesthesia, the HPCSA specifies in booklet 4: “In some cases, the nature of the risks to which the patient may be exposed makes it important that a written record is available of the patient's consent and other wishes in relation to the proposed investigation and treatment. “ (HPCSA 2017, 12)[2]

In other words, when a patient is exposed to a significant or invasive procedure, it is important that a written document of the patient’s consent is available. General anaesthesia can be viewed as a significant procedure as it induces a state of unconsciousness and introduces definite risks. Although current day anaesthesia can be seen as safe (Jenkin sand Baker 2003, 975), it is still an invasive procedure and it is appropriate to follow the guideline from the HPCSA and obtain written consent from the patient.

The legal requirements for informed consent are extensive in South African legislation and place a big onus on the health care professional to act within complex and sometime contradictory legal guidelines.

3.2.4. The South African Society of Anaesthesiologists (SASA)

In the SASA practice guidelines the chapter entitled ‘Consent and Explanation’ (SASA 2018) states that informed consent *must be obtained*. SASA further recommends the use of a written consent form that is anaesthetic specific. The SASA guidelines go on to emphasise that patients’ fears should be allayed and that information and assurance should be given. It also says that “only the more common and relevant risks of the anaesthetic procedure need to be explained” (SASA 2018, s73). The SASA guidelines comprise only one page in their anaesthetic guidelines booklet, therefore many anaesthesiologists look for more extensive guidelines from other societies such as the Anaesthetics Association of Great Britain and Ireland.

[2] Of note is that the National Health Act does not make comment on the documentation of consent.

3.3. Patient Requirements For Informed Consent To Be Valid

3.3.1. Patient mental competence

To obtain valid informed consent the patient should be judged as competent. (Beauchamp and Childress 2013). Patient competence implies that the patient should be *able to grasp* the information that they are supplied. They should be able to *deliberate* and come to a decision. The patient should be able to think logically and rationally about the information in order to *be able to make a decision*. The patient needs to have a *meaningful understanding* of both the process of informed consent, but also of the impending procedure (Maclean 2000).

Patients may have psychological, cognitive or mental impairment that may render them incompetent to give informed consent. In these cases one reverts to the legal guidelines as given by the National Health Act as to who provides consent.

3.3.2. Legal competence

A patient may have legal reasons for not being competent to give consent. Among many valid reasons, these can include incarceration and mental incompetence, and age (generally, in SA under twelve).

3.4. The Anaesthetic Consent Form

A guideline anaesthetic consent form for anaesthesiologists is supplied by the South African Society of Anaesthesiologists (SASA) (see Annexure A). This is not used by all anaesthesiologists and is a guideline only.

The SASA consent form has a clinical element and a monetary element, with the anaesthetic fee required to be discussed with the patient according to legal guidelines. This legal document does not, and cannot, in its current format, as well as the reality of daily practice, take into account the many elements required for a patient to give authentic informed consent.

The future of improving the authenticity of anaesthetic consent in terms of provision of information is promising. Information on the internet is readily available. To this end, many anaesthesiologists in private practice have anaesthetic-specific information available on their websites and patients have the ability to access the information and contact them before their scheduled surgery.

3.5.Regulatory Guidelines From Other Jurisdictions

3.5.1. The Anaesthetic Association of Great Britain and Ireland (AAGBI)

The AAGBI has published an extensive booklet on informed consent in anaesthesia. Contrary to other approaches, they have deconstructed consent to two different aspects. One aspect is that of *obtaining consent*, because any failure to obtain consent can constitute a criminal act of assault. They then differentiate informing the patient of *material risks*, those risks that would make a patient alter their decision-making (Association of Anaesthetists of Great Britain and Ireland 2017). They feel that these two aspects, namely obtaining consent and disclosure of material information are so distinctly separate, that they do not even use the combined term "Informed Consent " in their document.

Regarding the documentation of informed consent in anaesthesia, the AAGBI says:

> *As in previous versions of this guidance, the Working Party' s view continues to be that a signed consent form is not necessary for anaesthetic procedures that are done to facilitate another treatment, since it is the process of consent itself that is important; a signed form is evidence that a consent process has been undertaken but does nothing to validate or invalidate the consent….*
> *Whether consent is oral or written, it is essential for anaesthetists to document clearly both a patient's agreement to the intervention and the discussions that led up to that agreement, including the patient' s questions and the responses given.* (Association of Anaesthetists of Great Britain and Ireland 2017, 8)

This booklet is seen as overly demanding by many practising anaesthesiologists, and the cries of "unrealistic, unethical and untenable" being heard from the

Australian anaesthesiologists (Cyna and Simmons 2017), are reflected by many a practicing anaesthesiologist.

My opinion is that these guidelines are excessively demanding in a practical setting of daily anaesthesia. I do not disagree with the content of the booklet, and the important distinction between obtaining consent and disclosing material information is very important on a practical level. To follow the detailed guidelines of this booklet practically would imply an separate consult with the patient at a different time. My own practice (similar to many of my colleagues) is indeed to consult with patients on a separate occasion, especially in cases where complex surgery will be requiring complex anaesthetic management. Pre-operative phone calls to patients are employed when a pre-operative consultation is not possible and is very valuable in aiding the anaesthetist to identify risk factors pre-operatively.

3.5.2. Australian and New Zealand College of Anaesthetists (ANZCA)

The guidelines for informed consent for anaesthesia from ANZCA is a four-page document. This document references the AAGBI's guidelines booklet as a source document for their guidelines.

Their main guidelines are:

1. The patient's consent should be voluntarily.
2. The patient should be competent to give consent.
3. The consent obtained should be *informed* consent and this document refers to supplying consent to the *reasonable patient* standard of disclosure. It also advises to discuss material risks, and place importance on the *risk versus benefit* discussion.

3.6. Conclusion

This chapter looked at the published requirements placed on health care professionals by the law and regulatory bodies regarding obtaining informed consent. The legal and regulatory guidelines for clinicians and in this case anaesthesiologists imply clear and important responsibilities and obligations.

These guidelines are simultaneously an impediment to informed consent to anaesthesia. The fact that informed consent is seen as a legal doctrine only can be a huge problem, both for clinicians and ethicists. Jay Katz, an American legal scholar, has criticised this model repeatedly in his career*:* "He regarded the declaration of the courts as filled with overly optimistic and morally emotive evasive rhetoric" (Beauchamp 2011: 518).

Beauchamp says that the law is not the ideal vehicle to help us think about informed consent. It can lead to practising defensive medicine, thus impairing the clinicians' ability to act without second guessing his or her decisions from a legal perspective (of which the clinician does not sufficiently know enough anyway) (Beauchamp 2011).

As a practising anaesthesiologist, one strives to comply with the legal requirement and regulatory guidelines, while aiming to keep the patient at ease during this period of peri-operative duress. Practising anaesthesiologists also realise their moral duties towards the patient, and these duties are *not enforced by law*, at least not to the same extent.

The anaesthesiologist's moral duties towards the patient include respect for the individual patient and their specific needs. It involves divulging information to the patient that is of a subjective standard of disclosure, which means what that individual patient needs at that specific time. It can mean omission of certain facts (immaterial facts) because the patient is under duress and needs reassurance instead of strictly disclosing all information as per the extensive legal prescription in the regulatory and legal guidelines.

De Roubaix says, with regards to the treatment of patients, subject to contractual legal requirements, including disclosure and a consent process:

> *This does not satisfy the moral nature of the professional relation. Two parallel and simultaneous relations thus exist: the moral relation operates*

> *through the notion of 'responsibility'; the legal through 'contractuality'* (De Roubaix 2011: 14).

He emphasises that even when we adhere to the legal requirements of the informed consent process that does not imply that our ethical judgment should be impaired. The anaesthesiologist should still act as a moral agent, defending right from wrong in the process of obtaining informed consent. The anaesthesiologist should meet the moral requirements that are implicit while obtaining informed consent: respecting the patient as an autonomous human being (De Roubaix 2018).

The dilemma of informed consent can also be seen as tension between what the anaesthesiologist *should do*, as per legal requirements and regulatory guidelines versus what the anaesthesiologist actually does in daily clinical practice. Whilst the anaesthesiologist may apply inherent virtues, moral guidelines and practice medical professionalism in their daily practice as health care professionals, this may not always strictly comply with the legal and regulatory guidelines. The added complexity of the questionable authenticity of informed consent in anaesthesia complicates the motivation to honour the ideal informed consent consultation. Impediments to the competency of the patient, the appropriateness of the information supplied to the clinical scenario, the patient's decision-making skills in this specific peri-operative environment and his/her ability to truly decide, without undue influence, are but some of the multitude of stumbling blocks to obtaining authentic informed consent in anaesthesia. Chapter 4 will further investigate these impediments to true informed consent in general clinical practice, anesthesiology and clinical research.

CHAPTER 4: IMPEDIMENTS TO AUTHENTIC INFORMED CONSENT

4.1. Introduction

This chapter will examine the challenges and impediments that exist in obtaining authentic informed consent, both in anaesthesiology practice as well as in general medical practice and research scenarios. The process of effective transfer of information to the patient, and the impediments thereto, as well as the role of the patient as an active participant in the process will be highlighted.

4.2. Factors That Affect Authentic Informed Consent

In chapter 2 (see 2.8), the paradigm of informed consent outlined the different sequential steps in obtaining informed consent. These aspects are discussed below.

4.2.1. Patient competence

Patient competence is the first of the seven elements of informed consent as stipulated by Beauchamp and Childress (2013). Patient competence can be seen as a threshold element, therefore a precondition for authentic informed consent to be taken by the medical practitioner. Patient competence implies the ability to understand and comprehend the information given to him/her and then to be able to deliberate and ultimately make a decision, based on his/her understanding of the information.

4.2.1.1. Patient comprehension

Understanding of the information that is passed on during informed consent consultation is very important. Not only is it ethically and legally binding to be informed, it also enhances the benefits of the treatment. If patients can understand

what the treatment is about they will be more likely to be able to follow treatment prescriptions and advice, and adhere to 'instructions' when it is given (Priluck, Robertson and Buettner 1979). Unfortunately many studies show that although informed consent is practised by medical professionals, patients are not adequately informed by the process and their recall is often very poor (Brezis, et al. 2008).

The nature of information that is given to patients has been shown to influence the patient's ability to understand and comprehend the information. Several investigators have found that patients tend to forget threatening information (Silva and Sorrell 1988: 2; Priluck, Robertson and Buettner 1979; Robinson and Merav 1976). This is consistent with findings that patients will have denial of possible negative effects in multiple studies where questionnaires regarding recall had been completed and analysed. Kamath, Up and Shenoy (2014) in India showed that second-year medical students, after agreeing to a clinical trial, could not remember the drug name, nor the adverse effects of the drug, after signing the informed consent form. Despite being in medical training, those important details could not be recalled. Besides, clinical treatment may be more stressful than clinical trial participation. (Kamath, Up and Shenoy 2014)

Patients' capabilities to understand information given to them is paramount for authentic informed consent. One of the primary requirements of informed consent as discussed in chapter 2 is patient competence *to understand, deliberate and decide* (Beauchamp and Childress 2013:124). While this requirement is very important, many patients may lack the skills required to understand complex concepts. They may lack literary or numerical skills. Patients may also be unable to decide how much information they want or need, because they are not in control of the delivery of the information by the health care professional (Siegal, Bonnie and Appelbaum 2012).

The *information asymmetry problem* also contributes to patients' difficulty in understanding information. The health care professional would disclose information as medical professionals with years of training. This information should now be understood and interpreted by a patient who may have very limited knowledge of the basics of biology and physiology. This asymmetry in levels of education with regards

to the knowledge of the medical procedure is a huge impediment to patient competence to understand and make decisions. (De Roubaix 2018).

In the South African context, the questions of culture and different languages also play important parts in the ability to convey information. If the health care professional and the patient have different first languages, it can be problematic. The linguist, Professor Deumert, points out that that if the language of the consultation (English) is not in the patient's first language, their limited ability to speak English "silences the patient's voice" (Deumert 2010: 58). This is particularly relevant in government-provided medical services. The problem of respecting patient autonomy while the patient is essentially silenced by the impaired communication between patient and health care professional is clear.

Studies have been done on readability of printed informed consent material using different scoring systems. Often the information sheets may contain information that requires college-level education, yet the population it is aimed at is not educated to that level (Sorrel and Silva 1988: 3). These studies show the most important aspect of obtaining authentic informed consent, namely for the patient to understand the information, can be hindered on many different levels. This needs to be overcome to get over the first step of consent, which is transferring the information to the patient adequately.

Methods that can be used to enhance patient comprehension are:

1. Using non-physicians: Patients seem to understand and relate to health care personnel, such as nurses, better than the physician.
2. Increasing the length of time spent with the explaining and signing of the consent form
3. Using a different format of information, such as using audio-visual media
4. Considering the age of the patient while conducting the informed consent process.

The complexity of patient comprehension has been highlighted to me by a conversation with an esteemed colleague. He headed up the surgical department at

University of Cape Town's Faculty of Surgery and relayed his own experience of informed consent to me. This anecdote illustrates the complex processes involved in conveying information and the intricacies of understanding and internalising information. It illustrates the fact that even the most qualified medical professional can have difficulty with the interpretation of information.

As a young man he had to undergo chemotherapy. He was already a qualified surgeon at the time. Before his chemotherapeutic treatment he was informed of all possible side effects in an extensive informed consent consultation. The oncologist pointed out that one of the complications of the chemotherapy was peripheral neuropathy, and that this could be permanent. When this complication did in fact occur, it still had not, even in the mind of a surgical specialist really sunk in that permanent meant the same as forever. Using the term *permanent* did not convey the fact that it is *forever, for the rest of your life.* This illustrates how mere semantics, even if all other aspects of the informed consent process are adhered to, can influence the interpretation of the information being conveyed (Delawar Khan, personal communication).

4.2.1.2. Assessing the understanding by patients

In order to attempt to assess how much information patients understand during the informed consent process, several informed consent comprehension assessments have been developed. Some of the more common tests are:

1. The Deaconess Informed Consent Comprehension test (DICCT)
2. Quality of Informed Consent (Quick) questionnaire
3. Brief Informed Consent Protocol (BICEP)

Buccini et al (2009) did a systemic review of these three comprehension tests, and although they were aimed at research subjects in this instance, they are also valuable as in the assessment of understanding in a clinical setting (Buccini et al 2009):

Table 1: Summary of informed consent comprehension instruments (Buccini, et al. 2009)

DICCT	Quick	BICEP
Open-ended questions	Agree/disagree questions	Open-ended questions with 3-point response-scale interview questions
Developed for clinical trials	Developed for cancer clinical trials specifically	More for general use
<10 min	<10 min	<10 min
Based on American Federal consent	Based on American Federal consent	Based on literature on informed consent and advise

These tests were developed as attempts to get a measurable score that indicates how well a patient understands the information. The higher the score the better the understanding is purported to be. However these tests do not elucidate how well the patient is interpreting the data. The authors state:

> *Further work related to the development of standardized instruments should consider the strengths and limitations of currently available instruments. As well, research should aim to better define the construct of informed consent comprehension and how best to assess understanding of clinical trial information. The emergence of multimedia, interactive, and web-based technologies could help further the exploration of novel methods for testing comprehension of informed consent* (Buccini et al 2009: 7).

I believe that these questionnaires and other methods to quantify understanding of informed consent will continue to develop as the litigation on the ground of inadequate informed consent continues to escalate.

4.2.2. Recall of the information supplied during the informed consent process

Multiple studies have shown that patients have very varied recall of information. (Kamath, Up and Shenoy 2014). In an Israeli study of 2008, 613 patients (combined surgical, obstetrics and gynaecology patients) who were to undergo invasive surgical procedures were enrolled. The study attempted to look at the quality of informed consent, and not necessarily the quantity of information that patients received and recalled. The patients were given the routine informed consent as is standard at the institution. This consisted of written consent being obtained, with particular focus on asking patients to repeat the information given to them during the informed consent procedure. The assessment of informed consent was made by being interviewed by medical students via an anonymous questionnaire. The questions focused on the recall patients had of specifically the *risks* of the procedures and also of *alternatives* discussed. Most patients did not recall the complications or alternatives (Brezis, et al. 2008). This study is important because the level of education varied in the study group with 37% having had a high school education and 43% academic education after high school. The phenomenon of patients having varied recall is consistently seen in many other studies (Siegal, Bonnie and Appelbaum 2012). In an orthopaedic study the recall of complications following joint replacement surgery, where a very thorough informed consent process is followed, the recall of complications was extremely varied (Hutson and Blaha 1991).

These studies, and many others, highlight a perturbing aspect of informed consent, namely that patients generally have very poor recall of the details of the procedure that are discussed with them. This directly impacts the validity and authenticity of the consent.

4.3. Relevance Problems

When a patient is supplied with information during the informed consent process, it can be assumed that he/she will know and understand which part of the information is relevant to him/her. The reality however is that a patient will not always know what information is '*material*' to him/her. The health care professional will attempt to

supply *material information* as was discussed in chapter 2. This should be the information that would be significant for a particular patient, to guide them in their decision making (Beauchamp and Childress 2013: 126). The patient however may not know which information is material to them, especially if confronted with very detailed and voluminous information. This can be referred to as the '*relevance problem'* (Siegal, Bonnie and Appelbaum 2012).

Without the appropriate guidance patients may not be able to make sense of the information they are confronted with. The patient needs the information that is relevant to them, rather than extensive information. In anaesthesia the patient can be bombarded with a multitude of information both on the types of anaesthesia as well as on the numerous complications, but this may not be *relevant* to the patient because it would not alter the patient's decision-making. (Siegal, Bonnie and Appelbaum 2012)

To this end, Siegal, Bonnie and Appelbaum (2012) propose that we move to a model of *Information on Demand (IOD)* where **patients are in control** of the information that they receive. They would be presented with an information pathway in which they can choose a green, blue or red pathway. These different pathways would represent different levels of information that would be shared. The green pathway would allow the patient to receive only basic information. In the blue path the patient would receive intermediate information and in choosing the red pathway the patient would receive extensive information. Garden et al (1996) had a similar approach when obtaining informed consent for their patients undergoing coronary artery bypass grafts (CABG). They offered the patients one of three information sheets. The information sheets either contained 'full', 'standard' or 'minimal' levels of disclosure. The patients could choose which information sheet they wanted (Garden, et al. 1996). In this study 63% of patients thought the 'minimal'-level leaflet contained too little information, after they had a chance to study all three leaflets. This stresses the importance of the health care professional to assess the specific patient and his/her subsequent attempt to supply this individual patient with the level of information that they would be comfortable with and that would be appropriate for them.

4.4. Exhaustive And Over-Information

Health care professionals who comply with all the rules and regulations as stipulated by the legal documents, may present patients with exhaustive or over-information and this phenomenon can lead to the patient actually being less informed, as processing over information may lead to abandoning the effort to understand the relevant information. This has been communicated to me personally by patients who were exposed to pre-operative consultations that were exhaustive. The informed consent process in this instance has the opposite effect of what it is supposed to achieve. Instead of empowering the patient with knowledge, and thereby respecting his/her autonomy, the exhaustive information intimidates and leads to the patient abandoning an attempt to truly understand the information.

4.5. Lack Of Time And Motivation To Deliver Information

In a busy medical practice, the time to deliver adequate information may simply not be available. Despite the best intention of the health care professional, adequate time to explain the treatment and all the risks and benefits may not be available. The time to ensure that the patient really has insight and understanding in the treatment is often lacking. The motivation to deliver information can also be lacking, especially in certain situations where the health care professional delivering the information and the health care professional performing the treatment are not the same person, as exists in government operated medical facilities.

It is in this scenario that Moore sees the role of the *medical information specialist* who can step in here and relieve some of the duties of the health care professional (Moore and Slabbert 2013)(see 10.5).

4.6.The Practice Of Defensive Medicine

The practice of defensive medicine refers to the action of the health care professional to obtain informed consent, and to practise medicine in such a way to prevent legal action against the health care professional. The health care

professional can be influenced by the legal obligations, to the point of altering treatment. Practising defensive medicine can lead to the practitioner changing from the optimal choice to a less optimal treatment option, because it is less likely to result in legal action. This may change professional behaviours of health care professionals in a very real way.

In South Africa there seems to be an increase in the practice of defensive medicine by medical practitioners. This not only impacts the day to day practice of health care professionals, but also has emotional consequences for the health care professional that can be destructive to their emotional well-being. Defensive medicine is also a move away from patient-centred care to a more clinical defence-based approach (Moore and Slabbert 2013).

4.7. Intentional Non-Disclosure

According to Robert Young, there are three exceptions to the requirement for obtaining informed consent: waiver, therapeutic privilege and emergency situations (Kuhse and Singer 2001). I will discuss the concepts of waiver and therapeutic privilege , as those are the most relevant in the practice of anaesthesia.

4.7.1.Waiver

The principle of autonomy theoretically gives the patient the right to refuse information, i.e., waive the right to information. Although this concept exists and may happen in practice, it is usually advised against. Anaesthesiologists are advised to attempt to get the patient to accept information as prescribed by bioethical guidelines. (Beauchamp and Childress 2013, 137)

In clinical practice and in my own experience, particular patients may insist on waiving the right to information. This usually occurs in a particularly anxious patient, awaiting major surgery. The ethical dilemma that the anaesthesiologist faces in such instances can feel unsurmountable. The anaesthesiologist will, in this situation, look to the principles of beneficence and non-maleficence and respect for the autonomy

of the patient and weigh these principles up in an effort to make the correct decision with regards to this situation (see 2.5 in chapter 2).

The most important discussion seems to be the balancing of the two principles of respect for autonomy versus beneficence. The principle of respect for autonomy places the requirement on the health care professional to fully inform the patient in order for informed consent to take place. The principle of beneficence requires of the health care professional to act in the best interest of the patient. The best interest of this particular patient may be to give assurance and guidance, but not necessarily full disclosure of information that the patient may not be emotionally able to process, while under stress. The legal and ethical requirement for informed consent demands of the health care professional to disclose all the details as explained in chapter 3. Regulatory frameworks demand disclosing this information, yet in a clinical situation it may be completely different. One is faced with an anxious patient, a patient who was given a diagnosis of cancer, a patient who is mentally and physically affected by his or her illness, a patient who is scared, awaiting surgery in a unusual environment, surrounded by unfamiliar nurses and other patients, and being seen by an anaesthesiologist that he/she has just met.

In my opinion, the principle of beneficence, and the virtue of benevolence of the health care professional plays an important role. Patients and their requirements vary, and the health care professional should use beneficence as a guiding principle to help him or her during the consultation. Acting in a professional manner to instil confidence and convey care is paramount in this clinical scenario.

A moral theory that may be helpful in this context is virtue ethics (see 2.6 in chapter 2 on p29). According to Beauchamp and Childress, “A moral virtue is a dispositional trait of character that is morally valuable and reliably present” (2013: 377).

The virtues inherent to caring health care professionals include honesty, trustworthiness, loyalty and benevolence. They guide the health care professional in his/her interaction with the patient. Virtue ethics demands of the health care professional to ‘do the right thing’; and in this instance, to obtain informed consent in

a manner that is in the best interest of the patient, whether it is to accept a request for waiver, or to insist on continuing with the informed consent process.

4.7.2.Therapeutic privilege

In some instances, an anaesthesiologist may invoke therapeutic privilege. Therapeutic privilege is invoked when the divulgence of some information is seen as potentially having a detrimental effect on the patient. In these very specific and unusual circumstances the clinician can invoke therapeutic privilege and information can be omitted under this clause (Beauchamp and Childress 2013: 127).

Using therapeutic privilege is something that is strongly advised against. Beauchamp and Childress say: ”A physician may invoke therapeutic privilege only if he or she has sufficient reason to believe that disclosure would render the patient *incompetent* to consent to or refuse the treatment” (2013: 128). They therefore feel that one can only invoke therapeutic privilege if one’s action of providing information will render the patient incompetent to give any kind of consent.

I would argue that as anaesthesiologists we do employ a certain level of discretion is used with regards to the supplying of information, which may be argued as using therapeutic privilege. Although all patients can be informed of the anaesthetic and the implications of it, describing intricate details such as placing an endotracheal tube and paralysing the patient to the point that they will be artificially ventilated may be just the type of information that may render a relatively competent, although anxious patient, while awaiting surgery, incompetent.

4.8. Transfer Of Information During The Informed Consent Process

Most health care professionals aim to conform to all the requirements for obtaining informed consent, but the practicality of delivering the information can be problematic. There may be *inadequate time* to have these multi-layered discussions. Another impediment can be the *lack of the ability* of the health care professional to convey the information adequately.

The patient, on the other hand, may lack the ability to have sufficient understanding of the information being conveyed. The patient is not able to control how and when the information is being given to him/her and lacks *control over the flow of information* (Siegal, Bonnie and Appelbaum 2012).

Effective communication is key to informed consent, yet a communication specialist is seldom involved in any informed consent discussions (Beauchamp 2011). There seems to be a hiatus in the process of informed consent where a *communication specialist* can play a role.

The ability of information to be transferred from the health care professional to the patient is important for the informed consent to be valid. Discussing the *transfer of information* is critical when discussing informed consent. Malcolm de Roubaix discusses this by looking at transfer models (De Roubaix 2017).

One model of knowledge transfer is that of a *container-conduit* metaphor. In this model we think of information as something physical that passes from one container to another. This implies that information is tangible, for instance a written document or a flash drive. The metaphor elucidates that the words are the containers of ideas and are sent via conduits (voice of the health care professional) to the patient, who then extracts his own ideas out of the words. De Roubaix points out that "*The ideas packaged by medical practitioners in the informed consent communication and delivered verbally are most likely vastly dissimilar from those extracted, understood and internalized by the patient*" (De Roubaix 2017: 26). The information extracted by the patient will differ from patient to patient, depending on their level of education, their own insight and their interpretation of the information.

> *The process is unique and contextual within each patient's own frame of reference, cognitive ability and past experience, culture and understanding through language proficiency* (De Roubaix 2017: 26).

Each individual patient will extract different information from the informed consent consultation, information that he/she can process subject to his or her ability. The

pitfalls that can arise during this process are evident and can impair an authentic informed consent process. In order to address these concerns in the transfer of information, the role of the medical information specialist (Moore and Slabbert 2013) as mentioned in 4.5 of chapter 4 is evident and will be discussed in chapter ten (see 10.5).

4.9. Patient Responsibility

The law and ethical practice requires from the health care professional to obtain authentic informed consent in anaesthesia, but what is the patient's responsibility in this interaction?

Draper and Sorrel says: "Medical ethics is one-sided" (Draper and Sorrell 2002: 335). They discuss the fact that bioethics tends to (incorrectly) interpret patient autonomy as mere participation in decisions, rather than a willingness to also bear the consequences (Draper and Sorrell 2002). Ethical practice views the concept of respect for autonomy with a one-sidedness to the exclusion of the other party in this relationship, namely the patient. It essentially acts paternalistically by the one-sidedness of the doctor–patient relationship, as though everything depends on the doctor. Ironically the health care professional should 'protect' the patient from the health care professional and the decisions he or she has made. Yet, if the autonomy of the patient is so highly regarded, then autonomy should equate to taking responsibility for your actions. In other words: does autonomy have a function or is it an empty concept? Draper and Sorrell argue that true respect for autonomy would mean that the patient, after giving authentic informed consent should carry responsibility for the outcome as much as the health care professional does.

Draper and Sorrell further argue that despite the vulnerable position in which patients may find themselves, they still carry some obligations. Reference to general ethics helps us to frame the responsibilities of the patient. These responsibilities include responsibilities to others, but also responsibilities to self. Patients or persons in general do have a responsibility to look after their own health, and make decisions to improve health or prevent illness. One aspect that I shall not explore here is the

possibility that being informed is also a patient duty to be informed, even or especially of bad news, since the patient may have to make arrangements.

Draper and Sorrell try to explain the interaction between the health care professionals and patients by looking at the model of motorists and pedestrians. It is the motorists who should obtain a driver's licence and learn the rules of the road. Yet pedestrians, who need no licence to be on the street, also carry responsibility towards road safety. They should also follow a certain set of rules and take responsibility for what happens on the road.

In the biomedical setting though, the duty of care, placed upon, and accepted by the health care professional will always be more important than that of the patient. The patient, in a vulnerable state, will rarely have to take any responsibility for consequences, even if they were party to decision making.

It is ironic that when increasing importance is placed on informed consent there seems to be an increasing breakdown in the trust between patient and health care professional. Draper and Sorrell write:

> *Perhaps the breakdown in solidarity is justified, because the patient and doctor can rarely really be equals in the decision-making process in the first place, it may be too much of an ideal. But can it always be so much of an ideal that he patient never carries any responsibility? Autonomy without responsibility is not autonomy, even where the autonomy is a vulnerable patient's autonomy* (Draper and Sorrell 2002: 340).

The above opinion is a unique look at patient autonomy, and I think it is not to be discounted. The more patients are empowered with knowledge, as is happening in the current digital age, the more informed they will be and the more they will be truly authentically involved in decision-making. I therefore think that patient responsibility goes hand in hand with patient autonomy, and there is a place for it to be explored in the bioethical literature.

4.10. Conclusion

Chapter 4 examined the impediments to authentic informed consent as existing in current clinical practice, both in the general medical field as well as the peri-operative field.

This chapter elucidated the practical problems to obtain truly informed consent. It looked at the first element of informed consent, namely patient competence to understand information. It investigated various factors that limit competence. It also looked at patients' ability to understand the information given to them. It looked at patients' recall of the information and the relevance problem. The practical factors that impair the health care professional's ability and willingness to obtain consent were discussed and the first mention of the medical information specialist was made as a way of solving some of the dilemmas and impediments to informed consent. The practice of defensive medicine and how the law has affected the practice of medicine in a very real way has been discussed. Intentional non-disclosure and the concepts of waiver and therapeutic privilege were discussed. I also examined the problems of knowledge transfer during the anaesthetic consultation and informed consent process. Lastly, I examined the role of the patient and patient responsibility in the informed consent process, which has by and large been overlooked in current day bioethical literature.

The next chapter will discuss the particular speciality of anaesthesia, this field being unique in its setting and practice in the peri-operative environment.

CHAPTER 5: ANAESTHESIA

5.1.Introduction

This chapter will delve into the dilemmas of informed consent in anaesthesia, a unique field of medicine with unique clinical scenarios. It will starts by looking at the history of anaesthesia first, followed on by what anaesthesia entails today, and the unique clinical and ethical aspects it brings to the medical and bioethical field.

5.2. The History Of Anaesthesia

> *"When the dreadful steel was plunged into my breast-cutting through veins-arteries-flesh-nerves-I needed no injunction not to restrain my cries*." exclaims Fanny Burney in a letter to her sister in 1811 (Burney and Crump 2002, 303).

Fanny (Frances) Burney was an English satirical novelist, diarist and playwright. On 30 September 1811 she underwent a procedure, which is thought to have been a mastectomy, performed by Dr. Larrey, who was Napoleon's surgeon, without any form of anaesthesia.

> *I mounted, therefore unbidden the Bed stead- & M.Dubois placed me upon the mattress, & spread a cambric handkerchief upon my face. It was transparent, however, & I saw, through it, that the Bed stead was instantly surrounded by 7 men and my nurse. I refused to be held; but when, Bright through the cambric I was the glitter of polished Steel - I closed my eyes. I would not trust to convulsive fear at the sight of the terrible incision… I began a scream that lasted intermittently during the whole time of the incision- & I almost marvel that it rings not in my Ears still! So excruciating was the agony* (Burney and Crump 2002: 302).

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She wrote the above in a letter to her sister after the dreadful experience of being operated on awake. She gave an extensive account of having surgery while awake, as well as her experience at the end of the procedure:

> *This removal* (being from the place of surgery to and carried to her bed) *made me open my Eyes -& I then saw my good Dr Larry pale as nearly myself, his face streaked with blood, & its expression depicting grief, apprehension, & almost horror* (Burney and Crump 2002: 305).

One can only deduce from the above quote, that these awake surgeries were horrendous experiences, not only for the patients, but for the surgeons as well.

Before the advent of anaesthesia, patients experienced the pain of surgery in full, with them even assisting the surgeon by positioning their body in such a way to assist with the procedure. This was seen as advantageous by surgeons, some of whom thought that anaesthesia was not an advancement, because a patient could now not assist, by holding a limb in a certain position. "A surgeon should be well assisted by the patient or he cannot succeed" was written in a textbook on surgery in 1846 (Schlich 2017: 1020).

With the advent of anaesthesia, the patient could now be in a state of unconsciousness, and the surgeon could perform his work without the suffering cries and movement of the patient. The advent of anaesthesia, together with the advent of antisepsis, changed the way surgeons could operate. In modern times, the thought of surgery without anaesthesia in some form or the other is unthinkable. Anaesthesia renders the patient unconscious and immobile, thereby creating ideal surgical conditions. But, as the sociologist Stefan Hirschauer opined "the patient is reduced to a body", (Schlich 2017,1020) or as John Snow stated in 1866 "reduced to a physiological organism" (Schlich 2017, 1020).

As early as 1847, surgeons voiced concerns about the changed interaction between an awake patient having surgery and the anaesthetised patient. In this discussion Francois Magendie argued against anaesthesia. This French experimental physiologist that was very vocal against anaesthesia and felt it reduced the patient to

a corpse. He also pointed to the moral implications of unconsciousness, noting that surgeons “with the doubtless goal of operating without pain ... intoxicate their patients to the point of reducing them to the state of a cadaver which one cuts or carves with impunity and without any suffering” (Schlich 2017: 1021). Magendie warned that the etherised patient was at the surgeon’s mercy: ‘without defence’ (Schlich 2017). It would seem to be more of an injunction against the over-zealous surgeon than against a caring anaesthesiologist!

It is clear the early physicians already recognised the fragile position that a patient was placed in when made unconscious, both from an ethical and clinical point of view, as the patient now has no choice but to trust the clinical judgment and action of the attending physician. The historian Martin Pernick, in his book “ A Calculus of pain, professionalism and anaesthesia in the nineteenth-century America”, noted that anaesthesia was a threat to the vital checks and balances governing professional authority. He discusses the fact that, with an anaesthetised patient, normal restraints that had been built into doctor-patient relationships , are altered (Pernick 1985).

Despite these protestations, the first public demonstration of anaesthesia with the use of ether was highly regarded. It was performed by William Morton on 16 October 1946 on Edward Abbott at the Massachusetts General Hospital in Boston. The surgeon John Warren removed a tumour from the neck of the patient while the patient was anaesthetised. He famously said after the procedure, “Gentlemen, this is no humbug” (Rutkow 2010).

Although this was not the first use of ether, this was the first widely published report and the news spread like wildfire around the world. Anaesthesia rapidly advanced to create better operating conditions, and various ways of controlling breathing and different airway devices made anaesthesia increasingly safe. The advent of muscle relaxant in the 1940s was the next big development in anaesthesia, and patients were now not only unconscious, but also paralysed to create the best operating conditions for surgery.

> *The patient is now a passive participant in the surgical encounter and can almost be seen as the substrate of disease. They can be described as*

> *being situated in an ambiguous state of presence and absence* (Hirschauer 1991: 305).

5.3. Definition Of Anaesthesia

The word anaesthesia is derived from the Greek word ‘an’ and ‘aesthesis’, which means without feeling. This term was first suggested by Oliver Wendell Holmes in 1846 to describe the state of sleep produced by ether. This word was previously used to describe the *lack of feeling*, similar to the effects of peripheral neuropathy where a patient loses sensation over a distal area of a limb of the body, such as arms or legs. Holmes also introduced words such as ‘anaesthetic agent’ of which *ether* was one of the earliest examples (Yentis 1993). Anaesthetising patients in its bluntest form is controlled poisoning. The patient is made unconscious and their ability to perceive pain and react to it is chemically eliminated. The patient is often paralysed and unable to breath or move.

Anaesthesia can be defined as a state, produced by medication, that results in reversible action on the central nervous system that produces immobility and amnesia in the face of noxious stimuli (Eger 2006). This is the state of general anaesthesia. The other form of anaesthesia is local anaesthesia, which produces immobility and anaesthesia of the local area or part of the body.

There are other forms of anaesthesia using for example acupuncture of hypnosis. This thesis will confine itself to the Western practices of anaesthesia.

5.4. Mechanism Of Action Of Anaesthetic Agents

During the early stages of the use of anaesthetic agents, the mechanism of action of anaesthetic agents such as ether was not well understood, and several different theories on the mechanism of action were promulgated. Now, however, the mechanism of action has been confirmed and we know that it is the action on excitatory and inhibitory neurotransmitters in the brain and nervous system that induces the state of anaesthesia. The anaesthetic gases, as it is generally known,

are really volatile liquids that act on neurotransmitters in the nervous system. GABA type A neurotransmitters (Gamma-aminobutyric Acid receptors type A), which is inhibitory neurotransmitters that exist on the membranes of neural tissue are activated and N-methyl-D-aspartate (NMDA) receptors, which are excitatory neurotransmitters are inhibited. (Hagihira 2015)

On a macroscopic level, the mechanism of action is both on a spinal and supraspinal level. At a spinal level, the afferent nerves that conduct noxious stimuli from the periphery of the body to the central nervous system are blocked, thereby preventing the patient from feeling pain. On a supraspinal level, the patient is rendered unconscious and amnesic. When doing an electroencephalogram (EEG), which measures electrical activity in the brain, during the delivering of anaesthesia the electrical brain waves are reduced both in frequency and amplitude, as the anaesthetic agents interfere with the normal electrical activity of the brain and the patient reaches an unconscious state (Hagihira 2015).

The typical stages of anaesthesia can be distinguished with the depth of an anaesthesia monitor. As the patient goes through the stages of anaesthesia, the EEG waves change in amplitude and frequency. Depth of anaesthesia generally equates with the level of suppression of EEG wave frequency and the increase in amplitude. The deeper under anaesthesia the patient is, the more the EEG waves frequency decreases and the amplitude increases. When the patient is made deeper by increasing the dose of the anaesthetic agents, the EEG pattern will eventually change into a burst and suppression pattern. This is characterised by high amplitude bursts and periods of suppression where the EEG has a flat trace. At an ever-increasing doses of anaesthesia, the EEG will eventually become completely flat, as seen in Figure 1 and Figure 2 below.

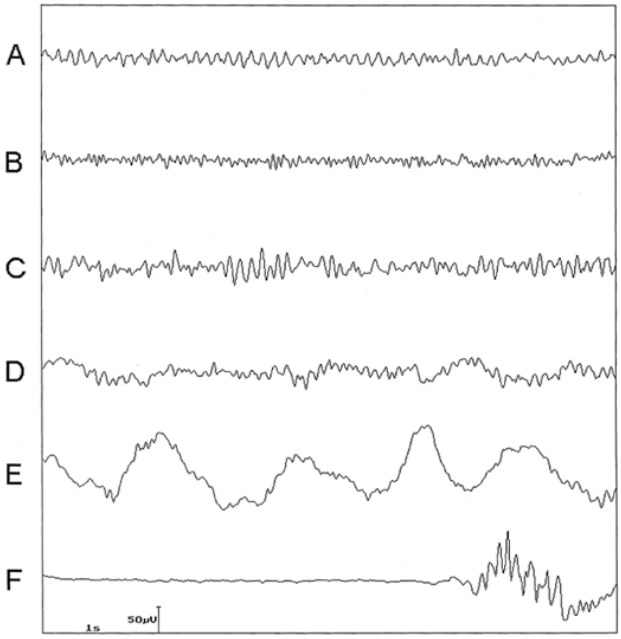

Figure 1: The Narcotrend monitor (Khan, Hayes and Buggy 2014)

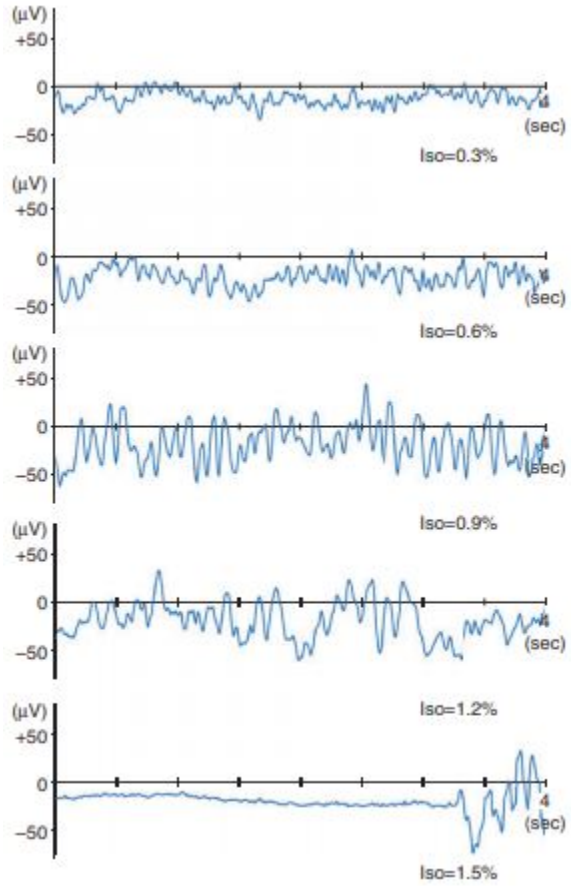

Figure 2: Changes in EEG (Hagihira 2015)

These changes in the EEG, that are artificially induced by anaesthesia are similar to those found in the unconscious patient. In Figure 2 from Hagihira's paper on the

EEG changes during anaesthesia, it can be seen how the EEG changes occur during anaesthesia with increasing concentrations of the anaesthetic agent Isoflurane (Hagihira 2015: 28). It can be seen how the status of the anaesthetised patient can be equated to that of the unconscious patient whose EEG trace is altered in the same way. Therefore, not only the physical, but also the ethical status of the anaesthetised patient can be compared to that of the unconscious patient.

5.5. Current Anaesthetic Practice

The practice of anaesthesia in the twenty-first century is vastly different from that in the initial years shortly after the discovery of anaesthetic agents. The risks introduced by delivering an anaesthetic has diminished from a very high accepted risk of serious complications, including death (a risk of 1:10) to a marginal risk of 1:100 000 (Jenkins and Baker 2003). Patients in the early nineteenth century would have a choice as whether to receive a form of anaesthesia for surgery, or to opt for the surgery while being awake, as anaesthesia introduced a significant risk.

In the current setting of peri-operative medicine, the anaesthesiologist's role is not questioned. A surgical procedure without anaesthesia of some form is not considered at all, and the role of the anaesthesiologist in many instances is assumed without question. This situation where the fact that an anaesthetic is seen as par for the course, has in part contributed to the current dilemma, where informed consent regarding the anaesthesia is neglected. The separate role of the anaesthesiologist is often not being given enough importance; and in some cases, not discussed prior to major surgical interventions. The role of the anaesthesiologist and the risk of the anaesthetic can sometimes outweigh the risks of the surgical procedure, and in these cases patients may struggle to understand the weight that the risk of anaesthesia carries. The anaesthesiologist will influence the outcome of the treatment decision if the risk of the anaesthetic outweighs the benefit of the procedure for the patient. An example of this is the excision of an unsightly but benign lipoma, an elective surgical procedure, in patient with particular co-morbidities. This procedure in a fit and healthy young individual may pose no anaesthetic risks, but in an elderly patient with comorbidities such as ischaemic heart

disease and emphysema can carry high risks, which can be life threatening. These facts, as pointed out by the anaesthesiologist can alter the decision-making process significantly. The particular role of the anaesthesiologist to weigh risks versus benefits is highlighted in this instance. It is the daily practice of the anaesthesiologist to weigh the risks of the anaesthetic to the benefit of the procedure in every single case. Risks versus benefits in this unique setting will be discussed further in chapter seven.

5.6. The Future Of Anaesthesia

In the last 150 years developments in the field of anaesthesia has been significant. These improvements in anaesthetic technique have also facilitated developments in surgical technique and diagnostic interventions. Marked improvements in the way we monitor patients under anaesthesia such as bispectral index monitoring (monitoring an algorithm of EEG waves) and cerebral oxygen monitoring has made anaesthesia safer than ever before. Jenkins and Baker quoted the risk of dying from an anaesthetic complication as about 1:180,000 (Jenkins and Baker 2003). That is less than the average person's chance to die in a railroad accident, which is 1: 140,000. This increasingly safe anaesthesia, together with other developments such as nanotechnology for the delivery of anaesthetic drugs, as well as oxygen and nutrients to targeted areas, will revolutionise anaesthesia (Arwal 2012).

These techniques will allow lives to be extended by various surgical and technological means. It is postulated in the lay press that the first person that will live to 200 years have already been born (Taylor 2017). These technologies will be integral to this extended lifespan of human beings. With it will come increasing ethical challenges, such as complicated end-of-life decisions. The ethical implications of this drastic increase in lifespan will soon confront bioethicists, as daily bioethical decisions will become more complex. These technologies may also complicate the obtaining of authentic informed consent, as the information that will need to be imparted to the patient regarding complex procedures will become more onerous and difficult to achieve.

5.7. Conclusion

In this chapter we have focused on the marked impact of anaesthesia on the physical state of the patient. We have alluded to the ‘person’ versus ‘body‘ state that anaesthesia induces. In this ethical investigation we had to consider that anaesthesia does not only impact the physical status of the patient but also, less obvious but equally important, impact on the moral status of the patient once anaesthetised.

CHAPTER 6: THE MORAL STATUS OF THE ANAESTHETISED PATIENT

6.1. Introduction

This chapter will explore an important aspect of anaesthesia that has by and large been glossed over in the literature. The change in *physiological status* of the anaesthetised patient creates an important change in the *moral status* of the patient. The state of anaesthesia induces a unique state to the anaesthetised patient both physiological, as well as a morally speaking.

This change in moral status has been alluded to by early physicians. In the 1800s, John Snow saw the anaesthetised patient as *being reduced to a physiological organism* (Schlich 2017), and later the sociologist Hirschauer said: “The patient is now a passive participant in the surgical encounter… They (sic) can be described as being situated in an ambiguous state of presence and absence” (Hirschauer 1991: 305).

To examine the moral status of the anaesthetised patient, we will first examine moral status as a concept. We will then look at what moral status a human being has and then investigate the concept of moral agency. Later we will look at the anaesthetised patient and the role that moral patiency place in the anaesthetised patient.

6.2.The Concept Of Moral Status

It can be said that an entity has moral status if its own interests morally matter to the entity itself (Jaworska and Tannenbaum 2018). Moral status can also refer to the moral standing of a person, or being. If a being has moral status it implies that the person/being has a degree of inviolability (a right to life, to bodily/psychological integrity, to be treated as a moral human being). All beings have moral status to a degree.

Humans are thought to have moral status, or what can be called full moral status because of their:

- *Consciousness and self-consciousness*
- *Cognitive ability, including the ability to reason*
- *Personhood, which includes awareness of themselves as temporal beings with a past, present and future with capability to reason* (McMahan 2009)

Many other thoughts on what confers moral status exist within the various schools of thought in philosophy, such as the utilitarian notion that all sentient beings, including animals, have moral status because they can experience happiness and pain. In common sense morality (moral principles to which all or most of us would agree), most people will agree that all humans have a similar level of moral status, regardless of their cognitive capacity. This can be illustrated by the following example. Most people will not be in favour of sacrificing a severely cognitively impaired human to save another human life, while the same would not be true if an animal for instance a chimpanzee could be sacrificed to save a human life (Jaworska 2018).

Some philosophers argue that whilst full moral status (FMS) is the highest degree of moral status, some human beings may have a lesser degrees of moral status. This concept is not universally shared, for example deontologist philosophers such as Kant feel that moral status exists on a singular level and that all human beings share the same moral status (Jaworska 2018).

It can be said that for those beings with full moral status (if one agrees with that term), there is a strong presumption that the person *should not be negatively interfered* with. In this instance, interference includes harming/killing the person, or negatively influencing its interests. It means that there would be a strong argument *to preferentially aid* someone with FMS to the detriment of someone with lesser moral status and a stronger presumption for that person with FMS to be *treated fairly*. Conferring full moral status to these persons will ensure their right to life, as all persons with equal moral status should be treated equally and given equal

opportunities to live. All persons with FMS should be treated equally.(Jaworska 2018).

Moral status as a concept and the elucidation of the concept is subject to various and different interpretations. Variable opinions exists on what exactly it means and what it confers to the entity. Today moral status (or full moral status) is ascribed to all human beings, regardless of their mental or physical status, but I can foresee that this issue will become more controversial as resources get scarce or when medical advances and artificial intelligence begins to pervade society.

6.3. Moral Agency

All beings may have some degree of moral status, but not all beings have *moral agency***.** In order to have moral agency, a being needs to have some capabilities:

- The being/person should have the ability to discern right from wrong and have certain inherent moral values of their own. Moral values are characteristics such as integrity, honesty and loyalty. Importantly, moral values are those which help us distinguish right from wrong.
- The person/being should be able to act according to their moral values.
- The person/being should be able to be held accountable for their actions.

Most human adults are regarded as moral agents. They have moral values that guide their actions and they take responsibility for their actions. Young children and some adults, who cannot take responsibility for their actions, can be seen *not to* have moral agency.

6.4. Moral Patiency

Moral patiency is a concept that is important in examining the moral status of the anaesthetised patient. Moral patients or moral patiency occurs when beings are acted upon or are at the receiving end of the actions of moral agents.

Anaesthetised patients undergo an *acute change in moral status* when they move from the awake to the anaesthetised state. They could be considered to move from being moral agents to moral patients. They get induced into a reversible state of unconsciousness, and during this state they lose the abilities that define them as moral agents. Anaesthetised patients cannot be seen as moral agents during the period of being anaesthetised. They will be under the influence of medically administered sedatives and anaesthetic agents, and cannot be held accountable for their actions while in an altered state of consciousness. Their moral agency will only return on complete recovery from the anaesthetic. The role of the anaesthesiologist in this situation, from an ethical point of view, can be seen as such: The anaesthesiologist should act as a moral agent for the anaesthetised patient in the peri-operative period. The altered state of consciousness of anaesthetised patient is unique, and although it can be compared with other altered states of consciousness such as illness-induced coma, the anaesthetised state is unique in terms of it being induced and reversed acutely.

A moral patient can also be described as a person who has the capacity to be the target of some action, whether right or wrong. The role of the moral patient can assume many different forms. It can be as far-ranging as being the victim of an attack, or it can take the role of a client accepting advice from a solicitor. A moral patient can also simply be the recipient of kindness. Of note is that the moral agent cannot exist without there being a moral patient. A promise made by a moral agent is made to a receiver of the promise: the moral patient.

McPherson argues that the doctor-patient relationship is a direct example of this moral agent/patient relationship (McPherson 1984: 179). He describes the patient as the person (moral patient) to whom something is done to by the moral agent (the doctor). The patient is taking on the true role of a patient: to suffer and endure (McPherson 1984).

In this perioperative situation, the role players are given these roles even more concretely. One can view the anaesthesiologists as the moral agents and the patients as the moral patients who are at the receiving end. The moral patient can be

described as the *object of moral agents*. It is the moral patient that is the receiver of concern, treatment, empathy and care (Winston 2008).

A moral agent can be both agent and patient at the same time, but in the peri-operative environment the anaesthetised patient is only a moral patient for that period of time. The anaesthetised patient is a *patient* in the true sense of the word. The word *patient* is derived from the original Latin *patientem*, which means bearing, enduring permitting and suffering.

6.5. The Anaesthetised Patient In Bioethics

The moral status of the anesthetised patient is of a complex nature. There has been limited bioethical debate with regards to this unique status. Perhaps due to its temporal nature, the marked change in the moral status of the anaesthetised patient has not come to the forefront of bioethicist minds, yet as one enters into the contract of informed consent for anaesthesia, the moral state that the patient enters and cannot be ignored.

It creates a conceptual challenge to bioethicists, clinicians and patients. Pragmatism has dictated so far that all medical facts regarding the upcoming anaesthesia are disclosed during any clinical discussion. The bioethical conundrum of the altered moral state has largely been ignored. But the question beckons: should the change in moral status influence the informed consent transaction? Does the altered moral state of the anaesthetised patient cause altered autonomy?

The complex questions of trying to confer moral status to embryos, foetuses, infants and persons with severe disabilities have been and will be examined at length in the past and the future. In those instances, surrogate decision-making comes to a fore (Beauchamp and Childress 2013: 63). Due to the temporary change in moral status of the anaesthetised patient, it could be seen to be that surrogate decision-making for the anaesthetised patient is made by the surgical team for the duration of the anaesthetic, similar to surrogate decision making as used for children or incompetent adults. In some senses the informed consent agreement is similar to an advance

directive that endures even if a patient becomes incompetent to take decisions, but surrogacy in this respect is not absolute and unlimited.

This unique moral status of the anaesthetised patient, the patient-person versus the patient-body introduces an ethical challenge to the anaesthesiologist. I have examined the transition of anaesthetised patient from moral agent to a patient-body or moral patient. The ethical and moral status of the anaesthetised patient is an exciting concept that demands more ethical deliberation and investigation. It may change the practice of informed consent in anaesthesia as it currently exists.

6.6. Conclusion

This chapter has touched on the unique moral status of the anaesthetised patient. Moral status is a complex concept and the unique moral status of the anesthetised patient even more so. This chapter was a preliminary attempt to address this challenging and exciting bioethical concept that warrants further investigation.

CHAPTER 7: INFORMED CONSENT IN THE UNIQUE PERIOPERATIVE SETTING

7.1. Introduction

The anaesthesiologist and patient find themselves in a unique setting when a patient is admitted for surgery. The peri-operative period is like no other in the normal patients' life. It is a period of acute anxiety and apprehension. The informed consent process is markedly altered by this unique setting. The ethical dilemma of authentic informed consent will be elucidated in the examining of this peri-operative setting.

7.2. Defining The Perioperative Setting, A Unique Environment

During the admission of a patient for a surgical procedure, a patient will be taken out of the comfort of normal daily life. He or she will be admitted to a hospital or clinic. The patient will be interviewed by admitting nursing staff and observations such as pulse rate, blood pressure and respiratory rate will be measured/made. A patient may also have some blood tests done. The patient is then asked to remove all her/his own clothing, to change into a hospital gown and disposable underwear. At this stage most patients will be in compromised positions, merely by virtue of being placed in a foreign environment.

The patient is now in a hospital bed, removed from all that is normal. He or she is even more vulnerable while awaiting surgery. There is no doubt that the patient will be under stress during this time. This compromised state can be aggravated by the type of disease which the patient are being admitted for and the extend of the proposed surgery.

In an ideal setting, the anaesthesiologist would have already consulted with the patient, well before the patient is admitted to hospital. In reality that is not how most of current anaesthetic practices function in private practice in South Africa. In most

cases the anaesthesiologist will see the patient after admission to the ward but before arriving in theatre. In some cases there will be no time to see the patient in the ward and the pre-operative consult will only take place in the holding area of the operating theatre complex.

It is clear that this is not an ideal time to consult with the patient with the objective to an authentic informed consent process. This informed consent interview, which takes place immediately prior to surgery, involves discussing the risks of anaesthesia and is unlikely to truly be authentic and empower the patient to make informed choices.

It is for this reason that in France a law was enforced in 1994, that states that a patient has to be seen by an anaesthesiologist at least two days before scheduled elective surgery (Aussett et al. 2002). This is also the case in the Netherlands where all patients will be seen at a pre-operative anaesthetic clinic shortly after being booked for surgery. This highlights the fact that the anaesthesiologist is not in the ideal position to discuss and obtain true informed consent in this peri-operative setting. One may question the inability or unwillingness of SA anaesthesiologists to demand that a similar practice be initiated in SA.

7.3. Anaesthetic Informed Consent Versus Informed Consent In Other Fields Of Medicine

In general practitioners' practices, many concepts may be easy to explain to a patient. The procedure of removing a thorn deeply embedded into tissue would be something that is easy to grasp by most patients. That local anaesthetic that has to be given to remove the thorn would also be grasped by most patients. When one is faced with explaining an anaesthetic, the concepts are not so easy to grasp. The idea of being made unconscious and being paralysed for the anaesthesiologist to take over breathing by inserting an endotracheal tube may be far more difficult for the average patient to grasp. Even highly educated individuals may struggle with some of the concepts that undergoing an anaesthetic entails.

In other disciplines of medicine, the use of visual footage can be very helpful to the patient, but not so much for the patient about to undergo anaesthesia. In the case of surgical procedures, a visual image, sketch or diagram may be very useful to understand the anatomy, but this is not necessarily true for anaesthesia. The different phases of anaesthesia, where different levels of anaesthesia represent different depths of unconsciousness is not easily put on a graph. Even using visual aids may be found to be unsettling for patients, as the concept of anaesthesia is not something that is comfortable to consider. An example of this is the video links on South African Society of Anaesthesiologists website (SASA Picture Stories 2019).

O'Neil, in an essay on the limits of informed consent, says: "Even in the maturity of our faculties, we may find it quite taxing to give informed consent to complex medical treatment when feeling lousy" (O'Neil 2013: 344). She appreciates that in a stressful situation, where you may feel unwell already, giving true informed consent is very difficult to achieve. O'Neil feels that informed consent is merely an opportunity for a patient to be able to rescind consent, and also a measure to not be coerced into treatment.

7.4. Anaesthetic Informed Consent

Jenkins and Baker suggest that the so-called BRAN technique is best suited and recommended to guide the informed consent process for anaesthesia (Jenkins and Baker 2003). They advise discussing the

- ***b****enefits*
- ***r****isks*
- ***a****lternatives*
- *and what would happen if one does* ***n****othing.*

This process aids discussion for the proposed course of action; explaining whether it is appropriate and whether the risk/benefit profile is balanced. The difficulty that is faced by the anaesthesiologist is that often there is no *alternative* to the anaesthetic as a means of facilitating surgery and doing *nothing* is seldom an option.

7.4.1. The risk versus benefit discussion

Jean Francois Paul de Gondi, a seventeenth-century French writer famously said: “That which is necessary is never a risk” (De Gondi 1718 cited in Jenkins and Baker 2003, 962).

It is undoubtedly true that for every anaesthetic administered examining the risk of the anaesthetic versus the benefit of the surgical procedure is of paramount importance.

As per De Gondi we are able to grasp the idea that *that which is necessary is never a risk*. Lifesaving surgery, whether emergency surgery for a traumatic accident, or surgery for cancer, that will be curative requires of us different input when it comes to informed consent, as opposed to cases where proposed procedure is not of a life-saving nature.

It is in these cases, where the surgery is not life-saving but purely elective, that discussing the risk of the anaesthesia vs. the benefits of the particular procedure becomes important. Risks that are likely to cause anaesthetic complications, for instance a respiratory infection, or patients who are not optimally treated for hypertension or cardiac failure should be heeded and surgery delayed until the risk versus benefit ratio is favourable. Another scenario may be: A pregnant patient is booked for an elective procedure to operate on uncomfortable piles. She decides to abandon an elective procedure in view of the risks of the effect of anaesthetic drugs to the unborn baby. Those risks are usually only explained during the pre-anaesthetic informed consent consultation.

7.4.2. What are the anaesthetic risks to be discussed?

> *Known risks should be disclosed when an adverse outcome is common even though the detriment is slight, or when an adverse outcome is severe even though its occurrence is rare, and complex interventions require more information, as do interventions when patients has no illness* (Jenkins and Baker 2003: 962).

The question of how much detail of the anaesthetic risks needs to be disclosed is constantly changing, and legal cases influence the standards of disclosure (see 2.7 in chapter 2). The legal requirements place an increasing burden on the anaesthesiologist to discuss risks according to the reasonable-person standard or the subjective-person standard of disclosure. Even with this guideline in hand the burden of what is sufficient information to be discussed is ever increasing.

The high court of Australia declared that the fact of whether a patient would decline to have the surgery, after having been informed of a particular consequence is in fact the crux of the matter. The high court said in the case of *Rosenberg v Percival*:

> *The more remote the contingency which a doctor is required to bring to the notice of a patient, the more difficult it may be for the patient to convince the court that the existence of the contingency would have caused the patient to decide against surgery* (Jenkins and Baker 2003, 962).

It is clear that the anaesthesiologist should make a judgement call with each individual case to decide how much and which information to discuss. Each patient has unique needs and each case has unique risks and the anaesthesiologist will be guided, not only by the legal guidelines, but also by clinical judgment. Jenkins and Baker also advise the anaesthesiologist to attempt to put risks and benefits into perspective. A useful tool for doing it is to compare the risks inherent in anaesthesia with risks inherent to daily life.

Very common occurrences can be explained this way, for instance, if you had four siblings, and each of your underwent anaesthesia at least one of you would have post-operative nausea and vomiting (a risk of 1:4). On the other hand, in terms of serious complications: If every person in a large town was given an anaesthetic, the risk of dying from the anaesthesia alone would be very low, in the order of one inhabitant of the town succumbing to the anaesthetic (1:180000) , or roughly equated to the risk of being involved in a railway accident (Jenkins and Baker 2003, 977).

Comparing the overall risk of anaesthesia in children to the risks involved in using airplane travel is another useful comparison to put risks into perspective for the patient: “Anaesthesia for a fit child is as safe as travelling in an airplane“ (Allman and Wilson 2001: 775).

Aiming to put specific percentages to the risks of anaesthesia and comparing it to daily life is a useful attempt to fend off the biases that certain patients and anaesthesiologists may have due to personal perceptions and interpretation of facts. A caveat is that many patients find it difficult to conceptualise percentage in this respect; this is why Jenkins and Baker used common life scenarios. Comparing anaesthetic risks to events of daily life helps to simplify the important discussion of risk versus benefit. The feeling of loss of control can greatly increase some patients’ feelings of anxiety and the anaesthesiologist can attempt to put all risks into perspective for the patient to be able to assimilate the information given to them, in a way to understand.

I repeat the words of Paul de Gondi: “What is necessary is never a risk.” This sentence carries particular significance in anaesthesia where often the anaesthesia , and the risks it entails, is necessary for the surgery to proceed.

7.4.3. Decision-altering information

The above discussion takes me to the crux of the informed consent process. **What is the specific information that will alter the decision-making for the patient?** What information would alter the course of the action, the action being the patient going ahead with surgery.? What information will let the patient alter his decision to undergo surgery?

According to the literature, all common and serious complications should be discussed with the patient. One certain serious complication of anaesthesia is that of death, which is possible (albeit very remote with an incidence of 1:180,000 according to the literature) in all anaesthetic cases. Should this be disclosed to every patient about to go under anaesthesia? Will it alter their decision-making at this point of the process? I propose, and have experienced it only heightens anxiety, and does not

add any meaningful value to the informed consent discussion. This experience of heightened anxiety has been conveyed to me by my own patients post-operatively.

My opinion is that anaesthetic consent should focus on decision-altering information, and that the option of different standards of disclosure should be offered, but not insisted upon, as it would very seldom lead to altered decision making.

7.5. Conclusion

An accepted paradigm of informed consent (see 2.8 in chapter 2) is the following:

To obtain authentic informed consent, the following should be in place:

1. *Competence* of the patient: The patient should be competent to understand the information that is supplied to them, and should have the ability to process the information, and come to a decision.
2. *Information supplied*: The patient should be adequately informed of all the appropriate information that is relevant to the specific clinical scenario. The patient cannot be expected to make appropriate decisions if all the information is not supplied.
3. *Decision-making:* When the competent patient has received all the appropriate information, he or she can now, without undue outside influence, make a decision. This decision making includes the right to refuse treatment (De Roubaix 2005)

The patient about to undergo the anaesthetic therefore should be *competent* to make a decision, and the consent should be given with the understanding that it can also be a decision against the procedure. All possible and realistic information should be conveyed on a level that the patient can understand (a subjective standard of disclosure) and the patient should understand the risk versus benefit of the particular clinical scenario and the choice of anaesthesia.

Having discussed the specific setting of informed consent pre-operatively and how markedly it differs from informed consent in other medical settings, the ethical

dilemma is emphasised. The difficulty in conforming to the above requirements is highlighted when placing the patient in the peri-operative environment. Patient competency under duress is questionably. The patient's ability to refuse surgery is highly unlikely. Conveying complex concepts of physiology and pharmacology, and the inherent significant dangers of anaesthesia, on a level the patient will truly understand is debateable. Are the decisions made, based on information that is not truly understood, by a patient who is not truly competent, truly valid?

The further ethical dilemma of explaining to the patient that they will enter a different moral state is not within the scope of this thesis, but it warrants further investigation and begs the question: Should we reframe all our pre-operative discussions with our patients?

CHAPTER 8: THE ETHICAL DILEMMA OF ANAESTHETIC INFORMED CONSENT

8.1. Introduction

To address the ethical dilemma that the anaesthesiologist is faced with while obtaining informed consent, I turned to the bioethical and philosophical fields for guidance. These points of discussion are not all specifically directed at informed consent in anaesthetics, but are applicable to all informed consent consultation processes.

8.2. Hippocratic Ethics

Hippocrates advised that one should think *ethically* about what you do. The first formalised guidelines for the medical profession in the form of the Hippocratic Oath in 274 AD recognised that inherent to being a medical professional is the premise that you should distinguish *right from wrong*. You have to deliberate about the right thing to do and act in a morally acceptable way. The Hippocratic oath states: “I will use treatment to help the sick according to my ability and judgement, but never with a view to injury or wrong-doing” (Jones 1923: 299).

In the Hippocratic Oath, the principles of beneficence and non-maleficence are clear, but the principle of respect for autonomy, which would necessitate obtaining informed consent had not yet been developed. It was well accepted that in the years AD the honing of a doctor’s medical skills was a combination of altruism on the one hand, but also self-interest on the other. The honing of their medical skills bestowed on the medical professional knowledge and status that could not be separated from the advantages and therefore self-interest that it brings.

During the development of medicine from the time of Hippocrates (275 AD) to today, there has been some distinct shifts. One of the shifts has been the conversion from

medicine as an art to medicine as a profession. This shift occurred during the middle ages. Through the later licensing of medical practitioners, they were turned into professionals. Doctors are now deemed 'professional' and they have to adhere to certain rules of the profession. Another important historical shift has been the medical practitioner moving from being merely the consoler of the sick, to being in the powerful position of actually being able to cure diseases. Medicine moved from being virtue-based, where the doctor only had to be a good person with good values, to being contractual. The doctor is now bound by contracts to deliver good quality care.

These historical changes were followed by the move from paternalism, where the doctor was acting in a paternalistic fashion, to that of respect for the autonomy of the patient. The patient now has a fundamental right to consent or refuse the treatment.

Medicine has also inevitably moved from being compassion-based while attempting to treat all people at all cost, to having to take into account the social justice aspect of delivering care. Since resources are limited, and treatment options are increasing, the utilitarian concept of doing what is best for society as a whole is increasingly important. The cost-benefit factor has entered the medical field and influences treatment decisions.

8.3. The Role Of Prinicplism And Virtue Ethics

These shifts in medicine have begun to challenge the value of the principles of biomedical ethics. The principles, as discussed by Beauchamp and Childress, namely autonomy, beneficence, non-maleficence and justice, are becoming more difficult to apply to the ever-changing field of medicine. Developments such as gene therapy and biomedical enhancements that can prolong life have put new challenges in the way of healthcare. The re-emergence of virtue ethics as a possible guideline for the health care professional to act ethically is subsequent to these dilemmas (Holland 2011). Virtues such as beneficence, caring, compassion, courage, modesty and patience seem to be increasingly important for the health care professional to have in order to act ethically in this new complicated and regulated world of medicine.

8.4. Choice-Less Choices

Epstein and Peters (2009), in their article “Beyond Information: Exploring Patients Preferences”, explored the idea of “*choice-less choices*”.

Despite the fact that health care has become increasingly patient-centred and that health professionals work towards shared decision-making, we seem to still present our patients with choice-less choices, where patients preferences is not explored.

> *”In novel, unanticipated, and emotionally charged situations, preferences may not be elicited as much as they are constructed - shaped by how much information is presented and by the opinions of family, friends and the media”* (Epstein and Peters 2009: 195).

One can see how the peri-operative period falls into this category, where patient centred care may be what is aimed for, but can be very challenging to achieve.

In an uncomplicated situation, for instance the removal of a piece of glass from the body that is causing pain and infection, it is easy to describe the situation, and in this case, true informed consent can be taken. The case plays out in a simple clinical scenario. Compare that to a patient with liver cancer, where a myriad options is put to the patient, who has no prior knowledge of such a disease, and is not equipped with anatomical, physiological and pathological knowledge. In the second case it could ostensibly take the patient weeks to really get to grips with the information to make an informed decision, and the timeline of such a disease does not allow for that luxury The patient is simply not equipped to have specific preferences in this unfamiliar territory. The idea that real choice is put to the patient is simply not applicable. Although the patient may seem to be able to choose, it is really a situation of *choice-less choices*. The patient will be guided and influenced towards a decision, regardless of what the patient may think he/she has chosen. The decision-making is simply too complex to really fall into the category of shared-decision making or patient-centred care.

The patient's decision is further influenced by *cognitive, emotional and relationship* factors (Epstein and Peters 2009). The physician, by the manner of delivering the information, influences the *cognitive* decision-making. Stating complications and outcome in a positive way, i.e., survival rate vs. negative outcomes such as a five-year mortality scenario will influence the decision-making of the patient. The *emotional state* of the patient will also influence decision-making because logical thinking is affected by emotions. A critically ill patient may say "do anything that you can", out of their sense of desperation and fear, but this may not be the correct choice. "More is better" is a heuristic that can be detrimental in this setting (Epstein and Peters 2009). The *relationship* with the physician, and the trust of the patient in the physician, will further influence the decision-making of the patient.

8.5. Collaborative Cognition

Collaborative cognition is a phrase introduced by behaviour specialists, and in an ideal situation it can help both physician and patient to work through complex medical situations, resulting in an outcome of decision-making that makes sense for both physician and patient. The requirement for this collaborative cognition is that the physician should be able to practise mindfulness, and to be fully aware of the patient's needs and wants (Epstein and Peters 2009). The question which arises is whether the health care professional can ever be fully aware of the patient's needs and wants? It seems like an impossible task. In order for health care professionals to try and do the best for their patient, they may ask: What would I do if it was me/my family?

Truog (1999) examined the effect of a patient asking "What would you do if it was your child?" He points out that our biases influence our recommendations. The clinician may aim to give information without any bias, but our inherent bias and personal experience and beliefs will influence what information we divulge, and in how we may lead a patient. Counter-transference is almost impossible to combat as physicians bring their own feelings and beliefs to the discussion in the decision-making process (Truog 1999). Furthermore one cannot attempt to simplify the decision-making discussion by asking: *If this were your child/mother/ father what*

would you as physician do? This can blur the boundaries between clinician and patient and their families. Truog does admit that in some cases a clinician can be guided by intuition as to how to guide the decision-making. In 2006 Alexander Kon further explored this scenario, and as a practising paediatric intensivist assessed the question, “What would you do?” in a different sense. He makes three distinctions in the question that the patient is actually asking. For him, ‘What would you do?’ really means:

1. What treatment would give the best outcome?
2. Am I doing the right thing?
3. Please advise me, I cannot decide for myself.

He points out that only if one *really listens* to the patient you can give the correct advice to that particular version of the question (Kon 2006).

8.6. The Role Of Micro-Ethics

Micro-ethics is a concept that brings a different element to the ethical dilemma faced by the anaesthesiologist. It is relevant in the ethical behaviour of the anaesthesiologist during the daily activity of obtaining informed consent from the patient. It is the ethics of everyday clinical encounters. It is unique to every situation and occurs in both verbal and non-verbal ways. Micro-ethics is really at the front line of medical care. It is the small decisions and gestures that are made by medical professionals on a daily basis. Dr Rebecca Dresser, who is a law and ethics professor, became acutely aware of micro-ethics when she herself had to undergo cancer treatment. When she went through the taxing months of treatment, she experienced the small elements of patient care and realised what a difference it makes to the patient experience (Dresser 2012).

Tod Chambers examined micro ethics further by calling on stories of personal experiences of engaging with the healthcare system. He was struck by the fact that in bioethics, a lot of time is allocated for academic and philosophical discussion, yet nobody speaks of their own personal experience when faced with these challenges in real life. He commends Rebecca Dresser who is one of the few bioethicists that

have spoken publicly of her illness and how it has affected her life and views as a bioethicist (Chambers 2013). Micro-ethics refer to the many small everyday decisions that clinicians should make, that may have big consequences. Dr Sharon Kling, a paediatrician at University of Stellenbosch proposes that clinicians could be assisted in their ethical decision-making by creating groups of colleagues to assist with those seemingly small ethical decisions (Kling 2018).

Micro-ethics plays a role in solving the ethical dilemma of consent for anaesthesia because micro-ethical decisions are made during the consultation for informed consent. The process of acquiring informed consent in any peri-operative setting is wrought with obstacles, as will be discussed further in the chapter 9, and the informed consent consultation will be influenced and guided by micro-ethical considerations of the anaesthesiologist during the obtaining of the consent. The amount of information and how it is conveyed will be, possibly unconsciously, guided by the micro-ethical decision that the anaesthesiologist makes.

8.7. Patient Autonomy And Physician Beneficence

Stephen Wear wrote on informed consent, considering patient autonomy and physician beneficence within clinical medicine. His work is important because he tries to recognise the practicalities of bringing authenticity to the practice of informed consent in daily clinical practice (Wear 1993). He criticises the current writing on informed consent calling it 'ritualistic and rhetoric' (Wear 1993: 4). He questions the role of ethical discussions on informed consent and whether it has real impact on the practical application in a complex clinical medical decision making scenario. Andrew Lustig analysed the writings of Stephen Wear and makes some interesting observations (Lustig 1996). He points out that Wear has a different outlook on the development of informed consent, and questions whether it really did develop from the precedent-setting court cases. Wear also questions whether the courts really had patients' self-determination at heart when the concept of informed consent was legalised. Wear argues that if self-determination really had been the major force behind informed consent: *"Courts would have developed more specific disclosure requirements and guidelines"* (Wear 1993, 8). He goes on to say *"[i]f courts were*

truly concerned about patient self-determination, then an offense against it…would in and of itself be treated as an actionable harm" (Wear 1993, 8).

Lustig points out: "In fact, whatever its ethical basis, informed consent has remained a *minimalis*t notion in the law, best understood within the context of tort law on malpractice rather than as embodying a robust commitment to patient autonomy "[3] (Lustig 1996, 102). Wear therefore questions the true motives of the courts. He acknowledges that research abuses and some extra-ordinary cases have fuelled the drive toward the legalisation of informed consent. However the reality of daily medicine is that treatment can and is given, despite formal informed consent being obtained, and patient autonomy is still respected by the inherent virtue of the health care professional.

Wear also recognises *moral pluralism* as a stumbling block to obtaining authentic informed consent. He cites that the differences between what clinicians' and patients' views of 'the good life' may be, can be so vast in today's multicultural world, that the authenticity of informed consent is questionable at best. He also cites the fact that one need not legally obtain 'informed consent' when buying a car, or entering into marriage. The salesman will not quote percentages of repairs required, or the priest officiating the wedding quote the percentages of divorce as one enters into these legal contracts. Weir points out that by not getting informed consent in these instances, it does not necessarily undermine the respect for autonomy of the individual. Another view of the same dilemma is that the authenticity required of biomedical transactions vastly exceeds the requirement in everyday life. However, one can argue that there are good reasons for this, the most important being the nature of the biomedical interaction and the vulnerability of the patient.

Wear also puts informed consent into perspective by comparing it to the illness itself. Wear points out that if the illness is presumed to warrant a medical intervention the illness itself has already caused significant undermining of the individual self-determination (Wear 1993). He points out that the biggest threat faced by the patient is not necessarily by the physician, who by acting in a patriarchal manner neglects to

[3] Note the timeline; these ideas may be dated.

obtain informed consent, but in reality by the illness itself. This freedom from interference, in terms of decision-making, may not be in the patient's best interest.

8.8. Limits Of Informed Consent

The ethical dilemma of informed consent is also dissected by O'Neil (2013). She discusses the limits of informed consent in the way that it purports to be valuable in the sense that it supports the principle of respect for individual autonomy. She argues that there are many different views on the precept of individual autonomy and since their ethical importance varies, proposes that informed consent is more valuable in that it *protects the patient from being deceived or coerced*. She does not think that informed consent justifiably satisfies the principle of autonomy. She does agree that it does give patients an opportunity to gather information and can also be an opportunity to *rescind consent* if already given.

She stresses the fact that patients should know that they can refuse consent, even if given before. They should feel comfortable to withdraw their consent. O'Neil makes the following important points:

- *Information should be extendable; the patient should be able to get more information if they need more.*
- *Consent should be rescindable.*

She points out that consent also exists in many other spheres of daily life, for instance in financial transactions, and in all these spheres, including medical, they are increasingly seen as protective from litigation.

8.9. Contrast Between Legal And Moral Precept Of Informed Consent

Another element of the ethical dilemma of informed consent is the tension that can exist between the moral and legal precepts of informed consent. The requirements of the anaesthesiologist to act morally correct, to distinguish right from wrong and keep the best interest of the patient at heart can in some instances not be in line with the legal requirements. An example of this has been discussed earlier: invoking the use

of intentional non-disclosure (see 4.7 in chapter 4). This can be in direct contravention of the legal guidelines, yet be in line with ethical considerations and be in the best interest of the patient. These clinical scenarios may not be common, but can create a very real dilemma where bioethics and the law do not concur.

8.10. Conclusion

As a practising anaesthesiologist, attempting to solve the ethical dilemma I am faced with, I appreciate that most basic premises of ethical behaviour, distinguishing right from wrong and acting accordingly are inherent to the informed consent consultation. Despite the development and change in the manner of how medicine is practised, changing from an art to a profession the ethical behaviour of the health care professional remains paramount. Micro-ethical decision-making will instinctively guide the health care professional to obtain relevant and as-close-to-authentic informed consent as possible.

I agree with O'Neil (2013) on her take-home points. On a practical and ethical level, my informed consent consultation will ultimately offer an option to get more information about the anaesthesia, should the patient request it, and the patient will also be offered the option to opt out of the procedure. I also focus on decision-altering information and focus on what information will make the patient change their mind regarding the impending procedure.

The ethical dilemma of informed consent in anaesthesia, with all the challenges thereof complying with the seven elements of informed consent, as discussed in chapter one, is a dilemma that possibly needs to be solved by a completely different approach from an ethical perspective. The next chapter will look at ethical alternatives for informed consent in the anaesthetic setting.

CHAPTER 9: ETHICAL ALTERNATIVES TO INFORMED CONSENT

9.1. Introduction

This thesis is a deliberation on the ethical dilemma of obtaining authentic informed consent in anaesthesia. In order to address this dilemma and when faced with all the challenges involved one is forced to look for solutions outside of the traditional construct of informed consent. To this end, one can look at other models of reasoning and moral theories.

Phronesis and the ethics of responsibility is an approach to moral reasoning proposed by Professor Van Niekerk (Van Niekerk and Nortje 2013). When examining this theory, as a health care practitioner the premises of phronesis and the ethics of responsibility are so relevant as to be self-evident in this context. Therefore, it seems the most appropriate ethical alternative to discuss and will be investigated first. When seeking other ethical legitimate options, I will also discuss the heuristic of the Golden Rule, as well as a practical ethical discussion of risk versus benefit as discussed by Tom Beauchamp.

Informed consent *as a transaction* is another model of patient–doctor communication that is proposed instead of a formal informed consent model. It merits discussion as in this model it proposes a waiver of informed consent and all its requirements, but instead proposes a form of communication where two moral agents interact with each other. Shared decision-making is increasingly popular in the biomedical literature and should be examined as it will be increasingly prevalent in daily medical practice.

Medical professionalism and what it encompasses will be discussed next and how it addresses the problem of informed consent in anaesthesia. Human dignity will briefly be discussed and its relationship to autonomy, followed by an investigation into the autonomy and trust in the healthcare setting.

9.2. Phronesis And The Ethics Of Responsibility

Phronesis is an age-old word that is used to describe *practical wisdom*. It has been revived in current discussions in biomedical ethics (Van Niekerk and Nortje, Phronesis and an ethics of responsibility 2013).

The discipline of biomedical ethics is evolving exponentially, not only in the developments in anaesthesia, but in medicine as a whole. Topics such as transhumanism challenges biomedical ethicists to develop new ways of dealing with the inherent ethical dilemmas to these new ethical quandaries. Through the advancement of medicine, life is prolonged or altered and with it comes bioethical challenges. In order to address these ethical dilemmas biomedical ethicists are increasingly looking to phronesis and practical wisdom to solve the ethical conundrums.

Phronesis was first described by Aristotle in his Nicomachean ethics (Aristotle 1953). It is used to describe 'prudence' or 'practical wisdom'. Aristotle distinguished the practical ethics from theoretical ethics, and for him, as opposed to Plato, that which is practical carried a lot of weight. He felt that moral knowledge should empower one as to know how to act every day in a practical manner. Van Niekerk and Nortje summarise this thus:

> *Phronesis is not simply knowing what good is, what virtue is and what the rules that govern your behaviour are. More importantly it is knowing how to act in the practical situation of everyday life where the norm and rules need to be applied ….Phronesis is practical knowledge of how to live a good life* (Van Niekerk and Nortje 2013).

Deliberation is seen as an important part of phronesis. To deliberate means there is something to deliberate about – pros versus cons, arguments for or against a certain decision or action. To deliberate with prudence would mean to deliberate with wisdom and to apply both universal wisdom as well as particular wisdom to a certain situation or decision. By recognising that prudence requires deliberation it also implies that there cannot always be one correct answer. It therefore recognises the

possibility of failure or the wrong decision. Comte-Sponville said that a god would have no need of prudence, as for a god no uncertainty exists, but for man, we cannot go without it (Van Niekerk and Nortje 2013). Prudence is what enables us to act with wisdom and make the most correct decision we can. We can be prudent while engaging within our self and our moral norms, but also engaging with society, and in that way come to a conclusion. This conclusion will be made with our moral knowledge but will be applied to the best of our ability, by deliberating.

Seen in a medical context, phronesis can be seen as the practical wisdom of how to be a ***good doctor***, and to make good decisions. The clinician is required to make decisions on a daily basis, and those decisions will influence the lives of others. The clinician will deliberate on a daily basis about the correct path to follow when consulting a patient. Seeking the consent of the patient is undeniably paramount. If the clinician acts with practical wisdom while conducting the informed consent consultation, he is bound to make the most morally and clinically appropriate consultation, while informing his patient of the risks and benefits of the procedure and disclosing the correct amount of information for this specific patient.

When examining the ethics of responsibility, the clinician is drawn to this approach to moral reasoning. Van Niekerk and Nortje says the ethics of responsibility ”is the ethics that springs from the application of phronesis” (Van Niekerk and Nortje 2013: 31).

The ethics of responsibility is inspired by the work of Levinas, Zygmunt Bauman and Hans Jonas (Van Niekerk and Nortje 2013). This ethical theory implies that one takes responsibility for your actions. The ethics for responsibly holds you accountable, regardless of the outcome of your actions. In that way the ethics of responsibility recognises that failure is always a possibility and must be accepted as an outcome. It also raises an important question: To whom are we accountable? We are accountable to others. We are to have the best interests of others at heart. This fits very well in the biomedical ethical framework; in the healthcare setting, we are accountable to our patients.

The *ethics of responsibility* is also attractive to biomedicine because it entertains the notion of failure. In ethics, particularly biomedical ethics, one is always striving for the ideal, but in the very real world of daily clinical medicine, failure is an integral part. The ethics of responsibility demands the best of the clinician, but it also allows for the possibility of failure. The clinician has to bear that responsibility. We should be open to a rebuttal of our actions and decision-making. This encourages the clinician to always, after deliberation, make the most appropriate decision. The ethics of responsibility can also be seen as an ethics of fallibility. It will accept that wrong moral decisions may be made. But the ethics of responsibility will accept that although a moral decision may turn out to be proven wrong in the future, as long as the moral agents that made the decisions can justify their reason for that decision, their action is acceptable. (Van Niekerk and Nortje 2013)

The ethics of responsibility is an ethic that can help us tackle the new challenges that we are faced with in the evolving world of bioethics, that is filled with new innovation never dreamed of before. Because the ethics of responsibility insists that we take responsibility for our actions it also makes us take into account what effect our actions will have in the future (Van Niekerk 2002).

The ethics of responsibility, being derived from practical wisdom, as argued by Van Niekerk and Nortje, is bound to be further explored as a possible alternative in the context of informed consent, as the demands made of the clinician to obtain authentic informed consent ever increases. The practice of an ethics of responsibility, encompassing phronesis, will be the guide to a practical approach to doing the right thing in a moral sense, and that can encompass all the demands otherwise placed on the clinician. It can be seen as a way to a solution to ensure true authentic informed consent for anaesthesia.

9.3. The Heuristic Of The Golden Rule

Entering the field of bioethics as a clinician and being faced with patient interactions, particularly that of informed consent for anaesthesia but also in cases of difficult ethical decisions, I have found that, unwittingly and without thinking of it as a moral

framework, I have often used one of the oldest dictums in the world: Do unto others as you would want done to yourself.

This has been described as “The Golden Rule“ and is a maxim that is common to many different religions and belief systems. Confucius wrote: Surely it is a maxim of kindness. Do not unto others that you would not unto you.” (Analects 15:23) It is also described in many other religions: Buddhism, Christianity, Taoism, Islam and Judaism.

Thomas Hobbes, after reflecting on the 19 rules of natural law in his seminal work *Leviathan*, wrote:

> And although this may seem too subtle a deduction of the Laws of Nature, to be taken notice of by all men; Whereof the most part are too busie in getting food, and the rest too negligent to understand; yet to leave all men unexcusable, they have been contracted into one easie sum, intelligible, even to the meanest capacity; and that is, Do not that to another, which thou wouldest not have done to thy selfe (sic) (Ebbeson 2002, 13).

Hobbes comes to the conclusion that all 19 of his natural laws can be contained in this is statement which is now known as the golden rule.

Peter Singer discussed the rational core of human ethics and opines that the core of human ethics is the ability to universalise it (Singer, 1981). He comes to the conclusion that human beings will place themselves in the place of others and in this way will decide what the right course of action is. This is the way they will make their decision: as the Golden Rule (Do unto others as you want them to do to you) states (Singer, 1981). Singer finds particular value in the universality of the Golden Rule.

Robert Kane writes that the Golden Rule is an obvious candidate for a universal moral principle, as it is to be found in many of the world’s religions and therefore moral codes (Kane 1994). He also emphasises that the Golden Rule does not presuppose universal values, because according to the rule you put yourself in

someone else's shoes, and in that way one has to pursue the values of that person, and not you own. This is the way in which it becomes universal.

The Golden Rule is about how the individual should act towards others (Ebbeson 2002: 83).

I would argue that in a bioethical setting *others* mean your patients, or persons involved in the medical care, as well as participants of a clinical trial, or society who is involved in public healthcare. In this way the Golden Rule can assist the doctor/anaesthesiologist when difficult decisions need to be made that involve informed consent. The clinician can be guided as to what to disclose and what not, by keeping the Golden Rule in mind. Although it may seem to be too subjective, in many instances it can be the only guide a physician has.

An example of a clinical scenario where the above rule can be implemented, is that of an elderly patient, who is incapable of communicating, but in need of emergency treatment. A neurosurgeon personally related his ethical dilemma to me: A 90-year-old gentleman has collapsed in an old age home. He has a head injury and a subdural haemorrhage. His level of consciousness is markedly impaired. In addition to this, he suffers from cardiac failure and may not survive a surgical intervention. This patient has no family left in South Africa, and the family overseas is not contactable. The neurosurgeon has to decide, whether to go ahead with a very risky procedure to relieve the haematoma, or to take a watch-and-wait approach. In this clinical scenario the Golden Rule would act as a useful heuristic to help with the decision-making process. However, the Golden Rule is not popular in bioethics at the moment. Philosophers have also not been as fond of the Golden rule as popular moralists and religious scholars have been (Fiala 2009: 25).

The criticisms of the Golden rule are numerous. Many say that the rule is over-idealistic, and that diminishes its prospects of being influential. It has been seen as unconditional altruism, that ultimately places too much of a burden on the individual (Goodman 2015). Kant famously argued in a footnote to his *Groundwork* that the problem with the Golden Rule is that it permits too much subjectivity in the thinking about ethics. The individual differences between the different 'yous' cause too many

different desires and therefore cannot be a universal law (Fiala 2009). The gist of Kant's criticisms is that its morality is not sufficiently transparent, and that the basis of any global ethical system cannot logically be centred solely on what is wanted or preferred but, categorically, on what's *right*.

The advantage of using the Golden Rule is that it asks of us to use our imagination, our moral imagination in this case (Fiala 2009). It asks of us to use complicated cognitive abilities, and it can be difficult to do. It can also be difficult to carry out in a world with so many differences in social, political and cultural backgrounds.

I would argue that the Golden Rule can be a very useful heuristic, particularly in the unique anaesthetic setting, where challenging decisions should be made whether to go ahead with a particularly risky anaesthetic. Regardless of how much information the patient has, ultimately the decision will lie with the anaesthesiologist as to whether to proceed. *Do unto others as you would want done to yourself*, will undoubtedly be a guide, both in a moral and clinical sense in these challenging situations.

9.4. Risk Versus Benefit

The discussion of risk versus benefit takes place on a daily basis in anaesthesia. Is the risk of the anaesthetic justified by the benefit of the surgery? This decision-making process takes place with every single patient interaction in the life of the anaesthesiologist. In some instances, it can be very clear, such as life-threatening conditions that can be easily treated. In other instances, it may not be that clear and the anaesthesiologist has to investigate the risk versus benefit profile carefully. I would argue that the risk versus benefit discussion is one of the most important, if not the only really important discussion while obtaining informed consent. The anaesthetic always carries risk. Even when all risks, particularly material, as discussed before, have been explored, the most relevant question will be: Does the risk of *this specific* anaesthetic, for this specific patient, outweigh the benefit of *this specific* procedure? In this scenario, the surgeon and anaesthesiologist should act as a team and use their clinical acumen and make a joint decision regarding the

procedure. If the risk of the anaesthetic outweighs the benefit of the procedure then a decision against surgery, or for delay in surgery to optimise patient's health should be made. This is a rare but relevant scenario. The real importance of risks versus benefit in the informed consent discussion is that the patient should understand and consent to the risks they are exposed to by the anaesthetic and understand that they are necessary for the benefit of the surgical procedure.
"That which is necessary is never a risk" (De Gondi 1718) is once again relevant in this daily clinical scenario. Note, however, that contrary to e.g. surgery, the risk of anaesthesia is weighed up against the risks of surgery.

9.5. Informed Consent As A Transaction

Another way of approaching informed consent is to look at informed consent as a transaction. In this instance, it becomes a communicative action that involves both the patient and the clinician. It recognises that this is not a one-sided conversation but that each party has an influence on the other. By accepting informed consent as a transaction, both patient and clinician essentially agree to a waiver of sorts. It recognises that informed consent as it exists is arguably practically impossible. It recognises that the full extent of satisfying respect for autonomy and obtaining true informed consent is simply not possible because information (here used as a verb), to the extend required is unrealistic. The patient does not waiver a right to informed consent, but waives a right to be informed comprehensively and specifically. The proponents of this notion argue that informed consent is a transaction that involves the flow of information between two parties.

> *It legistimises relative instead of absolute/specific informing. This transaction demands effective communication, comprehensibility and accuracy as the foundation of this type of interaction* (Manson and O'Neill 2007).

I would argue that in daily clinical practice, informed consent in anaesthesia already takes on this form, at least in part. Although the informed consent process follows

the regulatory and legal guidelines as discussed in chapter 5, the actual consultation in day-to-day practice resembles a transaction between two parties.

9.6. Shared Decision-Making

Shared decision-making is increasingly seen as an integral part of everyday medical practice and it has been argued as an ethical imperative (Whitney 2013). Shared decision-making aims at levelling the playing fields between doctor and patient. It is a process of communication to enable the patient to participate in a meaningful manner in the medical decision-making process. Simon Whitney proposes we take two important factors into account to simplify the difficult process of shared decision-making.

1. What is the **level of certainty** implied in the decision? How much medical certainty is inherent to the decision?
2. What is the **level of importance** of the decision? How much will the decision impact the patient? This impact may be both physically, but also financially and emotionally.

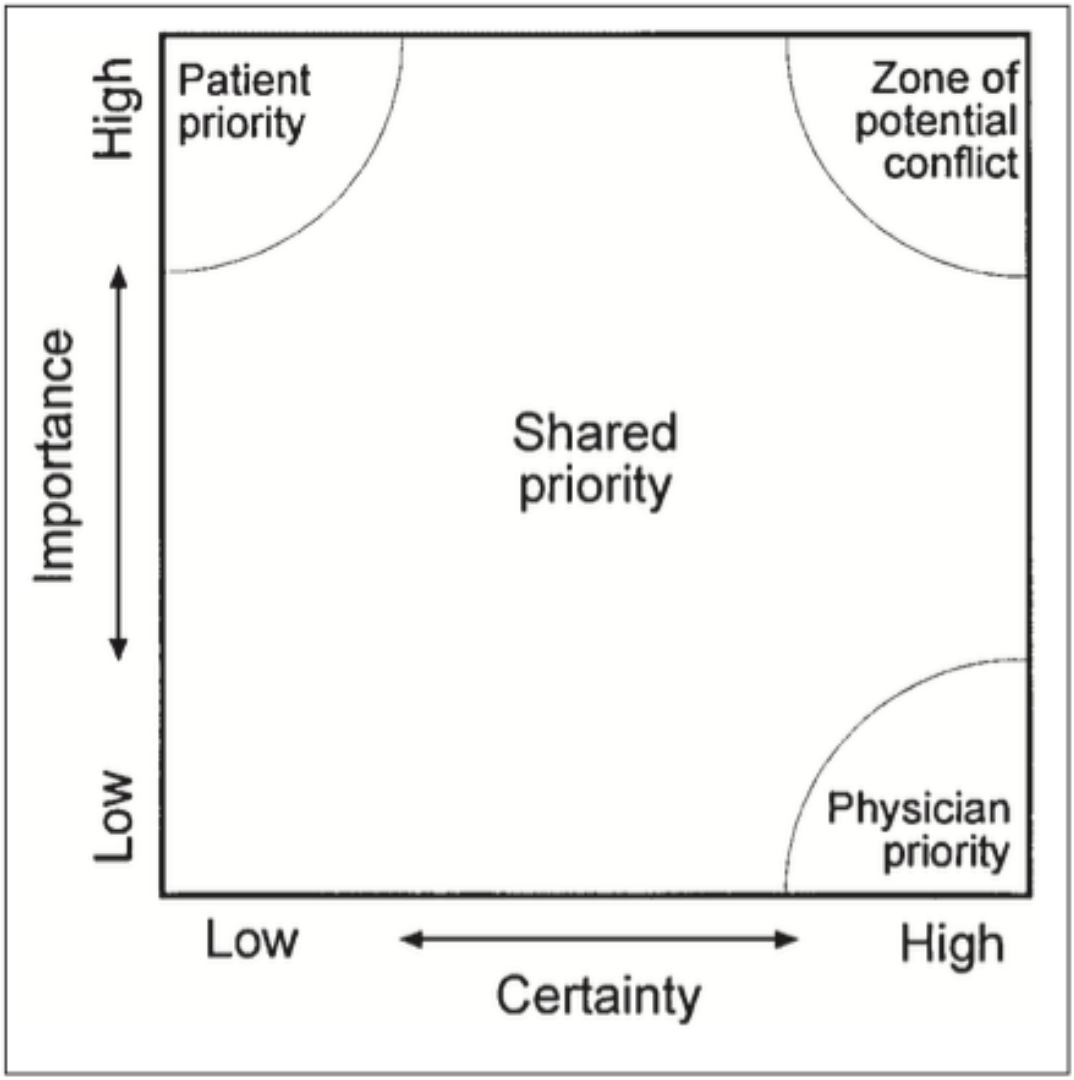

Figure 3: The Decision Plane (Whitney 2013)

Whitney then uses the decision plane as a graph that decisions can be mapped onto on the basis of their *importance* versus their *certainty.*

Whitney says that should a decision be of high importance, but low certainty, the decision should unequivocally rest with the patient, whereas if the decision is of high certainty, but low importance the decision-making is for the physician to make. It can be seen that the majority of the decision plane is of shared priority and this fits in with the concept of shared decision-making (Whitney 2013).

Using the decision plane, each individual case is assessed, considering each case's individual specifics. A simple scenario would be: a patient with acute appendicitis,

who needs surgery. There is a high certainty that the operation, and therefore the anaesthetic, is necessary, so even if the patient disagrees with the decision, it would fall into physician priority plane, as the certainty of the positive/lifesaving outcome is high.

In another scenario: A fit and well patient wants a lipoma removed. It is of low importance and its necessity is of medium certainty, therefore a true shared decision-making process will follow. The zones of potential conflict will be if a surgery/anaesthetic is deemed necessary by the physician, for instance excising a big malignant tumour on the face, but this surgery will impact the patient significantly in terms of their physical appearance and ability to swallow. This scenario falls into the zone of potential conflict. Shared decision-making will still have to prevail in this difficult scenario.

9.7. Medical Professionalism And Virtue Ethics

The word professional comes from the word: ”profess’. The definition of profess being ‘to have or claim knowledge or skill in (a subject or accomplishment)’. Professionalism can also be seen as a commitment to a particular way of life. It implies that the professional *professes* to have specific skills, required of that specific profession. In the case of a medical professional, it would require of the professional to have all the skills of the particular speciality, but medical professionalism also implies that at present society may expect of medical professionals to adhere to core principles of biomedical ethics, and medicolegal and regulatory facets of practice (De Roubaix 2017). De Roubaix also emphasises that professionalism requires sacrifice and commitment to the profession. The medical professional, in this case the anaesthesiologist, should firstly be in possession of the required clinical qualifications and skills, should also have a second characteristic, i.e. to have certain moral attributes, as described in the bioethical literature (De Roubaix, 2017) Virtue ethics has made a resurgence as a guiding moral theory and may enlighten on the nature of these moral attributes, and is a moral theory particularly applicable to the medical profession. Virtue ethics as a way of ensuring moral soundness is an ancient approach, harking back to what Aristotle wrote in the Nichomachean Ethics.

Moral virtues such as courage, temperance, magnanimity, truthfulness and modesty are virtues that should characterise any medical professional.

To apply an Aristotelian analysis of virtues to anaesthesiology, De Roubaix looks at the virtues applicable to anaesthesiology, such as sincerity, honesty, moderation, diligence, patience, accountability. The list is endless. De Roubaix points out that: "The experienced practitioner may recognise moments in his/her career when he/she was required to practice each of these virtues and may reflect on the meaning of each" (De Roubaix, 2017: 82).

If an anaesthesiologist practices as a true medical professional, and has the appropriate moral attributes, then it follows that many of the requirements of authentic informed consent will be adhered to. The anaesthesiologist will implicitly act with honesty, integrity, benevolence, diligence, compassion and consideration. The moral virtues of the professional will inherently assure that the requirements of informed consent are met, whether it be explicitly or implicitly.

9.8. Human Dignity

The right to human dignity is an essential human right and may be seen as the basis of human rights (Aasen, Halvorsen and Da Silva 2009: 60). This is also the case in South Africa. (SA Bill of rights 1996) It is important that human dignity exists independently of autonomy or the capacity to be autonomous. Although there is a close relationship between human dignity and respect for a patient's autonomy, both in moral philosophy and the law, a person who lacks the autonomous capacity for decision-making retains human dignity by nature of being human. Human dignity is inherent and therefore, in the medical setting, every person deserves to be treated in a manner respectful of his/her human dignity by nurturing his/her utmost well-being.

> *"Respect for human dignity as an inherent property of each human being requires respect for all human rights since all of them reflect basic individual and societal needs and interest, such as respect for life, health, liberty security and private life*" (Aasen, Halvorsen and Da Silva 2009: 61).

The recognition of human dignity of the anaesthetised patient is integral to the treatment of the patient while anaesthetised. The anaesthetised state cannot be seen as a loss of dignity, but rather a state that requires even more from the health care professional to treat the patient with the utmost care and respect for the patients' dignity, in fact, to safeguard the patient's dignity or act as his/her moral advocate.

There are of course situations where patients' autonomy conflicts with their dignity, in a health-care context. "In these cases the respect for and protecting human dignity will triumph over autonomy (Aasen, Halvorsen and Da Silva 2009: 52)." This implies that the health care professional may at times refrain from respecting the patient's autonomy for the sake of respecting their dignity. This scenario may be encountered by a plastic surgeron, who refuses to do extreme or unusual body altering surgery that a patient requests. The health care professional should respect the patient's dignity and may make the decision not to proceed with a procedure that would do harm to the patient's dignity, although other surgeons may decide to respect autonomy is this instance. This would come down to personal choice by the professional.

Liberty and autonomy, which can also be called self-determination, are important aspects of protecting human dignity (Aasen, Halvorsen and Da Silva 2009: 64) and are at the core of human rights. *Informed consent can as such be seen as being respectful of human dignit*y and therefore is a human right. In the Scandinavian countries, it is specified in legislation as a patient right (Aasen, Halvorsen and Da Silva 2009).

9.9. Patient Autonomy And Trust

The bioethical requirements for informed consent seem to erode an element of the patient-health care professional relationship, namely that of trust. In the former paternalistic way of practising medicine, the trust that the patient placed in the doctor

was unquestioned. Although respect for autonomy was not practised, patients trusted their health care professionals implicitly.

Autonomy and respect for autonomy have been the driving force in the quest for obtaining informed consent and it is the constant motivation to perfect this ideal. Onara O'Neil asks the question: Where has **trust** gone? (O'Neil 2002). She argues that trust is surely an inherent part of the doctor-patient relationship, and that for some reason, trust has been side-lined in the bioethical discussion of doctor-patient relationship. Respect for autonomy has been made the main focus of discussion. She feels by gaining patient autonomy we have lost the element of trust that is integral to the ethical doctor-patient relationship, and of patients' trust in the healthcare system (O'Neil 2002). "It seems one has to choose between respect for individual autonomy and the relation of trust" (O'Neil 2002: 3). It is ironic that this current element of 'mistrust' has reared its head at the same time as when significant medical advances are made, and life expectancy has risen (O'Neil 2002). Yet we trust our fellow human beings to drive on the correct side of the road or obey the laws of the country. We expect goodwill from our fellow human beings. Annette Baier says "Reasonable trust will require good grounds for reasonable confidence in another's good will or at least absence of grounds for expecting their ill will or indifference" (Baier 1986: 235). However, with the increasing importance of autonomy in bioethics, the public seems to mistrust medical professionals and medical science more than other professionals.

When autonomy is understood as independence, in the setting of obtaining informed consent for treatment, the independence and liberty of the patient can be questionable. Does the patient really have the liberty to choose treatment, or demand treatment that may not be offered, or does the patient actually only have the liberty to refuse treatment. Even that liberty may not be truly available for the patient who requires lifesaving surgery. O'Neil asks : "Is 'patient autonomy' not only there to mask the patient's role to say 'yes' or do without treatment?" (O'Neil 2002: 26) The patient is brought under the illusion that he or she is autonomous and independent and has free choice, but actually he/she only has the power to refuse treatment, and that does not honour the true principle of respecting autonomy. This highlights how important true trust is in the clinical situation. For the anaesthetised patient, trust (in

the anaesthesiologist) is of the utmost importance and trust in his/her ‘good will’ is paramount. Patients have to trust that anaesthesiologists will perform their duties to the best of their abilities.

In the paternalistic way of practising medicine in the past, the trust the patient placed in the doctor was unquestioned. The advent of autonomous choice at least in principle puts the patient on a more equal footing with the physician, but the onus is on the physician to ensure an understanding of the treatment or intervention. This transaction (of obtaining informed consent and the transactional nature of it) erodes the implicit trust that was placed in the treating physician. It places a distance between the patient and doctor and has given rise to the term: “Strangers at the bedside” (Rothman 1991) The transactional nature of the Informed Consent Process can turn the health care professional into a stranger who conducts a ‘transaction’ at the bedside, instead of the caring physician that aims to heal.

9.10. Conclusion

When investigating ethical alternatives for informed consent specifically in the peri-operative setting, the fact that there are so many different concepts to consider and discuss highlights the complexity of this ethical dilemma. Phronesis and the ethics of responsibility emphasises that the health care professional inherently should have a certain practical wisdom that can be equated with the ‘clinical intuition’ of the health care professional. The golden rule can be a useful heuristic, particularly in challenging scenarios. The inherent trust that patients should have in their health care professional is increasingly important as healthcare decisions become increasingly complex.

In our legalised society, concepts such as shared decision-making and consent as a transaction may ultimately triumph. While investigating the authenticity of informed consent in anaesthesia, the difficulties in truly achieving each of these requirements became increasingly clear. The next chapter will aim at finding some solutions to the conundrum of adhering to the current regulatory requirements.

CHAPTER 10: PRACTICAL SOLUTIONS TO IMPROVING THE AUTHENTICITY OF INFORMED CONSENT IN THE PERI-OPERATIVE SETTING

10.1. Introduction

This chapter will address some practical solutions to the dilemma of informed consent in the peri-operative setting. The anaesthesiologist should attempt to incorporate the informed consent process into clinical practice on a practical level and attempt to reach an authentic ethical standard. To that end using personalised information on demand (IOD) can be very useful, and as a practical solution, I think it has the most merit and will therefore be discussed first. This will be followed by some other practical solutions to achieve the goal of authentic informed consent in anaesthesia.

10.2. Personalised Disclosure By Information On Demand (IOD)

Siegel, Bonnie and Appelbaum discuss the process of treating different patients differently according to their informational needs. They discuss a process called information on demand or IOD, where the patient can choose the amount of information that they require (Siegal, Bonnie and Appelbaum 2012) (see also pp 10 & 62).

Information is divided into minimum, medium or maximum in terms of quantum and comprehensiveness. The principle is that patients have different information needs and that the physician caters to these needs. The patient is empowered to control the flow of information to them, and by pronouncing their need for information they choose a specific aisle with regards to their informational need. This is definitely something that one practically sees in clinical scenarios that play out in the everyday life of an anaesthesiologist. In Table 2 below is an example of how Siegel, Bonnie

and Appelbaum envisage the information pathways and how it would be implemented.

Table 2: Information Pathways (Siegal, Bonnie and Appelbaum 2012)

	Green: Basic Information	Blue: Intermediate Information (Green plus+)	Red: Extensive Information (Green and Blue plus+)
Type of information	1. Nature of procedure/ treatment 2. Why it is being recommended 3. Prognosis without treatment 4. When patient can resume daily-life activities 5. Expected impact on patient's life * Do you want to hear about alternatives?	1. Basic description of alternatives 2. Major/significant risks of proposed treatment and alternatives, defined by severity and frequency	1. Extensive information about the proposed procedure 2. Extensive information about alternatives 3. Extensive information about possible risks and unwanted outcomes
Ramifications	Preserves the "right not-to-know" certain medical information, especially the risks of treatment. Minimum content of the disclosure will depend on state law	Should be generally compatible with either the professional standard or the reasonable patient standard	Resembles exhaustive IC protocols currently in use that are designed to minimize liability exposure

Different patients have different demands of information, and the patient who demands the maximum information may have sought out information on the internet already, and is just confirming it with you, the clinician. Other patients may want minimum information, as they are already under duress awaiting surgery, and they may feel that more information would change their decision to progress to surgery, and put them under increased stress.

This IOD approach can potentially shift the legal and ethical paradigm of informed consent in the direction of patient control (Siegal, Bonnie and Appelbaum 2012: 361). The authors also suggest that the patient-desired specificity of disclosure should be binding if informed consent is being retroactively challenged.

The same authors discuss the future of fully individual disclosure. With advances in information technology, patients will be able to choose the information they require

by means of software or web-based information that can be tailored to their needs. Patients may also be able to take a test to assess their level of understanding, and receive information based on the level that would be appropriate for them.

10.3. Alternative Sources Of Information About Anaesthesia

Alternative sources to enhance the informed consent process as well as facilitate the informed consent process have made huge strides. Internet-based information is universally available online and is also available on the websites of anaesthetic societies. The use of audio-visual aids in the pre-operative environment will also be increasingly used as most patients have access to internet based sources. Zhang and Ruan investigated the use of video footage to assist ophthalmologists in the informed consent process. Though the informational video did not manage to improve patient comprehension, it did increase patient satisfaction with the overall process. (Zhang and Ruan 2017). A similar study in Boston found both comprehension and patient satisfaction to be increased (Shukla, Daly and Legutko 2012). Mawhinney, Thakar and Williamson published the findings of using their Oxford Video Informed Consent Tool OxVIC on patients who were scheduled to undergo spinal surgery (Mawhinney, Thakar, Williamson (2019). The OxVIC were sent to the patients via a secure link, and patients could view the video in the privacy their own home and in their own time. A majority of the patients viewed the video with their families. This investigation found that patient-satisfaction levels were very high and bodes well for the future of video-consent tools.

The future of using internet-based audio-visual information, both for information and as an adjunct to informed consent, is exciting and still needs to be explored in the field of anaesthesiology.

10.4. Preoperative Clinics

In France, a legal ruling made on 5 December 1994, stated that all patients who are to undergo elective anaesthesia should be seen at least two days prior to the event by an anaesthesiologist in a dedicated office. This consultation should be complemented by an anaesthetic visit within 48 hours prior to the administration of

the anaesthetic. Dr J-J Lehot from Lyon in France wrote a letter to the Journal Anaesthesia in which he recognises the burden it placed on the anaesthesiologist but acknowledges that this arrangement has ultimately been beneficial to all involved (Lehot 2003). This pre-operative visit allows not only sufficient time to deliver adequate information, but it also allows the patient time to consider and digest the information supplied before the actual surgery takes place. This has been hugely advantageous for both patients and anaesthesiologists as true authentic consent is a possibility in this scenario (Lehot 2003). The mandatory anaesthetic pre-operative consultation is something that we as a group of specialist anaesthesiologists should aim to institute in order to obtain authentic informed consent.

10.5. The Medical Information Specialist

The concept of a medical information specialist was coined by W. Moore (Moore and Slabbert 2013). This concept was originated in his doctoral thesis, 'Patient Autonomy and Evidence-based Patient Choice: Philosophical and Ethical Perspectives'. His study examined the concept of evidence-based patient choice. He stressed that the concept of personal identity is central to the philosophical foundations of evidence-based patient choice. This evidence-based patient choice approach will give patients access to information previously thought not possible (Moore and Slabbert 2013).

In his thesis, Moore advocates the use of a medical information specialist, who would be able to fulfil the requirements of evidence-based patient choice that considers personal identity. This medical information specialist would be a person who has medical, ethical and sociological background. This specialist will have the communication skills to not only be able to relay important clinical information, but he would also be able to supply information in a more cohesive way, taking into account not only the medical aspect, but also the overall impact on the patient from a sociological view. This specialist could really support the patient, not only with medical information, but also with support and guidance for the patient as a person as a whole. The medical information specialist has no vested interest in the patient's decision and can guide the patient with empathy to the right decision. They will act not only as an information specialist, but also as ethics consultant (Moore and

Slabbert 2013). This concept is an ideal in the endeavour for authentic informed consent.

10.6. Conclusion

This chapter entailed a short discussion of some practical solutions to the dilemma of informed consent in anaesthesia. There is a myriad of possible solutions to enhance the informed consent process, but because the peri-operative environment is a unique clinical setting, only some solutions will make a practical difference in the daily practice of the anaesthesiologist. The peri-operative informed consent consult is variable. It can vary in time, being emergent or not, and it also vary from patient to patient and procedure to procedure. I have touched on practical solutions in order to satisfy the legal and regulatory requirements as they exist currently. The future of informed consent with the aid of a medical information specialist is exciting, and in the increasingly complex world of medicine it could be the most practical; this includes the concept of an anaesthetic-specific pre-operative clinic. The current practical dilemma of authentic informed consent will continue to plague the anaesthesiologist.

CHAPTER 11: CONCLUDING REMARKS

As a practising anaesthesiologist, the daily ethical dilemma of obtaining informed consent for anaesthesia, and the question regarding the authenticity of the consent obtained, prompted this thesis, which became an investigation into the dilemma of authentic informed consent in anaesthesia.

The aim of this thesis was twofold: firstly, it investigated the construct of informed consent by studying the available literature in biomedical ethics, philosophy and the law; and secondly, it deliberated possible solutions, both ethical and practical, to this ethical dilemma faced by anaesthesiologists

The thesis started by investigating the history and development of the construct of informed consent, both from a bioethical and legal point of view. It investigated autonomy and the principle of respect for autonomy and how it became an important bioethical principle. It is this bioethical principle that informed the development of informed consent in the bioethical field. The thesis looked at the evolution of medicine and of how it progressed from the goodwill of the treating physician, as evidenced in the Hippocratic Oath, to a paternalistic way of practising medicine and ultimately, after the atrocities of the Second World War, changed to a patient-centred approach, with respect for patient autonomy being paramount.

The thesis looked at the legal and regulatory guidelines for obtaining informed consent, as specified by the HPCSA and the other regulatory bodies. After establishing the details of the current guidelines, the thesis investigated the real practical dilemmas faced by most health care professionals in daily practice while obtaining informed consent. The thesis then focused on anaesthesia as a speciality, investigating both the history and development of the speciality to its current status.

Subsequently, the peri-operative period and the specific challenges that the anaesthesiologist faces during the pre-operative consultation were analysed. The following chapter investigated the ethical dilemmas faced by the anaesthesiologist

and attempted to answer this dilemma by investigating ethical alternatives for informed consent in anaesthesia.

The thesis concluded by suggesting practical solutions for the deficiencies in the current practice of anaesthetic informed consent, keeping in mind a future ethical alternative for informed consent in anaesthesia that is exciting and deserves further investigation.

An important point that significantly influenced my view of the authenticity of anaesthetic informed consent arose during my personal realisation of the unique ethical and moral status of the anaesthetised patient. This realisation was made during the investigation of the history of anaesthesia which revealed the significant change in moral status of the person commented on when the first anaesthetic was performed. The earliest practitioners were highly cognisant of the change in the status of the patient; from patient as a person to patient as body that could not move or resist surgery. This altered moral status leads one to questioning the validity of the term 'informed consent in anaesthesia' as we know it. Until the ethical and moral status of the anaesthetised patient has been more clearly validated, the basic premise of the consent can be drawn into question: What exactly is the patient giving consent for? Is consent for the anaesthesia truly valid if the change in moral status of the patient is so profound?

The investigation in this thesis has opened a void in our knowledge of ethical nature of the anaesthetised patient in particular. The answer to the authenticity of informed consent in anaesthesia, following ethical reflections can only be that both the anaesthesiologist and patient find themselves in an inconclusive state as to what this agreement entails from an ethical point of view.

This ethical interrogation into the authenticity of informed consent in anaesthesia highlighted some important concepts for me.

- ***Patient autonomy and trust***

The importance of patient autonomy is emphasised repeatedly in bioethics literature, but that seems to be to the detriment of trust in the medical professional and the medical fraternity as a whole. Onara O'Neil's question of 'Where has the trust gone?' (O'Neil 2013) reflects my own perception of the complexities of autonomy and trust, where the trust of the patient in the health care professional and the anaesthesiologist has been eroded. Instead of instilling trust in patients, the laws and regulations have changed the traditional patient–doctor relationship into a business like transaction. The principle of respect for patient autonomy has placed on the anaesthesiologist an onus to obtain authentic informed consent that is riddled with obstacles.

- ***Altered autonomy***

Can the patient presenting for anaesthesia be seen as having non-substantial autonomy, by virtue of their illness, or their altered moral state? That would go against the grain of current patient-centred approaches. It would however seem that patient autonomy can be impaired to a degree in the pre-operative setting. This would differ between patients with different levels of both cognitive and emotional functioning. One highly functioning individual may have full autonomy, despite being under duress, while another is compromised by the inherent stress of the pre-operative situation.

- ***Virtue ethics***

I foresee that the moral virtues inherent to the health care professional, and specifically the anaesthesiologist, will become increasingly important as the complexity of medical interventions escalate. The medical fraternity should aim to regain the trust of the patient; as this trust grows, the guidelines will automatically be adhered to. Moral virtues of the health care professional can ultimately be a guide and assist him/her to comply with the ethical ideals and regulatory guidelines of informed consent.

- ***Choice-less choices***

The concept of choice-less choices has been discussed (Epstein and Peters 2009) and the reality of that in the peri-operative period is often evident.

Despite revealing all relevant and material information, at the end of the consultation, the choice to make is really not a choice. In anaesthesia, the choice is situated with being given the option to opt out (of the anaesthetic and procedure) when given the details, or more importantly to make a choice to trust the attending health care professional, in this case the anaesthesiologist. The element of trust that the patient should have in the anaesthesiologist is indisputable. The autonomous choice, therefore is, not necessarily to exert autonomous choice, but the choice to trust.

- ***Risk versus benefit***

The importance of the risk versus benefit discussion during the informed consent interaction is paramount. The real importance of making informed consent authentic is divulging *material* information. That is information that would make patients change their decisions. Discussing the risks of anaesthesia in this format provides, in my opinion, the best framework for the patient to have a relevant and true understanding of the risks involved and to give a decision that is authentic.

- ***Transfer of information***

The personal communication from my colleague highlighted the complexities of the transfer of information during the informed consent process (Khan 2018). The fact that a highly qualified specialist in the field of medicine personally experienced the complexity of informed consent and that this has impacted on him for the duration of his life, made me aware of how, even using the subjective standard of disclosure during the informed consent process, may not have a satisfying outcome. (see 4.2.1.1 in chapter 4)

Using the word *permanent* did not convey the fact that it is *forever, for the rest of your life*. This illustrates how mere semantics, even if they are correct, can influence the interpretation of the information being conveyed.

When examining the elements of informed consent, as they exist in current bioethical literature, from the perspective of a clinical peri-operative scenario where the

anaesthesiologists would find themselves, the challenges of meeting the requirements are vast.

When looking at the paradigm of informed consent, the basic elements of informed consent can be summarised as such. (see 2.8 in chapter 8)

1. The patient should be competent to give informed consent.
2. All relevant and appropriate information should be supplied.
3. The patient should be able to make a decision without undue outside influence, including the right to refuse treatment. (De Roubaix 2005)

In the anaesthetic pre-operative setting, the *patient's competence is compromised*, as an anxious patient awaiting surgery. The patient can also be compromised by the illness itself which reduces the capacity of the patient to be at his/her normal level of intellectual and emotional functioning.

The *relevant information for anaesthesia is complex*, anaesthesia carries real risks, and the information that could be conveyed is unlimited. The risks are real and serious. Morbidity is a certainty (e.g., surgical pain) and side effects such as nausea and vomiting relatively common. In my opinion, no matter how comprehensive the informed consent discussion, the only real issues that will matter are those that would make the patient alter their decision regarding accepting the treatment, namely the anaesthetic and the surgery. This is a highly unlikely decision outcome, but not impossible, as discussed in the example of a pregnant patient booked for an elective procedure (See 6.4.1 p.85)

Lastly, to achieve a state of no *undue influence and pressure* on the patient to accept treatment is improbable. The patient has presented for surgery, and is to be anaesthetised and operated on. The practical fact of implied consent, although not acceptable to bioethicists, no doubt exists here.

Tom Beauchamp said:

> *The history of informed consent is still unfolding, and the recent failures may be no less apparent to future generations than are the failures that I*

> *have found in the past and present. Clearly we still face unresolved and critical moral challenges.* (Beauchamp 2011: 522)

This statement summarises my perception of informed consent very well. This investigation made me to appreciate that the concept of informed consent in anaesthesia is in its infancy. The field of biomedical ethics is a relatively new one, and as it increasingly expands, it will shape the daily activity of the health care professional. I believe the pendulum may swing away from the increasingly regulatory demands to a more patient-centred concept of informed consent (in anaesthesia) that gives each individual patient the informed consent consultation that he or she deserves and requires.

While the above notion is the ideal, one should realise the reality of the moment, as it exists in bioethics and law. A possible practical solution for the dilemma of inauthentic informed consent as it stands today which may have significant future possibilities is information on demand as proposed by Siegal, Bonnie and Appelbaum (2012) where the flow of information is placed in the hands of the patient. This concept speaks to patient autonomy and choice, and can be important to satisfy bioethical demands of the consent process. The medical information specialist who is trained in communication and sociology and has an ethics and medical background as proposed by Moore (Moore and Slabbert 2013) has all the hallmarks of a solution to many of the dilemmas that is faced during the informed consent process, and the future of training specialists in this field is an exciting proposal, to develop authentic informed consent, though at this stage it is little more. Mandatory pre-operative clinics may address some of the practical dilemmas of the informed consent consultation and the use of information technology will definitely play an increasing role in obtaining authentic informed consent.

Lastly, this thesis has elucidated the unique moral status of the anaesthetised patient. By investigating the patient-body when anaesthetised, versus the patient-person while awake, it uncovered the unique moral state that the anaesthetised patient enters into and which merits further reflection. .

Such an investigation may change the landscape of informed consent in anaesthesia as it exists today. The current legal and regulatory guidelines are all rooted in the bioethical and legal literature regarding requirements for informed consent, as it exists for general clinical and research practice. Investigating the unique status of the anaesthetised patient my result in a complete shift in the approach to obtaining informed consent for anaesthesia, as this 'treatment' or procedure has unique implication.

De Roubaix said, at the end of his article on seeking patient's consent in anaesthesiology:

> *As a trainee, I was taught that anaesthesiology is a science, but its practice an art; to my mind, obtaining adequate informed consent is at the heart of this art* (De Roubaix 2005: 129).

In biomedical ethics, one aspires to the ideal and accepts the challenges that it brings. During my investigation into the authenticity of informed consent in anaesthesia, I have found that it is currently far from ideal. The construct of informed consent in anaesthesia has been shaped by legal precedents and bioethical principles, but obtaining authentic informed consent in the field of anaesthesia has demands that are difficult to adhere to with current bioethical principles. It demands more ethical deliberation and moral investigation to ultimately find a solution to this ethical dilemma.

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Addendum A

Anaesthetic consent form as supplied by the South African Society of Anaesthesiologists

ANAESTHESIA FORM NARKOSEVORM

SA Society of Anaesthesiologists
www.sasaweb.com

LEES ASSEBLIEF AFDELINGS A, B, C, & D, VUL GEGEWENS IN, TEKEN ONDER EN OORHANDIG AAN DIE ANESTESIOLOOG.
L.W. AFDELING C MOET INGEVUL WORD DEUR DIE REKENINGPLIGTIGE

PLEASE READ AND COMPLETE SECTIONS A, B, C, & D, SIGN BELOW AND HAND TO THE ANAESTHESIOLOGIST.
N.B.SECTION C. MUST BE COMPLETED BY THE PERSON RESPONSIBLE FOR THE ACCOUNT.

A

OOREENKOMS TUSSEN DIE ANESTESIOLOOG EN PATIËNT
AGREEMENT BETWEEN THE ANAESTHESIOLOGIST AND PATIENT

PATIËNT:

A1. Ek begryp dat 'n insidentvrye narkose nie gewaarborg kan word nie.
A2. Ek begryp dat teatertoerusting en personeel deur die hospital verskaf word. Narkosetoerusting word daagliks getoets.
A3. Ek onderneem om nie alkohol te verbruik, 'n motorvoertuig te bestuur of enige gevaarlike toerusting te hanteer, belangrike besluite te neem of dokumente te teken vir 'n tydperk van 24 uur na narkose toegedien is nie.
A4. Ek verleen toestemming dat my persoonlike inligting bekend gemaak mag word aan belanghebbende instansies, soos deur die wet bepaal, asook anonieme data van 'n kliniese en praktykbesturende aard wat tot die bevordering van die pasiënt se welstand mag bydra.

Ek het bostaande gelees, begryp en aanvaar die voorwaardes soos uiteengesit. Ek verklaar dat ek by my volle verstand is ten tye van ondertekening en dat ek dit uit vrye wil doen. Hiermee gee ek toestemming vir narkose vir myself.

GETEKEN: DATUM:

BETALING:

A5. U narkose rekening is totaal onafhanklik van enige ander rekening wat deur die hospitaal of chirurg uitgereik word.
A6. Die koste (beraming) vir die narkose was met my bespreek:
A7. Die koste (beraming) soos uiteengesit in deel C is gebasseer op hoe lank die procedure sal duur, en mag verander weens onvoorsiene omstandighede of onverwagte komplikasies.
A8. U is persoonlik verantwoordelik vir betaling van u rekenning en nie u mediese fonds nie. U mediese fonds mag dalk nie die hele bedrag dek nie, afhangend van die mediese fonds en die plan opsie wat u gekies het.
A9. Sou u rekening oorhandig word vir invordering, sal rente van 2% per maand gehef word op alle agterstallige bedrae. Alle koste verbonde aan die invordering sal van u verhaal word teen prokereur en kliënt skaal.

Ek het bostaande gelees, begryp en aanvaar die voorwaardes soos uiteengesit. Ek verklaar dat ek by my volle verstand is ten tye van ondertekening en dat ek dit uit vrye wil doen. Hiermee gee ek toestemming vir narkose vir myself.

GETEKEN: DATUM:

PATIENT:

A1. I understand that no one can guarantee an incident free anaesthetic.
A2. I understand that the theatre staff and equipment are supplied by the hospital. Anaesthetic equipment is checked on a daily basis.
A3. I agree not to drink alcohol, drive a car, or operate any dangerous equipment, make important decisions or conclude agreements for 24 hours after recovering from anaesthesia.
A4. I agree to allow my personal data to be forwarded to the relevant organisations as required by law and to allow anonymous data of a clinical and practice management nature, to be collected to help to improve the patients healthcare experience.

I have read, understood and agree to the conditions mentioned above. I declare that I am of sound mind at the time of signing this agreement and that I am not under duress. I hereby give permission for anaesthesia on myself.

SIGNED: DATE:

PAYMENT:

A5. Your Anaesthetic account is rendered completely independently from the accounts rendered by the hospital and the surgeon.
A6. The make up of the cost estimate for the anaesthetic service has been discussed with me:
A7. The cost estimate as set out in section C is time-based and may change as a result of unforeseen circumstances and unexpected complications.
A8. You are personally responsible for payment and not your medical scheme. Your medical scheme may not cover the full amount on your account, depending on the medical scheme and the plan option which you have chosen.
A9. Should your account be handed over for collection, interest will be charged at 2% per month on all outstanding amounts. All costs incurred to collect the arrears will be for your account on attorney and client scale.

I have read, understood and agree to the conditions mentioned above. I declare that I am of sound mind at the time of signing this agreement and that I am not under duress. I hereby give permission for anaesthesia on myself.

SIGNED: DATE:

B

PASIENT VAN :
PATIENT SURNAME :
GEB.DATUM:
BIRTH DATE:
VOLLE VOORNAME :
FIRST NAMES :

MEDIESEFONDS :
MED FUND :
OPSIE:
OPTION:
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Anaesthesiologist

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AstraZeneca
PAIN AND ANAESTHESIA

AMPTELIK OFFICIAL

PLAK HOSPITAAL PLAKKER HIER
PASTE HOSPITAL STICKER HERE

PRECISION MEDICAL SOLUTIONS

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