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Anaesthetists' Knowledge Regarding Decision-Making Capacity:

A Bioethical Enquiry



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Submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine in Bioethics and Health Law.

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(Director: Steve Biko Centre for Bioethics, University of Witwatersrand)

Declaration:

I declare that this research report is my own unaided work. It is being submitted to the University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Science in Medicine (Bioethics and Health Law). It has not been submitted before for any degree or examination to any other University.

Signature of Candidate.....

Date. 23 SEPTEMBER 2019

Dedication:

"A good decision is based on knowledge, and not on numbers."

Plato

This research report is dedicated to the vulnerable, who sometimes find themselves at the mercy of those who must decide for them. May those decisions be based on virtues and knowledge.

Acknowledgments:

To my supervisor and mentor, Professor Ames Dhai, thank you for your time, expertise and support. Your guidance has been invaluable, even long before my journey to bioethics.

To Professor Colin Menezes, thank you for driving me to fulfil my potential.

I am deeply indebted to Dr Sameerah Mahomed, Dr Zainub Jooma, Dr Pieter de Jager and Lizeka Tandwa for their input, assistance and advice.

List of Acronyms:

DMC: Decision-making capacity

HPCSA: Health Professions Council of South Africa

HCW: Health care workers

BRICS: Brazil, Russia, India, China and South Africa

MMSE: Mini-mental state examination

MacCAT-T: MacArthur Competence Assessment Tool – Treatment

HREC: Human Research Ethics Committee

ACE: Aid to Capacity Evaluation

CAT: Capacity Assessment Tool

CCTI: Capacity to Consent to Treatment Instrument

DAM: Decision Assessment Measure

HIC: Higher Income Countries

MUD-VH: Measuring Understanding of Disclosure: Voluntary Hospitalisation

Abstract

In healthcare, decision-making capacity (DMC) refers to a patient's ability to make treatment related decisions. It is a prerequisite of informed consent and has moral and legal significance. The majority of capacity assessments are performed by doctors using clinical judgement. Studies have shown that doctors fail to recognise a significant proportion of patients who lack DMC. In order to improve reliability, formal tests of DMC have been developed but these have several shortcomings.

Mixed methods were used in this study which investigated anaesthetists' level of knowledge regarding decision-making capacity. The normative component emphasised the importance of doctors' knowledge in DMC assessment. Medical education ought to be reformed in order to improve doctors' knowledge. Formal tools for DMC assessment ought to supplement doctors' knowledge.

The empirical component of the study was a prospective, cross-sectional descriptive study conducted in the Anaesthetic Department at the University of the Witwatersrand. Of the 89 anaesthetists who completed the survey 3 (3%) had extracurricular education about the assessment of DMC and 11(12%) were aware of a standardised test that could be used for DMC assessment.

Fifty-seven percent (57%) indicated that they had never used an objective test to assess DMC. The survey identified that there were several areas where significant knowledge deficits exist. These deficits pertained to decisional relativity, the conflation of cognition and capacity, the use of the Mini-Mental State Examination (MMSE) for capacity assessments and consent in emergency situations. These deficits in knowledge may affect anaesthetists informed consent process and have the potential for ethical and medicolegal violations.

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Chapter 1: Background

1.1 Background Literature Analysis and Critique

1.1.1 Medical Paternalism and Informed Consent

According to Dworkin, paternalism is the process of interfering with the autonomy of a person in order to act in their best interests.[1] Beauchamp and Childress make the further distinction between soft paternalism and hard paternalism.[2] Soft paternalism occurs when the interference occurs with the goal of preventing a *non-voluntary action* e.g. in the case of patients with altered mental capacity who may not completely understand what they are consenting to. Hard paternalism occurs when the interference occurs with the goal of preventing an action that is "informed, voluntary, and autonomous."[2] An example of this is the legal prohibition of the use of illicit recreational drugs. In this case people are aware of the effects of drugs and may still want to use them (i.e. they are making a choice that is informed and voluntary) but the law still prohibits illicit drug use thereby acting in a hard paternalistic way

In the healthcare setting, soft paternalism is often justified if the patient lacks capacity to fully understand the situation and if they cannot act in their own best interests, for example, children below the age of 12 are not legally recognized as having the capacity to consent to medical treatment. In these situations, others (usually parents) act on behalf of the child and in the best interests of the child. This is considered an acceptable form of soft paternalism.[3]

1.1.2 Decision-making Capacity (DMC)

Central to these issues is a patient's decision-making capacity (DMC). This is defined by some as "the *ability* of health care subjects to make their own care decisions."[3] DMC is a complex measure that is made up of several elements. There is still much ethical and legal discourse around what elements are essential to DMC but some experts agree that understanding, appreciation, reasoning and expressing a choice are central components.[3] If patients lack any of these components then they may be seen as having diminished decision-making capacity in which case a substitute decision maker may need to be sought. Several conditions may affect DMC e.g. delirium, psychosis and severe anxiety.[4] Medical conditions that have systemic effects like sepsis, diabetic ketoacidosis and hypoxia may also affect cognitive functioning and can therefore impair the capacity to make decisions. Capacity impairments are not always overt; they may be subtle but still significant. As such, impairments in capacity are often not recognized by clinicians.[5]

1.1.3 The Legal Basis of Informed Consent

Anaesthetists are ethically and legally required to obtain valid informed consent prior to the administration of an anaesthetic. Informed consent for treatment is one of the foundations of ethical medical practice and is a legal requirement that has its basis in section 12(2) of the Constitution and section 6 of the National Health Act No.61 of 2003.[6,7] Common law precedents also lay the foundation for informed consent in the medical setting e.g. in the case Stoffberg v Elliot CPD 148 at 149 where Judge Watermeyer remarked that any operation performed without consent is "an unlawful interference".[8] The Health Professions Council of South Africa (HPCSA) also provides clinicians with guidelines regarding informed consent.

The HPCSA guidelines state, “Patients must be given sufficient information in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. This is what is meant by an informed consent.”[9]

The Patients’ Rights Charter states, “Everyone has a right to be given full and accurate information about the nature of one’s illnesses, diagnostic procedures, the proposed treatment and risks associated therewith and the costs involved.”[10]

1.1.4 The Foundations of Informed Consent

For informed consent to be considered valid, two threshold elements need to be fulfilled first. These elements are *liberty* and *agency*.[2] *Liberty* dictates that the person making a decision and giving consent does so with full liberty (freedom) without coercion, influence or duress.[2] *Agency*, relates to the person’s mental ability to make an informed decision and grant consent.[2] Ethicists refer to it as ‘capacity’, whilst in the legal framework this is referred to as ‘competence’. However, some authors use the term interchangeably. DMC therefore critically relates to the element of agency. The standards for DMC vary greatly depending on jurisdiction and the legal framework that is applicable. South African law does set standards for capacity to consent to treatment as it relates to age (e.g. children can consent to medical treatment from the age of 12 years), but it does not dictate the standards for determining mental capacity.[11] Whilst the judgment of adequate or inadequate capacity can be legally made, the law invariably takes into consideration the *medical* assessment of capacity.[12]

1.1.5 Clinical Assessment of Decision-making Capacity

The current practice nationally and internationally is for doctors to use their own clinical judgment as to whether patients have DMC or not. In some situations, it can be quite difficult for clinicians to determine whether a patient has the capacity to consent to treatment. Appelbaum[13] suggests that there are four criteria that are applicable to determining a patient's decision-making capacity, namely:

i) the ability to understand the relevant information,
ii) the ability to appreciate the situation and its consequences,
iii) the ability to reason about the options and
iv) the ability to communicate a choice.

Whilst these criteria are helpful, they do not provide a definitive means of objectively and conclusively determining DMC. In the vast majority of cases clinicians have to use their clinical judgment to make that determination.[14]

In an attempt to formalize DMC assessments and to reduce subjectivity, structured tests have been constructed, like the MacArthur Competence Assessment Tool for Treatment (MacCAT-T).[15] However formal tests like these often require training to perform and interpret. Additionally, they may take time to administer which, in environments with large patient loads, may make them impractical to use routinely. There is no widely available, easy to perform and locally validated test of DMC in South Africa that can be considered a gold standard and as such clinicians are left to continue to use their own judgment.

Determining whether a patient has the capacity to accept or refuse medical treatment is a complex exercise. It requires that clinicians have a good knowledge and understanding of

DMC. Experts with specialist knowledge of DMC and DMC assessment, have noted that it is common for clinicians to have deficits in their knowledge or have misconceptions regarding DMC. In their study, Ganzini et al described several common misconceptions that clinicians may have which could significantly affect the validity of the DMC assessment that they make.[16]

1.1.6 Assessing DMC – Challenges from The Perspective of Anaesthetists

Anaesthetists may face unique challenges in the process of obtaining informed consent and in determining whether a patient has adequate DMC. Firstly, anaesthetists often see the patient only on the day prior to surgery or on the morning of surgery. This leaves little time for the anaesthetist to establish rapport with the patient let alone to establish a meaningful doctor patient relationship. This brief interaction may be insufficient to develop a sense of the patient as a whole and of the values that are important to the patient. Subtle changes in mental status that may result in diminished capacity may not be apparent to an anaesthetist who sees the patient only once. Secondly, anaesthetists receive little training in ethics and no training in DMC assessment. This, together with the brief window of time that is available preoperatively, makes assessment of capacity quite challenging for anaesthetists. The ethical and legal significance of this is that consent for anaesthesia may be invalidated if an anaesthetist fails to recognize a patient with impaired DMC and proceeds with the administration of the anaesthetic. This situation may result when an anaesthetist lacks adequate knowledge regarding DMC, the elements constituting DMC and the issues surrounding the assessment of DMC.

1.1.7 Significance of The Study

Since DMC is closely related to the concept of agency, it can be viewed as a critical foundational element to informed consent. DMC can be assessed formally using tests/instruments like the MacCAT-T tool[15] or DMC may be assessed informally as part of a doctor's routine interaction with a patient during which a doctor will use his/her own judgement. The latter method is the most common practice[17,18] and anecdotally this is the case in anaesthetists' practice as well. Anaesthetists' judgement regarding DMC is based on their knowledge therefore if anaesthetists' knowledge is lacking, their assessment of a patient's DMC may be flawed. Consent taken from a patient who lacks capacity would be legally invalid and ethically unsound.

1.2 Rationale for the Study

In the hospitals affiliated to the University of the Witwatersrand, anaesthetists are required to obtain informed consent from patients prior to the administration of an anaesthetic. The process of obtaining informed consent for anaesthesia is separate from that of obtaining consent for surgery. In part, this is due to the fact that the risks involved in anaesthesia (e.g. anaphylaxis, airway obstruction, malignant hyperthermia, hypotension, nerve injury related to regional anaesthesia etc) are distinct from those related to surgery.

The current practice is such that no formal DMC assessment is performed using any of the tools described in the literature. Anaesthetists use their clinical judgement alone during the pre-operative assessment to determine whether a patient has capacity to consent. The literature shows that clinicians may have limited knowledge and many misconceptions regarding DMC.[17] This raises questions around the accuracy of anaesthetists' DMC assessments. The risks involved in anaesthesia are significant and consent obtained for anaesthesia needs to be held to the highest standard. DMC, as a threshold element of consent, needs to be indisputable. However, in practice, this may not always be the case.

It is possible that poor understanding about DMC may lead to inaccurate DMC assessments by anaesthetists. This raises a question about the ethical relevance of the knowledge of anaesthetists regarding patients' decision-making capacity.

1.3 Hypothesis

As with other clinicians, anaesthetists lack significant knowledge regarding decision-making capacity. Therefore, their clinical judgment regarding patients' DMC may be poorly informed.

As such their assessment of DMC may be flawed, undermining valid informed consent for anaesthesia.

1.4 Research Aim and Objectives

AIM:

To study the assessment of patients' decision-making capacity by anaesthetists.

OBJECTIVES:

1. To normatively discuss patients' decision-making capacity from an ethico-regulatory perspective.

2. To determine anaesthetists' level of knowledge regarding patients' decision-making capacity.

3. To compare the level of knowledge of anaesthetists of different categories (according to qualification and experience) regarding patients' DMC.

4. To critically assess the ethical relevance of the level of knowledge of anaesthetists regarding patients' DMC.

1.5. Research Design

This was a normative study with an empirical component. The empirical component used a quantitative study design. It was a prospective, cross-sectional, descriptive study. With the use of a self-administered questionnaire, it aimed to describe the level of knowledge of the anaesthetists currently working at hospitals in the University of the Witwatersrand circuit (Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital, Helen Joseph Hospital and Rahima Moosa Mother and Child Hospital). The normative component of this study addressed the issue of what anaesthetists *ought* to do in their assessment of a patient's decision-making capacity, that is, should they use formal tools and tests of decision-making capacity or should they rely purely on their own judgment. In order to do this, the relevant literature was reviewed and analysed. This was sourced from, amongst others, Pubmed, Google Scholar and Jstor and the University of the Witwatersrand Library.

The findings of the empirical component of the study were then compared with the normative expectations.

1.6. Research Methods

1.6.1 Population and Sampling

All doctors from the University of Witwatersrand Department of Anaesthesia constituted the study population. Due to limited numbers of participants, convenience sampling was

utilized, and all members of the department present at the academic meetings were invited to participate in the study.

The measuring instrument was a self- administered, closed-ended questionnaire, which included demographic details and well as fifteen questions relating to decision-making capacity.

The questions are based on the findings of a study by Ganzini et al, that describe the most common misconceptions regarding decision-making capacity.[1]

1.6.2 Data Collection and Analysis

At the Department of Anaesthesia academic meetings held at the respective hospitals, an information sheet and questionnaire were handed out by an administrator. Prospective participants were invited to complete the anonymous written questionnaire. Descriptive statistics were used to analyse the data. Data was entered using a Microsoft Excel spreadsheet for analysis and analysed using SPSS Software. Chi square test was performed to test for correlation.

1.6.3 Argumentative Strategy

First, it is established that patients requiring anaesthesia are a vulnerable group and as such are at risk of harm. The principles of bioethics include respect for autonomy, non-maleficence, beneficence and justice.[11] The tension between the principles of autonomy and beneficence as they apply in the setting of DMC assessment are expanded upon. Autonomy advocates that patients make their own decisions, however, if they do make such important decisions without sufficient capacity this may hinder beneficence and limit the health care worker's ability to provide care and protection from harm.

The notion of duty is central to Kantian ethics. Clinicians have a duty to do what is in the best interest of their patients. However Kantian ethics also suggests that "ought implies can".[18] This means that what we ought to do should fall within the boundaries of what we *can* do. If doctors are unaware of their knowledge deficits in the first place, then it is unreasonable to deem their practice as a result of this knowledge deficit as falling short of what they *ought* to do.

The reliance of clinicians on their judgment alone as opposed to the use of validated tools to determine decision-making capacity is critiqued. Literature is drawn upon to describe the limits of clinical judgment. A consequentialist argument of cost versus benefit is made as pertains to the use of formal tools for DMC assessment. Whilst these tools may be of some assistance, they cost time to administer and interpret. This time may be better spent attending to more patients, particularly in the busy public sector setting. The concept of harm and its application to patients requiring anaesthesia is examined. Patients who are incorrectly judged as having DMC may consent to an anaesthetic that places them at risk of harm from the complications or adverse effects of anaesthesia. In patients with impaired capacity, the principle of non-maleficence also guides us towards protecting those patients from harm that may come about as a result of their own decisions, especially if those decisions are made without sufficient capacity. It can be argued that this soft paternalism is a duty of clinicians since it is a means of protecting patients from harm and of acting beneficently.

1.6.4 Reliability and Validity

In order to ensure reliability of the quantitative design, only closed ended questions were included in the questionnaire. In order to ensure validity, the questions used were based

on the issues raised in a previously published study by Ganzini *et al*. that lists common misconceptions regarding decision-making capacity. A group of experts analysed the research tool and provided feedback which was used to modify the questionnaire in order to ensure validity.

1.6.5 Ethics

Ethics clearance by the Wits HREC (Medical) was obtained – Clearance Certificate No. M170639 (see appendix 3). Permission was obtained from the Academic Head of Anaesthesia to perform the study (see appendix 4). Completion of the self-administered questionnaire was taken as implied consent to participate in the research project. Confidentiality was maintained since no names or identifiers were recorded on the questionnaire. Only the researcher and supervisor had access to the completed questionnaire. An administrator assisted in handing out the information sheets and questionnaires without the researcher (myself) being present, in order to avoid influencing or unintentionally coercing prospective participants since I am a senior member of the department. All questionnaires, whether or not they were completed, were then placed in a sealed box. This protected those who chose not to participate from being identified. Participants were made aware of the risk of cohort identification (since the numbers at the extreme ends of the age and experience categories were likely to be small) by pointing this out in the information sheet so that they could decline to participate in the study if they deemed it necessary to do so.

1.6.6 Research Outcomes

Since the outcomes indicate that anaesthetists' level of knowledge of DMC is poor in some areas, recommendations are made to include a module on decision-making capacity in the

undergraduate and postgraduate curricula. Additionally, a recommendation for guidelines to be drawn up to assist anaesthetists in making an assessment of patient's decision-making capacity is made.

Since there is a paucity of data in South Africa regarding clinicians' knowledge of DMC, the study may also be repeated in other disciplines and at other sites to determine whether the issue applies broadly to health care workers and not just to anaesthetists.

The outcomes will be published in academic journals and presented at congresses.

1.6.7 Problems / Limitations

Since the study focuses on the anaesthetists at the University of the Witwatersrand, the results may not indicate the level of knowledge of anaesthetists at other sites. However, since no other study of this nature has been done in South Africa, the study may be repeated at other sites to produce a more generalizable picture.

1.7 Overview of Chapters

Chapter 1: Background

This chapter provided the background to decision-making capacity and its assessment and described the research design and methodology.

Chapter 2: Decision-Making Capacity and Decision-Making Capacity Assessment

In this chapter the distinction between capacity and competence is made. The definition of decision-making capacity (DMC) and the elements that are thought to constitute DMC are expanded upon. The current assessment of DMC and tools that

have been formulated to assist in this process are described and discussed. Formal and informal assessments are compared. The literature as it pertains to doctors' knowledge of capacity is discussed.

Chapter 3: Regulatory requirements regarding decision making capacity in patients undergoing anaesthesia

In this chapter the regulatory requirements regarding decision-making capacity (DMC) is discussed. The South African legal framework and the Health Professions Council's description of DMC are discussed. The way in which the law in various countries informs capacity assessments is then described.

Chapter 4: Ethical requirements regarding decision making capacity in patients undergoing anaesthesia

In this chapter an analysis of decision-making capacity and its assessment is made using the ethical frameworks of deontology, consequentialism and principlism. The closely related issues of dignity, vulnerability and harm are discussed as well as the duty of doctors to protect patients from harm. A connection is also made between values and decision-making capacity. Finally, the ethical implications of the current practices surrounding capacity assessment are discussed.

Chapter 5: Empirical Component of Study: What is the Knowledge of Anaesthetists Regarding Decision-Making Capacity?

The significance of an investigation into the knowledge of anaesthetists regarding decision-making capacity is discussed in this chapter. An outline of the methods of the study is made and the aims and objectives are stated. This chapter also describes the development of the research instrument i.e. the questionnaire and the results of the survey are then presented.

Chapter 6: Discussion

This chapter includes a discussion of the ethico-regulatory significance of the survey findings

Chapter 7 Recommendations and Conclusion

This chapter summarises this study and recommendations are made for the improvement of knowledge of decision-making capacity amongst anaesthetists.

Chapter 2:

Decision-Making Capacity & Decision-Making Capacity Assessment

2.1 Introduction

Informed consent for treatment is a legal and ethical requirement.[7,19] A patient's ability to make their own decisions regarding their health and treatment is in turn a fundamental requirement of the informed consent process.[2] This ability is referred to as decision-making capacity (DMC). Adults are presumed to have this capacity unless there is evidence to the contrary.[9] Competence, which is a legal determination by a court of law, is a closely related yet separate entity.

This chapter commences with making the distinction between capacity and competence. The definition of decision-making capacity (DMC) and the elements that are thought to constitute DMC are expanded on. The assessment of DMC as is currently practiced is then described. Tools that have been formulated to assist in this process are discussed. A comparison between formal and informal assessments is made. This is followed by a discussion on the literature as it pertains to doctors' knowledge regarding DMC. This chapter responds to objective 1 of the study i.e. to normatively discuss patients' decision-making capacity from an ethico-regulatory perspective.

2.2 Capacity and Competence

In order to exercise their autonomy, patients must possess the capacity to make their own decisions regarding their treatment. This capacity is also a prerequisite for valid

informed consent. Decision-making capacity (DMC) therefore has serious ethical and legal implications.

In the healthcare setting the terms capacity and competence are sometimes used interchangeably. Whilst the two terms are related and may share common elements, there are distinct differences. *Capacity* is decision or task specific e.g. a patient may have the capacity to consent to a simple intervention like a physical examination but may not have the capacity to consent to a complex intervention like surgery. *Competence* refers to the ability to perform a range of activities e.g. a patient may be competent to manage their financial affairs.[20] Capacity is usually determined by a healthcare professional whereas competence is determined by the courts.

2.3 How is Decision-Making Capacity (DMC) defined?

The definition of DMC varies across the literature and across disciplines. Most definitions do however recognise that cognition or cognitive function is central to DMC.

Charland defines DMC as "the ability of healthcare subjects to make their own healthcare decisions."[3] This definition provides a general impression of what DMC is but fails to mention the cognitive elements e.g. understanding, appreciation and reasoning, that need to be present for a patient to be able to make a decision.

Appelbaum and Grisso's definition remedies this by defining decision-making capacity more specifically as "the ability to understand relevant information and to appreciate the reasonably foreseeable consequences of a decision."[19] Whilst they include a greater focus on cognitive elements like understanding and appreciation their definition does not take into consideration whether or not the decision is in

keeping with the patients beliefs and value system. In some situations, patients may experience subtle impairments in DMC. These impairments may not present with overtly diminished understanding but may result in patients making choices that are out of keeping with their usual preferences. This subtle change is demonstrated in many geriatric patients who undergo cardiac surgery and experience post-operative cognitive dysfunction. This neurological condition may be overt and easily recognised by doctors and nurses but it some cases it is subtle and is only detected by family members who recognise that their family member is not their usual self.[21]

Siegal et al state that DMC refers to "the ability of a person to utilize information regarding a proposed medical intervention in order to make a meaningful choice; that is, a choice that is congruent with a patient's preferences and values."[20] Their definition puts the patient's decision into the context of the patient's usual preferences and values.

For the purposes of this Research report, Siegal et al's definition is preferred since it addresses both the cognitive elements of DMC (the ability to utilize information to make a choice) and secondly it recognises that the decision must be meaningful, and it highlights the importance of the patient's values.

2.4 The Elements of DMC

It is generally accepted that decision-making capacity consists of four separate elements, all of which need to be present for a patient to be deemed as having the capacity to make a treatment related decision. These elements have been discussed in section 1.1.5 of Chapter 1.

This four-component model, although widely used, has been criticised for focusing entirely on the cognitive ability to make a decision. It does not factor in other important elements that may come to bear on a person's ability to make a decision e.g. a patient's values or the effect of emotional states on decision making.

Karel suggests that clarification of a patient's values regarding life is an important step in decision making and advanced planning.[22] For example, if a surgery offers an expected three years of survival but with poor functional status, a patient may value quality of the remaining years of life more highly than the actual number of years of survival that a treatment may offer. It is important for clinicians to realise how patients' values inform their decision-making process.

Additionally, Herman et al have argued that the four criteria do not include elements that relate to a patient's emotional state.[23] As an example they discuss the effect that a depressed patient's emotional state could have on their sense of self-worth. This may then affect the decisions that patients make with regard to their treatment.

There is still much debate and discussion surrounding the definition of decision making capacity. DMC is defined in various ways in the literature and the legal standards in different jurisdictions is likewise not uniform.[24,25] This lack of a standardised definition contributes to much of the debate that surrounds DMC.

2.5 Assessing Decision Making Capacity

In general, healthcare workers make implicit assessments about whether or not a patient has decision making capacity during each encounter with the patient.[26] A formal assessment of decision-making capacity is not routine or everyday practice. It

usually follows a patient's refusal of treatment or an overt change in the behaviour of a patient.

2.5.1 Intuitive vs Formal Assessment of Patients' DMC

In day to day medical practice, doctors' interactions and discussions with their patients allow them to intuitively identify patients who lack understanding or who do not display logical rational thinking.[18] They are able to use their clinical intuition or clinical judgement to identify patients who may lack decision-making capacity. In most cases e.g. a minor patient, a patient with confusion, delirium, dementia or a depressed level of consciousness, it may be easy to deem the patient as having insufficient decision making capacity and a surrogate decision maker would need to be consulted. In a few situations, however, this determination may not be as easy or intuitive and a healthcare practitioner may need to perform a more formal, objective analysis in order to determine decision making capacity or lack thereof. Barstow et al suggest instances where a formal assessment would be required.[18] These include

1. When there is an abrupt change in the patient's mental status
2. The patient refuses a beneficial treatment
3. The patient readily accepts a risky (potentially harmful) treatment without the appropriate discussion or consideration
4. Or the patient has risk factors for having an impairment in decision making capacity e.g. age older than 85 years or younger than 18 years, chronic psychiatric conditions etc.[18]

2.5.2 Instruments Used to Assess DMC

At present the most commonly used and accepted method of determining a patient's decision making capacity is the clinician's judgment.[27] In some literature this is referred to as an implicit assessment. [28] However it has been shown that there may be variability between clinicians in their assessments of capacity and a clinician's own bias may affect the capacity determination. Due to these limitations, there has recently been an increase in interest in developing instruments that could increase objectivity and inter-user reliability. These objective tests and formal methods are also referred to as explicit assessments.[28]

Moyes et al suggest that the rapidly aging populations of the world have resulted in increasing numbers of people with dementia and neurocognitive impairment and this could be a reason for the increased interest in the field of capacity assessment.[29] Additionally courts are increasingly faced with cases where wills are contested and guardianship comes into question.[29]

In their review on the objective tests of DMC, Palmer et al describe 11 instruments that are designed to test the four components of DMC.[26] Despite the large number of instruments available there is considerable discussion around their merits and shortcomings. Palmer et al raise the issue of lack of standardisation between the various instruments.[26]

2.5.2.1 Main Types of Instruments

There are two main groups of instruments. One group uses a set of standardised case vignettes. The other group uses structured or semi-structured interviews.

The first group uses a set of case vignettes that are presented to patients e.g. the Hopemont Capacity Assessment Interview uses two clinical vignettes, one involving

the treatment of an eye infection and another involving cardiopulmonary resuscitation. Patients are then asked to recount the information from the vignette, to explain the risks and benefits of the treatments, make a particular decision and explain how they came to that decision.[30] The assessor uses the patient's response to evaluate the various elements of DMC. The shortcoming of this type of instrument is that the vignettes do not necessarily correspond to the situation that the patient is currently in themselves i.e. they are merely hypothetical.

The second group of instruments uses structured or semi-structured interviews that are tailored to the patient's diagnosis and situation e.g. the MacArthur Competence Assessment Tool for Treatment (MacCAT-T).[15] The benefit of this is that it tests DMC within the patient's specific context which is valuable considering that capacity is, after all, context specific i.e. a patient may have capacity to decide about a particular treatment option in one context and lack capacity to make a decision about another more complex decision in another context. Scorings systems in some instruments allow for a final score to be calculated which can then be used to assess the degree of capacity or incapacity.

Many of the instruments that have been studied focus on the cognitive aspects of DMC. They do not consider the role that a patient's emotional state may have in their decision making. Some are of the opinion that emotions embody certain values and as such they are an important part of decision making.[31]

Examples of other tests/instruments include the MacArthur Competence Assessment Tool (MacCAT), Aid to Capacity Evaluation (ACE), Capacity Assessment Tool (CAT), Capacity to Consent to Treatment Instrument (CCTI) and Decision Assessment Measure (DAM).[27] There is currently no literature on the

validity of these instruments in the South African context. These instruments have been developed in Higher Income Countries (HIC) with English-speaking patients. As yet there are no instruments that have been developed and validated in Africa for use in patients who speak African languages and who may have significantly varying levels of literacy.

2.5.2.2 Criticism of Instruments for Testing Decision Making Capacity

The use of clinical judgement or opinion to determine a patient's decision making capacity raised concerns about a lack of objectivity and of a lack of standardisation. These concerns were addressed in the last few decades by the development of objective tools designed to assess decision making capacity. The emergence of these tools has also allowed for empirical research to be conducted in this area. These tests are by no means universally accepted and have come under criticism for several reasons.

Firstly, not all of the tests measure all of the cognitive components thought to be involved in DMC e.g. The MacCAT-T measures understanding, appreciation, reasoning and the ability to express a choice whilst the DAM does not measure appreciation at all. Similarly, the DAM measures patients' ability to retain and recall information but the MacCAT-T does not measure this element of cognition.[27]

Secondly, not all tests incorporate scenarios that are relevant to a patient's specific situation. The Hopemont Capacity Assessment Interview, for example, uses two scenarios.[24] This raises the question of how applicable those two scenarios are to a patient who is about to undergo a different procedure like an amputation, for

example, which is a more emotionally involved process than treating an eye infection.

Instruments may also differ with regard to the population that they were designed to be used in e.g. the Competency Interview Schedule is specifically developed to determine capacity to consent to electroconvulsive therapy.[31] The Measuring Understanding of Disclosure: Voluntary Hospitalisation (MUD-VH) instrument is used to determine capacity in psychiatric patients for voluntary hospitalisation.[32] This raises concerns about the ecological validity of tests when they are used in populations that differ from those in which they were developed for.

Edelstein raises concerns about the vocabulary used in various tests.[24] This would be of particular concern in a multicultural, multi-lingual country like South Africa. Tests that have been formulated with English speaking populations, who have good levels of literacy may not be applicable to patients who have not had a formal education or who speak little English.

Whilst many clinicians may not be familiar with many of the tools developed for assessing DMC, most clinicians would have come across the Mini Mental State Exam (MMSE) in their training.[33] It is a widely used test for cognitive impairment and has been used for research and clinical purposes. Many doctors erroneously use the MMSE as a DMC assessment tool, however, the MMSE has been found to lack sensitivity as a test for DMC and its use for this purpose is discouraged.[34]

Finally, from a practical standpoint, tests of capacity can be time-consuming to perform and this is especially pertinent in the public health care setting in South Africa where large patient numbers make time an especially scarce resource.[26]

2.5.2.3 Problems with the “Capacimeter” Approach to DMC Assessment

Kapp and Mossman refer to the rush to develop an objective test of DMC as an effort to develop a ‘capacimeter’.[35] They caution that the appeal of such a test must be tempered against the intrinsic problems of using *any* objective test to measure a complex phenomenon like decision-making capacity. One of the fundamental issues they raise is the lack of a standardised and widely accepted definition of DMC. They state,

“Any measurement tool at best produces results only as accurate and reliable as is the delineation of the phenomenon that it is supposed to measure. Put differently, it is impossible to properly measure X without clearly defining X.”[35]

Kapp and Mossman also add that even if such a test were developed, validated and widely accepted, it would still not eliminate the element of clinical judgement. This is because the healthcare practitioner still has to decide *which* patients require the administration of such a test in the first place. This then, would still leave room for subjectivity.

Banner suggests that a fundamental conceptual flaw in the idea that capacity can be measured objectively is the reality that capacity assessments are based on normative judgements. Even when capacity is broken down into certain cognitive elements, the person performing the test still has to decide whether the patient demonstrates or lacks the individual element that is being tested. Banner states that, “assessments of mental capacity involve an inherently normative judgement about what constitutes an appropriate or reasonable use or weighing of information, and it is by no means clear what normative standards discipline such judgements, or whether they might diverge between clinicians and patients.”

This argument lends itself to the position that capacity assessment is more of a normative determination than a threshold determination i.e. we are deciding what the norm would be for someone making a decision in that position rather than determining a score that crosses the threshold for capacity.

2.5.2.4 Is There a Place for Objective Tools in the Assessment of DMC?

In light of the above criticism, one is led to question whether there is a place for objective tests of capacity in clinical practice. Moye suggests that, "These instruments are meant to aid clinical evaluation; however, a score on such an instrument is never meant to supplant clinical judgment."[27] Several authors suggest that in much the same way as a physician would utilise several modes of enquiry when diagnosing a condition (taking a clinical history, performing a physical exam and interpreting the results of special investigations), instruments of capacity assessment should form *part* of a capacity evaluation. Edelstein cautions that the "importance of a multimethod comprehensive assessment cannot be overemphasized".[24]

2.6 Studies Evaluating Doctors' Knowledge Regarding Decision-Making Capacity

Despite the fact that there has been a significant increase in awareness and discussion around DMC, there is still a paucity of studies that examine doctors' knowledge regarding DMC. In their review of health-care professionals' knowledge, attitudes and behaviours relating to patients' capacity to consent to treatment, Lamont et al found only 23 studies involving capacity, capacity assessment and the

informed consent process, however only 5 of these studies related to capacity exclusively.[36] Of these only 2 (Evans et al. and Jackson and Warner) examined doctors' knowledge regarding capacity. None of the studies specifically assessed anaesthetist's knowledge of DMC.

Evans et al assessed the knowledge of emergency health-care workers (doctors, nurses and paramedics) regarding capacity and found that they lacked adequate knowledge in this regard..[37] Only 60% of senior house officers knew how to assess capacity. These findings are concerning since the emergency department is the first point of contact for most patients admitted to public hospitals.

Jackson and Warner assessed the knowledge of capacity amongst general practitioners, psychiatrists, geriatricians and final year medical students. They found that the knowledge of doctors, including some psychiatrists, was deficient.[38] However their study used an 8 question structured questionnaire with only two questions pertaining to capacity to consent to or refuse treatment. Of note, the two questions related to legal aspects (common law and statutory law) relevant to mental health and did not enquire about other aspects (e.g. elements of capacity, decision specific nature of capacity, who could perform such assessments etc) as the questionnaire developed for this research report has done.

More recently Young et al conducted a survey of hospital doctors and general practitioners and found that doctors had deficiencies in their knowledge.[39] Of significance was the finding that many doctors did not understand that a capacity assessment applied to a specific decision.

Some studies addressed broader concepts like doctors' knowledge regarding the informed consent process.[40,41] These studies have included a few questions related

to capacity however the majority of questions focused on informed consent itself. A limited amount information about doctors' knowledge of capacity can be gleaned from these surveys.

Whilst no study of South African doctors' knowledge regarding capacity has been published, Chima used a semi-structured interview to evaluate the quality of informed consent obtained by South African doctors.[40] The study included questions regarding capacity and when asked to rank the most important factors in assessing capacity the majority of doctors ranked level of consciousness, age and educational level as the three most important elements. These findings suggest that South African doctors may have knowledge gaps regarding capacity.

2.7 Conclusion

In this chapter the areas of debate and discussion surrounding DMC have been discussed, namely; how it is defined and what the elements are that constitute DMC. Considering that DMC is a complex and multi-faceted concept it is easy to appreciate the challenges involved in defining it. The definition proposed by Segal et al includes several important components and as such is the preferred definition based on the current understanding of DMC. The methods that are currently in use to assess DMC have been described, however, it is not clear whether they may be applied in the South African setting. The formulation of a DMC assessment tool for the local setting is an area that requires further work. Indeed, many more studies conducted in the South African public healthcare setting are required for this. Finally, this chapter has shown that based on several studies doctors, both locally and internationally, lack adequate knowledge regarding DMC and DMC assessment. The

ethical implications of this are far reaching and it is an area of medical education that requires urgent attention. Furthermore, since it impacts on the soundness of the informed consent process there may be important medico-legal repercussions. The medico-legal/regulatory requirements in this context will be discussed in the following chapter.

Chapter 3:

Regulatory requirements regarding decision making capacity in patients undergoing anaesthesia

3.1 Introduction

By providing or refusing consent to treatment, a patient exercises his or her basic human right to freedom and security of their person.[6,42] Since decision-making capacity is the gatekeeper to informed consent (and therefore to autonomy), its importance in legal and regulatory frameworks should not be overlooked. This chapter discusses the regulatory requirements regarding decision-making capacity (DMC). It explores how the South African legal framework and the Health Professions Council of South Africa describe DMC. Thereafter it examines how the law in various countries informs capacity assessments in those jurisdictions. Together with chapter 2 and chapter 4, this chapter aligns with objective 1 of the study i.e. to normatively discuss patients' decision-making capacity from an ethico-regulatory perspective.

3.2 Regulatory Requirements in South Africa

In South Africa, the Bill of Rights of the South African Constitution together with statutory and common law form the legal basis for informed consent and therefore decision-making capacity. Other regulatory frameworks like the Patients' Rights Charter and the Health Professions Council of South Africa (HPCSA) Guidelines for Good Practice in the Healthcare Professions echo these legal positions.

3.2.1 The Constitution of the Republic of South Africa

The Constitution of South Africa took effect on the 4th February 1997 and is the supreme law of South Africa.[43] Chapter 2 of the Constitution, The Bill of Rights, enshrines the fundamental rights of South Africans. Section 10 of the Constitution states, " Everyone has inherent dignity and the right to have their dignity respected and protected."[6] Additionally Section 12.2 states "Everyone has the right to bodily and psychological integrity, which includes the right to security in and control over their body;". In addressing the rights to human dignity and to bodily and psychological integrity, the Constitution speaks to the basic elements of decision making capacity.

3.2.1.1 Dignity

The Oxford dictionary defines dignity as: "The state or quality of being worthy of honour or respect."[44]

In order to honour and respect patients, their decisions about their bodies and their health must also be respected when they have intact DMC. When their capacity is impaired, their dignity is preserved by making decisions that are in their best interest and in keeping with their values. Decision making and therefore decision-making capacity are central to preserving patients' dignity. The constitution recognises that *everyone* has a right to dignity and it is important to note the value placed on dignity since it is a non-derogable right.[43]

3.2.1.2 Bodily and Psychological Integrity

As reflected in the Bill of Rights, a patient is guaranteed the right to bodily and psychological integrity. This includes the right to control over their body. Since all medical and surgical treatments including the administration of an anaesthetic, affect the body in some way it is a patient's right to decide whether to consent to or refuse therapy. This can be seen as an expression of the patient's autonomy. Section 1(e) states that everyone has the right not to be treated in an inhuman or degrading way.[6] This aspect of the right to freedom and security of the person is non-derogable and not subject to the limitations of Section 36.[43] A patient may indeed refuse medical therapy provided that they are acting autonomously and a patient may only be considered to be acting autonomously if there is no limitation such as a lack of understanding.[45] Since understanding is a key component to DMC, it can be appreciated that DMC is a threshold element to having "control over their body". In circumstances where capacity is impaired, the control of the person's body, with respect to treatment, is placed in the hands of a surrogate decision maker who then has the duty to act in the patient's best interest.

3.2.2 The National Health Act 61 of 2003[7]

The National Health Act provides the framework for a South African healthcare system and it aims to realise the rights set out in the Constitution.[7] Section 7 of the Act addresses the issue of informed consent and Section 8 addresses participation in decisions.[7]

Section 8 (b) of the Act states that

"A user who is capable of understanding must 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."[7] In addressing the issue of 'understanding' in the consent process, the Act can be seen as referring to understanding as an element of DMC.

As discussed previously in Chapter 2, section 2.3, understanding of information is a vital component to decision-making capacity.[19] Section 7 (1) of The National Health Act stipulates that " a health service may not be provided to a user without the user's informed consent."[7] Additionally in section 7(3) the Act states that " "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." Despite mentioning capacity, the Act does not define what it considers "legal capacity". The Act does however place an emphasis on the *understanding* of the user (patient) and the user's (patient's) participation in the decision regarding the health service.

Health care practitioners should guard against deeming a patient as lacking in capacity if their lack of understanding stems from language and literacy issues. Sessums et al refer to this as "pseudo-incapacity".[5] The National Health Act takes cognizance of this stating in Section 6(2) that "The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy."[7]

3.2.3 The Mental Health Care Act 17 of 2002[46]

The Mental Health Care Act 17 of 2002 replaced the Mental Health Act of 1973.[47] The new Act was welcomed by most as having a more patient centred approach to health care and was founded on the relevant WHO principles.[48] The main purpose of

the Act is to regulate mental health care services in South Africa.[49] Amongst other things, the Act provides direction on the provision of healthcare services to persons who have impaired capacity as a result of mental illness.[49] The Act makes reference to users (patients) who are "incapable of making an informed decision" (Section 32(c)) but fails to clarify how this incapability is defined or determined. The Act is therefore of little use when seeking guidance on how to assess a patient's decision-making capacity.

3.2.4 The Patients' Rights Charter

The National Department of Health has recognised the historical violation of the rights of most South Africans to health care services. As such it developed the Patients' Rights Charter which sets the standard for health care in South Africa.[10].

Section 2.8 of the Charter reiterates the National Health Act's provisions regarding informed consent and section 2.9 addresses the patient's right to refuse treatment.[10]

Health care workers should be cautious in respecting the right to refuse treatment if the patient lacks decision making capacity. This highlights the need for appropriate DMC assessment so that patients who lack sufficient capacity are identified and subsequently protected from the decisions that stem from incapacity which may endanger their health. The scenario of the agitated or confused patient who refuses a life or limb saving surgery is not a rare situation.[50] Such a patient without capacity needs protection from their refusal of treatment.

3.2.5 Health Professions Council of South Africa (HPCSA) Guidelines

The HPCSA is a statutory body that regulates healthcare professionals. The Health Professions Act 56 of 1974 sets out the terms for the establishment of such a regulatory body whose regulatory mandate includes the governing of the activities of healthcare professionals and the maintenance of standards of practice.[51]

The HPCSA Guidelines for Good Practice in the Health Care Professions goes a step further than other regulatory documents in recognising the importance of DMC as a separate but related concept to informed consent. Section 8 of Booklet 4 deals with establishing capacity to make decisions with section 8.1 addressing specifically the assessment of capacity.[9]

These guidelines advise HCW that every adult is presumed to have decision making capacity unless it can be shown that they lack understanding.[9] Like the National Health Act[7], these guidelines highlight the importance of 'understanding' as it pertains to capacity.[7] However the guidelines are silent on other components of DMC like appreciation and reasoning.[9]

The guidelines do caution that a seemingly irrational choice (or refusal) of treatment is not evidence of a lack of capacity rather it may be an opportunity to review the information with the patient. The guidelines however stop short of defining the elements of DMC and neither do they advise on how it should be assessed except for guiding the HCW to seek the advice of the appropriate professionals.

"9.3 Where health care practitioners need to assess a patient's capacity to make a decision, they should consult the guidance issued by the relevant professional bodies."[9]

Whilst I do not disagree with the advice of the guidelines i.e. seeking advice from professionals, seeking advice should occur *after* a capacity assessment is performed

or attempted. Directing doctors to immediately seek advice seems to relinquish them of their responsibility of knowing how to assess capacity. Doctors are not directed to seek advice if they need to obtain informed consent - it is understood that that is a basic skill that all doctors should have. A basic capacity assessment is even more fundamental, in fact it *precedes* the informed consent process. The guidelines should at least provide some guidance as to how to perform a capacity assessment and then suggest that in equivocal cases professional advice should be sought.

Of note is that the guidelines recognise that capacity in some patients may not be constant i.e. a patient's cognitive functions may change over the course of a few hours to a few days as is seen with some forms of dementia. This is referred to as 'fluctuating capacity'. In this situation the guidelines advise that the patients should be provided with assistance to reach a decision, i.e. there is a positive obligation on practitioners to expound on the agency component of autonomy in these patients.

On a practical note the guidelines advise that while a patient does possess capacity the HCW should document significant portions of the consultation including the patients views on issues (section 9.2.2 and 9.2.3). This should be done at regular intervals to be certain that the patients views are consistent and reliable. In the event of a change in mental status these notes may be referred to in order to assist HCWs or surrogate decision makers.

3.2.6 Common Law Application to Decision Making Capacity

In the case of *Castell* vs *De Greef* (1994), a patient underwent a prophylactic mastectomy that was complicated by tissue necrosis. The claim by the patient was

that the possible complications of the procedure were not fully disclosed by the surgeon and as such the consent for the surgery was not fully informed. The court found in favour of the plaintiff. Whilst the case is considered the locus classicus in South African law for the issue of informed consent and disclosure, the findings by Judge Ackerman are also relevant to the discussion on decision making capacity.

The judge made reference to Van Oosten and found that “For consent to operate as a defence the following requirements must, inter alia, be satisfied:

a) the consenting party 'must have had knowledge and been aware of the nature and extent of the harm or risk';

b) the consenting party 'must have appreciated and understood the nature and extent of the harm or risk';

c) the consenting party 'must have consented to the harm or assumed the risk';

d) the consent 'must be comprehensive, that is extend to the entire transaction, inclusive of its consequences'.”

It is notable that the judge’s statement makes reference not only to the issue of ‘understanding’ but also of ‘appreciation’. This stands to separate the ability to understand from the ability to appreciate, the latter being the ability to apply the understanding of the facts to one’s own life and situation. This is in keeping with the four component model of decision making capacity as described by Appelbaum and Grisso which considers appreciation a separate and necessary component of DMC.[19]

3.3 Regulatory Requirements in Other Countries

In the following section the regulatory requirements in other countries, as they pertain to decision-making capacity, is examined.

3.3.1 Kenya

Both Kenya and South Africa are members of Africa Medical Association (AFMA). In addition to being countries on the African continent both share a history of British colonisation and as such have inherited certain aspects of British law. Both countries also have many healthcare issues in common (e.g. HIV/AIDS and other infectious diseases).[52]

In Kenya, section 8(2) of the Health Act No.21 of 2017[53] states,

“The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.”

Whilst this may appear similar to section 8(b) National Health Act 61 of 2003[7], the Kenyan Act narrowly focuses on the understanding of language. The South African Act implies understanding in general and as such can be interpreted as the cognitive ability to understand something in general and not merely understand something as described in a particular language.

Additionally section 9(3) of the Health Act No.21 of 2017[53] states,

“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 provided for in section 8 of this Act.”

However, their courts have not defined legal capacity and have often relied on medical opinion regarding legal capacity.[54]

3.3.2 United States of America

US law shares an important commonality with South African law in regard to decision making capacity. Both jurisdictions suggest that decision making capacity is implied as being present in all adults unless otherwise proven.

In their landmark publication, Appelbaum and Grisso recognise the variation in legal standards regarding decision-making capacity from state to state.[19] They note that the various legal standards fall into one or more of the four categories that form part of the four component model of DMC i.e. understanding, appreciation, reasoning and communicating a decision. These four components or core capabilities have been derived from US case law.[55]

Similar to the South African context, it has been suggested that the 'understanding' component of DMC is the one that is most often mentioned in US case law and statues.[19] It is also noted that whilst the 'appreciation' component is given much less attention it is distinct from 'understanding'.

In the case of *Lane* vs *Candura* in Massachusetts, 77 year old Mrs Candura was diagnosed with a gangrenous leg that required a lifesaving amputation which she had refused.[56] Her daughter, Ms Lane appealed to the courts for guardianship so that she could consent to the surgery. The courts found in favour of Mrs Candura stating that despite the fact that the patient's decision may be 'unfortunate', the court did not feel that it was the decision "of a person incapable of appreciating the nature

and consequences of her act." The court's ruling gives weight to the ability of the patient to appreciate the consequences of their decision.

3.3.3 The United Kingdom

South Africa, being a former British colony, has incorporated a significant portion of British law into its own legal system. As such there are many similarities in South African and British law. However, the Mental Capacity Act of 2005, which is applicable in England and Wales does not have a comparable South African piece of legislation.[57]

The Mental Capacity Act of 2005 is considered by many to be a landmark piece of legislation.[57] Prior to the Act, the courts approached issues relating to capacity from the standpoint of common law. Whilst the Act echoes the South African and American idea of a presumption of capacity in adults, the Act differs in that the age of capacity is 16 years in England and Wales. It also makes specific mention of the ability to understand. According to the Act, lack of capacity is characterised by the " inability to understand, retain, use, or weigh information relevant to a decision or to communicate a choice."[57]

In Scotland, the Adults with Incapacity Act of 2000, defines a lack of capacity in the following way:

" "incapable" means incapable of—

(a) acting; or

(b) making decisions; or

(c) communicating decisions; or

(d) understanding decisions; or

(e) retaining the memory of decisions,"[58]

Part 5, section 47 (1) a states that the Act applies in situations where the physician who is primarily responsible for the patient " is of the opinion that the adult is incapable in relation to a decision about the medical treatment in question;".[58]

Like the Mental Capacity Act of 2005, this Act recognises the age of capacity as 16 years. It mentions 'understanding' but not 'appreciation' and states that incapable means being incapable of making a decision but does not expand on this. This is open to being interpreted as being a component of 'reasoning' but this is not clear.

Both the Mental Capacity Act of 2005 and the Adults with Incapacity Act of 2000 are entire pieces of legislation that address the issue of capacity.[57,58] This recognises and highlights capacity as an issue that warrants legislative attention. It can therefore be viewed as a significant advancement in patients' rights advocacy. There is no comparable legislation in South Africa.

The Mental Health Care Act 17 of 2002 regulates mental health care in South Africa.[46] Section 26 of the Act states,

"Subject to section 9(l)(c), a mental health care user may not be provided with

assisted care, treatment and rehabilitation services at a health establishment as an

outpatient or inpatient without his or her consent, unless at the time of making the application--

(i) there is a reasonable belief that the mental health care user is suffering

from a mental illness or severe or profound mental disability, and

requires care, treatment and rehabilitation services for his or her health or safety, or for the health and safety of other people; and

(ii) the mental health care user is incapable of making an informed decision on the need for the care, treatment and rehabilitation services."

The Act however does not explain what "incapable of making an informed decision" means or how this incapacity is determined. Therefore, the Act falls short of the guidance provided by legislation in the United Kingdom.

3.3.4 Commonwealth Countries

Canada, Australia and New Zealand share a history with South Africa of once being part of the British Empire. These former British colonies and provinces have all inherited strands of British law that they have incorporated into their legal frameworks. The following is a description of the regulations as they pertain to capacity in these countries.

In Canada, according to the Law Commission of Ontario, there are several descriptions of capacity across the ten provinces of Canada, however, they share the common elements of 'understanding and appreciation'.[59] Whilst no mention is made to the capacity to reason, the courts do value the process of the decision-making over the actual decision that has been made and as such one is led to assume this implies that the rational processing of the facts and how they apply to one's situation is a vital part of DMC.

In Australia, as in South Africa, adults are presumed to have decision making capacity to consent or refuse treatment. Tasmania's Mental Health Act of 2013[60] states,

"7. Capacity of adults and children to make decisions about their own assessment and treatment

(1) For the purposes of this Act, an adult is taken to have the capacity to make a decision about his or her own assessment or treatment (*decision-making capacity*) unless a person or body considering that capacity under this Act is satisfied that –

(a) he or she is unable to make the decision because of an impairment of, or disturbance in, the functioning of the mind or brain; and

(b) he or she is unable to –

(i) understand information relevant to the decision; or

(ii) retain information relevant to the decision; or

(iii) use or weigh information relevant to the decision; or

(iv) communicate the decision (whether by speech, gesture or other means)."[60]

With the exception of the US, Tasmania's legislation on DMC appears to be the most comprehensive in terms of specifying the elements of DMC. It does vary slightly with regard to the U.S criteria as stated by Appelbaum in that 'appreciation' is not mentioned but retention of information is mentioned. This is also a contrast to the South African legislation which only mentions the understanding component of DMC and not any of the other components.[7]

In New Zealand, the Code of Health and Disability Services Consumers' Rights neither defines decision-making capacity nor advises on the legal standards for capacity.[39]

However, section 5 of the Protection of Personal and Property Rights Act of 1988 states that,

"For the purposes of this Part, every person shall be presumed, until the contrary is proved, to have the capacity—

(a) to understand the nature, and to foresee the consequences, of decisions in respect of matters relating to his or her personal care and welfare; and

(b) to communicate decisions in respect of those matters."[61]

In this aspect, both the South African and New Zealand legislation are somewhat limited when compared to the more extensive description of capacity that the Tasmanian Mental Health Act affords.[60]

3.3.5 Brazil

The economies of Brazil, Russia, India, China and South Africa have collectively been referred to by the acronym BRICS.[62] Like South Africa, Brazil has had to deal with the combined challenges of poverty and HIV.[63]

In Brazil, the Consumer's Defence Code was put into effect in 1997. In terms of this code the patient is considered to be a consumer of a service and the physician is considered to be a service provider. This view of the medical profession as mere

service providers has created strain between the courts and medical associations in Brazil.[64] According to Dantas, “The patient needs not only to receive, but also to understand the information that is being conveyed. Information without comprehension is legally void…” [64]

It would therefore appear that a gap exists in Brazil’s regulatory framework in terms of recognizing the importance of decision-making capacity.

3.4 Conclusion

The South African regulatory framework is notable amongst other countries that share similar economic and healthcare challenges like Brazil and Kenya in that it recognises and makes specific mention of the value of patients’ understanding in the informed consent process. As discussed in Chapter 1, Section 1.1.5, understanding is an important element of decision-making capacity. This is a step in the right direction especially when compared to countries like Brazil and Kenya. Legal reform, however, is still necessary if decision-making capacity is to be elevated in importance within the legal framework.

The United Kingdom has made a commendable advance in this aspect by passing the Mental Capacity Act of 2005.[57] This Act was specifically formulated to address the issue of capacity and in doing so it rightfully highlights the importance of capacity in legal discourse.[57]

In order to construct a more complete legal approach to decision making capacity, South Africa should take direction from the US and from Tasmania’s Mental Health

Act of 2013[60] which mention not just understanding but other important elements of capacity like the ability to retain and weigh information and then to communicate a decision.

It is understandable that the law can only aspire to be completely comprehensive when addressing a complex and as yet incompletely defined notion as decision-making capacity. It is therefore imperative that the law draws on ethical principles to inform decisions in these matters. These ethical requirements will be discussed in the following chapter.

Chapter 4:

Ethical requirements regarding decision making capacity in patients undergoing anaesthesia

4.1 Introduction

A person's capacity to make decisions about their bodies and their health is not only an extension of the basic human right to liberty but an expression of the fundamental ethical principle of autonomy.

This chapter analyses decision-making capacity assessment using the ethical frameworks of deontology, consequentialism and principlism. The closely related notions of dignity, vulnerability, harm and values are discussed as well as the duty of doctors to protect patients from harm. This is followed by a discussion on the ethical implications of the current practices surrounding capacity assessment. This chapter responds to objective 1 of the study i.e. to normatively discuss patients' decision-making capacity from an ethico-regulatory perspective.

4.2 Autonomy and Decision-Making Capacity

Autonomy refers to self-rule that is free from interference and it allows for meaningful choices. [65] It has been suggested that decision-making capacity is the gatekeeper of autonomy. This is because a person who lacks capacity by definition cannot act autonomously. According to Beauchamp and Childress, "a person of diminished authority is in some material respect controlled by others or incapable of deliberating

or acting on the basis of his or her desires and plans...Mental incapacitation limits the autonomy of a person with a severe mental handicap".[2] As such DMC and autonomy are inextricably linked.

4.3 Ethical Perspectives: Autonomy, Decision-Making Capacity and The Duty of Doctors

In order to present a balanced view of autonomy, decision-making capacity and the duty of doctors, each concept is examined from the viewpoint of the different and relevant ethical frameworks, namely deontology, consequentialism and principlism.

Deontology is a philosophical framework that is grounded in the idea of duty. Its primary advocate was Immanuel Kant and it is often referred to as Kantianism. Kant argued that all people were worthy of respect since human beings possessed the ability to reason and think rationally.[66] Kant placed the highest value on human rationality and by extension autonomous rational action. Additionally, Kant stated that one ought to act in a way that one would will all others to act i.e. the Formula of Universal Law.

Kantian ethics dictate that our actions should be in keeping with our duties. The practice of medicine is largely guided by duty. These duties precede Kant's ideas and can be traced as far back as Hippocrates e.g. the duty to help the sick. Deontology considers the morality of an action purely on the basis of the action itself rather than the outcomes that the action would produce. For example, deontology considers lying to be unethical in all situations irrespective of the circumstance. According to deontology lying, even to spare someone's feelings would be considered unethical. Deontology is therefore useful in highlighting the ethical importance of the individual

duties of doctors, but it proves to be less useful in situations where duties may be in conflict with each other. Deontology affirms the importance of autonomy. Its focus on the ability of humans to think rationally highlights the notion that capacity is indeed the gatekeeper to autonomy.

Since it is a doctor's duty to protect the sick and vulnerable, failing to recognise incapacity in a patient would equate to a failure of doctors to fulfil their roles and perform their duties. On the face of it, a Kantian analysis might seem to condemn this failure on the part of doctors. However, Kant also put forward the idea that what we *ought* to do should be within the realm of what we *can* do – "Ought implies can." This suggests that we cannot be held accountable for not doing something that is beyond our capabilities. Most doctors do not receive adequate training in bioethics and those curricula that do incorporate bioethics training focus largely on broad elements like informed consent without examining deeper concepts like decision-making capacity. As such, doctors would not be aware that they lack adequate knowledge regarding DMC i.e. they do not know that they do not know enough. It is because of this that a Kantian perspective would not hold them accountable for failing to recognise all patients who lack DMC. However, if doctors are made aware that their knowledge in a critical area of practice is deficient, then they have a moral obligation to address this deficiency so that their practice changes.

As discussed in Chapter 2, section 2.5.2 there has been increasing interest in developing objective tests of decision-making capacity. These tests are largely used in research settings and are not widely validated for use in the general population. This lack of universality indicates that Kantian ethics would not endorse the use of objective tests of decision-making capacity in their current form.

Consequentialism judges an action based on the outcome or consequences of that action. Utilitarianism is a specific type of consequentialism in which the amount of good that has been brought about by an action determines the moral status of that action.[67]. Within this ethical framework, an action is ethical if it brings about good consequences i.e. the end justifies the means. Utilitarianism may then be a more useful framework in the healthcare setting since every patient and every situation is different and instead of imposing universal rules, utilitarianism guides us to examine the outcome of our actions. This is in keeping with the tenet of acting in the best interest of our patients.

It stands to reason that doctors who lack knowledge about DMC are bound to make errors in its assessment resulting in poor outcomes for patients. It is not in the best interest of patients for doctors to lack knowledge about capacity as this would inevitably result in harm whether or not the doctor's intention was good. Since utilitarianism deems the end result of an action to be the most important determinant of the morality of the action, it is irrelevant whether doctors knew that they lacked knowledge in the first place.

Ultimately, if their actions, based on deficient knowledge, resulted in a poor outcome for the patient then utilitarianism holds them accountable. However, the usefulness of utilitarianism as a moral guide in this sort of situation must be questioned. Utilitarianism can only function as a guide on a presumption that the agent is aware of the consequences of the deliberated actions. Additionally, the agent must be able to assign a valuation of good or not good to the various actions that are being considered. Finally, the agent chooses which action brings about the most good and therefore the agent's actions are considered moral. If we take away the agent's knowledge of the consequences how is the agent supposed to weigh the options and decide on what is most good? Therefore, in situations where doctors do not have knowledge of DMC

and its correct assessment, they cannot be fully aware of which action is good and which is harmful. As such, it can be argued that utilitarianism cannot be called upon to guide actions in these circumstances.

On addressing the issue of whether or not doctors should be utilising objective, standardised tools, a utilitarian argument would likely not be in favour of such a practice since the time cost of using such tools (i.e. taking more time to train doctors on how to use such instruments and the time taken to perform assessments using these instruments) outweighs the benefit. This time would be better spent on taking care of more patients resulting in a greater amount of good.

Principlism is arguably the most widely used framework in the Western world for addressing bioethical dilemmas. It is based on the four principles namely respect for autonomy, beneficence, non-maleficence and distributive justice. Situations where DMC is in question reveal the tension between autonomy and beneficence. Since Western philosophy highly values individualism, it is no surprise that respect for autonomy is considered to most important of the four principles. Beauchamp and Childress, who originally developed this approach, emphasise that an impairment in capacity limits a person's autonomy.[2] In such situations, a doctor is duty bound to act beneficently and in the patient's best interest since the patient cannot act in their own interests. The correct application of principlism hinges on a doctor's knowledge of DMC since without it a doctor would not be able to determine which principle i.e. respect for autonomy or beneficence should guide action in any particular case.

A lack of knowledge regarding DMC would mean that doctors may fail to identify patients who cannot make important decisions for themselves as such patients could erroneously be left to the consequences of their own poorly formed decisions.

Alternatively, a person may be mistaken as lacking in capacity and consequently be deprived of their autonomy. These ethically grave outcomes highlight the importance of doctors' knowledge regarding DMC.

Non-maleficence is an important principle that instructs doctors to cause no harm.[2] Doctors are advised that in order to prevent negligence and harm, they are to maintain good standards of practice.[68] Presently, the standards of decision-making capacity assessment by doctors require significant reform. As discussed in Chapter 3, section 3.2, South African law and the HPCSA Guidelines are not comprehensive in describing what capacity is or how it should be assessed. Therefore, if doctors have deficits in their knowledge they cannot be seen to be falling short since the standards currently in effect are themselves wanting. From the point of view of principlism, doctors cannot be seen to be acting negligently (and therefore in violation of the principle of non-maleficence), if they have deficits in their knowledge regarding DMC and DMC assessments.

Objective tools to assess DMC have several flaws as discussed in Chapter 2, section 2.5.2.2. It is doubtful that the widespread use of these tests in clinical practice would allow for a resolution of tension between autonomy and beneficence. Firstly, we have yet to develop a tool that would be widely applicable to all populations and that could be used in most situations. Secondly, a doctor needs to have knowledge of what capacity entails in the first place in order to recognise a situation where a patient's capacity is questionable. A doctor with poor knowledge regarding DMC may fail to recognise when to use the tool. As it stands, none of the tools available are quick and easy to use. It takes time to train the user and time to administer. From the point of view of distributive justice i.e. the fair allocation of resources, it would be unjustifiable to strain the resource of doctors' time in the already overburdened public sector.

In summary, Kantianism and Principlism would not hold doctors individually accountable for their lack of knowledge or for their actions based on the current standards of training. The central argument being that doctors are not aware of their knowledge deficits since their training in this respect was lacking. It is also important to note that interest in examining, defining and assessing DMC is a relatively recent phenomenon worldwide and so it is likely that new information and understanding has yet to filter down to medical educators and ultimately to doctors on the ground. Consequentialism, and specifically utilitarianism fails to be a useful guide in this situation since it requires doctors to have knowledge in the first place.

The routine use of objective tests is not supported by any of the ethical frameworks mentioned since the tools that are currently available are themselves flawed in many ways. However, not assessing patients clinically for DMC when necessary to do so could negatively impact their dignity.

4.4 Human Dignity

Whilst the Oxford dictionary defines dignity as “The state or quality of being worthy of honour or respect”, the concept of *human* dignity has proven to be more difficult define. [44] Lebech states that when the words ‘human’ and ‘dignity’ are used together, it refers to the highest value of human beings and that the term is a presupposition i.e. it is an intrinsic quality of human beings.[69] Steinmann states that the term human dignity refers to “to man's unique qualities that are priceless and irreplaceable and constitute every individual's inherent dignity.”[70]

Autonomy and human dignity are intimately linked. Kant believed that the highest expression of human rationality was autonomous action.[71] He believed that the special value of human beings was as a result of their rationality thus tying together autonomy and human dignity. Indeed, if a person is to be valued and their dignity to be respected then allowing the person to make choices regarding their own wellbeing maintains their self-worth which is inherent in human dignity. Likewise, if patients are denied the opportunity to have a say in their medical treatment, that is, to either consent or refuse, then this becomes a violation of their dignity, and they are harmed ethically. As such an assessment of a patient's decision making capacity (DMC) should not be taken lightly since an erroneous finding of *lack* of DMC would be an infringement of the patient's autonomy and may amount to a dignity violation. Furthermore, violating human dignity would result in an erosion of the principle of non-maleficence.

4.5 Vulnerability

There has been considerable discussion around the definition of vulnerability in the bioethical context. The Council for International Organisations of Medical Science (CIOMS) defines the vulnerable as those who are "relatively or absolutely incapable of protecting their own interests".[72]

According to Rogers et al, vulnerability is defined as "being at increased risk of harm, and/or having a decreased capacity to protect oneself from harm."[73]

Dhai has suggested that since all humans may, at some point, be unable to protect themselves from harm, vulnerability may be an intrinsic quality of being human.[74]

Despite this certain groups or individuals may be considered particularly vulnerable.[74]

The issues of harm and the lack of capacity to protect oneself are therefore closely linked to the idea of vulnerability. It is believed that when patients are faced with a decision regarding the management of their medical condition amongst the considerations are the perceived benefits and perceived barriers.[75] These considerations form part of the Health Belief Model which was developed in the 1950s and is used to explain the decisions that patients make regarding their condition and its treatment.[75] Patients are taught to consider their condition and its effects and weigh this against the proposed treatment and its costs or risks.

Patients who lack decision making capacity cannot appreciate these risks and therefore cannot decide whether the potential benefit from the treatment (i.e. anaesthesia and surgery for the purposes of this research report) is worth those risks. When patients are deemed as lacking in decision making capacity to consent to treatment, their treatment decisions are placed in the hands of a surrogate decision maker who needs to act in the patient's best interest based on their knowledge of the patient's usual beliefs, preferences and values.[76] However, in acting for another person, the surrogate decision maker needs to make several assumptions on what they think the patient *would* have chosen if they had capacity at the time.[77] As such there is always the possibility that a surrogate decision maker, despite their best intentions, may make a choice that is inconsistent with what the patient would have made. It is for this reason that pronouncements of incapacity need to be done with the utmost of skill, knowledge and care.

Similarly, patients who have cognitive deficits may refuse life or limb saving anaesthesia and surgery. As a result of acute confusional states or dementia, patients may become uncooperative, refusing all medical treatments.[78] Health care workers who do not appreciate that the patient lacks capacity to refuse may therefore be abandoning patients to the patient's own irrational behaviour. These patients do not have the ability to act in their own interests and are at risk of harm resulting in them being vulnerable. In the same way, a small child who lacks capacity may be reluctant to undergo surgery but his or her parents understand that the child's refusal is on the basis of a lack of understanding and appreciation of their medical condition and their need for treatment. In such a circumstance, the parent consents on behalf of the child, acting in the child's best interest.

Incorrectly labelling a patient as lacking in decision making capacity therefore places them at risk of complications from anaesthesia and surgery that they otherwise may not have accepted. In erroneously transferring the power to make treatment decisions to another person, the patient is then stripped of their ability to protect themselves and to act in their own best interests and are therefore vulnerable.

4.6 Duty to protect the vulnerable

As discussed above, patients who have impaired DMC can be considered to be vulnerable and at risk of harm. The principle of beneficence requires that doctors act in the best interests of patients. According to the HPCSA, health care professionals should "always regard concern for the best interests or well-being of their patients as their primary professional duty".[79] Similarly the General Medical Council of the UK states that the primary duty of a doctor is to make the care of their patients their first

concern.[80] Moreover, the Declaration of Geneva (commonly known as the modern day version of the Hippocratic Oath affirms that "…the health and well-being of my patient will be my first consideration" and "I will respect the autonomy and dignity of my patient."[81]

Therefore, it is clear that it a doctor's duty is to protect their patients from harm, this includes harm that may arise as a consequence of the poor decisions the patients themselves may make if they lack adequate DMC. This form of soft paternalism is often thought to be a part of a doctor's duty to care for and protect their patients.

With regard to the vulnerable, Hurst states that they have an even greater claim to protection.[72] In order to protect the vulnerable, health care workers need to first identify them and their vulnerabilities. Recognising patients who have impaired DMC is the first step in protecting them from harm. Therefore, the DMC assessment takes on a moral weight, in addition to being purely a clinical assessment.

4.7 Harm and the Duty to Protect

Due to the risk of harm inherent to medical treatment, it is imperative that the patient possesses the capacity to understand what the risks are and to appreciate the risks that apply to their situation. Should patients make decisions regarding healthcare (either to proceed with a particular course of treatment or indeed to refuse that treatment) without sufficient capacity they potentially place themselves at risk of harm – a risk that they may not have found acceptable if they possessed sufficient capacity.

It is the duty of the healthcare professional to appreciate when a particular patient does not have sufficient capacity to understand, appreciate and reason regarding a

healthcare decision and to protect them from this incapacity, indeed not to do so would be to abandon patients to a false assumption of their autonomy.

Legally and ethically we appreciate that children (especially those less than 12 years old as indicated by the Children's Act 38 of 2005[11]) are in the process of development as pertains to their autonomy and decision-making capacity.[82]This appreciation compels parents to act in the best interests of children. In certain circumstances this responsibility falls to healthcare workers. In the same vein, an adult patient who lacks capacity (due to any pathology that affects their mental functioning) may find themselves in a situation that requires a treatment decision. A healthcare worker who fails to appreciate that the patient lacks capacity may be placing the patient in harm's way by allowing the patient to make treatment decisions. From a legal standpoint consent given by a patient who lacks capacity is invalid as discussed in Chapter 3, section 3.2.2. It is for this reason that assessments of decision making capacity are of ethical and legal importance.

4.8 Values and Decision-Making Capacity Assessment

According to the Collins English Dictionary values are "the moral principles and beliefs or accepted standards of a person or social group."[83] The World Medical Association (WMA) describe compassion, competence and autonomy as the foundational values to medical ethics.[84] Values can be described as that which motivates us to act correctly. In the ethical domain they are what we strive to achieve. Due to the nature of the medical profession, the values upon which medical practice is based have particular ethical relevance. According to the WMA, doctors, more than most other professionals, are expected to "exemplify them to a very high

degree."[84] In correctly and appropriately performing DMC assessments, doctors demonstrate the value they place on competence and patients' autonomy. A doctor performing such an assessment must take into consideration the patient as a whole i.e. not just their cognitive abilities, but their beliefs, attitude and indeed their values. Seeing the patient as a whole person, and not just identifying them by their illness, can be seen as a fundamental appreciation of their humanity and in doing so their doctors demonstrate the value of compassion.

4.9 How Capacity Assessments Are Made – Current Practice

At present most doctors assume that patients have capacity to consent to treatment based on their interactions with patients and by applying their clinical judgement and intuition. Doctors obtain a general impression of whether or not a patient has decision making capacity during typical clinical encounters.[85] This is often referred to as an implicit assessment. In their study of Swiss physicians, Herman et al found that most physicians undertake an implicit assessment of patients' capacity.[28] The use of specific tools to assess DMC (as discussed in Chapter 2, section 2.5.2) like structured questionnaires or scoring systems (sometimes referred to as explicit assessments) is not widespread. Only 2.5% of physicians in the Hermann et al study used specific instruments to assess DMC. This may be due the fact that as a formalised field of research, capacity assessment is relatively new and such tests have not yet migrated from the research realm to that of clinical practice.[29] Additionally healthcare workers may not even be aware that such tools exist. In their survey conducted in Croatia, Novosel et al found that only 1.7% of primary care physicians had ever used a DMC specific tool to perform a capacity assessment.[86] In certain circumstances some health

care workers rely on cognitive tests like the Mini Mental Status Exam (MMSE) to determine DMC.[33] In his evaluation of the informed consent process amongst South African doctors, Chima found that in difficult cases 72.6% of doctors said that the MMSE was their first choice amongst objective measurement tools of capacity. Whilst cognition does play a role in decision making there are other important factors that affect DMC that are not tested by the MMSE. Therefore the MMSE cannot be relied on solely to determine DMC.[5] Formal tests of DMC are also time consuming – they require specialised training in order to be administered correctly and they require additional time to be used and interpreted as discussed in Chapter 2, section 2.5.2.2 This additional time requirement may be prohibitive in the South African state healthcare sector where large patient numbers are the norm.

4.10 Clinical Judgement and Intuition in Medicine

Many experienced health care workers would attest to the fact that their clinical diagnoses are sometimes informed by intuition and clinical judgment.

Intuition has been referred to as having understanding or coming to a judgement without a rationale.[87] A doctor interacting with a patient encounters a multitude of non-verbal and sensory cues that may be subliminally integrated to form an impression of the patient.[88] Some studies have found that in some circumstances, when compared to analytic reasoning, intuitive decision making led to better performance.[89,90] In their systematic review, Sanders et al found that clinical prediction rules were rarely superior to clinical judgement in terms of diagnosing several medical conditions.[90]

However, it is interesting to note that clinical judgement and intuition may not fare as well when it comes to detecting lack of DMC in a patient. Studies have shown that physicians often fail to recognise when a patient lacks DMC.[5] Burton et al found in their study that a significant proportion of patients receiving hospice care had undetected cognitive impairment that was significant enough to raise concerns about DMC.[91] In their study, Sessums et al found that physicians only detected diminished DMC in 42% of cases.[5] Certain patient populations, like the elderly and those with psychiatric illnesses, also pose unique challenges to physicians and studies have shown that doctors have difficulty in assessing DMC in these patient populations.[31]

However, one needs to question why clinical judgement may not have been sufficient to detect impairments in capacity in the studies performed. Could this be because clinical judgement is only as good as the knowledge base that informs it? It is known that a doctor's ability to come to a proper diagnosis is dependent on the doctors knowledge in the clinical area of concern.[92] If knowledge is deficient then it stands to reason that the diagnostic process would be flawed. Several studies have confirmed that doctors do indeed lack knowledge regarding important aspects of DMC and DMC assessment.[16,38,39] An extensive search of the literature reveals that no study has as yet been undertaken that examined the effect that capacity related education would have on doctors' subsequent ability to perform a capacity assessment.

4.11 Conclusion

This chapter has analysed capacity assessment and the duty of doctors through the lens of deontology, consequentialism and principlism. It has shown that doctors have a duty to protect patients from harm since patients are considered to be vulnerable.

Correctly and appropriately assessing patients' DMC will both respect and safeguard their dignity. Taking the above into consideration, it seems that there are shortcomings in doctors purely using their judgement and intuition in making capacity assessments. Some have suggested that there is a need for more objective tests and instruments to test capacity.[26] Standardised tools have been developed in order to improve the reliability of assessments that rely solely on the physicians judgment.[29] However these tests should be seen as a supplement to a doctor's clinical judgment and not as a replacement for it. The doctor-patient interaction involves a wealth of information and cues, both verbal and non-verbal, that a doctor takes into consideration.[93] It would be impractical and likely impossible for a test, questionnaire or scoring system to incorporate all these information points. Indeed as Palmer suggests, education of doctors may play a significant role in improving the reliability and validity of capacity assessments.[26] The next chapter will discuss the empirical part of this study that examines the level of knowledge of anaesthetists regarding decision-making capacity.

Chapter 5:

Empirical Component of Study: What is the Knowledge of Anaesthetists Regarding Decision-Making Capacity?

5.1 Introduction

The need for doctors, and in particular anaesthetists, to have a proper grasp of how to establish DMC has thus far been explored from a normative and legal perspective. However, in addition, it is imperative to examine what the reality on the ground is. It is important to understand the knowledge base of South African anaesthetists. This is because knowledge is an important standard of good anaesthetic practice.[94] Additionally knowledge deficits, once identified, may direct recommendations for the improvement of medical education.

For an overview on the methodology for this component of the study, see chapter 1 section 1.6. This chapter describes the development of the questionnaire which is the research tool that was used, and the results obtained in this component of the study. It is aligned to objectives 2 (to determine anaesthetists' level of knowledge regarding patients' decision-making capacity) and 3 (to compare the level of knowledge of anaesthetists of different categories (according to qualification and experience) regarding patients' DMC.)

5.2 Development of Research Instrument (Questionnaire)

For the purposes of this study there was a need to develop a research instrument since none existed that would appropriately test anaesthetists' knowledge regarding decision-making capacity. This section describes the process that was involved in the questionnaire development.

In order to assess anaesthetists' knowledge regarding decision-making capacity a self-administered, closed ended questionnaire was developed. A closed ended design was chosen as it was considered to be the most practical to administer, answer and analyse.[95,96] Considering that the questionnaires were to be answered at departmental academic meetings, and because open ended questions would have taken an excessive amount of time to complete, using this method could have resulted in a lower response rate.

No other study addressing knowledge of DMC has been performed in the South African setting. As such it was felt that true/false questions would be an appropriate method of questioning in order to delineate the areas of adequate/ inadequate knowledge in broad strokes. Subsequent studies may then address the areas of inadequate knowledge in greater detail.

The questionnaire was divided into two sections. Section A addressed demographic information including age, gender and anaesthetic experience. The rest of the questions in section A addressed whether the participant had extracurricular education regarding DMC capacity assessments, whether they were aware of any tests of DMC and how often they were used.

The fifteen questions in Section B were based on the work of Ganzini et al in their study titled "Pitfalls in Assessment of Decision-Making Capacity".[16] In their study psychiatrists, geriatricians and geriatric psychologists were asked to rate the frequency and importance of misunderstandings that clinicians may have regarding DMC assessments. This was based on the referrals for capacity assessments that the group had received in their regular practice. The pitfalls and misunderstandings

that were most common, as identified by their study, were re-formulated into true/false questions for the purpose of my study.

For example, pitfall number 7 as identified in the Ganzini study states, “In assessing capacity to make medical decisions, the practitioner gives greater weight to the patient’s final decision than to the process the patient uses in coming to that decision.”

This was used to formulate question number 12 in the questionnaire that was used in the current study –

“12. In assessing a patient’s capacity to consent, the patient’s final decision is more important than the process by which they arrived at that decision.” The correct answer for this question is “False”.

Face Validity and Content Validity

In order to validate the questionnaire a group of ten experts was consulted. These experts were chosen based on their expertise in bioethics and/or decision making capacity. They included 5 bioethicists and 5 psychiatrists. The experts were asked to review the questionnaire and suggest changes, additions or to comment on the questions. Additionally, they were asked to suggest a pass mark for the questionnaire i.e. how many questions they thought a doctor should answer correctly if they were to be assessed as having adequate knowledge regarding DMC. None of the experts suggested any additions. One expert with a background in psychiatry commented that the questionnaire was comprehensive. Experts in the validation group did recommend changes as described below.

Changes to Questionnaire

1. Changes to the questionnaire were made based on expert feedback regarding language, spelling and typographic errors.
2. Experts suggested clarifying Question 8 with regard to treated or untreated disorders. The original question read,

   “8. Patients with psychiatric disorders e.g. schizophrenia lack capacity.”

   It was amended to read,

   “8. Patients with untreated psychiatric disorders e.g. schizophrenia lack capacity.”
3. It was suggested that the term “involuntarily committed” in Question 9 be explained. The phrase “undergoing court ordered treatment for mental illness” was therefore added in order to provide an explanation.
4. Question 15 was expanded upon to clarify what was meant by “doctor’s attitude”. It was amended to read, “15. In assessing a patient’s decision making capacity, the doctor’s feelings about the patient could affect the doctor’s assessment.”

Pass Mark

The majority of the experts declined to comment on a pass mark for the questionnaire. No other studies that tested knowledge regarding DMC could be used as a reference to determine a pass mark. Therefore, a pass mark was not calculated. It was decided that the doctors’ answer for each true/false question would be considered individually as knowledge pertaining to the specific subject of the question.

5.3 Questionnaire Administration

The questionnaires were administered over the course of four departmental meetings. Permission to conduct the survey was obtained from the Academic Head of Anaesthesia (see appendix 4). Verbal consent was also obtained from the chairperson of the meeting at the beginning of each meeting.

The purpose of the research was explained to the prospective respondents and they were invited to participate in the study. Taking into account my senior position in the department, the questionnaires were distributed by an administrator after I had left the room, in order to avoid any unintentional coercion.

5.3 Results

The Wits Department of Anaesthesia consists of approximately 8 Heads of Clinical Units, 63 specialists, 12 career medical officers, 108 registrars and 21 medical officers, i.e., a total of 212 doctors. The department consists of approximately 70% females and 30% males. Due to clinical obligations (emergency theatres, being on-call, elective lists running late) it was estimated that approximately 139 anaesthetists would be available to attend the academic meetings and be available to participate in the study.

The total number of completed questionnaires that were returned was 89 over the course of 4 meetings. All questionnaires were answered (i.e. no blank questionnaires were returned), yielding a response rate of 100%, There were 53 female (59.6%) and 36 male (40.4%) respondents.

Table 1 depicts the ages of the respondents. The majority of the respondents were in the 25-35 year age group (n=58).

Table 1: Age ranges of respondents

Age range (years)	Number of respondents (n=89)	Percentage
25-35	58	65.2%
36-45	19	21.3%
46-55	4	4.5%
>55	8	9%

Table 2 depicts the number of years of anaesthetic experience of the respondents. The vast majority (80%) had less than 10 years of anaesthetic experience.

Table 2: Anaesthetic experience of respondents

Experience category (years)	Number of respondents (n=89)	Percentage
<5	36	40.4%
5-10	36	40.4%
11-15	5	5.6%
>15	12	13.5%

Only 3 (3%) respondents claimed to have had extracurricular education about the assessment of decision making capacity and 11(12%) respondents were aware of a

standardised test that could be used to assess a patient's decision-making capacity. Only 1 of the 3 respondents who claimed to have had extracurricular education about DMC was aware of a standardised test for DMC.

More than half of respondents (n=51(57%)) indicated that they had never used an objective test to determine decision making capacity in a patient. Twenty-two (25%) indicated that they rarely used such tests. Eleven (12%) respondents indicated that they sometimes used objective tests and only 5 (6%) of the anaesthetists involved in the study often used objective tests of decision making capacity.

The total number of correct answers for each question as well as the number of correct answers in each experience category is reflected in Table 3. There was no statistically significant association between experience and the number of correct answers for any of the 15 questions.

Table 3: Number of correct answers per question and per experience group together with p value

QUESTIONS	NUMBER OF CORRECT ANSWERS				p value
	Total sample n=89 (%)	Group 1: < 5 yrs experience n=36 (%)	Group 2: 5 - 10 yrs experience n=36 (%)	Group 3: > 10 yrs experience n=17 (%)	
1. Capacity to give consent and legal competency to give consent are the same. (correct answer = false)	81 (91)	34 (94)	31 (86)	16 (94)	0.41
2. If a patient goes against medical advice, then it can be presumed that they lack capacity (correct answer = false)	85 (96)	34 (94)	35 (97)	16 (94)	0.81
3. Even if a patient agrees with and consents to medically advised treatment, there may still be a need to assess capacity in that patient. (correct answer = true)	85 (96)	34 (94)	35 (97)	16 (94)	0.81
4. A patient either has capacity to consent or does not have capacity to consent (i.e. there is no middle ground). (correct answer = true)	55(62)	21 (58)	25 (69)	9 (53)	0.44
5. Cognitive impairment does not equal a lack of capacity to consent. (correct answer = true)	44 (49)	20 (56)	18 (50)	6 (35)	0.39
6. Lack of capacity to consent is a permanent condition (correct answer = false)	89 (100)	36 (100)	36 (100)	17 (100)	-
7. If a patient has not been given relevant information about their treatment, then they lack capacity to consent. (correct answer = false)	24 (27)	10 (28)	7 (19)	7 (41)	0.25
8. Patients with untreated psychiatric disorders (e.g. schizophrenia) lack capacity. (correct answer = true)	60 (67)	38 (43)	18 (20)	4 (4)	0.73

9. Patients who are involuntarily committed (i.e. undergoing court- ordered treatment for mental illness) lack capacity to consent to surgery. (correct answer = false)	30 (34)	10 (28)	13 (36)	7 (41)	0.58
10. Anaesthetists can assess a patient's capacity to consent (correct answer = true)	66 (74)	31 (86)	25 (69)	10 (59)	0.08
11. If a patient lacks capacity to consent for anaesthesia, then it can be assumed that they lack capacity for other medical decisions. (correct answer = false)	39 (44)	16 (44)	15 (42)	8 (47)	0.93
12. In assessing a patient's capacity to consent, the patient's final decision is more important than the process by which they arrived at that decision. (correct answer = false)	73 (82)	32 (89)	28 (78)	13 (76)	0.38
13. In emergency situations where no surrogate decision maker is available, the treating physician may provide consent for treatment on behalf of a patient who lacks capacity. (correct answer = true)	32 (36)	12 (33)	16 (44)	4 (24)	0.31
14. The Mini-Mental State Examination may be used to determine a patient's capacity to consent. (correct answer = false)	30 (34)	12 (33)	11 (31)	7 (41)	0.75
15. In assessing a patient's decision making capacity, the doctor's feelings about the patient could affect the doctor's assessment. (correct answer = true)	84 (94)	34 (94)	34 (94)	16 (94)	1.0

The findings for part 2 of the questionnaire, show that correctly and incorrectly answered questions were not aligned with particular areas of knowledge. More than 90% of anaesthetists correctly answered questions 1,2,3,6 and 15. Questions 7,9,13 and 14 were answered correctly by less than a third of respondents. These groups of questions do not reflect specific knowledge areas; therefore, themes of knowledge or knowledge deficits cannot be inferred.

5.5 Conclusion

The findings of the study indicate that the vast majority of anaesthetists have not received extracurricular training on decision-making capacity and are unaware of objective tests that could be used to assess capacity. Additionally, there are several questions which the majority of respondents answered incorrectly, indicating knowledge deficits. Finally, there is no statistically significant correlation between experience and knowledge. A detailed discussion of the findings will be set out in chapter 6.

Chapter 6: Discussion

6.1 Introduction

The twentieth century has seen the idea of autonomy as a human right gain near universal acceptance. Respect for patient autonomy has also mirrored this dramatic rise in prominence. Medicine has moved from strict paternalism, where doctors withheld information from patients and made unilateral decisions on what was best for them, to an era of informed consent and shared decision making. In most cases, patients who have intact decision making capacity carefully weigh their treatment options and communicate their decision to their treating doctor. In some cases, however, due to mental or severe medical illness, a patient may lack this ability.

It is important that doctors recognise these patients since failing to do so would result in actions or treatment that may not be in the best interest of that particular patient. Doctors who lack adequate knowledge about decision-making capacity are at risk of making errors in their judgement of capacity and their actions may undermine legally and ethically sound informed consent.

In this chapter, key findings from the survey are discussed in the context of the normative and legal components of the study where relevant. This chapter is aligned with objective 4 of the study i.e. to critically assess the ethical relevance of the level of knowledge of anaesthetists regarding patients' DMC.

6.2 Discussion: survey findings

This study aimed to determine the level of knowledge of anaesthetists regarding decision making capacity. The are no other local or international studies examining anaesthetists' knowledge in this field that have been published.

The study was conducted in the University of the Witwatersrand Department of Anaesthesia. Anaesthetists who attended departmental meetings were invited to participate in the survey and convenience sampling was used to obtain a sample which amounted to 89 respondents. This represented 42% of the study population.

Approximately two-thirds (65%) of the respondents were less than 35 years old and 72 (80%) had less than ten years anaesthetic experience. This is not surprising considering that the study population are anaesthetists at University affiliated training hospitals.

The vast majority of anaesthetists (88%) were unaware of formal tests of DMC and 57% indicated that they had never used an objective test to assess DMC. In their study Novosel et al evaluated the knowledge, attitudes and evaluation of DMC by primary care physicians and psychiatrists in Croatia. They found that only 1.7% of physicians in their study had ever used an objective test of capacity.

Even though most medical schools include an ethics module in their undergraduate curriculum, the focus is largely on broad issues like informed consent resulting in certain deficits.[97,98] This gap is also reflected in the postgraduate syllabus.[99] It is therefore understandable that most doctors are unaware of capacity and capacity assessments. This is an area that needs to be addressed for future teaching programs at both the undergraduate and post graduate levels.

Almost all respondents (91%) knew that capacity to consent and legal competency were separate concepts (Question 1). This is in contrast to the findings by Ganzini

et al[16] in which 43% of their group of experts (psychiatrists, geriatricians, physicians and ethicists) felt that in their experience it was very common for doctors to misunderstand this distinction between the concepts.

All respondents (100%) knew that a lack of decision-making capacity may not necessarily be permanent (question 6). Ninety-six percent of respondents correctly answered question 2 ("If a patient goes against medical advice then it can be presumed that they lack capacity.") and question 3 ("Even if a patient agrees with and consents to medically advised treatment, there may still be a need to assess capacity in that patient."). This reflects an understanding that the patient's final decision is not necessarily a reflection of their decision-making capacity. This understanding is confirmed in participants response to question 12 ("In assessing a patient's capacity to consent, the patient's final decision is more important than the process by which they arrived at that decision.") in which 82% of respondents answered correctly. Once again these findings contradict Ganzini et al[16]. In their study, most experts felt that doctors very often mistakenly assume that if a patient agrees with the treatment plan then that patient possesses DMC.

Almost half (49%) of those experts also believed that it was 'very common' for doctors to think that a mental health professional is necessary to perform on capacity[16]. In the study for this research report almost two thirds (74%) of anaesthetists understood that an anaesthetist could perform a capacity assessment (question 10).

6.3 Cognition and Decision Making Capacity

The dominant view currently is that decision making capacity is largely a cognitive function. Evidence for this viewpoint is the fact that formal tests of DMC mainly incorporate cognitive elements like understanding and reasoning. Some authors suggest that this narrow approach to decision-making omits important elements like emotions and values.[22,23] The Mini-Mental State Exam (MMSE) is a well-known tool for screening for cognitive deficits.[33] However, it is not an adequate tool to determine decision making capacity. Ganzini et al suggest that it is common for doctors to incorrectly assume that the MMSE is an appropriate test of capacity and they point out that this is an important point to address in medical education.[16] The current study found that only 49% or respondents understood that cognitive impairment did not equate to lack of capacity (question 5) and more than a third (34%) thought that the MMSE may be used to determine capacity (question 14). This reinforces the finding in other studies that doctors often conflate issues of cognitive impairment and incapacity. Chima's study conducted amongst South African doctors also found that when faced with a difficult case most doctors chose the MMSE as an objective test of capacity.[40] Patients with mild cognitive impairments (as determined by the MMSE) may still possess sufficient capacity to make a treatment decision provided that they are supported. Cognitive support may take several forms e.g. repeating the information to the patient or using models, videos, teaching aids etc.[4]

Other authors also caution against the use of the MMSE as a sole determinant of capacity.[34,100] Etchells et al suggest that the MMSE does not assess whether patients may have delusions that may be affecting how they make decision and so it would be of limited use in patients with certain psychiatric illnesses.

6.4 Information and Capacity

If a patient has not been provided with sufficient information regarding their treatment options, then they may be unable to make a decision. This, however, is not an indication that they lack capacity, rather it reflects a failure on the part of their doctor to provide the relevant information. Most respondents failed to appreciate this since only 27% correctly answered question 7.

6.5 Psychiatric illness and Capacity

Untreated psychiatric illnesses like schizophrenia, may cause patients to experience false beliefs (delusions) and hallucinations. These serious thought disorders are likely to affect a patient's decision making capacity. It is surprising that only two thirds (67%) of respondents understood this, as indicated by the answers to question 8. This may be a reflection of misunderstanding of the question (as a result of ambiguous or unclear wording). Further research would be required in order to explore this issue.

6.6 Decisional relativity

Decision-making capacity pertains to a *specific* decision i.e. a patient may have capacity to make decisions about certain issues and lack capacity to decide about others. This is referred to as decisional relativity.[3] In general, the greater the risk involved, the greater the degree of capacity that is required. A patient may lack the ability to understand and appreciate the risks involved with general anaesthesia, but they may have the capacity to consent to an intramuscular injection of an antibiotic.

A significant knowledge gap is evident since less than half (44%) of respondents answered question 11 ("If a patient lacks capacity to consent for anaesthesia, then it can be assumed that they lack capacity for other medical decisions") correctly. This implies that respondents lack knowledge regarding decisional relativity. Hermann et al found that almost half of the physicians in their survey did not think that DMC related to a specific question.[28] Doctors' lack of knowledge regarding decisional relativity was the most common pitfall in DMC assessment identified by Ganzini et al in the United States.[16] This might suggest that certain deficits in medical education regarding capacity assessments may be common to both developing and developed countries.

6.7 Capacity is binary for specific questions

Sixty-two percent of respondents in my study correctly answered question 4 ("A patient either has capacity to consent or does not have capacity to consent (i.e. there is no middle ground).). When it comes to a specific question e.g. "Does this patient have capacity to consent to an epidural?" the answer has to be yes or no i.e. it is binary.

6.8 Consent in emergency situations

According to the National Health Act, Section 7. 1(e) allows for the provision of treatment in emergency situations without consent provided that it is lifesaving treatment that the patient has not previously refused or made a written mandate refusing such treatment and there is no surrogate decision maker available.[7] This is done with the patient's best interest in mind. Almost two thirds of respondents did

not correctly answer question 13, reflecting a lack of knowledge regarding consent in emergency situations in those patients lacking capacity as described in the Act.

There was no correlation between levels of experience and deficits of knowledge. This might be due to the fact that education around DMC was and continues to be deficient. Whilst less experienced anaesthetists are likely to have graduated more recently and to have been exposed to a more significant bioethics curriculum than more experienced anaesthetists, it is likely that decision-making capacity and its assessment did not form a significant part of the teaching program. Additionally, unlike anaesthetic expertise, bioethics knowledge is less likely to improve with time unless of course one specifically seeks out training in these areas.

6.9 Summary: survey findings

In summary, the findings of the survey identified areas where anaesthetists do have adequate knowledge regarding aspects of decision making capacity. These include the fact that capacity to consent and legal competence are separate concepts and that an impairment in capacity is not necessarily permanent. Anaesthetists also seem to understand that the patient's final decision (i.e. their consent to or refusal of treatment) was less important as compared to the process by which the patient arrived at the said decision. Finally, nearly three quarters of respondents understood that anaesthetists could perform capacity assessments and it was not just psychiatrists who could undertake such assessments.

The survey also identified that there were several areas where significant knowledge deficits exist. These deficits pertained to decisional relativity, the conflation of cognition and capacity as well as the use of the MMSE for capacity assessments.

Additionally, knowledge regarding consent in emergency situations was incomplete. These deficits in knowledge may affect anaesthetists informed consent process and have the potential for ethical and medico-legal violations.

6.10 Ethical and Regulatory Implications of Survey Findings

Doctors' lack of knowledge regarding DMC may result in incorrect assessments of patients' capacity. If patients are incorrectly presumed to have capacity when in fact they do not, then their treatment related decisions may result in procedures that may not to be in line with their values and goals and hence, not in their best interest. This implies that doctors would have failed in their duty to act beneficently. This may also result in harm to vulnerable patients. Taking into consideration that doctors are unaware of their lack of knowledge, according to deontology ("Ought implies can") their lack of knowledge may not necessarily be considered unethical. After all, how can doctors perform better if they do not know that they are making ethical errors? Similarly, from a utilitarian point of view, doctors' lack of knowledge regarding DMC may render them ignorant to various options with regards to their actions. As such they cannot truly make a determination about which course of action will result in the greatest amount of utility. If doctors are aware that they lack this important knowledge and they continue to perform capacity assessments and procure informed consent, then this would be considered unethical. According to principlism, unless doctors are acting carelessly and negligently (thereby violating the principle of non-maleficence) their actions which stem from a lack of awareness cannot be considered unethical.

From a regulatory point of view however, doctors may still be held accountable. The HPCSA guidelines highlight the importance of DMC by making specific mention of capacity assessment and encouraging doctors to seek assistance in this regard if needed. It is likely that a doctor who overlooks DMC during the informed consent process may be considered guilty of unprofessional and unethical behaviour by the standards of the HPCSA.

Likewise the law is clear in its emphasis on patients' understanding (National Health Act[7]) and appreciation (*Castell* vs *De Greef*). Informed consent that is not based on the decision of a patient with agency, i.e. DMC, is invalid. Procedures performed without valid informed consent may result in civil or criminal proceedings for breach of the doctor-patient contract or assault.

6.11 Ethical blind spots

In their review titled "Ethical blind spots: explaining unintentional unethical behaviour", Sezer et al describe several reasons as to why people may behave unethically even when they do not intend to do so.[101] They suggest that "unconscious attitudes can lead people to act against their ethical values."[101] I submit that in addition, a lack of knowledge can similarly cause an "ethical blind spot". These blind spots may result in actions that may be unethical (e.g. incorrectly assuming that a patient has DMC). However, the intention behind the action is in fact to do good and this is an important point in judging the ethical dimension of that action.

Let us consider the evolution of medical knowledge. Scientific journals from decades ago abound with news of the discovery of drugs that were heralded as exciting new

therapies in the war against disease. In subsequent years, the medical literature has been littered with articles describing the withdrawal of those drugs in the light of new knowledge[102–104]. As new knowledge and information comes to light about the negative effects of these medicines, action is taken to remedy the situation.[105]Similarly, one cannot deem a doctor's lack of knowledge of DMC as being unethical, especially if this knowledge did not form part of their training and when there is still ongoing debate about the area of concern i.e. decision-making capacity and its assessment.

6.12 The Use of Scoring Systems to Assess DMC

As discussed in Chapter 2, objective tools and scoring systems that have been developed to test DMC have several shortcomings and have been widely criticised. Most experts suggest that these tools should be used to augment a doctor's clinical judgement and never to replace it. The utility of these tools in the South African setting is particularly limited since none of them were designed for the local environment where there are vast differences in education and literacy.

What has become evident is that local and overseas doctors consider the use of the Mini-Mental State exam as being reasonable practice in the assessment of capacity.[16,106] This practice is incorrect and this is an important misconception amongst doctors that needs to be addressed.

6.13 Study Limitations

Since the study focuses on the anaesthetists at the University of the Witwatersrand, the results may not indicate the level of knowledge of anaesthetists at other sites. However, since no other studies of this nature have been done in South Africa, the study may be repeated at other sites to produce a more generalizable picture.
A true/ false format was chosen for the questionnaire in order to aid with the ease of completion of the questionnaire and to encourage participation. This format however does limit the amount of information that can be inferred about the participants' lack of knowledge. Subsequent studies could consider the incorporation of open ended questions to obtain a more detailed picture of the participants level of knowledge.

The questionnaires were completed by doctors attending academic meetings. It is possible that regular attendees to academic meetings may have a different knowledge base than those who do not regularly attend meetings. This may reflect a potential source of bias.

This study employed convenience sampling (also referred to as availability sampling). This method was chosen for its ease of utilisation. Although convenience sampling may be a source of bias, in this study the sample represented 42% of the population (i.e. 42% of the total anaesthetic department) which is almost half of the entire anaesthetic department.

6.14 Conclusion

Despite the above limitations, this study confirms several findings of other studies i.e. doctors across specialties whether practicing medicine locally or abroad have serious deficits in their knowledge. In some ways this is not surprising since the field of capacity assessment is relatively new and scientific knowledge about DMC itself is

far from complete. There are still many questions that even experts in DMC assessment have difficulty in coming to a consensus about.

The findings of this study do however alert us to specific areas of deficiency thereby guiding us as to how our educational efforts can be directed. Becoming aware of the problem is the first step in starting to resolve it. Steps should be taken to highlight this lack of knowledge amongst doctors and efforts made to improve their education. A failure to do so would be considered more unethical than the performance of doctors who may be acting from within ethical blind spots.

Chapter 7: Conclusion and Recommendations

The aim of this study was to study the assessment of patients' decision-making capacity by anaesthetists. In order to do so decision-making capacity and its assessment was discussed from an ethico-regulatory perspective. The empirical component of the study assessed anaesthetists' level of knowledge regarding patients' decision-making capacity and found that anaesthetists lack knowledge regarding decision-making capacity. Additionally, in order to compare the level of knowledge of anaesthetists of different categories (according to years of experience) a statistical analysis (Chi square test) was performed and no statistically significant relationship was found between level of knowledge and years of experience.

A lack of knowledge regarding decision-making capacity may lead to ethical and medico-legal errors in the informed consent process. This study has found that anaesthetists lack sufficient knowledge regarding capacity and as such are at risk of these errors. Patients presenting for anaesthesia are vulnerable and are at risk of harm if incorrect decisions are made. The areas where anaesthetists significantly lack knowledge include decisional relativity, separating cognition and capacity (including the inappropriate use of MMSE for capacity assessments) and capacity to consent in emergency situations. These deficits in knowledge may affect the procuring of informed consent by anaesthetists. This results in the potential for ethical and medico-legal violations.

This lack of knowledge is not only a local phenomenon nor is it restricted to anaesthetists. Other local and international studies have also found doctors (of varying specialties) to be lacking in knowledge regarding capacity and capacity assessments.[16,86,106] Despite the fact that incorrect actions stemming from this lack

of knowledge may result in ethical violations, the lack of knowledge itself cannot be considered unethical according to the Kantian approach. In line with deontological principles, what we *ought* to do should be within the reach of what we *can* do. Education surrounding decision making capacity does not form a part of doctors' training and as such very few are even aware of the concept. This is the case even in higher income countries. One reason for this might be the fact that there remain many unanswered questioned relating to decision-making capacity. Considerable debate continues even around such fundamental issues as how capacity is defined or even what elements constitute capacity.

According to the principle of non-maleficence, if doctors knowingly and intentionally behave in a way that causes harm or is not in the best interest of patients then this would be considered negligent and unethical. Anaesthetists' lack of knowledge regarding capacity stems largely from deficits in their education program rather than from a lack of interest on their parts and therefore they cannot be held individually accountable for the deficiencies in their knowledge.

Recommendations based on study findings

This study identified several important areas where anaesthetists require education and training in order to improve the standard of capacity assessments prior to the informed consent process.

Recommendations following this study include:

1. The health sciences undergraduate curriculum needs to be revised to include education on decision-making capacity and capacity assessments. Whilst there is some focus on this in bioethics, there is often not enough emphasis on decision-

making capacity. The ethical and medico-legal repercussions of poor knowledge regarding decision-making capacity assessments as well as the impact on valid informed consent make compelling arguments for medical educators to provide more weight to this subject in curricula.

2. Likewise, the postgraduate anaesthetic curriculum (fellowship and diploma in anaesthesia) needs to emphasise decision-making capacity as a separate learning topic. Whilst the current curriculum does include informed consent as a learning objective, it does not sufficiently highlight decision-making capacity. A revision of this is therefore recommended.
3. Departmental academic meetings, Continuing Professional Development (CPD) meetings, conferences and workshops must also raise awareness about anaesthetists' knowledge deficit and the practical importance thereof. These educational events are ideal opportunities to disseminate this important information amongst those anaesthetists who have already completed undergraduate and postgraduate training.
4. Guidelines for the assessment of DMC by anaesthetists should be drawn up after consultation with clinical, ethics and legal experts.
5. A request should be made to the HPCSA to review the guideline booklet on Informed Consent (see appendix 7). Recommendations could be made for the inclusion of guidance points on the ethical and legal assessment of DMC.
6. There are several unanswered questions that surround capacity and capacity assessment. These questions can serve as important points for future research. Empirical research into decision-making capacity can be undertaken by both under- and postgraduate students. There is a particular need to understand the challenges of capacity and its assessment in the local South African context.

Concluding Remarks

Decision-making capacity and its assessment have recently received an increasing amount of attention in ethical and legal discussions. This is justified considering its link to autonomy and the basic human rights to dignity and security of the person. This attention and discussion surrounding DMC has uncovered deficits in doctors' knowledge regarding these important concepts as has been shown in studies conducted internationally and confirmed by this study. It is therefore vital that these deficits are addressed by significantly reforming medical education and regulatory guidelines regarding DMC and its assessment. Doing so is a step toward preserving the hard won right to determine what happens with one's own body.

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Appendix 1: Study Questionnaire

Questionnaire **Unique Identifier Number:**

1. Age
   - 25 - 35 yrs □
   - 36 - 45 yrs □
   - 46 - 55 yrs □
   - >55 yrs □

2. Gender
   - Male □
   - Female □

3. Anaesthetic experience
   - < 5 yrs □
   - 5 - 10 yrs □
   - 11 - 15 yrs □
   - >15 yrs □

4. Have you had any extracurricular education regarding assessments of decision-making capacity?
   - YES □
   - NO □

5. Are you aware of any standardized test that can be used to measure a patient's **decision making capacity?**
   - YES □
   - NO □

6. How often do **you** use an objective test of a patient's **decision making capacity** before obtaining informed consent for anaesthesia ?
   - NEVER □
   - RARELY □
   - SOMETIMES □
   - OFTEN □

The following questions relate to a patient's **capacity to provide informed consent** for treatment i.e. decision-making capacity.

Please select true or false by marking your choice with an X

1. **Capacity** to give consent and **legal competency** to give consent are the same. TRUE □ FALSE □

2. If a patient goes against medical advice then it can be presumed that they **lack capacity** TRUE □ FALSE □

3. Even if a patient **agrees** with and consents to medically advised treatment, there may still be a need to assess capacity in that patient. TRUE □ FALSE □

4. A patient either **has** capacity to consent or **does not have** capacity to consent (i.e. there is no middle-ground). TRUE □ FALSE □

5. Cognitive impairment **does not** equal a lack of capacity to consent. TRUE □ FALSE □

6. Lack of capacity to consent is a permanent condition TRUE □ FALSE □

7. If a patient has not been given relevant information about their treatment then they **lack capacity to consent.** TRUE □ FALSE □

8. Patients with untreated psychiatric disorders (eg schizophrenia) **lack capacity.** TRUE □ FALSE □

9. Patients who are involuntarily committed (ie undergoing court-ordered treatment for mental illness) **lack capacity** to consent to surgery. TRUE □ FALSE □

10. **Anaesthetists** can assess a patient's **capacity to consent** TRUE □ FALSE □

11. If a patient **lacks capacity** to consent for anaesthesia then TRUE □ FALSE □

it can be assumed that they lack capacity for other medical decisions.

12. In assessing a patient's capacity to consent, the patient's final decision is more important than the process by which they arrived at that decision. TRUE □ FALSE □

13. In emergency situations where no surrogate decision maker Is available, the treating physician may provide consent for treatment on behalf of a patient who **lacks capacity**. TRUE □ FALSE □

14. The Mini-Mental State Examination may be used to determine a patient's capacity to consent. TRUE □ FALSE □

15. In assessing a patient's decision making capacity, the doctor's feelings about the patient could affect the doctor's assessment. TRUE □ FALSE □

Appendix 2: Participant Information sheet

Participant Information Sheet

Dear colleague,

Hello, my name is Alastair Moodley and I am post-graduate bioethics student at the Steve Biko Centre for Bioethics at the University of the Witwatersrand.

I would like to invite you to participate in a research study entitled "Anaesthetists' Knowledge Regarding Decision-Making Capacity: A Bioethical Enquiry". This will be submitted to the University of the Witwatersrand as a part of my M Sc. (Bioethics and Health Law) Degree.

The aim of the study is to investigate anaesthetists' level of knowledge regarding patients' decision-making capacity. The results of this study will be made available to you if you wish.

Whilst there may be no immediate benefit in participating in the study, the results of the study may be used to improve undergraduate and postgraduate teaching about decision-making capacity.

Should you agree to participate in the study, I invite you to please complete the questionnaire and place it in the sealed box provided. No identifying information is required and you will remain individually anonymous. However due to the small numbers of anaesthetists in the department, it may be possible to identify your age or experience group. Returning a completed questionnaire will be taken as consent to participate in the study. The questionnaire will only be accessed by my supervisor and myself in order to maintain confidentiality.

This study has been approved by the Wits Human Research Ethics Medical Committee (Ml 70639) and the Postgraduate Committee of the University of the Witwatersrand. Permission has been granted by the Academic Head of Anaesthesia.

Should you require any further information, please contact me on 0828347123 or alternatively the Chair of the Human Research Ethics Committee Prof Cleaton -Jones on (011) 717 1234.

Thank you for your attention.

Alastair Moodley

Appendix 3: HREC Clearance Certificate

R14/49 Dr Alastair Moodley

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M170639

NAME: (Principal Investigator)	Dr Alastair Moodley
DEPARTMENT:	Steve Biko Centre for Bioethics, Deprtment of Anaesthesia University of the Witwatersrand
PROJECT TITLE:	Anaesthetists' Knowledge Regarding Decision-Making Capacity: A Bioethical Enquiry
DATE CONSIDERED:	30/06/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Ames Dhai
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	11/10/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review June and will therefore be due in the month of June each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 15/10/2017

Appendix 4: Departmental Permission Letter

DEPARTMENT OF ANAESTHESIOLOGY
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Tel.(011)933-9334/5 / Fax (011)933-1843

3rd August 2017

Prof Peter Cleaton-Jones,
Chairman,
Wits Human Research Ethics Committee (Medical).

Dear Prof Cleaton-Jones,

Re: Request for permission to undertake research within the Department of Anaesthesia.

The purpose of this letter is to grant Dr Alastair Moodley permission to conduct research within the Witwatersrand Department of Anaesthesia.

The project entitled "Anaesthetists Knowledge regarding Decision Making Capacity: A Bioethical Enquiry" entails the utilisation of a self -administered questionnaire.

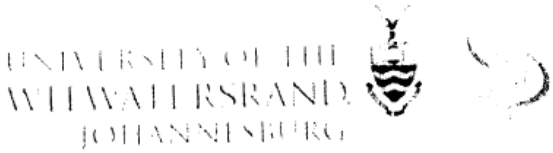
This approval is subject to all the conditions set by the Wits Human Research Ethics Committee (Medical) and all the necessary approvals from the various authorities.

With kind regards
Yours sincerely

Chris Lundgren

Prof AC Lundgren
Head, Dept. of Anaesthesiology
University of the Witwatersrand

Appendix 5: Plagiarism Declaration



PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I ALASTAIR WAYNE MOODLEY (Student number: 9803011Y) am a student registered for the degree of MSc (Med) Bioethics & Health Law in the academic year 2015.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: [signature] Date: 23 SEPTEMBER 2015

Appendix 6: Turnitin Originality Report

9803011y:Msc_Bioethics_Final.docx

ORIGINALITY REPORT

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7	Submitted to University of Sheffield Student Paper	<1%
8	Submitted to University of Stellenbosch, South Africa Student Paper	<1%

Appendix 7: Letter to HPCSA Suggesting Amendments to Guidelines

Suggested amendments to HPCSA Booklet 4: Informed Consent

Alastair Moodley

Mon 5/27/2019 8:23 PM

To:raybilla11@gmail.com <raybilla11@gmail.com>;

Cc:Ames Dhai <Ames.Dhai@wits.ac.za>;

Dear Dr Billa,

I am currently completing a Master of Science in Medicine (Bioethics and Health Law) at the University of the Witwatersrand. The title of my research report is "Anaesthetists Knowledge Regarding Decision-Making Capacity: A Bioethical Enquiry. " My supervisor is Professor A Dhai (copied).

The normative component of my research has examined decision-making capacity and its assessment from an ethico-regulatory point of view.

It is becoming increasingly clear that decision-making capacity is a complex notion that includes several elements like understanding (the cognitive ability to comprehend), appreciation (the ability to recognize how the information applies to one's own life and life circumstance) and reasoning (i.e. the ability to weight up the options). Purely having understanding may not be sufficient to assess a person as having adequate capacity to make treatment decisions for themselves.

International regulations (e.g. US and Australia) recognise that these other elements (appreciation and reasoning) are as important as understanding.

However, in section 8.1 of the HPCSA Booklet 4 Seeking Patients' Informed Consent: The Ethical Considerations, the guidelines only refer to the ability to 'understand information'.

In order to better guide healthcare practitioners and to protect patients, it is my suggestion that the guidelines be amended to include appreciation and reasoning as components of decision-making capacity as well as understanding.

I am willing to make the research report available to the HPCSA as soon as the examination process is completed so that these suggested changes may be understood in the context of South Africa.

I thank you for your time and consideration.

Regards,

Dr Alastair W. Moodley
MBChB, DA(SA),FCA(SA)
Head of Department of Anaesthesia/ Lecturer
Edenvale Hospital/ University of the Witwatersrand

082 834 7123