THE MORALITY OF OBTAINING BLANKET CONSENT FOR INVASIVE PROCEDURES IN THE INTENSIVE CARE UNIT

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DECLARATION

I, Arisha Ramkillawan, student number 1789630, declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Science in Medicine in Bioethics and Health Law, at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Arisha Ramkillawan

28 June 2022 in Pietermaritzburg

DEDICATION

For my parents and sister, Yeishna, my gratitude is unquantifiable.

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LIST OF ABBREVIATIONS AND TERMINOLOGY

aka	Also known as
Blanket consent	Informed blanket consent (used interchangeably)
CAM	Confusion Assessment Method
CIOMS	Council for International Organizations of Medical Scientists
COVID-19	A disease that occurs when a patient is infected with SARS-Cov-2 (1) This also refers to the pandemic where millions of people around the world have been infected with SARS-CoV-2
CPD	Continued Professional Development
CT scan	Computerized Tomography scan
CVC	Central venous catheter – a intravenous catheter carefully placed in the central vein for the purpose of infusion of fluid, medication, nutrition or monitoring of central venous pressure. May also be used for convenient blood sampling.
Designated proxy	A legal guardian of a patient or court appointed representative (2)
GCS	Glasgow Coma Scale
GDPR	Global Data Protection Regulation
HPCSA	Health Professions Council of South Africa
ICU	Intensive Care Unit
Intensivist	A medical specialist trained in the field of critical care medicine (3). Sometimes referred to as and 'ICU specialist', 'Critical Care Specialist', 'Critical Care Subspecialist'
MMSE	Mini Mental State Examination
MTA	Material transfer agreement
PICS	Post ICU Syndrome
POPIA	Protection of Personal Information Act
PPE	Personal Protective Equipment

PTSD	Post-Traumatic Stress Disorder
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2 – a coronavirus that is responsible for causing COVID-19 (1)
Tracheostomy	A surgical procedure involving the making of an opening through the skin into the windpipe (trachea) so that a breathing tube can be inserted to assist with breathing either whilst on a ventilator or whilst breathing on your own (4)
US	United States used interchangeably with USA
USA	United States of America, used interchangeably with US

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CHAPTER 1: INTRODUCTION

1.1. THE INTENSIVE CARE CONTEXT

Technological advances in critical care patient management over the past few decades have resulted in improved patient outcomes and survival of more patients (5). These improved technologies have enabled faster diagnosis of complex medical conditions. Improved monitoring devices support physiological processes, especially in respiratory and cardiovascular mechanics (5,6). However, despite these advances, the Intensive Care Unit (ICU) represents an unfamiliar and potentially hostile environment for patients (6).

Some of the commonly reported environmental stressors that affect patients in the ICU are the constant noise levels, almost 24-hour ambient light, inability to move around freely, and social isolation (6). Patients are often confined to bed, sedated or unconscious and, therefore, usually unable to express themselves adequately. As part of their care, they are also often attached to multiple monitoring and support care devices via a variable array of tubes, catheters or electrodes which impede their movement and don't allow them to verbalize. These devices also have very sensitive loud alarms that can exacerbate anxiety and panic in patients who are aware enough to hear them (6).

Noise levels in an ICU regardless of the source (alarms, equipment use or noise generated through routine patient care) adversely affect patient sleep patterns and precipitate delirium (6). Delirium, according to the Confusion Assessment Method (CAM), is characterized by the presence of either: an acute change in mental status with a "fluctuating course, inattention, disordered thinking or an altered level of consciousness" (p. 991, 7). Additionally, disordered sleep patterns in the ICU caused by other factors, namely mechanical ventilators, pain or bright light may result in impairment in memory or cognition (8-10). In fact, many ICU survivors often complain about impaired thinking, judgement and other mental health problems long after discharge from ICU--a syndrome known as Post ICU Syndrome (PICS).

PICS requires a multidisciplinary treatment approach involving, not only the patient,but their families also. The various stakeholders involved in engaging with the patient or their families include: psychiatrists, psychologists, physiotherapists, occupational therapists, etc., who attempt to provide holistic care to the entire family (11). Thus, admission to the ICU, regardless of the cause, can be extremely distressing for the patient.

Often, ICU patient families and loved ones also feel helpless and afraid, too. Up to 30 percent of family members who have experienced a loved one in an ICU may also develop depression, anxiety or Post Traumatic Stress Disorder (PTSD) (11) with more than 50 percent of them experiencing distress and anxiety for up to two years post ICU discharge (12).

Intensivists, i.e., medical specialists trained in the field of critical care, and other ICU caregivers including specially trained nurses, physiotherapists, occupational therapists, dieticians, etc., are all highly qualified and experienced in managing critically ill patients (13). They lead the multidisciplinary team who focus primarily on the clinical management of critically ill patients (13). This usually requires performing serial clinical examinations, taking serial blood samples, multiple radiological investigations and insertion of invasive monitoring devices that aid clinicians in diagnosis and treatment of these patients (14,15). These tests and procedures are invaluable in assisting the clinician in their duties, but due to time pressure (they often need to be performed urgently), patient consultation about the consent process is somewhat limited (if at all) (16). The perceived exclusion of the critically ill patient in their own medical decisions may exacerbate the PTSD experienced following discharge from the ICU (12).

Thus, in view of the disordered thinking as well as memory and judgement impairment, the ICU patient represents a vulnerable population (16). This vulnerability occurs regardless of their decisional capacity at that moment. ICU patient families are also vulnerable since they may also feel overwhelmed, anxious and extremely uncertain especially when asked to become involved in surrogate medical decision making for their loved one (e.g. being asked to sign a consent form when invasive procedures are performed in the ICU) (12).

1.2. LITERATURE PERTAINING TO OBTAINING INFORMED CONSENT IN THE CRITICALLY ILL

Decisional capacity, as shall be explored later, in this context refers to a person's ability to make their own medical choices regarding treatment (17). A person with decisional capacity is allowed to legally consent to medical procedures provided that they have fully understood all the risks and benefits of the procedure, and agreed to it of their own volution and without

coercion by anyone (such as a medical practitioner, family member or another interested party).

Such agreement to the described treatment or procedure is referred to as *informed consent*. The prerequisites and intricacies of informed consent will be explored in the next chapter. For informed consent to be valid, the patient with decisional capacity must have *full understanding* of the proposed treatment and the consequences of consenting or refusal of such treatment (18).

Informed consent, in accordance with South African law, is required prior to performing invasive procedures on patients in accordance with Section 7 of the National Health Act No. 61 of 2003 (19) as well as Booklet 9 of the Health Professions Council of South Africa (HPCSA) guidelines (20). They also make allowance for a designated family member to give consent on behalf of a patient who is deemed incapable of making their own choices. This is called consent by proxy, and I explore this concept further in Chapter 2.

These acts and regulations also govern clinicians' actions with respect to providing emergency medical treatment in life threatening situations. However, they do not explicitly address how one should obtain informed consent from critically ill individuals who, once stabilized, may not necessarily require emergency medical treatment, but may still require invasive procedures urgently, since a delay may result in clinical deterioration. Time pressure does not always allow for full understanding and appreciation of all the risks and benefits of the procedure for informed consent to be obtained in the traditional way. This report interrogates the concept of obtaining informed consent in the critically ill along with the related challenges and pitfalls in the current legislation.

On the other hand, ethical opinions acknowledge that obtaining informed consent in the critically ill is difficult (16,21). Consequently, emphasis has been placed primarily on protecting patient autonomy and innovating new methods to obtain consent for clinical research purposes in the ICU (22-24). Whilst, research in this vulnerable population is important, a critical evaluation of how one *ought* to obtain the necessary informed consent for invasive procedures in the critically ill also deserves to be highlighted .

In 2003, Davis *et al*. (16) suggested that obtaining an all-encompassing blanket informed consent either from the patient or their designated proxy just prior to, or upon admission to the ICU, would improve the informed consent process, and also streamline treatment in the critically ill. The consent process was either explained to the patient or an appointed representative for approval to proceed. The trial was conducted in two phases, namely an initial observational and then interventional phase that evaluated the process by which consent is obtained in the critically ill (16).

During the observational phase, Davis *et al.* demonstrated that obtaining informed consent in the critically ill was an extremely variable process (16). Whilst the trial participants (ICU clinicians) believed that informed consent was indeed necessary, this belief did not mirror their behaviour. There was such a lack of consistency amongst clinicians that some even performed invasive procedures without any consent.

The study also revealed that some clinicians believed that procedures that carried more risk (because they were associated with a higher complication rate or higher medico-legal risk) mandated strict informed consent, whilst others thought to be associated with fewer complications did not warrant obtaining consent (16). This inconsistent approach to obtaining consent in this vulnerable group proved that even highly skilled ICU clinicians did not fully understand informed consent as a concept and thereby potentially disrespected patient autonomy as well (16).

During the interventional phase of the trial, the clinicians implemented an all-encompassing blanket informed consent form for the patients undergoing certain pre-defined invasive procedures in the ICU (16). Again, vast inconsistencies were found, however upon re-evaluation post ICU discharge, patients and their nominated proxies who had signed the blanket consent form had a better, deeper understanding and appreciation of what happens in an ICU and they were less anxious about being in the ICU (16). This study was then used to canvas for the implementation of a blanket informed consent form in the ICU, without fully interrogating the morality of its implementation first.

Another more recent South African survey, aimed at evaluating the perspectives of anaesthetists with respect to consent to anaesthesia, revealed that whilst most doctors were

familiar with informed consent, in reality, the theoretical knowledge did not translate into practice in the state hospitals that were surveyed (25). The study revealed that most doctors spent less than ten minutes explaining the anaesthetic procedure to the patient. The documentation of invasive procedures also occurred less than 50% of the time, thus again demonstrating that despite the theoretical knowledge, doctors did not comply with the process of obtaining informed consent in patients (25). The reasons for this lack of compliance were unclear, but it can be extrapolated that the process of obtaining informed consent varies vastly amongst clinicians.

The variability of implementing the informed consent process was replicated in another study in an ICU in England, where again, most study participants conceded that they only used informed consent occasionally, depending on the procedure being performed (26). The clinician's behaviour, again, brings their moral integrity into question.

In the meantime, the topic of obtaining informed consent in critically ill individuals in bioethical literature remains confined to the protection of the patient's autonomy, i.e., still attempting to uphold one of the foundational pillars of bioethics, which is respect for autonomy. This approach emphasizes focussing on protecting the patient's right to choice and determining the decisional capacity at the time of critical illness (21,27). Whilst this information is relevant, the literature regarding the ethics of how one ought to obtain informed consent in the critically ill seems lacking. Additionally, no mention is made about the ethics of obtaining all-encompassing blanket consent for invasive procedures performed in the Intensive Care Unit. In doing so, ICU clinicians are forced to rely heavily on past experience and intuition for direction on how to act when obtaining informed consent for invasive procedures in the ICU, thus fuelling the vast inconsistencies in practice. In South Africa, the all-encompassing informed consent concept for critically ill patients has not been described.

Whilst there is little doubt that ICU patients are vulnerable, their management requires invasive procedures and serial diagnostic investigations as part of their management in the ICU. Without these crucial investigations, diagnoses would be delayed putting patients at risk of complicating or deteriorating rapidly.

Obtaining valid informed consent in this setting is extremely challenging, owing mainly to time pressure and the risk of the patient deteriorating (28,29). A clinician may not be able to deliberate the pros and cons of consenting to a procedure with the patient or the designated proxy, because a delay in proceeding may cause harm to the patient (16). On the other hand, any undue pressure that the clinician places on the patient or family would then constitute coercion, which often fuels the anxiety and stress suffered by both the patient and the family. Family members sometimes seem reluctant to give proxy consent either because they are too emotional to comprehend the magnitude of the problem, fear the potential complications, or may need to consult with other family members (30,31).

Despite the laws and professional regulations, clinicians still behave in a variable manner, with no consensus on which procedures mandate informed consent and which do not. This choice (how and when to obtain informed consent) is ultimately determined by the moral conscience of the clinician (25). For example, a clinician who deems a procedure an "emergency", forgoes the need to obtain a patient's informed consent. Emergency consent as a concept remains ill-defined in legal and ethical literature, and it seems to be based on the clinician's moral character and not what ought to be done in such a scenario (32).

Implementing an all-encompassing blanket consent for critically ill individuals would then seem logical, because not only would it be convenient for the clinician, it would also empower the patient (and/or the designated proxy) to understand that these procedures are part of the ICU course. However, simply implementing a concept such as this, without interrogating the morality of it first would, on the face of it, be premature. The morality of this concept needs to be thoroughly debated first to evaluate the moral validity of blanket consent as the first step.

1.3. OUTLINE OF THIS REPORT

This report will explore the moral essence of blanket consent and try to ethically justify its utility for critically ill individuals, *prior* to it being implemented in clinical practice. I ask if is it morally acceptable to obtain blanket consent for invasive procedures in the intensive care unit? To my knowledge, this question has not been answered yet.

I will thus examine the presupposition that it is morally acceptable to obtain blanket consent for invasive procedures from critically ill patients (or a designated proxy), just prior to or upon admission into an ICU. Prior consent may be obtained in the case of a planned or elective admission to an ICU; otherwise, the blanket consent form may be signed upon admission to the ICU (in the case of an unplanned admission).

In this normative report, a detailed account of obtaining informed consent in the critically ill will be conducted. To achieve this, a library and web-based search of the current literature pertaining to obtaining informed consent in the critically ill was done. Only studies published in English were perused in the search. Although this report is written from a South African perspective, with the intention of justifying blanket consent utility in South African public ICUs, the search was not limited to the South African context to ensure generalizability in the report. Common and case law were also used to establish current practices of application of the law in relevant instances.

The term ‘informed consent’ is sometimes used interchangeably with ‘consent’ which in this report implies that consent always be ‘informed’. Similarly, the term ‘blanket consent’ has also been shortened to imply ‘blanket informed consent’ since blanket consent constitutes a type of informed consent. Adding the word ‘informed’ is sometimes used merely for emphasis, but should not detract from the true meaning of the term, which in this report refers to an all-encompassing informed consent taken from a patient or their surrogate to allow the clinician the necessary permission to perform a defined range of procedures as and when the clinician deems them necessary for a critically ill patient.

Using moral pluralism as a theoretical framework, whilst invoking deductive logic, deontology and ethics of care as argumentative strategies, I argue that it is morally acceptable to obtain blanket consent for invasive procedures in critically ill individuals who require treatment in the ICU.

Moral pluralism refers to the acceptance that an ethical stance may be valid despite several correct, yet conflicting moral arguments (33). Deductive logic is using a systematic process of using multiple premises to reach a specific conclusion (34). Deontology is a theory, where

the morality of actions is determined by rules and obligations (35), and the ethics of care is moral theory based on establishing caring in our relationships (36).

By establishing the moral eligibility of blanket consent in the critically ill, a more comprehensive argument may be made regarding its clinical application. The intention here would be to obviate the current inconsistencies in obtaining informed consent from critically ill individuals and thereby comment on potential areas of further research to advise upon future practice and policy making with respect to this topic.

The report structure is outlined as follows:

Chapter two defines the different types of informed consent performed in clinical practice and the prerequisites required for obtaining valid informed consent in the ICU, with emphasis on its dynamic nature. The concept of obtaining blanket informed consent for invasive procedures performed in the ICU is introduced and interrogated. I also explore the origins of medical paternalism in its various forms culminating in the rationale for implementing a shared decision-making model in the intensive care unit.

Chapter three discusses the moral benefits and harms of obtaining blanket consent in the critically ill and draws an ethical comparison amongst the various types of informed consent, with the aim of providing proof that the argument for a blanket consent for invasive procedures in the ICU is morally permissible and should be implemented.

Finally, citing the hypothesis proven, chapter four seeks to construct informed recommendations about reform in both clinical and legal practice with respect to improving the informed consent process when performing invasive procedures in critically ill individuals. However, I acknowledge the limitations of this report, the first being that it is a purely normative analysis.

CHAPTER 2: INFORMED CONSENT IN THE CRITICALLY ILL

2.1 BACKGROUND

Obtaining informed consent for medical procedures originates from the cornerstone of medical ethics--the right to autonomy (37). This principle heralds from our fundamental ability to think and act freely, thus defining our existence as a human species. It is the ability to possess “free will” that allows humans to make conscious moral decisions and to accept their consequences (38).

The process of obtaining informed consent has evolvedconsiderably since ancient times. Although the early Egyptian, Greek and Roman doctors informed patients when procedures needed to occur, it was seldom written down or questioned by patients (39). At that time, this trust had embraced the paternalistic viewpoint that: “The patient is an ignorant person who does not have the knowledge, the intellectual capacity or moral authority to oppose or disagree with the wishes and decisions of the physician who, instead, on account of his doctrine, knows exactly what is good for him” [patient] (p. 312, 39). The doctor was also usually regarded as a holy man with pious qualities and was given a social class status close to God; therefore, obtaining consent did not focus on counselling about risks or benefits of the procedure, but merely acquired permission to proceed usually without protest from the patient (39,40). Thus, the patient assumed the submissive role in the doctor-patient relationship and did not question the risks or complications that could occur following any procedure.

Even the Hippocratic Oath also did not compel a doctor to seek permission to perform procedures on patients (40). It did, however at least, stipulate that a doctor should always try his best to heal, and not inflict harm when treating patients (41). It was this allegiance to the Oath that protected patients from harm or experimentation by doctors (39). In addition, this form of tacit consent or “permission to proceed,” without fully understanding the risks or potential complications of a procedure, also did not place any legal obligations on the doctor whose decisions were never questioned, let alone called to account or held liable (39,40,42).

“Informed consent has been an axiom of post-World War II clinical research and practise” as noted by author Paul Weindling in 2001 (p. 37, 42). The Nuremberg Trials concluded in 1947, culminating in the Nuremberg Code being promulgated in 1947 (43). This set of rules

outlined the expectations to be adhered to when conducting scientific medical research. It upheld a patient's right to choose freely, following disclosure of enough information without any fear of coercion or force. It emphasized the importance of decision making through consensus (39,43).

The United States of America (US) is known for developing the informed consent process as we know it (39). This was due to the raised awareness in civil and consumer rights of the 1950s and 1960s in the US (40), which promoted protection of people in the post war era. Patients now began viewing themselves as consumers of a health care service, and doctors needed to justify investigations and treatments with several doctor's decisions being challenged in court (40). Thus, the founding pillars of informed consent, i.e., protecting patient autonomy and information sharing (disclosure) about required procedures or treatment, began being properly defined after being tested in court (39,40,42,43).

New doctrines and laws began being promulgated from 1957 onwards (40). In 1964, the World Medical Association's Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects emphasized the importance of informed consent in research (44). Particular attention was given to the participant's voluntary willingness, full disclosure of information pertaining to all aspects of the research and funders, and the proposed benefits and risks of the study (25,44).

South Africa, on the other hand, lagged behind. Although as a concept, informed consent was tested in court in 1976 in the *Richter v Estate Hammann* (45)*,* it only became law in 1994 with the promulgation of the National Health Act (19). The South African National Health Act: Chapter 2 – Sections 6-8 emphasizes informed consent with respect to health users having full knowledge of the planned treatment or procedures, consent of users and user participation in health decisions (19).

As is now clear, informed consent is not merely an authorization (46). It creates legal and ethical expectations amongst all stakeholders involved, i.e., the person(s) taking the consent (consent seeker(s)) and the person giving consent (health care user). In most cases, the health care user, i.e., the patient, consents to medical treatment themselves, hence assuming both legal and ethical consequences (46). This is provided that the patient has

decisional capacity to consent by themselves. Decisional capacity along with other prerequisites of informed consent are discussed later in this chapter.

In contrast, in the ICU the stakeholders involved are not just the patients themselves. A designated proxy or surrogate decision-maker is often appointed to aid in giving informed consent on the patient's behalf (2). According to South African law, the National Health Act stipulates the order in which the next of kin may be approached to give consent for an ICU patient without decisional capacity to do so themselves (19). It states in Section 7(1)(b) that if: "The user is unable to give informed consent and no person is mandated or authorised to give such consent, (then) the consent is given by the *spouse* or *partner* of the user or, in the absence of such spouse or partner, a *parent, grandparent, an adult child* or a *brother* or a *sister* of the user, in the specific order as listed" (p 20, 19). This is referred to as consent by proxy. Consent by proxy is commonly used to obtain valid consent in the ICU (16).

The ethical conundrum created here is the assumption that the people, as stipulated in the abovementioned order, are suitably qualified to act in the patient's best interests (47). The Act presumes that these people would have a reasonably good idea of the patient's wishes in that particular scenario (47). This is far from true. Next of kin or surrogate decision makers often do not know the patient's wishes at all times, especially when it comes to consenting about complex, time-sensitive decisions or regarding performing invasive (potentially painful) procedures on their loved one who is critically ill (48,49).

For informed consent to be valid, it requires several prerequisites to be fulfilled, namely: decisional capacity, voluntariness and full disclosure (50) which I will discuss in detail:

2.1.1 Decisional Capacity

Decisional capacity refers to a person's ability to make their own medical choices regarding treatment (17). The term differs from mere understanding, because the person should also be able to appreciate the risks and potential consequences of a test, procedure or therapeutic intervention (18).

Legally, age and capacity are linked (51,52). According to South African law, a person 18 years and older is considered a major, i.e., assumed to be an adult and therefore, capable of making legally binding decisions for themselves (53). The age required to consent legally to medical treatment has many nuances in South Africa. For example, children aged 12 years and older may consent to a surgical procedure, unless that procedure is a termination of pregnancy-–when there is no age restriction (53,54). There are several reasons for this allowance in the law, which are beyond the scope of this report. Suffice it to say that although the legal age to consent for a medical procedure in South Africa is 12 years, this allowance in the law acknowledges that age alone cannot be the only factor to be considered when obtaining informed consent.

Critical to this understanding is the acceptance that obtaining valid consent goes deeper than one's age. It is based on the individual's physical and psychological maturity to fully comprehend a situation. Maturity is assessed using cognitive developmental tests and depends on achieving certain predetermined developmental milestones (52,53,55). Psychological and emotional maturity is far more complex and also beyond the scope of this report (56).

Kohlberg's stages of moral development were initially viewed as an acceptable method of assessing moral developmental stages (57). However, Carol Gilligan, a psychologist, wrote a book entitled, In a Different Voice, where she challenged Kohlberg's interpretation of these stages with respect to moral development and the different ways in which men and women think (57). The debate raised questions regarding the differences between men and women, leaving the quest for determining when we are capable of making moral choices largely unsolved.

The elements of decisional capacity are choice, understanding, appreciation and reasoning (58). One's ability to listen, process and assimilate the information being shared conveys the understanding to be able to make an informed choice (51). This understanding of the information conveyed, ability to convey one's choice, and finally willingness to accept the consequences thereof is what makes informed consent different than mere disclosure (18). Therefore, when medical information is relayed to a patient or a surrogate, it needs to be in the patient's vernacular language, and conveyed at a level that enables the recipient to grasp all aspects of the concepts fully (19, 59). This step is critical to clinical decision making

in the ICU since many of the procedures and decisions taken will have longstanding binding consequences for the patient and/or the family.

Clinical assessment of decisional capacity in general is complex, with no single validated method that does not have some problems, too. Commonly used scoring systems such as the Glasgow Coma Scale (GCS) or the Mini-mental State Exam (MMSE) are quoted when assessing decisional capacity, however they have several limitations in ICU patients and are generally not very useful (60). Additionally, doctors have admitted to feeling non-confident when it comes to assessing capacity (25,59) since it is an all-or-none concept with the clinician having to make a final (often binding) assessment (17,61). This is also evident by the variable way informed consent was taken in the Davis *et al*. trial (16).

Another important point is that capacity is dynamic. One's ability to make one's own decisions can fluctuate over time (17). Frequently in the ICU, patients may be admitted awake, conscious and fully aware oftheir surroundings, i.e., having retained decisional capacity. However, over time, capacity can begin to wane, as many of drugs used in the ICU cause drowsiness or alter one's mental state. The ICU itself is often a common precipitant of delirium (fluctuation in level of consciousness) (62). It is therefore imperative that patients are adequately counselled whilst they have capacity.

Hence, we realise that assessing decisional capacity in critically ill patients can be extremely challenging. On the one hand, there are several physiological factors to consider--such as fluctuating level of consciousness, liberal use of sedatives, disturbed sleep cycles due to loud noise levels and the 24-hour work environment. On the other hand, emotional factors may significantly impair one's judgement, e.g., pain, fear of a procedure or enduring one of its potential complications, fear about loss of income, or not being able to be with family. The emotional assessment is often more difficult to objectively predict. Seeing that true understanding is closely linked to the emotional component of decisional capacity and is therefore integral to the assessment–the clinician often relies on the co-counselling of next of kin, especially when taking time-sensitive decisions in the ICU.

2.1.2 Voluntariness

Voluntariness is important since the principle of respect for autonomy is upheld here. One cannot inflict pain and/or suffering on a patient who, whilst in sound mind and in full control of all their faculties, is not willing to accept treatment or medical advice (63). There are very few exceptions to this, e.g., when managing diseases that threaten public health. A classic example of this had been the mandatory isolation of patients (in the pre-vaccination era) infected with coronavirus to curb further community spread. In this scenario, the wellbeing of the community supersedes the individual's wellbeing (64).

2.1.3 Disclosure

Historically, as informed consent became more accepted by most people, and medical decisions began being challenged in court (65), clinicians adopted the 'professional practice standard', aka the 'professional community standard', which addressed the amount of information disclosed to a patient or their family about their medical condition (37). The clinician, regarded as a reasonable practitioner, was expected to disclose enough information to a patient that any reasonable practitioner would have done under similar circumstances (37). Although this standard greatly improved the disclosure of medical information to the patient, it was still done at the discretion of the clinician (37,50).

Subsequently, the professional practice standard, also challenged in court, was replaced by the 'reasonable person standard', aka the 'reasonable patient standard' (37,50,66). Disclosure of medical information was further refined and compelled the clinician to disclose all 'material risks' to the extent that it would satisfy a hypothetical reasonable person. A 'material risk' is any risk that "A reasonable person, in the patient's position, if warned of the risk, would be likely to attach significance to it if warned about the risk" (p56, 67); as well as anything the patient would consider important for medical decision-making" (67).

The South African National Health Act Chapter 2(6)(1) deals with disclosure (19). It stipulates that although all patients need to be informed of their health status, there are some exceptions, i.e., when the clinician feels there is substantial evidence that the disclosure would be contrary to the patient's best interests (19). Also, the Act allows a clinician to only discuss "The benefits, risks, costs and consequences *generally* associated with each [therapeutic] option" (p. 20, 19). This allowance for the clinician to tailor information according to the patient's wants and needs (37) is open to interpretation and

may be challenged in court–where the clinician would need to prove that all material risks had been discussed and give clear explanations why information was withheld (50, 68).

Withholding some clinician information is called the ‘therapeutic privilege’ (37,67,69). Should a clinician feel that a patient’s condition is too fragile to be able to cope upon receiving a specific detail about his/her care, the clinician has the authority to withhold such information until such time that they deem it safe to be revealed (70). The clinician must be certain that this information would not constitute a material risk, or that if divulged the patient’s condition would deteriorate or affect their recovery adversely.

Proponents advocating for the use of therapeutic privilege claim that it protects the patient’s wellbeing by respecting the principle of non-maleficence (first, do no harm) (70). The counter-argument to this is the trust created in the doctor-patient relationship should be based on honesty. Being deliberately dishonest to the patient is the ultimate disrespect to their autonomy and is likely to exacerbate anxiety and distress, rather that relieve it (70).

Deciding how much information to disclose to a critically ill individual (if they have capacity) or their surrogate is even more complicated. Bearing in mind that the nature of the relationship between the patient and the surrogate is often unknown, divulging confidential medical information to the surrogate, although well-intentioned, may not be what the patient would have wanted. Disclosed information, especially with the view that to obtain informed consent also has the potential to make the surrogate more anxious and distressed, may impede the consent process, rather than assist it.

2.2 TYPES OF INFORMED CONSENT:

From the above explanation on the origins of informed consent, its pre-determined pre-requisites and nuances in the critically ill, its evolution from the initial verbal acceptance to the written, now legal requirement that it is been shaped into can be understood.

Although informed consent may be obtained verbally (also referred to as assent), written forms of consent are required, especially when invasive medical procedures are performed

(46,50). The main types of informed consent applicable to the critically ill patient that will be discussed in this report include:

- Consent by proxy
- Broad consent
- Emergency consent
- Blanket consent will be addressed in on its own in this chapter

2.2.1 Consent by Proxy

Consent by proxy refers to the use of: “Consent based on a substituted judgement from a proxy who has the capacity to consent” (p.2, 30). As a legal term, sometimes referred to as ‘power of attorney’, proxy consent allows a designated person, who is legally competent *and* has a legal right to consent in that scenario, to make medical decisions on behalf of a person who does not have the capacity to do so by themselves (71).

The legally appointed person is thus required to sign informed consent on behalf of the patient when he/she is mentally incapacitated. This person can either be appointed by the patient (when they had the capacity to do so) or may be a family member appointed by the State (hierarchy stipulated in the National Health Act (19)) (72). The Act assumes that the order in which it is stipulated is an accurate representation of how the patient would have chosen to have their best interests at heart. Unfortunately, studies do not support this assumption—demonstrating that families are often not able to accurately predict the patient’s wishes (73).

Surrogates or proxies make decisions based on two principles (30,73,74):

- A substituted judgement standard, i.e., the surrogate decides based on what they believe the patient would do if they had the capacity to do so;
- A best interests standard, i.e., the surrogate decides about what would be in the patient’s best interests.

A systematic review by Shalowitz, Garrett-Mayer, and Wendler (73) revealed that surrogate decision makers failed to accurately predict the wishes or desires of the patient about one third of the time. This means that one out of every three decisions were incorrectly predicted,

with one study noting that decision accuracy was “frequently inaccurate” or even “not better than chance” (73). Others revealed that although patients confidently believed that their families and doctors could make end of life decisions for them if they were unable to do so, less than ten percent ever openly discussed their wishes with them (75).

The principle of respect for patient autonomy has been used to justify the use of surrogate decision-makers in situations where patients are mentally incapacitated (autonomy is discussed in detail later in this report) (73). However, it is now evident that surrogate decision-maker decisions, although mostly well intentioned, do not assist with upholding patient autonomy (31). Although the patient may trust the decision-maker, the decision-makers seem to make the wrong decision frequently (73).

Some of the reasons for the poor accuracy by surrogate decision-makers, were alluded to earlier. Surrogate decision-makers , are often dealing with an acute stress disorder or PTSD themselves on account of their loved one now being critically ill. Wrigley, in his paper, argued that proxies do not have sufficient moral authority to make decisions for their loved ones (31). Wrigley’s argument assigns the proxy decision-maker as an advisor to the medical team only in the best interests standard, citing the substituted judgement standard not attainable by a family member (31).

To illustrate the confusion that Wrigley’s argument could cause, consider the following example: a designated proxy decision-maker refuses to give informed consent (assuming all prerequisites had been adequately met) for a (non-urgent) procedure that the ICU clinician deems necessary and beneficial for an unconscious patient. According to Wrigley, the proxy does not hold much moral authority, except to make a case on the best interests standard (31). On the other hand, the clinician, advocating for the procedure, is also using the best interests principle, which may be synonymous with Beauchamp and Childress’s principle of beneficence (37). Both these moral justifications may be valid and would need to be considered carefully before making a final assessment. The clinician needs to be aware of the duality of best interests and needs to approach the moral conflict with patience, compassion and sensitivity (33). Legally, the clinician may even be able challenge the proxy’s decision by obtaining a court order to override the decision. However, each scenario is different and a case-by-case assessment needs to be done. Only if the procedure is deemed an emergency, would the clinician be able to continue without explicit consent.

2.2.2 Broad consent:

Broad consent is defined, according to the igi-global.com dictionary as “A type of consent where a participant expresses his/her general consent that his/her own personal information, including biomedical or health related information and/or tissue samples can be used in future research, without a new explicit consent from his/her side” (76). “Participant” in this context refers to a person taking part in a clinical trial. The consent may not only be limited to the use of information, but also of previously collected biological material. These samples are usually stored in a biobank or a healthcare database (77,78). Typically, an all-encompassing informed consent form is signed upon entry into the biobank or repository, which then allows researchers the convenience of already collected data or biological samples when conducting a particular study (79). These future dated trials then have the convenience of the data which allows for more inclusivity in participants, more heterogeneity in sampling, multi-national collaboration and hopefully expedited results (77). In turn, the participant is only sampled once with minimal disruption.

There are two subtypes of broad consent: blanket, also known as (aka) open, and narrow, aka specific consent (80). Blanket consent is usually construed as vague and nonspecific, whilst narrow consent might be too constrictive particularly in the context of research. One of the main limitations of accepting broad consent in ethics is that it can be perceived that its all-encompassing nature compromises patient autonomy and exposes participants to possible exploitation and harm.

To combat exploitation and potential patient harm, robust safeguards in the form of material transfer agreements (MTA) and legislation have been put into place with regards to biobanking (81). The Protection of Personal Information Act (POPIA) passed in 2013, but implemented fully only in 2021, ensures any personal information collected by either public and private sectors is adequately protected, kept confidential and does not exploit the person whose information is being collected (82). Chapter 3, Section 19 – 22 (condition 7) deals with the specifications regarding safeguards to be implemented by the party collecting the information (82). The General Data Protection Regulation (GDPR) is the European equivalent passed in 2016 (83).

It may seem that broad consent has minimal utility in the clinical context, especially when performing invasive tests or procedures in the ICU. Current ICU practise involves separate consent forms for each procedure and clinicians would obtain consent specific to the procedure only. This approach is pragmatic as the patient (or designated proxy) is only counselled about procedures that are relevant and clinically indicated.

However, consider this hypothetical scenario-–a patient requires a tracheostomy for long-term ventilation (84). Since the patient is ventilated, obtaining consent would be via proxy. Proxy consent can be time-consuming, as family members often need time to deliberate and discuss the pros and cons of the procedure (80). Although the tracheostomy is unlikely to be an emergency, it does offer several distinct advantages in a patient who is likely to need a ventilator for longer than a week, namely improved oral patient hygiene, improved patient comfort and possibly decreased need for sedation (84). An undue delay in obtaining proxy consent may delay the procedure and result in more complications.

In this scenario, broad consent may have some clinical value. By obtaining the consent either from the patient (prior to ventilation), or from the proxy upon admission, the procedure could have been done easily, if indicated, by the end of the first week without the unnecessary delay of waiting for the family to deliberate before the procedure was performed.

Another example of clinical utility of broad consent is in the use of electronic health databases (85). Many countries utilize electronic health databases to store personal medical information of patients in lieu of paper-based files, as they require a huge amount of storage space, are easily mislaid and are not environmentally friendly. These repositories contain confidential medical information that may compromise a person’s right to autonomy and privacy; however, the overall benefit of being able to access all one’s health information when necessary (especially in an emergency) is of important clinical value and may even save the person’s life in the future.

Translating this concept into clinical practice, especially for critically ill individuals, is difficult. In this report, I advocate for the use of blanket consent for critically ill patients undergoing

invasive procedures. By establishing a sound argument for the morality of blanket consent, it will enable clinicians to implement it into practice for critically ill individuals.

Sheehan et al., describes three distinguishing features that broad consent creates (80):

- An account of the general program (of research)
- An account of the general goals (of research)
- An account of the institutional values and aspirations (of the biobank).

Extrapolating these features into the clinical ICU context, where blanket consent may be utilized for commonly performed invasive procedures in the ICU, potentially can create:

- An account of what the patient is likely to expect in the ICU (general program)
- An account of what the expected end points of therapy may be (general goals)
- An accountability of care in the unit (institutional values and aspirations).

Using this model of thinking, potential safeguards to be created would be the clinician acting in accordance with standard treatment guidelines based on evidence and science (akin to the MTA in research) and medical regulatory authorities such as the HPCSA (in lieu of Council for International Organizations for Medical Scientists (CIOMS)) (86).

With these elements in mind, Sheehan *et al*., (80) drew the ethical conclusion that broad consent is morally permissible in research since the patient's freedom of choice is upheld and therefore their autonomy is still respected. For broad consent to be accepted as ethical in clinical practise, a few more ethical considerations need to take place. These considerations are explained further in Chapter 3.

2.2.3 Emergency consent

The South African Constitution states that in terms of Section 27(3): "No-one may be refused emergency medical treatment" (p. 11, 87). Additionally, the National Health Act, Chapter 2(5) solidifies this claim by stating that: "A health care provider, health worker or health establishment may not refuse a person emergency medical treatment" (p. 20,19). Emergency care is also addressed by the HPCSA, in Booklet 9, which states that: "In an emergency, where consent cannot be obtained, health care practitioners may provide medical treatment to anyone who needs it, provided the treatment is limited to what is

immediately necessary to save life or avoid significant deterioration in the patient's health" (p. 7, 20).

These statements pertain to the medical practitioner's legal and ethical duty when dealing with a medical emergency. Medical practitioners are required by law to treat a patient in an emergency, however, what was not explicitly addressed is what constitutes such an emergency.

Consequently, in a landmark court challenge in 1997, i.e., Soobramoney v Minister of Health (KwaZulu-Natal) Case CCT 32/97, a patient claimed that he had the right to ongoing life-sustaining haemodialysis in terms of the Constitution, Sections 11 (right to life) and 27(3) (as defined above) (88). The Constitutional Court, on appeal, ruled in the Minister's favour.

The Constitutional Court's explanation then became important, as it delineated some of the limitations to one's rights and attempted to give more detail about what constitutes an emergency. It defined emergency as "A dramatic, sudden situation or event which is of passing nature in terms of time" (p. 22, 88). Additionally, the term 'emergency treatment', used in the Constitution did not include the treatment of terminal illnesses, which is not included in the ordinary meaning of the term (88). The Court ruled that Mr Soobramoney's case was not an emergency, since he had chronic renal failure and would have required regular haemodialysis for him to remain alive. Thus, the ruling recognised the limits to emergency treatment. The right to life is also limited and needs to be interpreted contextually, i.e., within the available health resources (88).

In South Africa, in accordance with Chapter 2 (7)(1)(e) of the National Health Act, emergency medical treatment may be performed without the consent of the patient. No explicit definition for an emergency is offered--except to mention that "Any delay in the provision of health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct not refused that service" (p. 20, 19).

In the public health sector, a safeguard is implemented in case of an emergency. An "emergency consent" form is required when performing emergency medical treatment for a patient without his or her explicit consent. The form requires a medical practitioner to obtain permission ("consent") from the Medical Superintendent, or a designated person (often a senior medical specialist) before the procedure is allowed to proceed. This safeguard does two things: firstly it ensures that the senior medical practitioner agrees that the procedure is necessary and secondly that the case is indeed an emergency (thus forgoing the regular consent process) (59,89).

In the private health sector, a medical emergency is defined by the Medical Schemes Act No. 131 of 1998, as: "The sudden and, at the time, unexpected onset of a health condition that requires immediate medical or surgical treatment, where failure to provide medical or surgical treatment would result in serious impairment to bodily functions or serious dysfunction to a body organ or part, or would place the person's life in serious jeopardy" (p.5, 90). The Council for Medical Schemes also outlined a similar statement regarding performing emergency medical treatment, when claiming it as a prescribed minimum benefit (91). Even the Medical Doctors Coding Manual in South Africa made amendments to the codes allowing private medical practitioners to bill for emergencies assessed in their homes or rooms. A new code was also created so that practitioners could bill a patient for an unscheduled consultation to his/her home or rooms (92).

From these amendments, it is evident that there are several iterations of what constitutes an emergency in the medical context. Although they all have a similar theme, i.e., that the treatment needs to be delivered quickly to prevent death or severe morbidity for the patient, it must also be acknowledged that practitioners are allowed to bill for the emergency treatment performed. In so doing, the intentions of the medical practitioner, although still good and sincere, are not the only motives for administering treatment, as they are expected to be appropriately remunerated for the service delivered. This is far from the totally altruistic notion that medical practitioners perform emergency procedures because it is the "right thing to do".

In the ICU, where the risk of a life-threatening event occurring is quite high, emergency procedures occur very frequently. As alluded to earlier, critically ill patients, and their surrogates, are vulnerable, especially when it comes to making decisions about complex

medical scenarios that could result in either their own death or that of a loved one. Also demonstrated by Davis *et al*., clinicians behave variably with respect to which procedures require informed consent in the critically ill (16).

On the other hand, whilst admitted to the ICU, patients may expect to receive treatment that will involve invasive procedures. Some of these procedures can be planned, leaving sufficient time to obtain valid informed consent from either the patient or their legal representative. However, all too often, many procedures may be required in a hurry to save a life or prevent a severe complication. In the latter scenario, procedures are often performed as an emergency, forgoing the informed consent requirement, as seen in the Davis *et al*., paper (16). In that trial, clinicians conceded that because they viewed some procedures just part of standard ICU care, consent was not obtained, whilst other procedures were deemed as emergencies (16).

Medical practitioners must therefore concede that they are afforded great “latitude” when defining what they believe constitutes a medical emergency (93). Therefore, they may have unknowingly exploited the vagueness of definition to avoid obtaining proper informed consent for procedures in the ICU, thus attempting to justify their variable behaviour when taking consent for invasive procedures in the ICU (16).

However, in the ICU, there are several necessary procedures that could be predicted in the general course of a standard ICU stay. These procedures, namely tracheostomy, insertion of central and arterial lines, amongst others, may be necessary to save a life and/or prevent serious complications, but are not necessarily strict emergencies (13). A clinician should not have to obtain emergency consent to perform them, as standard informed consent methods should suffice. The dilemma here is that, although not true emergency procedures, many of these procedures are certainly time sensitive. It is here that informed blanket consent taken beforehand may allow the clinician to proceed without potentially compromising care owing to time delays.

2.3 BLANKET CONSENT AS A FORM OF INFORMED CONSENT

Blanket consent is a form of broad consent (80). Broad consent, as explained in 2.2, has traditionally only been used in the research context. I made an argument for the utilization of

broad consent in the clinical context, too. In this section, I build on that argument by claiming that blanket consent can be utilized also in the clinical context and go further to advocate that it be implemented in the ICU. Chapter 3 will discuss the ethical basis of this claim.

Blanket consent is also known as open consent (80). This form of informed consent was initially designed to facilitate health research for information and biological material stored in databases or biobanks (79). It permits the wide use of the information or biological material for research of any kind (94). As with broad consent, blanket consent also has the same three main components, namely: creating accountability in the general program, general goals and institutional values of broad consent, which in the clinical context can be represented by ensuring accountability in meeting patient expectations, implementing therapeutic end-points, and the creation of accountability of care, respectively (80).

Important to note is that blanket consent in research is not without strict safeguards such as robust MTAs, which prevent the misuse or abuse of health information or biological material by corporates (77,81). Ideally, where possible, the patient needs to be consulted about any new procedures that may be envisioned. However, creating adequate safeguards in clinical practice before implementation is imperative also. These safeguards include the clinician who will still have to evaluate each decision regarding performing a procedure on its own clinical merits. The indication, contra-indication and patient stability to tolerate the procedure will have to be evaluated in real time, so that the clinician's judgement can be finalized.

In the clinical context, blanket consent would represent an all-encompassing prospective perspective of the clinician's description of the patient's condition, i.e., it would create a roadmap of the expected future-dated procedures that may or may not be in the pipeline for the patient.

Using a scenario, I will illustrate what I mean more clearly. A common indication for elective admission to the ICU is following a surgical procedure (e.g., for removal of a suspected malignant tumour) that is expected to involve a long time in theatre, have a high chance of complicating (e.g., haemorrhage) and/or require specialized care post operatively (e.g., epidural for pain control). The requirements in the ICU can sometimes be predicted by the clinician, i.e., in the ICU, this type of patient may require: post-operative mechanical

ventilation, insertion of an arterial blood pressure monitoring line, insertion of a CVC monitoring line, blood transfusion and an insertion of a urinary catheter (just for 'basic' admission) (14). Should the patient have any additional co-morbidities, further invasive procedures may be required, e.g., an insertion of a cardiac output monitoring device or a haemodialysis catheter.

The roadmap for this hypothetical patient's expected trajectory should ideally be explained to them at the onset, preferably *before* the elective procedure and informed consent for all of these procedures can be discussed upfront at the first consultation. Thus, the patient would be aware of all the benefits, risks and potential complications associated with each of these interventions. This deviates from current practice where the ICU clinician obtains consent in a variable manner, if even considered at all (16,25, 95).

In the research context, blanket consent has been heavily criticized for not adequately respecting individual autonomy, despite Hannson *et al*. trying to defend it (96-98). In contrast to this, blanket consent's utility in the clinical context has several advantages. Firstly, individual patient autonomy is genuinely respected by ensuring that patients with capacity fully comprehend their condition and the proposed treatment, along with all the potential additional procedures that may be necessary in the ICU*, beforehand (if possible)* (80,99). Secondly, it solidifies the trust in the doctor-patient relationship with the doctor explaining all aspects of the procedure and the patient remaining an integral part of a shared decision-making process. Patients who are informed accordingly are more likely to trust their medical team, and more likely to be heed their medical advice (46).

Critical illness, however, cannot always be anticipated or planned for, e.g., someone having a motor vehicle accident and requiring admission to the ICU. In this scenario, the patient's condition is usually critical enough to warrant emergency treatment, thus forgoing informed consent. However, once stabilised, the patient may still require further ongoing invasive procedures in the ICU that carry risks and complications that the patient or their surrogate may still need to be aware of. Establishing the same roadmap of care for the emergency patient admission is therefore equally important. This can be done upon admission, to foster the shared decision-making ethos early on and not create mistrust.

One of the central arguments favouring blanket consent's utility is the prospective plan to promote better patient and surrogate understanding of a seemingly everchanging cascade of events that may occur in the ICU. As the ICU is a foreign environment for most patients, an unanticipated admission will invariably be overwhelming for the patient and their family members (100). By introducing a blanket consent policy, the patient and their family would have as much information as possible at the beginning so that they can prepare and manage their expectations accordingly, thus fulfilling the first component of blanket consent.

A well-designed blanket informed consent form would include consent to insertion of invasive monitoring lines such as arterial catheters, CVC's, cardiac output monitors, urinary catheters, haemodialysis catheters, performing serial chest radiographs, CT scans, transfusion of blood products, a tracheostomy (if indicated) or performing an endoscopic procedure (16). This is not an exhaustive list and would need to be tailored according to the available ICU resources. In doing so, the general program for the patient's stay in the ICU would be outlined, in congruence to the general program outlined by Sheehan (80).

The case of Fitzpatrick vs White demonstrates the importance of obtaining informed consent in a timely manner to allow patients time to process and deliberate their choices before a procedure (101). Paul Fitzpatrick was scheduled for elective eye surgery at a public hospital, in Ireland, where the operating doctor introduced himself and asked him to sign the consent form approximately 30 minutes prior to his operation. (This was apparently in accordance with the standard clinical practice at that time). Mr Fitzpatrick signed the form but unfortunately suffered an extremely rare complication and required an additional procedure to only partially correct the problem. In the initial lawsuit filed against the doctor, Mr Fitzpatrick claimed that he was not duly informed about all the risks associated with the procedure and that had he been informed thereof, he would have declined the procedure.

On appeal, his lawyers further argued for negation of the informed consent completely--citing the first interaction between the operating doctor and the patient being unacceptable for an elective procedure. (The patient was already dressed in a theatre gown on his way to the operating theatre.) Although the doctor conceded that this time-frame was not sufficient (even for a minor day-case procedure), the court held that the doctor acted in accordance with standard clinical practise at the time and was not found negligent. The case was dismissed at appeal also.

Despite the outcome, this case illustrates that patients undergoing elective procedures need time to process and deliberate their choices (101,102). In the ICU, some invasive procedures may be elective and time-frames need to make allowance for adequate discussion of risks and benefits with key stakeholders. A blanket consent form containing a list of potential common procedures displaying the expected time-frames would create a general idea of the goals and therapeutic expectations for the patient and their families. Although Mr Fitzpatrick was not being considered for the ICU, his claim would have been obviated by a blanket consent form given to him well in advance of his procedure.

In the ICU, long time-frames to deliberate choices cannot be guaranteed by a blanket consent policy; however, the outline of the therapeutic end points can be explained. For example, the policy may state that should weaning from the ventilator become difficult, a tracheostomy would be considered.

The third component of blanket consent is the institutional creation of an accountability of care. As explained earlier, the ICU is an unnatural environment (6). It is the responsibility of the ICU team to try to allay the patient's and the families' fears. The team needs to imbue trustworthiness, confidence and a caring attitude to deliver a standard of care that is within the precepts of its available resources. In return, the family may also be able to hold the team to account by seeking clarity for certain procedures or even getting a second opinion.

Since blanket consent is all-encompassing, some limits need to be set up as well. Davis *et al*. implemented their blanket consent form following a 15-minute training session given to all the new ICU doctors on their first day of their rotation (16). The exact details of the discussion were not published in the paper; however, it is evident that some advanced training for hospital staff is necessary before implementation of any novel idea in medicine. I would suggest that this training be implemented in a standardized way so that clinician behaviour can be monitored. Standardization of the consent process sets limits to ensure that the information shared does not overwhelm the patient or the proxy. It should also not contain too much medical jargon (74).

A possible criticism of blanket consent would be that it creates a therapeutic misconception that once the form is signed, it automatically means those procedures are all necessary and will all benefit the patient. Therapeutic misconception is another term borrowed from research and means that the trial participant inadvertently believes that the intervention being studied would automatically benefit them directly and, in so doing, may feel obliged to consent to participating in the trial (103). There are many safeguards that are used to prevent therapeutic misconception in research which can also be extrapolated into the clinical context as well.

The gatekeeper of the blanket consent policy is therefore the clinician. To combat the accusation that blanket consent use in research is too liberal (97,98), clinicians need to ensure that the invasive procedures need to be performed in accordance with current standard accepted guidelines by trained clinicians and are within institutional standard operating practices. The legal and regulatory authorities for clinicians, i.e., the National Health Act (19), the critical care societies (104), or the HPCSA (105) all still govern the clinician's actions and therefore he/she must ensure that their license, and recently of practise, is always up to date.

This novel concept of informed blanket consent is almost wholly reliant on the trust built in the doctor-patient relationship. The initial consent and family counselling session establishes rapport, trust and builds a partnership between the medical practitioner, the patient and their surrogates. Section 2.5 addresses the dichotomy of autonomy and paternalism with respect to the doctor-patient relationship, whilst Chapter 3 will explore the morality of blanket consent for invasive procedures specifically in the ICU.

2.4 CHALLENGES TO INFORMED CONSENT IN THE CRITICALLY ILL

The most common element contributing to the challenging nature of obtaining informed consent in the ICU is the fact that it is difficult to fulfil the prerequisites of consent (46). Capacity, one of the major components of valid informed consent, is often most compromised in critically ill patients–because they are unconscious, sedated or mechanically ventilated.

As demonstrated above, surrogate decision-makers also struggle with decisions. Patient decisional capacity respects the patient's right to individual autonomy (24), however this right is limited when the patient is critically ill and overwhelmed. There are various factors that overwhelm decision-making amongst patients and their surrogates. The terms: 'emotional overwhelm' and 'informational overload', were introduced by Johan Bester, Cristie M. Cole and Eric Kodish (100). In their paper, they claimed that the emotional burden of the medical condition is in itself enough to make the critically ill patient overwhelmed, which invariably impacts on his or her capacity (100). They defined this burden as emotional overwhelm (100).

Informational overload relates to medical jargon used to explain the patient's condition to them or update their family (100). The ICU patients often have pathologies in multiple organ systems, so it becomes difficult to explain this situation to family members. For example, a common complication of a severe pneumonia (a respiratory disease) is renal failure (106,107). The pathophysiological process explaining this is difficult to understand and can also be difficult to explain. Severe renal failure may necessitate haemodialysis and is associated with a poor prognosis (107). A clinician seeking consent to insert a haemodialysis catheter (a process not without significant potential complication) may find it difficult to explain this process without using medical terms and possibly confusing the patient or their surrogate decision-maker.

The claim to autonomy is further challenged by Todorovic *et al*., who claimed that thinking is "Hard work even in the mature autonomous person" (p. 425, 21), indicating that humans are taught to be social beings who consult others when faced with having to make an important decision. In the above scenario, the patient, assuming that he or she was able to make their own choices, would have likely consulted a family member to assist with the decision. Hence, the patient's decision itself was not made totally autonomously (24).

Another limitation to capacity is that fluctuates over time (49). A patient may be awake and aware of their surroundings and choices, but may deteriorate very quickly becoming delirious and/ or unconscious. The method to assess decisional capacity in the critically ill is also not standardised (17). Most clinical units use a medical scoring system, i.e., GCS, MMSE, etc., to assess capacity, despite their several drawbacks.

The next challenge is disclosure of information. Since disclosure to the patient may not be possible in the ICU, disclosure to the surrogate often occurs so that proxy consent can be taken. As mentioned previously, consent by proxy for ICU patients is inherently flawed, since unless the patient appoints a designated proxy decision-maker, the law dictates the order in which this consent should be obtained, without taking into account the actual relationship status between the patient and those identified relatives (17).

Moreover, the time sensitive nature of procedures in the ICU are such that clinicians are usually unable to set long decision-making timeframes regarding some invasive procedures (100). There often is not much time to call the family and wait for them to arrive so that procedures may be discussed. In the South African public health system, intensive care units occur only in specialised hospitals that are usually located in big cities (108,109). Patients often travel great distances to access health care (108). In addition, most people in South Africa are dependent on the public transport system or reliant on walking to their destination (110). Visitors usually only visit their family members in hospital during the daytime or on weekends. A clinician requesting that family come to hospital to give consent for a procedure is usually impractical and expensive. Additionally, it may compromise the patient's care because the clinician will not be able to wait indefinitely.

Hence, the need for obtaining consent telephonically is borne from necessity. Telephonic consent has its own challenges. The most obvious barrier is that the conversation comes across as impersonal since there is no face-to-face contact. Being able to make eye contact and read body language is an important part of understanding trust building in a relationship (111). What needs to be borne in mind is that the doctor-patient relationship is not well established in the ICU, as patients or family members often meet the intensivist for the time in the ICU.

Compounding the communication problem are language and cultural barriers that impede adequate dissemination of information (25,28,112). This is particularly pertinent in South Africa, where there are 11 official languages with direct translation of medical concepts being difficult. The inability of doctors to be able to communicate with the patient further widens the gap in the doctor-patient relationship (25). Also of note is that still embedded in African tradition is the notion that consent for procedures needs to be supported by a husband, elder

or community leader (112). The communitarian decision-making approach defies the claim to individual autonomy (102,112,113).

The COVID-19 pandemic brought about its own challenges to the entire world. Intensive care units around the world were flooded and overwhelmed with unprecedented numbers of critically ill patients requiring treatment in an ICU. To curb the virus from spreading, lockdowns were implemented worldwide (109). Hospitals opted for a 'no visitors allowed' policy, as patients were being treated in isolation areas whilst all personnel wore special personal protective equipment (PPE). Families were therefore not allowed to visit patients in hospital because of the fear that they would become infected or infect other patients or staff as well (114). This inability to see family members compromised the traditional consent taking process and hence a new solution needed to be designed.

The only method of communication was then to use all available virtual platforms to convey even previously confidential information to patients and their families (who were often also in quarantine) (115). Doctors noted great difficulty with trying to convey the nonverbal aspects of communication such as empathy, sincerity and trust to their patients' families. Many experts would agree that the social isolation that patients felt increased their fear and anxiety associated with a loved one in the ICU (115). In the realisation that no patient-family contact may have contributed to worsened outcomes, most institutions permitted some leniency and amended their family visiting policies in their management plans for subsequent surges of COVID-19 (116).

To further complicate matters, there are few safeguards in place for obtaining informed consent in the critically ill. It is therefore not surprising that clinicians behave in such a variable manner. There is no structured, standardised process of discussing these concepts with patients or their surrogates in public hospitals in South Africa. A written outline of how to approach obtaining informed consent, which is clearly very complex and highly emotionally charged, is desperately needed for the ICU context. It needs to explicitly address the easily adaptable limitations such as language barriers, and should include standardized explanations in a standardized blanket consent form.

Finally, there has been a shift from the traditional approach--where informed consent was considered to be the ultimate respect to individual autonomy--to a more commercialized form of informed consent. There is a growing tendency to only focus on the contractual obligation between the doctor and the patient (28,117). The process of informed consent seems to have disintegrated into a document requiring mandatory signatories to absolve the clinician from litigation or accusation. Clinicians need to condemn the downgrading of informed consent and must guard against its degradation to a mere ‘document'.

2.5 PATIENT AUTONOMY VS MEDICAL PATERNALISM WITH RESPECT TO OBTAINING INFORMED CONSENT IN ICU

Decision-making in the ICU is complex and dynamic (29). Clinicians must make rapid potentially life-threatening decisions, usually without knowing the patient’s full history or having completed a comprehensive examination and investigative process to generate a list of probable diagnoses that they can either rule in or out following an order of priority (‘hypothetical deductive’) (118). They also rely on intuitive decision-making models which draw on the clinician’s experience to use disease pattern recognition to make a diagnosis and implement a treatment plan almost immediately (118). These decision-making models examine the problem from the psychological perspective of the clinician; however, of equal importance is ensuring that the patient and their family members remain central to the decision-making process.

Charles, *et al*. tabulated the different analytical stages to medical decision-making, i.e., information exchange, deliberation and who finally decides on a treatment plan (119). Cathy Charles, Tim Whelan and Amiram Gafni, suggested that true patient autonomy actually required a solid doctor-patient *partnership.* The common decision-making approaches are:

- Paternalism
- Informative
- Shared decision-making.

Paternalism can be thought of as “benevolent interference” (120). The benevolence comes from the inherent intention to promote good, whilst restricting liberty, hence the interference. Clinicians are as seen as paternalistic when they (usually unintentionally) make medical decisions for patients on their behalf. In this model of communication, clinicians usually

cascade information to patients and also make the final decisions for them. There is little or no engagement in terms of deliberation of therapeutic options, etc. Patients are also expected to accept these decisions passively (119).

The informative model creates a partnership between the doctor and the patient, where there is adequate information exchange and deliberation between the doctor and the patient to allow the patient to make the ultimate decision. The doctor is now the passive party that accepts the patient's decision (119). The informed decision making model is also known as the "patient empowerment ideology" (121). It encourages patients to do their own research, seek a second opinion and ask their clinicians more questions. In view of the severity of illness in patients usually admitted to the ICU, the utility of this model of clinical decision-making in the ICU is limited.

Shared-decision making, which is now the preferred model of communication and decision-making in medicine, is based on collaboration (49). The strong doctor-patient partnership is created where information is shared bi-directionally, and treatment options are discussed openly (49). The patient is encouraged to discuss preferences, fears and express their wishes to the doctor openly. Ultimately, the final decision is a collaborative effort because they are both equally invested in the partnership (119). However, for the shared decision-making model to work well, patient autonomy needs to be understood and respected (21). I explain the shared decision-making approach later in this chapter.

2.5.1 Patient autonomy

Autonomy is seen as the founding pillar of bioethics. '*Auto'* – means "self" (122) which implies that as humans, we have agency and free will. The suffix '-nomy' refers to "laws governing a certain field of knowledge" (123). 'Autonomy' is then directly translated as self-law (124).

Gerald Dworkin, an American professor of moral, political and legal philosophy, wrote in his paper on the Nature of Autonomy that autonomy in philosophy is associated with many different descriptive terms, and he emphasized that the definition is seldom standardized. Dworkin wrote that autonomy has been described as: "Equivalent of liberty…self-rule or sovereignty, sometimes as identical with freedom of the will. It is equated with dignity,

integrity, individuality, independence, responsibility and self-knowledge...qualities of self-assertion, critical reflection, freedom from obligation, absence of external causation and knowledge of one's own interests" (p. 8, 125).

All these synonyms, above, were used by Dworkin to describe the key features ascribed to autonomy, which culminate in autonomy being seen as a cornerstone of bioethics (21), and a desirable trait to have (125). The application of autonomy in bioethics is not as easy as it sounds, nor is it without its limitations.

Autonomy in bioethics involves two important steps: patient decision-making capacity (which has been discussed already), and the clinician who acts in accordance with the patient's choice (aka, *respect* for autonomy) (21). Respect for autonomy embraces the patient's agency to exercise their right to participate in the decisions being made about them, especially when the implications affect them directly, without undue interference or influence from others (126). In other words, respect for autonomy means the person is valued and that their choices are being upheld. Informed consent is commonly seen as the best way in which someone's autonomy is respected (21,126,127).

Other pertinent historic documents that identify autonomy as a cornerstone of bioethics include the Nuremberg Code (43), Declaration of Helsinki (44), Belmont Report (128), Barcelona Declaration (129). The moral theories discussing autonomy will be covered in more detail in the next chapter. Suffice it to say that almost every modern bioethical paper on autonomy mentions the writings of Immanuel Kant, a deontologist who wrote extensively about autonomy for the individual in the 1700s, making respect for autonomy and the related concepts of integrity, dignity, etc., all still relevant today (130).

Respecting individual autonomy in a clinical context is complex and not one dimensional (131). With all the emphasis on liberty and freedom of choice, we need to realise that medical decisions are seldom binary. For example, an autonomous person may decide to exercise his right to go to the beach. He can consult his friends and family about the decision, but ultimately his decision affects him alone and going to the beach is a non-life-threatening event. Therefore whether he goes or not, is immaterial. He exercised his autonomy and will bear the costs and consequences, and the benefits, of the trip.

However, decisions regarding one's health and safety usually are associated with more emotion with several factors being involved. For example, a decision to have major surgery is not taken alone. The person is usually part of a family unit, where the outcome of his or her decision will ultimately affect their family members, work colleagues and social network. Although the ultimate decision would rest with the individual concerned, he or she will have to weigh the benefits and risks of that decision in concert with their family, colleagues and friends. Even though the person is autonomous, the practicalities of exercising their autonomy is multifactorial and usually becomes more difficult if he/she is likely to potentially require intensive care after surgery (132).

Consulting one's family, colleagues, friends or religious leaders when making a complex decision does not mean that autonomy is lost, it just means that autonomy is relational (21,59). Relational autonomy (which I discuss in detail later in this report) takes into account the social reality in which an individual lives (133). Relational autonomy has its origins in care ethics, originally formally described by feminist scholars, and shares many traits with African and Asian philosophy described centuries ago (134). The common thread being the notion that humans exist as part of a complex web of relationships which provide us with the basis of our individual autonomy (134).

Gómez-Vírseda *et al*. described the role of the family and patient autonomy in relation to ICU decision-making (133). In the ICU, the vulnerable overwhelmed patient often cannot seek the advice of family, elders or other trusted people before making a drastic decision. The surrogate decision-maker can carry the burden of granting consent for the invasive procedures, usually without consulting the patient (because the patient may be unconscious). Gómez-Vírseda *et al*. argued for a move away from the traditional individualistic view of autonomy, favouring a new family orientated type of autonomy-–where the patient is seen as part of a greater social context (133). African communities have embraced this way of thinking already, with family-orientated collective decision-making approaches occurring quite commonly (59,112,135). Another ethicist, Anita Ho, also argued for more family inclusion in the medical decision-making process, citing one of the main reasons as the relational nature of autonomy (136).

Relational autonomy does not mean that patients' decisions will be overridden by their family if they are admitted to the ICU. Indeed, should the patient's explicit wishes be expressed in an advanced directive or living will, respecting their individual autonomy would be upheld by clinicians (137).

Thus, it must be acknowledged that autonomy, although still the cornerstone of contemporary bioethics, also has several limitations (124). According to Beauchamp and Childress, these limitations include elements of medical paternalism (discussed in detail, below) and legal moralism (37). According to Study.com, legal moralism is: "A theory of law that permits the criminalization of immoral actions," e.g., rape (138). Legal moralism seeks to go beyond John Stuart Mill's Harm Principle (implementing legal restrictions on a person's freedom if they commit an act that causes harm *only*) (139), by implementing legal restrictions on a person's freedom if they commit *any* immoral act, regardless of whether it caused harm or not.

The law has overridden individual patient autonomy in public ethics as well: where protection of the interest of overall populations is placed above individual interests at times (140). For example, many countries have taken a harsh legal stance by instituting mandatory vaccination polices against COVID-19 (141). This restriction to personal freedom of choice has resulted in several legal challenges and ethical debates all over the world–with no true consensus yet.

Limitations to patient autonomy in the ICU context may also occur about withdrawal of treatment. Patient autonomy may be overridden by the clinician if the patient's condition deteriorates so much that the treating clinician deems continuing medical therapy as futile and constituting harm to the patient. In South African law, withdrawal of medical therapy may be done without consent or even without consultation with the patient's family (19). In this instance, the clinician needs to demonstrate futility and then can legally and morally justify withdrawing therapy within the precepts of the HPCSA guidelines (142).

When someone is critically ill, although they may not be autonomous, i.e., they may not be able to verbalise their own wishes with respect to consent for medical procedures, it does not mean that they do not have value. "Humans beings are worthy of respect just in [by]

virtue of being human" implying that they have intrinsic worth and should be valued (p. 354, 127).

Hence, we see that respect for one's autonomy although revered as paramount in all bioethical literature, especially with respect to obtaining informed consent for medical procedures, is not without limitations, which sometimes results in patient autonomy being overridden (127). In terms of informed consent, clinicians still need to obtain surrogate consent to proceed. Creating the false idea that informed consent from surrogates upholds patient autonomy when they are incapacitated needs to be curtailed (73,74).

2.5.2 Paternalism in the critically ill

The literal definition of paternalism comes from the Latin word 'pater' meaning father – which implies the act of assuming a parental responsibility over another (120,124,143). In medicine, the clinician assumes this responsibility with the intention of promoting good and acting in the person's best interests (37).

Paternalism can be classified as (124):

- Hard
- Soft

Hard paternalism: fosters the "doctor knows best" attitude (124). It can be seen as overprotective with an attitude of superiority (143). This form of communication had been the traditional way of practising medicine. Hard paternalism is when someone overrides a person's decision, even if the person is fully autonomous, to protect them from a harmful consequence of that decision (131). Paternalism can be further divided into either strong or weak (131,144). Strong hard paternalism is sometimes justified in policies restricting freedom to make harmful choices, e.g., enforcing mandatory seat belt laws (121). Weak paternalism is sometimes referred to as 'coercive paternalism' (131). Coercive paternalism is when a third party forces someone to act or refrain from a certain action by imposing actions on them that they would not choose by themselves (131) e.g., the state instituting heavy fines for speeding may force people to refrain from speeding. This is a weak hard paternalistic rule because the intention of the state is to promote better autonomous choices from the public by coercing them to drive slowly to avoid the fine.

Talcott Parsons, a sociologist and author of The Social System, theorised a set of rights and obligations that a sick person and their doctor could subscribe to (145). Parsons claimed that the patient's role was a passive one of simply seeking medical assistance and blindly complying with the doctor's orders (48,145,146). This form of hard paternalism became known as Parsonianism (48). The model presumes that the doctor will always make the best possible decision for the patient and hence a doctor-patient relationship is not required. This theory has been replaced with a more collaborative relationship between the doctor and patient (49).

Soft paternalism claims that: "It is legitimate to interfere with the means that agents choose to achieve their ends, if those are likely to defeat their own ends" (p. 246, 131). This claim implies that it is right to interfere with a patient's plan to achieve an objective if the doctor believes that the plan is misguided or incorrect. The desire to assist the patient is good intentioned. For example, if a person expresses a desire to lose weight, but decides on an unachievable method that will not achieve the goal or may even cause further harm, the doctor's role in re-directing the patient to assist him/her is a form of soft paternalism (131).

Soft paternalism is seen to be justified when the expected outcome would have been harmful had the person continued with that plan. In other words, the action to assist the person to *autonomously* achieve their goals safeguards them from harm. However, this justification is limited only to cases where the overall values and goals are considered to be good (131).

By embracing a more family centred care approach, soft paternalism coaxes and convinces someone into a decision, rather than forces them into it (124). An example would be an HIV-positive person being gently coaxed by their family into continuing to take their antiretroviral therapy so that they can remain healthy and continue working to support the family. Whilst this may be construed as a subtle form of manipulation, the motive is usually to promote good. Nevertheless, critics of paternalism would still view even subtle paternalism as a restriction of one's free will. This notion runs contrary to autonomy and does not empower the patient to make up their own mind (124,143).

Paternalism can therefore be advantageous when its benefit to the patient outweighs the risk of harm and results in the least possible compromise of autonomy for the patient (133). David Rier, a medical sociologist in Israel, who happened to unfortunately find himself ventilated as a patient in an ICU, documented and published his own experiences as an ICU patient (48). This unique article, a seminal piece of sociology literature, was written from the first-hand experience of a critically ill patient because the author kept a journal of all the conversations that he had with people whilst ventilated.

Rier's message was unique, as he argued that the paternalistic way ICU patients are treated was actually the approach that he favoured for himself. His main argument was, "Post Parsonian literature, such as full disclosure of information to patients and patients' negotiation and collaboration with physicians, are of minimal relevance for critically ill patients" (p. 68, 48). Rier even conceded: "For, despite [his] deep commitment to disclosure, negotiation and patient participation, the reactionary truth is that [he] was too sick to know certain details of [his] case, too weak or be partner in decision-making (p 75, 48)." Thus, his argument is in favour of a paternalistic approach to care for critically ill patients. By this argument, he meant that all the prerequisites of informed consent: understanding, voluntariness and full disclosure meant nothing to him when he was connected to a ventilator in the ICU, facing possible death.

Rier also felt that he was not in control of all his faculties, as he struggled for breath and focused most of his energy on that. This was remarkable, since although he had the clarity of mind to be able write in his journal whilst ventilated, he still felt out of control. Rier required sedation intermittently to facilitate routine procedures, such as obtaining an arterial blood gas, the central venous catheter insertion or having a bed bath. He felt this condition led to short term memory loss, and he described struggling with orientating himself to time and place (48).

Most notably, the sociologist's account specifically mentioned that, "No informed consent forms were offered to [him] or [his] wife during [his] entire hospitalization, though the range of diagnostic procedures were performed" (p. 75, 48). This is worrisome indeed-–as both law and ethics require a contemporaneous account of events when treating patients. This is especially important when treating critically ill patients, since not only are they at their most

vulnerable, but the complex clinical management and ensuing complications open clinicians to scrutiny and litigation.

Sadly though, Rier's situation seems like standard practice in most ICUs, as noted in the Davis *et al*. article, where written informed consent seems to occur with incredible variability, if at all (16,25,26). Whilst this paternalistic approach may be tacitly accepted especially when caring for critically ill individuals, it needs correction. An informed blanket consent signed on admission, or just prior to admission (if possible), would be a small step toward achieving the mutual trust and respect that the clinician-patient relationship is founded upon.

A soft paternalistic management style was further supported in a study where almost 50% of people preferred to leave final decisions (when they are critically ill) to physicians looking after them (147). People tend to rely on the medical knowledge and expertise and trust the experience of the medical practitioners, thereby perhaps entrenching the notion that informed consent can be omitted. However, the reciprocal of this may also possibly be true, again proving the polarized variability of opinions on this issue. The degree to which medical paternalism is practiced amongst different communities also varies greatly.

In the West, paternalism is seen as an impediment to autonomy and therefore to informed consent as well (134). Contrary to this, many African communities find paternalism complementary to autonomy (148). A Ghanaian study showed that paternalism enhanced the health seeking behaviour of patients (148). Ghanaian and many other African societies are still dependent on family consultation with respect to informed consent and medical decision-making. The reasons cited were multi-factorial.

Firstly, the power dynamics between men and women are still largely paternalistic (148). Some women still need to ask for their husband's or partner's approval when consenting to supplying even personal information and undergoing medical procedures. Secondly, there is still a deep-seated respect for the opinion of elders and "educated people," who are people with influence, such as doctors or lawyers, for providing guidance about medical treatment and procedures (148). In fact, in some communities, "The patient expects the medical doctor to tell him what is wrong with him, despite his capacity to make decisions. Failure to do so by the doctor, at times would attract the vituperation of the patient or his surrogate. This is not

for want of capacity but it is rather in consonance with the social expectation that elders, the educated professional such as a doctor probably knows best, compared to the average man in the matters of medicine."(p. 99, 148).

Lastly, some rural African communities still have high general illiteracy rates, with clinics and hospitals expecting informed consent to be written. The patients therefore are dependent on the verbal explanation of procedures; however, many African languages do not have vernacular words for certain parts of the body, thus making explanations very difficult. Often in the end, the patient just blindly agrees (59,148).

South African perspectives on endorsing or refuting medical paternalism seem variable. Studies mainly focus on describing disparities in health care access amongst heterogenous communities (149). A sociological viewpoint of how dependent South Africans are on paternalistic attitudes in health care is lacking.

From the comparison drawn between autonomy and soft paternalism, moral arguments in favour of both concepts are justified. I have attempted to show their clinical value as well. Although seemingly ideologically opposed, it is possible to see how autonomy and paternalism can be inter-related to assist with improving the informed consent process in the critically ill. Thus, moral pluralism explains how autonomy and paternalism can exist harmoniously in bioethics.

CHAPTER 3: BENEFIT AND HARMS OF OBTAINING BLANKET CONSENT IN THE CRITICALLY ILL

Blanket consent, as defined earlier in this report, is an all-encompassing informed consent, taken from a patient with capacity, or their designated proxy, to allow the clinician the necessary permission to perform a defined range of invasive procedures, as and when the treating clinician deems them necessary during the patient's ICU admission. It can be obtained just prior to admission (if planned) or immediately upon admission (if unplanned) to the ICU. All the benefits and potential complications related to each of the procedures are explained in detail, so that if or when the procedure is necessary, the clinician may proceed without having to explicitly obtain consent for each procedure, as this process could be extremely time-consuming and may delay ICU care.

However, implementing a blanket consent policy must include the necessary safeguards in place, especially because consent is obtained in advance for procedures that may or may not be required, depending on the patient's clinical condition. In this chapter, I examine the morality of obtaining blanket consent for invasive procedures in the ICU. I will first show how the prerequisites of informed consent are met to ensure its applicability in critically ill individuals. Secondly, I will present two ethical arguments, i.e., respect for autonomy and an ethics of care approach to prove the moral permissibility of blanket consent for procedures in the ICU.

As I have outlined in earlier chapters, the prerequisites required for valid informed consent include: decisional capacity, voluntariness and adequate disclosure of information (39). The three components of blanket consent, i.e., meeting the patient's expectations, creation of therapeutic goals and ensuring accountability of care, and the clinician as the primary safeguard, were also explained earlier (80).

To recap, decisional capacity in critically ill individuals is challenging because many patients and their surrogate decision-makers have impaired capacity either by virtue of being mentally incapacitated or being too emotional to be able to make decisions respectively (73, 100). To obviate this problem as much as possible, the blanket consent concept should be explained just prior to, or upon, arrival into the ICU. Patients may be more likely to be mentally competent to make these decisions early in their ICU course. Decisional capacity is more likely to wane over time as the use of sedatives likely will increase. In addition, the

decisional capacity of the surrogate decision-makers may also wane with time as anxiety and panic increase.

Since voluntariness does not really apply to the intensive care context, I assume that all patients are admitted of their own free will, unless they are either patients of the State (63) or patients unidentified on arrival to hospital in need of emergency ICU care. In the latter scenario, consent is forfeited, as clinicians will act in the best interests of the patient to save the person's life.

It is with respect to disclosure that blanket consent could be most useful. The initial family discussion can be used as the opportunity to address all three components of blanket consent and share as much information about the inner-workings of the Intensive Care Unit in general. The patient-specific concerns may also be addressed along with what can be expected regarding recovery. The benefits and risks of the planned procedures can be explained in detail, also allowing a time frame for the family to discuss and deliberate before the procedure is performed.

Critical to the acceptance of the prerequisites for blanket consent is the acceptance that the clinician is the primary gatekeeper of blanket consent, and as such, must be trustworthy. The success of blanket consent depends heavily on the trust and rapport created in the doctor-patient relationship (150). In turn, the clinician is regulated by the standard operating practices of the institution, the HPCSA and the law.

3.1 RESPECT FOR AUTONOMY TO JUSTIFY BLANKET CONSENT

As explained earlier in the report, autonomy underpins informed consent (21,50,125,126). Blanket consent's utility in the ICU is ethically justified through the respect for autonomy argument in two theories: through Kant's moral theory (57), and relational autonomy (134).

3.1.1 Ethical Justification: The Kantian Deontologist argument

The German philosopher Immanuel Kant wrote extensively about morality in the 1700s (130). His fundamental ideas were expressed in a series of papers which described how we ought to live, and some of his ideas are still applicable today. His moral philosophy held the

deontological viewpoint that, actions do not depend on consequences, but are rather more *obligation*-based (130,134). This is in contrast to utilitarianism, where morality is seen as a creation of the “Greatest good, for the greatest number” of people. (p. 11, 50). Although it may be argued that utilitarianism supports blanket consent as the greatest good for the patient, the patient’s family and the clinician, my argument centers around Kant’s deontology.

Kant wrote extensively about his interpretation of philosophy, the common thread being the appeal to one’s autonomy (57,130). The basis of his teachings, created as a series of maxims upon which his morality is based, was that human beings are: “Valuable above all price” (p. 137, 57). A maxim, a “Rule that connects an action to the reasons for the action”, in Kant’s mind, was absolute and could not be waivered (p.1, 152). Using a series of absolute maxims in his writings, he outlines how one ought to live.

One of Kant’s core ideas was respect for persons (57). Kant believed that human beings have intrinsic worth just by being human, meaning that they have dignity (57). Kant stated that a human cannot be commodified as one can treat a good or a material possession. From this, Kant derived the principle: “Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means only” (p. 139, 57).

Kant explained that we need to respect people by virtue of their humanness (130,153). It also means that one should not use people as a commodity that can be acquired or lost. People should not be manipulated to further clinicians own ambitions. The applicability of this maxim to the ICU context is important. ICU clinicians' need to be aware of this maxim, especially when performing invasive procedures. The motive of the procedure should be the wellbeing of the patient, and not for the progression of the clinician’s career goals. Therefore, doctors who forgo obtaining informed consent in the ICU on the pretence that they are part of routine management, or that they don’t carry any significant risk, would in Kant’s view, be immoral.

A properly designed blanket consent form in ICU would recognise the patient as valuable and respect his/her dignity enough to inform them about the routine invasive procedures associated with ICU care. The respect for human dignity has nothing to do with decisional

capacity (99). It is about respecting a fellow human being, purely because they are human. “Autonomy is not restricted just to promotion of wellbeing …[it] has instrumental value as well” (p. 464, 21). Informed consent is underpinned by this principle (21,46). The two are inextricably bound. In the ICU, where the patient may not have decisional capacity or the family may be feeling overwhelmed, commitment to informed consent from the clinician is a way of valuing the patient and respecting their autonomy (133). The informed consent process will give the patient and their family solace that they are involved in their own wellbeing.

Autonomy also allows humans to exercise freedom of choice (154). In the ICU, patients who are admitted electively usually have the ability to make their own decisions. A blanket consent form explained to the patient prior to admission would allow them the freedom to express themselves, thereby preserving their own dignity, and remaining true to their own autonomy. They would be able to maintain their own intrinsic value, especially when they are may feel vulnerable and ill.

Another important Kantian principle is called the categorical imperative. This maxim stated: “Act only according to that maxim by which you can at the same time will that it become a universal law ”(p. 130, 57). This maxim assists us with how to live morally (134). In other words, for an action to be considered moral, it would need to phrased as if it were a rule. If that rule was applicable universally, then the action would be morally permissible. For example, in bioethics, a maxim that reads: as a health care provider, you should always try to save a life if you have the ability to. If this maxim were to applied to all health care workers, it would be universally permissible, therefore the above maxim would be considered a moral act and can be universally applied. The maxim is individualized to the scenario, but the morality comes from its universal applicability.

Kantian moral theory has also been criticized in philosophy (134). O’Neill’s paper on the limits to informed consent identifies what she termed a fundamental flaw in the relationship between autonomy and informed consent (117). O’Neill pointed out that in Kant’s explanation of autonomy, humans have intrinsic value, just by being human. To use autonomy as an argument to obtain informed consent is, in her view, unjustified. O’Neill argued that there is an obligation to protect the individual regardless of whether they are

autonomous or not (117). Following that logic, informed consent has no claim on an individual's autonomy (24).

In addition, Kant's teachings have been thought to be "too abstract" (134), implying that the rules and duties are too rigid and not appliable practically. Following O'Neill's argument for the rejection of autonomy justifying informed consent and the inability to consult others in Kant's idea of moral decision-making, the concept of relational autonomy therefore becomes very appealing (137). Individual autonomy fails to recognise the human relationships that are affected by decisions. Nevertheless, Immanuel Kant remains a well-respected deontologist whose ideas have been incorporated into many modern ethical principles in bioethics, as well as other fields such as law, finance and business (50).

Another possible rebuttal to respect for autonomy, but still favouring the moral permissibility of blanket consent in the ICU, is that in South Africa, unplanned surgical admissions account for a large percentage of ICU admissions (155). An over-emphasis on individual autonomy must therefore also be balanced against the patient's role in his/her family and society (133). Relational autonomy addresses this concern.

3.1.2 Ethical Justification: Relational Autonomy

Relational autonomy does not have a formal definition, however a working definition suggested by Gómez-Vírseda and colleagues is as follows: "Maintain the essential aspect of [individual] autonomy, namely control over one's life, while at the same time, incorporate insights of a socially embedded notion" (p. 9, 133). The main characteristics of relational autonomy include its emphasis on human interconnectedness and our interdependency (133). This means that decision-making does not occur in isolation, humans will inherently seek consultation when faced with a difficult decision.

Relational autonomy came about as a direct rebuttal to the traditional respect for autonomy which is viewed as individualistic and therefore quite impractical (133). The re-conceptualization of autonomy was done to include those to whom human beings are close to (133). With its origins in feminist philosophy and ethics of care, (which I discuss next), the main characteristic of relational autonomy is that it is particular (meaning unique) to each

scenario. In view of this, I extrapolate its relevance to health care thereby justifying the need for family consultation when a patient is ill.

Consider the following example, an unconscious ventilated patient in the ICU who cannot verbalize would be considered non-autonomous by the traditional individualistic autonomy viewpoint, thus implying that all medical consent procedures follow the legal framework. However, using the relational autonomy interpretation, it can be argued that the patient is indeed still autonomous because the patient's family or close relatives would act autonomously on his behalf (102,135). From a moral standpoint, the concept of family autonomy may be more tolerable than the paternalistic alternative of just allowing the doctor to proceed without obtaining any informed consent at all (102).

The last component of the argument demonstrating moral permissibility of blanket consent for invasive procedures in the ICU is the ethics of care approach.

3.1.3 Ethical justification: Care ethics

Ethics of care is a recent moral theory and has its roots in the rise of feminism (57). The origins thereof started during the women's rights movements of 1960s to 1970s. During this time, women began philosophical writing offering a different way of thinking about morality (57).

Virginia Held described, in her book entitled: Ethics of Care Personal, Political and Global, ethics of care as a moral theory in its own right and that despite it being a mere few decades old, she demonstrated its relevance in modern everyday life (156). Rachel and Rachels eloquently sums up the theory in this quote by Virginia Held: "Caring, empathy, feeling with others, being sensitive to each other's feelings, all may be better guides to what morality requires in actual contexts than may abstract rules of reason, or rational calculation, or at least they may be necessary components of an adequate morality" (p. 151, 57).

The above quote is a direct rebuttal to deontology (Kantianism) and utilitarianism where morality needs to be deciphered amidst obligation-based rules (deontology) or riddles of potential consequences (utilitarianism) (134). The ethics of care theory has its roots in

feminism and the nurturing nature of motherhood (134). This comparison is in direct contrast to the paternalism, which is “like a father” (120). The characteristics mentioned in that quote are, in my opinion, qualities that ICU carers inherently possess, hence its applicability to the ICU context seems more relatable than Kantian rules and rights.

Nel Noddings, another proponent of the ethics of care, also wrote about caring and its importance in education entitled: ‘Caring: A Feminine Approach to Ethics and Moral Education’(157). Noddings’s fundamental argument was that caring was the foundational basis of morality (158). Noddings viewed relationships as humanity, again in contrast to Kantianism, where individuals have autonomy because they are human (134). In addition, caring can occur universally, i.e., for family, friends and strangers. Noddings, however also identified criteria in which caring applied to strangers. Strangers could be cared for if the relationship between the two parties has the potential to exist, or if that potential relationship has the potential to grow into mutually caring relationship (57).

There are three distinguishing features of ethics of care as a moral theory (134):

- Process
- Particularity
- Relational.

Process relates to the context sensitive problem-solving approach in care ethics theory. Each ethical dilemma is different, and therefore each process of problem-solving should also be different (134). In the ICU, each patient scenario is also different. Although sometimes pathologies may be similar, the differences come in the nuances in variable physiological responses to therapy or procedures. In addition, interactions with patient families are also different (134,159). Each contextual scenario needs its own contextual solution since patients (and their families) have different expectations of care in the ICU, and each ICU also has different levels of care that it can provide.

The blanket consent concept talks directly to this process, as it sets the template for the management of the patient in the ICU and in consultation with relatives. The problem-solving approach in care ethics invokes a team care approach where the family is involved in the patient’s management (134). The future-dated potential procedure list discussed in the

blanket consent procedure would allow the family time to deliberate the procedures ahead of time, setting the template for the patient's ICU admission.

Particularity means "distinctiveness". In ethics, distinctiveness means that each person is unique and is irreplaceable and non-substitutable, and hence the bonds that are created between people are also unique and distinct (134). Ethics of care theory values people and their unique relationships as irreplaceable. The greatest importance is given to the relationship and the bonds that are created (134).

Particularity also infers that the emphasis given to autonomy in ethical decision-making is misguided (134). For example, the unconscious person in the ICU does not have capacity to make autonomous decisions, yet they are still bound to the relationships with their loved-ones. Thus, in this scenario, the particularity, i.e., the distinctiveness of the relationship guides the decision-making process and not the patient's autonomy.

The hallmark of the ethics of care theory is that it is relational, i.e., morality is cemented in the relationships we create with others (133,137). In contrast to Kantian philosophy, where emphasis is placed on one's expression of individuality (160). Care ethics argues that behaviours are grounded in relationships with families, colleagues and friends i.e., the small-scale relationships of everyday life (57). Noddings stated that, "The caring relation can only exist if the cared-for can interact with the one-caring" (157). Hence, the relationship needs to a close one. Held thought of caring as "intrinsically relational," where the person being cared for has a need to be cared for that they cannot fulfil themselves (156). Care in this context cannot be replaced by a machine.

However, relationships with families and friends can also be estranged. Thus, does an estranged family member have a moral right to assist with decision-making if the person's parent is admitted and ventilated in ICU? Legally the answer is clear, with the hierarchy stipulated in the National Health Act, i.e., spouse or partner, then a parent, grandparent, adult child or sibling in that specific order (19). If the estranged person is the designated proxy, then the person does have a right to decision-making, even though the person's relationship with the parent is estranged and the person is unlikely to know what their parent would have wanted.

Care ethics, on the other hand, stipulates that caring relationships need to have a close inter-linking bond, inferring that the estranged person who did not have an established caring relationship with their parent cannot participate actively in decision-making after the parent has been admitted to the ICU, because a filial attachment doesn't accrue decision-making authority in the care ethics model (57,160).

Important to note, is that according to care ethics, the doctor-patient relationship cannot be viewed as a caring relationship. It does not meet the criteria set out by Noddings, as is it not expected to be a long-lasting mutually beneficial friendship. Although the inherent nature of the doctor is to be compassionate and caring, these are virtues that a doctor commits to in order to ensure their own flourishing, which does not satisfy relational caring as described by Held (156) or Noddings (157).

Care ethics in the healthcare context, however, is still relevant, as it forces the health system to engage with the patient in a more holistic way. It sees the patient as part of a family and a community (102). This interpretation of care ethics is important because some health decisions, especially issues around end-of-life care or organ donation, etc., also affect the family members. These decisions cannot be based solely on one's individual preference or in accordance with abstract rules. Humans share an interconnectedness by forming caring relationships, thus, explaining the concept of relational autonomy (159). The interconnectedness of humanity is also highlighted in African and Asian philosophy (134,161). I will only discuss Ubuntu in this report, as I am writing this report from a South African point of view.

Ubuntu describes the lifestyle of traditional sub-Saharan African societies, i.e., one of harmonious co-existence with others to ensure the survival of their particular village or community (162). The literal meaning of Ubuntu was analysed by Magobe B. Ramose, who defined "ubu" as "becoming whole" and "ntu" as "human", hence it is a term that seeks to encompass what is it to be human (135). Conceptually, Ubuntu seeks to establish a homeostatic balance between humans, their environment and the cosmos. Its origins pre-date colonialism as far back as preliterate communities living in sub-Saharan Africa (162).

Similarly, to the ethics of care as a moral theory, Ubuntu struggled to make its debut as a moral theory, too. It has often been overlooked, even by African bioethicists (163,164). Its teachings and values have essentially been conveyed via proverbs and stories, passed down from elders, within the community in which they lived. The general values that Ubuntu teaches are “justice, responsibility, equality, collectiveness, relatedness, reciprocity, love, respect, helpfulness, community, caring dependability, sharing, trust, integrity, unselfishness and social change” (163).

In Ubuntu, the community is seen as a single entity with a single mind and heart as described by Augustine Shute (165,166). John Mbiti described the phrase, “I am because we are, since we are therefore I am” (p.11, 162). In addition, there is significant emphasis on respect for the elderly, who are revered for their moral wisdom in life and their ancestral guidance after death (165).

The communitarian approach to life and moral values of Ubuntu can also be extrapolated to obtaining informed consent for healthcare, too. According to Ubuntu moral theory, decisions are made collectively; hence, patient autonomy is relational (134). Implementation of a blanket consent concept, especially for critically ill individuals, would have several advantages using this theory. Since decisions need to discussed amongst family members and elders, blanket consent, which consists of a list of procedures, can be discussed at one sitting. It allows some time for family engagement at the beginning of the admission so that information can be disseminated, deliberated and a consent form eventually signed through consensus. Eventually in time, as more of the family discussions are done in a standardized format, I believe, that blanket consent, would result in improved health literacy for the family.

Thus, I have used Kantian moral theory, relational autonomy and the ethics of care to show that blanket consent for invasive procedures in the ICU is indeed morally permissible. Respect for autonomy, although challenged and limited in some cases, can still be used to justify the use of consent taken prospectively in the end that the patients require these procedures. I have also argued in favour a soft paternalistic role of the clinician who needs to be trustworthy (150). Clinicians need to be trustworthy because trust creates a positive patient attitude and implies that they are more likely to heed advice and take their treatment (150). Hence in this context, these two dichotomously opposed concepts–-autonomy and

paternalism--can co-exist and assist in justifying a blanket consent policy for critically ill individuals in the ICU.

CHAPTER 4: STREAMLINING INFORMED CONSENT FOR INVASIVE PROCEDURES IN THE INTENSIVE CARE UNIT

4.1 OVERCOMING CHALLENGES IN INFORMED CONSENT IN THE ICU

Following my assertion that it is morally permissible for a blanket consent policy to be instituted for invasive procedures in critically ill patients, this chapter endeavours to make suggestions to improve and streamline informed consent for invasive procedures in the ICU.

As noted previously, there are several challenges in obtaining informed consent for critically ill patients. To combat some of the challenges compromising informed consent in the critically ill, a mind shift change amongst clinicians needs to occur. The current variable attitude adopted by clinicians when obtaining informed consent needs to be examined and evaluated. Clinicians need to become serious about establishing trust and rapport with their critically ill patient and the patient's family members.

Ideally, trust building begins before the patient is admitted to the Intensive Care Unit (150). This step is not always possible since most admissions to ICUs in the public sector in South Africa are related to emergencies (167). Establishing trust in this scenario is difficult within these limited time frames. Further compromising trust is the variable way clinical information is discussed and consent obtained for various invasive procedures in the ICU (16,25,168). The variability in communication style, the language used (including body language), the time spent explaining procedures and the overall demeanour results in a non-standardized, clumsy attempt at explaining complex information to an already stressed and vulnerable patient or the patient's caregiver or family members.

In addition, the vast majority of patients and their family members do not have a healthcare background (168). The ICU context is a foreign intimidating environment for most people, regardless of the indication for admission (6). To bridge the gap in understanding and alleviate patient anxiety, clinicians need to learn how to impart sufficient information to the patient and the surrogate caregivers in a uniform succinct manner that can be well understood by everyone.

Loftus et al. demonstrated that audio-visual aids improved patient and caregiver knowledge as well as comprehension of the commonly performed procedures in the ICU (168). Their pilot study designed a "bundled informed consent [video] module", explaining the procedures and nuances of the ICU environment, and was displayed on a television screen mounted to a wall

in a designated area in an ICU. Following this process, a “credentialed provider” discussed informed consent with the family. An evaluation was done thereafter to test the comprehension of the family member. Despite this study being a pilot study, with some limitations, i.e., that “credentialed providers” were not explicitly defined, it still revealed that improving health literacy and understanding amongst patients and family members is a step in bridging the gap created by the complexities in ICU (148,168).

Audio-visual modules have also been created and piloted to obtain informed consent for procedures in studies outside of the ICU (169). For example, in the fields of urology (170), bariatric surgery (171) and trauma surgery (172), pilot studies have been conducted utilizing videos as part of the consent process. Video calling has also proven to be beneficial in alleviating anxiety whilst managing clinically ill patients with COVID-19, who were being isolated and therefore had very limited access to their loved ones (168). A standardized video made in plain language with simple illustrations of the commonly performed procedures in the ICU will, in my opinion, greatly assist with enhancing trust and confidence building between the clinician and the patient, or their loved one, and streamline the consent process in the ICU.

In addition to a variability in information sharing, this report also identified that clinicians’ beliefs were also extremely variable with respect to consent for invasive procedures. Davis et al., indicated that clinicians attached variable degrees of importance to informed consent for certain procedures more than others (16). The reasons for this variability were not explained in the paper. In another survey by Naidu *et al*., clinicians admitted that the threat of litigation would make them change the way they practice, but did not explore reasons for this finding (25). From these studies results, it can be extrapolated that the reasons for the variable clinician behaviour need further study. Understanding these reasons are critical to effecting change.

Clinician training has also been highlighted as an area of focus. In South Africa, bioethics is taught to medical students with emphasis on respect for patient autonomy and informed consent. However, there seems to be little or no clinical governance of the process in practice. At the time of submission of this report, I have not been able to find any published audits looking at compliance in process of obtaining informed consent in the ICU.

In clinical practise, doctors need to ensure that they maintain their professional development in their field of practise. Attendance at workshops, seminars or congresses are crucial to maintaining a clinician's licence, which is a process is governed by the HPCSA. Owing to the vast variability in obtaining informed consent in general, and the lack of basic knowledge of the legal requirements of informed consent in South Africa (59), informed consent proficiency training workshops need to be conducted to raise the current standard of practise and ensure compliance with legislation and regulations at present.

At these proposed workshops, a multidisciplinary teaching team can be created, whereby other health professionals such as bioethicists, psychologists, trauma counsellors, etc., are asked to teach doctors and nurses exactly how to counsel patients and their families. The curriculum needs to teach clinicians how to deliver clear information, manage different cultural and family dynamics, manage their own personal emotions and hopefully try to alleviate some of the fear of patients and their loved ones. In so doing, more holistic ICU care would be achieved, thus uplifting the informed consent process.

4.2. INNOVATIONS IN IMPROVING THE INFORMED CONSENT PROCESS IN THE ICU

In redefining the informed consent process by suggesting the use of blanket consent for the critically ill, a change in current practice must occur. I therefore propose a change in the format when obtaining informed consent in the ICU.

Firstly, more clinical data must be collected regarding the common invasive procedures performed in the ICU. From my experience, this list would include procedures that occur frequently in most ICU patients such as intubation, insertion of invasive monitoring lines such as, but not limited to, arterial catheters, central venous catheters (CVC), haemodialysis catheters, blood transfusions, percutaneous tracheostomy, bronchoscopy, intercostal drain insertion and possibly special radiological investigations, e.g., x-rays or CT scans (14).

Following analysis of the data, a blanket consent form can be designed. The Critical Care Society (compromised of respected academic critical care experts in South Africa) would then need to agree upon a standardized format with respect to: the procedure list, timing of consent (e.g., within 24 hours off admission), estimated length of consultation to obtain consent, rank of the person taking the consent and many more intricacies, after which the implementation

process could be initiated. Central to the discussion of implementing the blanket consent form must be uniformity--with pre-formatted explanations regarding the potential risks and benefits. The form should not downplay potential complications, but rather impart a realistic idea of expected ICU etiquette for all parties concerned, i.e., staff, patients, families, religious persons, etc. I propose that a well-designed blanket consent form will strengthen professional interactions amongst all three parties, i.e., the clinician, patient and their family.

Imperative to any discussion about the future of informed consent processes are the lessons learnt whilst managing the COVID-19 pandemic and the various surges that have occurred. Owing to the cessation of family visitation privileges in hospitals, family members (even close family members) were not allowed to see their loved ones in the ICU (173). As a result of this situation, ICU clinicians were forced to think differently about how to communicate with patients and their families (150). New innovative methods of gaining trust and building relationships needed to be made in haste, as the ICU patient admission rates soared. In most cases, the clinician and the designated decision maker had never met, whilst the patient had never seen the clinician's face (owing to the PPE that was worn).

Telephones, and other virtual platforms, became an integral part of "meeting" the family. Often time sensitive confidential medical information, including obtaining informed consent, had to be discussed on these various virtual platforms. Although at first this seemed bizarre and unnatural to many clinicians, as time progressed it became a daily part of life. As emerging data gets published about the perspectives of the family members who received telephonic counselling, we will begin to learn more and tailor communication appropriately (116). However, it would be prudent to include virtual communication between clinicians and a patient's family members in subsequent informed consent design.

With advancing digital communication between doctors and patients and the established moral permissibility of blanket consent for invasive procedures in the ICU, an outline of the additional research and groundwork that needs to be done to ensure the proper implementation of the blanket consent policy for ICU patients could be developed.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 SUMMARY

The evolution of the informed consent process since the 1950s has resulted in its recognition and formalization in subsequent decades. The formalization of informed consent is considered a victory in advances in health care, since many atrocities were committed prior to its legalization and requirements established by several global regulatory bodies (46).

This report reflected on the origins of informed consent and discussed the fundamental objective of protecting patients against exploitation and potential harm. I discussed the prerequisites of informed consent and its nuances pertaining to the ICU patient (50). I explained why the critically ill patient is vulnerable and should be protected especially with respect to performing non-emergency invasive procedures in the ICU (16,21). I cited the challenges facing obtaining valid informed consent in critically ill patients and proposed the interrogation of a blanket consent policy for invasive procedures in the ICU (28,117).

After exploring several common types of informed consent used when managing critically ill patients i.e., proxy, emergency, broad consent and the nuances of blanket consent utility in the research, I suggested an alternative use of the blanket consent form in the clinical context, too. The working definition of blanket consent in the ICU is: an all-encompassing informed consent form, taken from the patient or their surrogate to allow the clinician the necessary permission to perform a defined range of invasive procedures as and when the clinician deems them necessary for a critically ill patient in the ICU. The informed consent is taken in advance and explained in detail before entry to the ICU, so that if/when procedures are required, the clinician may proceed without having to obtain explicit consent for each procedure to be performed individually.

Using Kantian moral theory and the ethics of care and drawing similarities to Ubuntu and relational autonomy, I demonstrated moral permissibility of blanket consent for invasive procedures in critically ill patients in the ICU. By claiming that respect for autonomy remains central to the process of obtaining informed consent in the critically ill and that autonomy also underpins blanket consent in the critically ill, i.e., relational autonomy, and the key elements of care ethics, I have demonstrated ethical support for my hypothesis.

Critical to accepting my hypothesis is the safeguard that the treating ICU clinician must be trustworthy and establish a robust doctor-patient relationship (46,150). The clinician is the gatekeeper of the blanket consent policy for the ICU and therefore must personify beneficence and non-maleficence to prevent any exploitation or foreseeable harm by implementing the blanket consent form in the ICU. The issue of paternalism in the critically ill is addressed in detail, demonstrating the need for a soft paternalistic approach that is coupled with a firm grounding in the belief of beneficence and non-maleficence in the clinician. Thus, the moral pluralism of seemingly conflicting ethical views, i.e., respect for autonomy and medical paternalism, co-exist in this report to justify the morality of blanket consent's use in the ICU.

This report also embraces a shared decision-making approach where possible (49). Clinicians must work in concert with family members to generate the best possible outcome for the ICU patient. They need to cultivate a culture of caring that is respectful of all South African cultures and languages in the ICU.

Citing the hypothesis as proven, areas of future research are suggested along with the addition of audio-visual aids in assisting the clinician in obtaining informed consent in the ICU. The report highlights the moral pluralism where autonomy and paternalism can co-exist and be used to solve moral conflicts such as the challenge of obtaining timeous adequate informed consent for the critically ill patient.

5.2 LIMITATIONS

There are however several limitations to this study. Firstly, it is purely a normative study. It is written through the eyes of a single person working exclusively in the South African public health sector, therefore more opinions need to be surveyed from a wider clinical spectrum of patients and providers, before solid conclusions can be drawn. In addition, the intended target audience for the implementation of a blanket consent policy is the South African citizen who is reliant on the public healthcare system. The private health sector may have different challenges in obtaining informed consent, e.g., a blanket consent form could be misconstrued as being financially motivated in the private health sector.

Another limitation is that all the literature obtained to write this report was accessed in English only and hence it may not be generalizable to all healthcare systems around the world.

Lastly, the challenges regarding informed consent in critically ill patients are overwhelming. The process of implementing a blanket consent policy will be a slow path to enlightenment–- a journey not many may want to undertake. To address these challenges, further interventional work with experiential learning and collaborating with others needs to be done.

5.3. THE FUTURE

The COVID-19 pandemic has posed unprecedented challenges in daily life, not just in healthcare. People have had to re-evaluate their own value systems and ethical stances even in ordinary everyday decision-making (174). During the earlier pandemic surges in 2020, in the pre-vaccination era, ICU mortality in patients with COVID pneumonia was extremely high. The staggering numbers of critically ill patients forced many clinicians to make difficult triage decisions and discuss palliative and treatment withdrawal strategies far more frequently than they would have liked (173). The concept of informed consent has already begun evolving with current ideas centered around how to obtain consent for critical research during a pandemic (166). “Old rules often cannot fit new situations, and the changing needs, knowledge and globalization in biomedical and genetic research may demand a new ethical and legal framework for consent,” an apt quote by Jacquelyn Kegley written in 2004 (p. 836, 28), encapsulates the paradigm shift that is likely to occur in obtaining informed consent in critically ill patients as well. Moving forward in this new era will demand that informed consent for ICU patients be critically re-examined. My proposition is that blanket consent for invasive procedures in the ICU would be an effective moral alternative to the current traditional (variable) manner.

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PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I, **Arisha Ramkillawan, Student number:1789630** am a student registered for the degree of

Masters of Science Medicine: Bioethics and Health Law in the academic year **2021**.

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:  Date: 31 March 2022

ANNEXURE A

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL

Human Research Ethics Committee (Medical)

Research Office Secretariat:
Faculty of Health Sciences, Phillip Tobias Building, 3rd Floor, Office 301/2/4, 29 Princess of Wales Terrace, Parktown, 2193
Tel +27 (0)11-717-1252 /1234/2656/2700
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Website: www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/

Ref: W-CBP-180828-3 28/08/2018

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical)

Investigator: Dr Arisha Ramkillawan (student no. 1789630)

Supervisor: Dr Anthony Egan

Department: Clinical Medicine

Project title: The morality of obtaining blanket consent for invasive procedures in the intensive care unit

Reason: Study is purely normative in nature. No human participants will be involved in the study.

Professor CB Penny
Chairperson: Human Research Ethics Committee (Medical)

Copy – HREC (Medical) Secretariat: Zanele Ndlovu, Charmaine Khumalo and Rhulani Mkansi.