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2020
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INTRAOPERATIVE NEUROMONITORING ETHICS AND GOVERNANCE

RESEARCH REPORT

Submitted to the Faculty of Health Sciences, Steve Biko Centre for Bioethics, school of clinical medicine,

University of the Witwatersrand, in partial fulfilment of the requirements for the degree of

Master of Science in Medicine

In the field of Bioethics and Health Law

2020

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Date: 25/07/2020

Dedication

I would like to dedicate this research report to:
My girlfriend, Chantelle Gunning,
My friend, Darren Lume,
My grandmother, Rosalyn Hunter.

Supervisor: Dr Christopher Wareham

Abstract

This research report sets out to evaluate the ethics and governance in the field of Intraoperative neuromonitoring (IONM) in South Africa. The purpose of this research report will be to identify the ethical and legal dilemmas that are present when performing IONM without being registered with the Health Professions Council of South Africa (HPCSA). The focus will be on the ethical controversies that arise when performing IONM without registration. Ethical principles such as respect for persons, autonomy, beneficence, non-maleficence and justice will be used to defend my position. There will also be a legal component which will focus on the issues of IONM in the courtroom within South Africa. National and international guidelines and recommendations will be used to defend the regulatory aspect of the argument.

In South Africa IONM is practised with a lack of regulatory and ethical policies in place. Performing and interpreting IONM constitutes a medical procedure and so a person wishing to perform IONM must have a particular set of medical skills under the constructs of healthcare. This not only ensures that the person understands and acknowledges ethics and health law within IONM but also allows the person to be regulated by a governing body, the HPCSA. The HPCSA serves as a body to regulate healthcare professionals and allows patients to lay complaints against healthcare professionals if there has been forms of negligence. There is, however, little mention of unregulated persons performing IONM without registration with the HPCSA.

Registration with the HPCSA ensures that persons performing IONM understand the function of a healthcare professional while performing IONM. Being registered with the HPCSA also enforces legal responsibility to the person performing IONM. There are currently no guidelines as to the ethical and legal responsibilities of both the surgeon and the person performing the IONM. Furthermore, there is also no

documented standard of skill that must be expressed by the person performing the IONM. This reveals several ethical and legal dilemmas, for example undermining autonomy and respect for persons and the possibility of harm and diminished benefit.

Acknowledgements

I wish to express my sincere appreciation to my supervisor, Dr Christopher Wareham, at the Steve Biko Centre for Bioethics University of the Witwatersrand, for his incredible support and constructive criticism. I have learned a great deal and I hope to carry the knowledge I have gained from you through my future academic career. Thank you for all your advice and being patient with me during this period.

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List of abbreviations

ABCN	American Board of Clinical Neurophysiology
ABEM	American Board of Electrodiagnostic Medicine
ABNM	American Board of Neurophysiological Monitoring
ABPN	American Board of Psychiatry and Neurology
ABRET	American Board of Registration of Electroencephalographic and Evoked Potential Technologists
AMA	American Medical Association
BHF	Healthcare Funders of Southern Africa
BLS	Basic life support
BTech	Bachelor of Technology
CAAHEP	Commission on Accreditation of Allied Health Education Program
CNIM	Certification for neurophysiological intraoperative monitoring
CPAP	Continuous positive airway pressure
CPR	Cardiopulmonary resuscitation
CRICE	Company representative in the clinical environment
DABNM	Diplomates of the Board of Neurophysiological Monitoring
EEG	Electroencephalogram
EMG	Electromyogram
EP	Evoked potential
HPCSA	Health Professions Council of South Africa
IONM	Intraoperative neuromonitoring

IONM-P	Intraoperative neuromonitoring professional
PSG	Polysomnogram
R.EEG.T	Registered electroencephalographic technologist
R.EP.T	Registered evoked potential technologist
SAMED	South African medical technology industry association
USA	United States of America

Chapter 1 – Introduction and ethical issues

Introduction

Intraoperative neuromonitoring (IONM) is a medical technique used to assess the functional integrity of the peripheral and central nervous system. The medical field is entering into an era of increased litigation and so IONM serves to warn and guide surgeons in certain operations where there is a high risk of injury or assists in identifying important neural areas. Clinical neurophysiological modalities such as electroencephalogram (EEG), electromyogram (EMG) and evoked potential (EP) are utilized and make up IONM. This allows for real-time analysis of the nervous system. Once the patient has been anaesthetised, knowledge of anatomy and physiology guides the IONM personnel in the specific placement of subdermal and intramuscular needle electrodes in order to obtain tracings from the IONM system. Feedback is then given to the surgeon after the IONM responses are analysed by a specialist (1). Important areas can also be stimulated by the surgeon and impulses received by the IONM system must then also be interpreted by the specialist to inform the surgeon whether there are functional areas that must be avoided. In summary, there are three major components to IONM: technological/technical, interpretative and interventional. Technological/technical includes the appropriate placements of electrodes, troubleshooting of problems, data recording and assessing of the patient preoperatively. The interpretative component includes the analysis of the data in the specific procedure and includes mapping out of important neural regions. Interventional includes giving feedback to the surgical team regarding neural structures. This can involve an action being taken to reduce risk of damage to neural structures and may include pausing or stopping the surgery altogether (2). The IONM professional (P-IONM) is the "provider of real time technological supervision, interpretation, and diagnostic/therapeutic (interventional) suggestions or recommendations during IONM"(2).

The term P-IONM is used in other countries, particularly in third world countries which have addressed the staffing and responsibilities of the involved parties, however, in South Africa these responsibilities and therefore titles are still undetermined. There is still discussion regarding the doctor-patient relationship and whether the IONM-P should be medical doctor or another healthcare professional (2). Typically, the South African healthcare system does not see medical doctors being involved in IONM at any stage and often relies on the feedback from the person performing the IONM. There may be an

exception where the surgeon himself/herself will be responsible for the interpretation of the IONM data, but this is uncommon. In South Africa, surgeons are not taught any form of IONM during their training and doctors may simply expect that another person be responsible for making important decisions relating to the IONM. The HPCSA serves as a regulatory body for health professionals in South Africa and is determined to promote standards of professional education and training in order to maintain excellent standards of professional and ethical practice. In South Africa, IONM remains unregulated, with persons unregistered with the HPCSA performing IONM and interpreting and giving important information back to the surgical team. The absence of standard of care for these persons performing IONM means that the possibility for illegal and unethical practice puts patients at risk.

My inquiry into the ethics of IONM in South Africa applies principles to critically assess the moral views and values relevant to the topic. My research question is whether it is ethically permissible for persons not registered with the HPCSA to perform IONM. I intend to argue that persons not registered with the HPCSA act immorally and that the practice is unethical and ought not to be done. In order to perform IONM a person needs to be registered with the HCPSA. My aim is to strengthen the ethics within not only IONM, but in the field of clinical neurophysiological in South Africa. To this end, in this chapter I provide the rationale and context for the study, before outlining the normative argumentative strategy pursued in subsequent chapters.

Rationale

The first use of IONM was performed in the first half of the twentieth century (3) and became popularised in the last couple of years, with an international survey revealing that 76% of neurosurgeons consider IONM a “very important diagnostic tool for identifying risky surgical manoeuvres” while 6% considered it of “no importance as a diagnostic tool” (4). IONM is growing in popularity in South Africa, with surgeons opting for increased safety during surgical procedures; however, the staffing of IONM team has become a looming problem (5). This is a national and international problem, with no clear consensus over the practice guidelines and training of persons performing and interpreting IONM (5). In theory, IONM should serve as a form of protection for healthcare, with IONM serving to make surgeries safer and assisting the surgeon identify important structures, however,

there is a number of unintended ethical, regulatory, legal and risk-management components (3). In the private and public healthcare sector in South Africa people are employed by companies to perform IONM. These persons may or may not have qualifications from a tertiary institution and may or may not possess an international certificate in IONM. However, both the individual and the company are not registered with the HPCSA. There may be some exceptions, with some of the persons being registered with the HPCSA. However, they would not be practicing within the field for which they are registered. They would be performing IONM without clinical neurophysiological experience and therefore would be practicing outside their scope of practice. Persons that have not undergone training in a medical environment and have not completed specific qualifications cannot register with the HPCSA under a medical profession. More specifically, it should be viewed that persons that are not registered under clinical neurophysiology cannot perform clinical neurophysiological procedures. Firstly, for their lack in knowledge and experience and their association with the HPCSA. Although the author understands there may be other councils such as the South African Nursing Council, there will be a focus on the HPCSA due to its relevance. Rapid technological advances such as IONM has left behind the proper implementation of important regulatory and ethical guidelines in South Africa. The author has identified various ethical problems and therefore information will be gathered in order to consider options and make a moral assessment. As healthcare professionals we have a duty to act on certain ethical injustices and highlight the importance of addressing ethical dilemmas. The following anecdotal issues will be explored in this research report and include:

- No guarantee of proper education and training by persons performing IONM.
- Possible harm due to inexperienced persons performing IONM.
- Diminished benefit due to incorrect decisions made by the person performing IONM.
- The surgeon having a false sense protection from an inexperienced person performing IONM.
- Stunting development within the field of IONM by non-healthcare professionals continuing to perform IONM without communication with healthcare professionals.
- The interest of the business is put before the interest of the patient.
- Undermine autonomy by providing IONM by persons not registered with the HPCSA.

- Undermine respect for persons due to the absence of regulation which would otherwise ensure the best standard of care.
- Exploitation of the field of IONM.
- Diminished efficacy due to a false impression given to the surgeon as to how IONM should be used within surgical cases.

During the American Medical Association (AMA) House of Delegates Resolution 201 June 2008 it was stated that:

> "It is the policy of the American Medical Association that supervision and interpretation of intraoperative neurophysiologic monitoring constitutes the practice of medicine, which can be delegated to nonphysician personnel who are under the direct or online real time supervision of the operating surgeon or another physician trained in, or who has demonstrated competence, in neurophysiologic techniques and is available to interpret the studies and advise the surgeon during the surgical procedures (6)."

This statement highlights that the interpretative aspect of IONM constituting a medical procedure and should therefore be performed by an appropriate medical professional that is answerable to the laws, ethics and regulations of other healthcare professionals. This is further support by Jeffrey, et al., (2018) in stating that "…based on the tenet that the delivery of IONM services by the Intraoperative Neuromonitoring Professional (IONM-P) constitutes a patient care activity; thus, important ethical mores guiding all medical professionals apply". In South Africa this way of thinking of IONM has not been adopted and therefore requires ethical scrutiny.

South Africa, with its lax implementation of regulations has resulted in a doorway for the practice of procedures such as IONM to continue without repercussions. The field of IONM is lucrative and several private companies have grown to provide IONM services. There is no doubt that what might be thought of as unethical may have become common practice in South Africa and therefore a compelling argument against it may seem unwarranted when

in fact it remains a serious ethical issue. The practice of IONM in South Africa deserves an ethical inquiry due to it having serious application in medicine. When humans experience illness or dysfunction doctors and healthcare professionals hold a special responsibility to ameliorate suffering in order to promote healing. This suffering and vulnerability of fellow humans allows healthcare professionals to enter into a trusting relationship with their patients. It is important that this relationship is not tainted through unethical practice.

Current regulations and practice guidelines for IONM staff

In the United States of America (USA) IONM is performed by a technician or technologist and interpreted by a PhD neurophysiologist, neurologist or other medical doctor that has proven competency. In most developed countries this would also apply, with a technical and interpretative component being performed by two different people with different responsibilities. When IONM was first being performed, medical institutions would employ neurophysiologists/medical doctors to interpret the IONM data on an individual basis but with the growing need, it is not unusual for a single neurophysiologist/doctor to oversee numerous IONM cases (2).

In South Africa, there are no regulations and practice guidelines for IONM. This allows persons to perform and interpret IONM without the need to register with the any governing bodies. Governing bodies such as the HPCSA serve various functions: continuous improvement, partner engagement, legal authority, oversight of the health department and policy development (7). These functions are pivotal to performing medical procedures in a sustainable, ethical manner. This would also allow persons to be held responsible for unethical acts. Furthermore, the HPCSA cannot regulate persons not registered with them, and therefore a presidency for the necessity for some form of regulation needs to be put in place to protect patients.

Education and training of IONM

There are various certificates with varying degrees of education. There is also no standard for credentialing IONM specialists. There are societies and boards available that offer certifications but there are no standards for confirming “qualified” IONM-P. In the USA hospitals create their own standard to assess whether the IONM firm is competent.

For personnel wishing to be accredited in IONM to perform the technical component of the monitoring there are several international accreditations. The American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) offers a Certification in Neurophysiologic Intraoperative Monitoring (CNIM). There are currently 4 pathways to obtain the CNIM qualification and they include: 1) possessing a Commission on Accreditation of Allied Health Education Program (CAAHEP) qualification, 100 documented IONM cases and possessing a cardiopulmonary resuscitation (CRP)/basic life support (BLS) certificate 2) being a registered electroencephalographic technologist (R.EEG.T) or registered evoked potential technologist (R.EP.T), with 150 documented IONM cases and a current CRP/BLS certification 3) possess a Bachelor's degree, with other higher degrees also being acceptable, with 150 documented IONM cases, 30 hours of IONM educational training and current CPR/BLS certification 4) certification of completion from ABRET recognised program listed on the ABRET website, along with 150 documented IONM cases and a current CPR/BLS certification (8).

To be accredited to perform the interpreted component of IONM The American Board of Neurophysiological Monitoring (ABNM) offers a certificate called the Diploma of the Board of Neurophysiological Monitoring (DABNM). In order to be applicable for the certification the applicant my possess a minimum of an earned doctoral degree in a physical science, life science or clinical allied health profession, completion of one neuroanatomy and neurophysiology graduate level courses and have completed a minimum of 300 IONM cases (9). There is also certification through the American Board of Clinical Neurophysiology (ABCN), which is available to licensed doctors that are board certified neurologists, neurosurgeons or psychiatrists that have completed at least 1 year of fellowship training in clinical neurophysiology (10). The ABCN also offer other examinations in clinical neurophysiology and additional qualifications are also offered by the American Board of Psychiatry and Neurology (ABPN) and American Board of Electrodiagnostic Medicine (ABEM) (10).

Scope of practice

There is no specific mention of who should perform and interpret by the HPCSA. This results in no standard of care being established. The 'reasonable person' standard holds that each person owes a duty to behave as a reasonable person would under the same or similar circumstances. In IONM the duties of the person interpreting the IONM data need to be held at a high standard given that the feedback provided by the IONM-P is so important. An incorrect decision made by the IONM-P could result in serious harm or diminish possible benefit.

In South Africa, the Board of Healthcare Funders of Southern Africa (BHF) enables clinical technologists specialising in clinical neurophysiology to be compensated for IONM services rendered. Clinical technologists, with a Bachelor of Technology (BTech) degree and a specialization in the field of clinical neurophysiology fall under persons regulated by the HPCSA to perform the above mentioned EMGs, EPs and EEGs (the key modalities used within IONM) in the laboratory setting. These modalities, along with knowledge in neuroanatomy provide a baseline of knowledge of IONM and are pivotal for understanding and interpreting IONM data and therefore establishing competency. The degree consists of 4 years of various theoretical and practical components that consist but are not limited to neuroanatomy, neurophysiology, neuropathology and interpretative aspects of the various neurophysiological procedures mentioned above. The "regulations defining the scope of the profession of clinical technology" published under Government Notice R721 in Government Gazette 13137 of 5 April 1991 states that the responsibility of clinical technologists specialising in neurophysiology includes the "The performance of electrophysiological [clinical neurophysiological] procedures, as well as tests on the brain, nervous system and muscular systems of the patient" (11). This describes the gross responsibilities that are essential for performing neurophysiological tests and since IONM is an extension of neurophysiological testing it would include all the skills necessary to perform IONM.

The definition of a healthcare professional has been laid out by the HPCSA and therefore I will refer to anyone registered with the HPCSA as a healthcare professional (12). Although it may seem obvious that a healthcare professional is anyone registered with the HPCSA in this context it remains important to highlight the fact given that persons are

performing medical procedures without being registered with the HPCSA. Healthcare professionals subscribe to certain rules of conduct (12). In the event of misconduct a healthcare professional is evaluated against the set of rules set out by the HPCSA (12). To practice as a health professional means that there is a mutual trust relationship between the patient and the healthcare practitioner (12). Good practice of a healthcare professional consists of a life-long commitment to sound ethical professional practices with a dedication to fellow humans (12).

Outline of chapters and argumentative strategy

This research report will be purely normative. A purely normative approach includes an analysis of a practice and how relates it back to established principles in order to argue the permissibility of it. Chapter 2 will address respect for persons and autonomy with respect in IONM and I will make the case that performing IONM without being registered with the HPSA undermines respect for persons and autonomy. Chapter 3 will consist of aspects of beneficence and non-maleficence within IONM and I will argue that there are various forms of harm and diminished beneficence when persons perform IONM without being registered with the HPCSA. Lastly, the ethical component chapter 4 will consist of addressing aspects of justice in the realms of IONM and I will state my claim as to why there are various forms of injustice when persons perform IONM without being registered with the HPCSA. Chapter 5 will consist of the legal and regulatory aspects of IONM and I will outline the various legal and regulatory injustices that take place when persons perform IONM without being registered with the HPCSA. I will primarily focus on the absence of registration with the HPCSA resulting in various ethical and legal dilemmas and that persons performing IONM ought to be registered with the HPCSA. My arguments will establish why it is ethically impressible and legally problematic to perform IONM without registration with the HPCSA.

Chapter 2 – Respect for persons and autonomy

In this section I will address the aspects of autonomy and respect for persons within the field of IONM within South Africa. Firstly, I will give an introduction of autonomy and respect for persons and I will highlight why these aspects are important to discuss when

persons perform IONM without being registered with the HPCSA. I will claim that autonomy and respect for persons is undermined when a person performs IONM without being registered with the HPCSA. I also point to several ethical 'blind spots' which further affect autonomy and respect for persons. I will also refer to various relationship-based theories and African ethics to support my argument.

The principles of autonomy and respect for persons

During the eighteenth and nineteenth century philosophers such as Emanuel Kant, Jean-Jacques Rousseau and John Stuart Mill introduced and attributed to the importance of liberty and social contract theory. However, it was not until the mid-twentieth century that autonomy became an important principle among healthcare practitioners and researchers (13). The need for autonomy came during a time when healthcare practitioners expressed a paternalistic approach to medical care. The ambitions of doctors regarding treatment and research outweighed the respect for their patients as fellow persons. This led to patients not having an opportunity to be informed of the treatment they received, nor partake in the decision-making process when it came to their healthcare management. This ultimately resulted in patients becoming vulnerable and uninformed. Patients were subject to the personal goals of healthcare practitioners which lead to a number of unethical events (14). This marked the need for protection of people within healthcare, and on July 12th, 1974 The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research established the Belmont Report and was set out to describe basic ethical principles. In 1978, the formulation of the Belmont Report took place and was published the following year in the Federal Register (13). The ethical principles include respect for persons, beneficence and justice.

Respect for persons refers to treating people with courtesy and respecting autonomy and informed consent. Moreover, when you have respect for persons, you accept that fellow humans have intrinsic value that need to be protected, acknowledged and respected. Respect for persons is particularly important because it highlights that importance of respecting the inherent values possessed by fellow persons. Later, Beauchamp and Childress' four principles which include: respect for autonomy, beneficence, non-maleficence and justice shadowed over the Belmont Report. Autonomy refers to the self-

governance of an individual and enforces self-ownership. Although respect for autonomy and respect for persons are similar there are some specific differences.

Respect for autonomy, especially in Western medicine, has become a strong principle in medical ethics. So much so that respect for autonomy and therefore choices that patients make has taken away from the respecting the intrinsic value of patients (15). This may not have been the intension when respect for autonomy was being described, however, there is no doubt that respect for autonomy outweighs a lot of other ethical principles that may confer respect for persons.

Respect for persons

The principle of respect for persons will be used to argue against the performing of IONM without being registered with the HPCSA. It may be unclear as to what constitutes respect for persons, but several studies have investigated what patients perceive as respect. This includes: care, autonomy, recognition of individuality, dignity, attention of needs, empathy and provision of information (16). An autonomous decision is made with understanding the consequences and circumstances of the decision, which is intentional and is free of external influences. A thorough understanding of neurological anatomy and physiology is important in correctly conveying the expectations of IONM so that an autonomous choice can be made by the patient undergoing IONM. The acknowledgement of patients having the right to make autonomous decisions confers respect upon the patient and therefore the absence of registration with the HPCSA undermines respect for persons given the lack of understanding the intricacies of every aspect of IONM that would otherwise ensure respect for persons.

It is important to understand why IONM plays such a vital role in surgery. It is therefore important to convey to the patient that intraoperative neurological injury is still possible, however, IONM tries to limit these injuries. As non-healthcare professionals, persons not registered with the HPCSA, firstly, cannot communicate clinical information to the patient. Secondly, if the risks and benefits of IONM are not properly discussed with the patient it may result in the patient requesting the surgical procedure not be done. This not only undermines autonomy but also disregards respect for persons. Persons not registered with

the HPCSA do not appreciate that IONM is a medical procedure that is also subject to ethical principles and this disregard results in further diminished respect for persons given that a medical procedure, that would otherwise be subject to basic principles, is absent. Furthermore, for a non-healthcare professional that is not registered with the HPCSA is inherently flawed, with patients expecting that their management be performed by qualified persons that are governed. This results in a complete disregard for respecting patients and therefore fellow persons.

Care

Care is an important aspect of respect for persons because it emphasises a healthcare professional's concern for the physical and emotional well-being of their patients. Care is closely linked to empathy as described by patients (16). Ethics of care is focused primarily on a relational model, with a proper understanding that humans are interconnected, vulnerable and dependent beings (17). Healthcare professionals have a duty to their patients and include being concerned with their best interest through characteristics such as empathy and a proper appreciation of the relational constructs of human beings. A person performing IONM, not registered with the appropriate governing bodies do not get exposed to the experiences of patients suffering from various medical conditions that warrants IONM. Also, a lack exposure to relational experiences between a healthcare professional and their patient makes for a lack in empathy and disconnection from the interconnectedness experienced when working with patients. This results in a lack of understanding of the conditions and various outcomes that would usually result in various empathic feelings. Therefore, important values such as care that would infer forms of empathy upon the patient are undermined when persons that are not registered with the HPCSA perform IONM. Values such as care assist healthcare professionals to make decisions and therefore the lack of care results in questionable decisions that may adversely affect the patient.

High-risk surgical cases that warrant IONM are also underappreciated by persons not registered with the HPCSA since they have not experienced the suffering caused by their condition, the surgery and the possible adverse outcomes. As fellow human beings the IONM team should be able to not only sympathise with patients, but also enter into a professional relationship that ensures the healthcare professional strives to prevent pain, gain consent, respect confidentiality and be truthful (12). These relational aspects are absent

when persons not registered as a healthcare professional perform IONM. When these aspects are absent it takes away from the duties of healthcare professionals and undermines the relational aspect of healthcare.

Relationships are fundamental to healthcare, with the prevention of harm and promotion of benefit being the relational good. Likewise, in IONM there is a patient-provider relationship with the IONM team (2). This relationship may commence by introduction by personal interaction in order to acknowledge who the IONM team are, their qualifications if desired and permission to provide care (2). The patient should, at any point be able to receive answers to questions relating to the procedure and the benefits and possible harms of IONM (2). This highlights not only a duty of care but also serves to confirm the importance of a relationship between the IONM team and the patient. Firstly, persons that are not registered with the HPCSA cannot enter into a relationship with a patient when they are not governed by principles that would otherwise ensure the proper utilization of a patient-provider relationship. This is due to the relationship being built upon various ethical principles that are possessed by a healthcare professional. Secondly, without proper understanding of clinical neurophysiology and neuroanatomy a person cannot always guarantee appropriate assessment of the possible harms and benefits and therefore cannot appreciate their relational duty.

Autonomy

Autonomy is arguably regarded as the primary concern of respect (16). Many patients believe that their values and translation of their situation should be an important component of the decision-making process when it pertains to their care and management. The patient may not even be aware that IONM will be performed on them during their surgical procedure. This is simply because surgeons and IONM personnel may not even appreciate that it is their duty to do so. This is due a lack in training in the field of IONM. IONM is an invasive procedure and requires needle electrodes to be placed in the skin. Only after the procedure the patient may find out that these needle electrodes were placed in their body or they remain completely unaware. The person performing and interpreting the IONM should be responsible for informing the patients of the expectations of IONM. When a person is not registered with the HPCSA they may not perceive themselves as a healthcare professional responsible for the informing the patient of the IONM or they may simply

believe informing the patient does not fall under the responsibilities of the person performing the IONM. Regardless of the reason, there is a definite chance that the patient may be uninformed. This ultimately undermines autonomy by not disclosing important information. IONM is used to mitigate intraoperative deficit, however it remains a medical procedure with limitations.

It is important that the patient understands these limitations in order to be well informed of the expectations of IONM. When the surgeon is asked for an IONM service to be rendered during a surgical procedure he/she is acting with the interest of the patient in mind, however, it cannot be ignored that a form of medical paternalism begins to emerge. The surgeon may not even be aware of this emerging, but it should still be addressed. The surgeon may simply not appreciate the ethical and legal constructs of IONM and may simply be acting on the knowledge and judgement that he has. This appears as an ethical blind spot, often overlooked because IONM should only be viewed as a beneficial procedure, aimed at protecting the patient. This can be viewed as a blind spot because there has been a failure to recognise the ethical components in the light of beneficence. An ethical blind spot refers to a practice that may be perceived as ethical because of internal or external factors. If a patient was to be fully informed in order to make an autonomous decision, it would involve revealing to the patient that the person performing the IONM is not a healthcare professional registered with a governing body. This can be viewed as revealing the ethical injustices that are found in the field.

Informed consent

Respect for autonomy ties closely in with informed consent. Informed consent entails providing the patient with all the details of the procedures including possible outcomes and allowing the patient to agree or disagree to continue. To perform a medical procedure such as IONM without being registered with the appropriate health governing bodies that exists in the South Africa would undermine respect for persons. In order to disclose all appropriate information, the person performing IONM would have to explain their involvement in the surgical procedure. Firstly, a person not registered with the HCPSA may not explain medical procedures since the person does not guarantee to have adequate knowledge on the subject to fully inform the patient and does not have the adequate credentials that allows for the conveyance of such information Secondly, for the person

who is not registered with the HPCSA to explain adverse clinical outcomes would be unethical given their lack of clinical knowledge and the fact that they are not healthcare professionals. The patient may assume the person performing IONM is appropriately trained and accredited, however there is no guarantee of this and therefore the patient's trust is undermined.

As explained previously, IONM is a medical procedure and should be performed by the appropriate healthcare worker that is governed by a regulatory body which would allow for proper informed consent to take place. Persons performing IONM that are employed by a company are tasked with generating income for profit making. To fully inform the patient would include informing the patient that the person is working for a company to provide a service and does not fall under persons regarded as healthcare professionals. Thus, IONM-Ps need to be registered with the HPCSA as it allows for the passing of information that allows for an informed decision to be made by the patient.

Individuality

Individuality ties in closely with respect for persons. IONM can be a very impersonal procedure, with little communication between the IONM team and the patient. Patients seek to be viewed as unique individuals, however this is underappreciated when a patient is degraded, to represent an array of responses derived from the IONM equipment. Ethical principles assist healthcare professionals in respecting patients for their individual value. This also ties closely in with respecting a fellow human within a larger human race. Healthcare professionals learn to appreciate the individuality of patients and this allows them to adhere to certain ethical principles. An appreciation of ethical principles is absent when a person who is not registered with the HPCSA performs IONM. There is also a large relational component of individuality. Healthcare professionals understand that a patient forms an irreplaceable place in their community and that the individual serves a certain function.

Dignity

Patients view dignity as an important aspect of respect (16). As mentioned previously, IONM can be an invasive procedure, with some of the most invasive electrode needles

being placed in the anal sphincter muscles and the muscles in the back of the throat. A patient would find it undignified for a non-healthcare professional to place needle electrodes in such invasive locations. For a person with no formal qualification nor regulation to perform such invasive procedures is simply unsettling and degrades the trust placed upon healthcare professionals. In the theatre setting the patient is vulnerable. In a study by Dickert and Kass trying to understand perception of respect, a patient stated that:

> Well, I certainly wouldn't want them having a yuk over me (while unconscious) whether it's the way or how I'm dressed or whether it's one of my physical attributes or lack thereof. I would like, I guess, [for them to] treat me the same as if I were conscious. (16).

This highlights how vulnerable patients are, especially when they are unaware (unconscious). Simply put, it is undignified when a person that is not registered with the HPCSA performs IONM. This includes the physical (placement of needle electrodes) and interpretative aspect of IONM. It is thus important that persons performing IONM understand the vulnerabilities of patients and this is established through the registration with the HPCSA. In this way the dignity of patients can be maintained.

Deception

The absence of registration and regulation undermines respect for persons as it results in deception by providing a false sense of skill, which would otherwise be ensured when a person that has the necessary experience, education and training is registered with the HPCSA. Medical doctors and other common healthcare professions may be well regulated in South Africa, however services such as that of IONM, where there are few persons available to even provide the services that are entrusted to them, may be left unregulated due to the sheer lack of persons available to highlight and formulate regulations for their services. This has resulted in various companies taking advantage of this lack of personnel and regulations in clinical neurophysiology. These companies may or may not completely appreciate the ethical dilemmas when providing these services, however it remains a subject that needs to be resolved.

In South Africa it is not unusual for companies to perform neurophysiological procedures for monetary gain. In a media statement released by the HPCSA, the professional board for radiography and clinical technology were concerned "about companies conducting/facilitating polysomnogram (PSG) sleep studies and CPAP [continuous positive airway pressure] titration studies" (18). These procedures are often performed in order to sell various sleep devices for monetary gain. Companies offering an IONM service with unregulated persons put the interest of the business before the interest of the patient, further undermining respect for persons, with the patient-centred philosophy being void.

The patient undergoing IONM may simply assume that the person performing the IONM is a healthcare professional and is governed by the appropriate governing bodies. When undergoing a surgical procedure, the patient trusts that the surgeon has adequate training to perform the procedure, however the patient may simply assume that the person the surgeon is using to perform IONM is equally competent. In South Africa, unregistered persons and companies have set the stage for IONM and have set their own standard of care, however inadequate. When these persons perform IONM there is a form of manipulation, with patients simply trusting that the 'care' being provided by IONM is absolute. This appears deceptive towards the patient. As mentioned previously, deception is a major part of ethics in healthcare and some have even being morally justified in some cases (19). Moreover, neurosurgery is an extremely complex field, and cases that warrant IONM often carry a high risk of intraoperative injury. Often, these cases carry a risk of morality or disability if surgery is not performed and therefore a patient will relinquish some of their autonomy and power to their healthcare professionals. When a person not registered with the HPCSA performs IONM on a patient, that patient is relinquishing some of their autonomy to the entire surgical team, who they believe are providing the best service available. However, they are relinquishing their autonomy to an unregistered person performing IONM, and this is deemed as a deception act.

Dehumanization through IONM

Medicine describes suffering as disease or dysfunction of the body. In IONM the body is reduced to neurophysiological responses and therefore interpreting these responses is an

extension of caring for the person – an ethical duty. Excellent interpretation of these responses represents excellent medical care, of which its ultimate goal is to prevent harm and facilitate beneficence. It is important that these responses never be considered in isolation, as a failure to recognise the patient behind the responses would be a form of dehumanization and is therefore unacceptable and a blatant disregard for the healthcare professional-patient relationship and care. Each decision made during IONM should have the well-being of the patient in mind as ultimately the responses obtained from the IONM translate to the patient's function and therefore their dignity and integrity. Recognising the relationship between the IONM data and the patient strengthens the respect for dignity and integrity, and therefore the absence of registration with the HPCSA would diminish this. Since IONM is a medical procedure it should be subject to the ethical principles that are present in healthcare. As mentioned previously, persons not registered with the HPCSA do not have any knowledge of ethical principles that allows for an understanding of protecting dignity and integrity.

African ethics and the patient-practitioner relationship

In South Africa, African ethics, also known as Ubuntu ethics, emerged as an ethical theory and served to outline the acknowledgement of relationality, community and culture as important aspects of morality (20). Ubuntu ethics often conflicts with Principlism outlined by Beauchamp and James Childress, especially due to the dominance of respect for autonomy (20). There are direct and indirect aspects of relationships in IONM. This may include having direct contact with the patient, explaining various aspects of IONM and continuing the relationship during the surgery in order to promote some form of beneficence and non-maleficence. Since IONM constitutes a medical procedure it falls within the spheres of medicine. There should be a decision-making process in IONM since every patient has values on which they base their decisions upon. These decisions are often complex since decisions influence not only the person, but also may affect groups and relationships which those persons fall into.

There is an ethical component to every medical decision (21). Ethical decision-making influences healthcare professionals and therefore an ethical component is always a factor. Every decision is unique, with the values of the individual along with the intrinsic value of medicine and communities playing a role. I claim that there is a great relational component

of decision-making in medicine and by extension, in IONM. Although you don't have to be a healthcare professional to understand and appreciate the role of community in decision-making, it is the marrying of healthcare and understanding community that enriches ethical decision-making within healthcare. In South Africa, traditional healers are urged to register with the HPCSA, and since this is the direction in which South African healthcare is heading, it can be viewed that a person not registered with the HPCSA is not a care giver as a function of a community. Therefore, a person not registered with the HPCSA cannot exercise these constructs as a care giver.,

In summary, registration with the HPCSA remains important because it binds a person to aspects that link them to a community as a healthcare professional and care giver, with the communal component of decision-making forming a part of this responsibility. Although the importance of relationships may not appear as a compelling argument, decisions are influenced by their community, religion, cultural and family upbringing. As fellow persons we have an innate duty to promote good simply based on that fact that we are members of a larger community with a common goal (12). This acknowledgement of humans making up a common community allows duties such as to promote good can flourish. Healthcare professionals, with a proper understanding of these constructs that affect and are affected by the decision-making process is an important aspect of IONM that is often overlooked but is nonetheless significant.

Ethical blind spots

'Bounded ethics' refers to the idea that people do not always recognise the ethical dimensions of their decisions due to various systematic or internal and external influences (22). This may be in the form of performing and accepting a particular action as ethical when the action is performed by others around you. I will highlight how this is relevant to IONM in South Africa. It may appear obvious for healthcare professionals to perform IONM, however, a false sense of competency is placed upon representatives by their respective companies and determine their own standards. The unethical practice of persons not registered with the HPCSA within a company continues, and other people can be employed by that company because others within that company perform the actions without repercussions – instilling a false sense of good ethical practice and results in respect for persons being diminished.

Some non-healthcare professionals may have a Certification for neurophysiological intraoperative monitoring (CNIM) qualification and therefore have defended their permissibility to perform IONM. CNIM is an international qualification allowing persons wishing to perform IONM to receive a form of certification. It is performed via distanced learning and the persons that are enrolled are not required to undergo any practical training nor undergo any practical, competency-based examinations. Although the participants are required to submit a logbook of their cases performed, there is no guarantee that these cases have been properly performed. They are however, required to write a theoretical examination in centres based in various countries. For those persons that have a CNIM qualification it is still viewed as suboptimal care for various reasons. Firstly, a CNIM qualification is a theory-based program that doesn't include clinical training. Although the persons that complete the program would have had to show evidence that they performed various IONM surgical cases, there is no reassurance that verifies whether the skills they show during IONM are adequate and serve the best possible benefit for the patient. Secondly, a CNIM qualification only serves to enforce the technical aspect, with mild emphasis on interpretation. The major parts of the interpretation and interventional aspects should still be performed by a neurophysiologist or medical doctor with a vast amount of experience in IONM. Lastly, although the CNIM qualification may be an international qualification, it is not recognised in South Africa as a qualification that adds value to standard of care for patients.

The IONM decisions made by a person employed by a company are made with a heavy burden of 'keeping the doctor's business', in order to ensure that the surgeon will keep making use of their service. This form of thinking is grounded in the rationality of business and ignores emotional, community and qualities of care. It serves to dehumanise and depersonalise medical practice. This does not veer far off from modern, autonomy-driven practice, which has been criticized in the past for the same reasons. With further investigation one can see that international certifications only hold weight when coupled with a qualification that is accepted by the HPCSA. Also, when employed by a company that holds priority of business in mind then it becomes a poor model for healthcare and overall, a poor model for having patient's wellness as the top priority. This undermines respect for persons and is therefore remains unethical.

It remains difficult to assess negligence within IONM and I will highlight why this is an important aspect of ethics within the field. “A well-designed, prospective, blinded, controlled study is considered ideal quality of evidence”; however, these forms of studies in IONM are almost impossible for various ethical reasons (23). To create a control group would mean that certain subjects would undergo high-risk surgical procedures without IONM. This is obviously unacceptable due to the possibility of harm and would be ethically unjust. This is a continued problem, especially in evaluating the efficacy of IONM in research, however this also applies to the clinical setting. Although IONM serves to limit intraoperative deficit it has limitations (24). An emphasis is placed on the fact that IONM does not always ensure a good outcome, but only reduces the risk of deficit. A similar scenario emerges when objectively assessing negligence in the clinical setting of IONM. It is difficult to assess whether the decision made by the IONM team is the best option for the patient in during a particular scenario, or whether an alternate intervention could have benefitted the patient. Therefore, if an IONM service fails to ensure a good outcome, it is difficult to prove negligence on the part of the IONM team. As mentioned previously, this is because it is impossible to determine whether an injury was one that could be reversible or whether it was inevitable. This makes the field inherently complex and therefore a person that is not registered with the HPCSA would be acting unethically given that such a complex medical procedure was to be performed by a non-healthcare worker. Non-healthcare workers ought not to make decisions that ultimately affects the outcome of patients. To do this would result in the disregard the well-being of patients and ultimately diminishes respect for persons.

There may be instances where incorrect information is provided to the surgical team. When the IONM team interprets and communicates a significant change in the IONM readings that requires an intervention the surgeon has no choice but to act. A failure to act could be seen as a form of negligence. The surgeon would have no choice but to assume the correct decision was made because the person performing the IONM is considered the expert at that time. In a hypothetical scenario where the person performing IONM stops the surgery due to his/her interpretation of the neurophysiological responses being dire, the surgeon would have no choice but to stop. If the surgeon were to continue after the person monitoring asks him/her to stop would be viewed as indefensible negligence. These points

highlight why experience and practical knowledge is important. Given that there is no guarantee of proper training and knowledge of persons performing IONM, it is difficult to prove obvious negligence and the persons performing IONM can be left without repercussions. This highlights how the complex assessment of negligence has allowed persons to exploit the field of IONM, and by extension exploit fellow persons.

In summary, this section has made the case that that autonomy and respect for persons is undermined when a person performs IONM without being registered with the HPCSA. Autonomy, an important aspect of modern medicine, is undermined with patients not fully informed about IONM in order to make an informed decision. Although IONM may be performed with the patient's best interest in mind, the knowledge and experience of the person performing the IONM is a large aspect to whether it is performed adequately, and patients should be aware of this. As mentioned previously, informed consent is undermined, and this can be viewed as a form of deception to the patient. Deception is also in the form of the patient simply assuming that they are being provided the best care – usually provided by a qualified healthcare professional. Aspects of respect for persons are also undermined, with aspects of care, individuality, dignity, relationships, and African ethics elaborating on why it is unethical to perform IONM without registration with the HPCSA.

Chapter 3 – Beneficence

In this section I will be addressing beneficence within IONM in South Africa. Beneficence is an ethical principle that every healthcare professional should respect. It is, after all, the key goal of medicine. I will address why it is important to apply beneficence within the realms of IONM and how beneficence is undermined when persons perform IONM without being registered with the HPCSA. I will include features of beneficence and non-maleficence and apply it to the practice of IONM in order to highlight the important aspects of each in order to argue why the acknowledgement and application of beneficence is a vital ethical principle and ought to be utilized. In IONM this comparison is important as it helps to describe the various decisions made by the IONM team that can result in an act that is beneficial or harmful. The absence of an action is interpreted as reassuring the surgeon that neural structures are intact. To act in IONM would be to inform the surgeon that an intervention must be taken to minimize the occurrence of an intraoperative injury.

I will claim that when a person is not registered with the HPCSA harm may occur and beneficence can be diminished. A lack of appreciation and comprehension for the skill necessary to perform IONM can lead to a false sense of trust for the person performing IONM and this can ultimately lead to harm, which may not even be apparent to the respective person nor to the relevant surgical team.

The principle of beneficence

In healthcare, the principle of beneficence relates to avoiding harm and promoting the good of the patient (25). Beneficence as described by the Belmont report addresses treating persons in an ethical manner, which includes their decisions, protecting them from harm and securing well-being (26). This explanation appears to include modern forms of beneficence (protecting patients from harm) and non-maleficence (securing well-being). There is often overlap between beneficence and non-maleficence in healthcare and many consider it as generally similar; however, there are some comparative differences. Non-maleficence can generally be described as not performing an action that would harm a patient. There is an assessment of the scenario and a decision is made based on knowledge and ethical premises. Beneficence can be regarded as more 'active', with an action one takes to serve good. In healthcare, a doctor prescribes medication to prevent or remove harm in order to promote good. A doctor does not prescribe medication that would harm their patients because it is viewed as malevolent.

Clinical knowledge and benefit

Clinical knowledge is what ensures that healthcare professionals make the best decisions for their patients. These decisions are based on clinical and ethical knowledge. It is important the person performing the IONM understands the clinical aspects of every case. Every healthcare profession has varying degrees of harm and benefit. It is important that within IONM there is a complete understanding of the harms and benefits in every surgical procedure. IONM can be used in various surgical fields, including neuro-, vascular, paediatric neuro-, ear, nose and throat (ENT), general and spine surgery. Cases that require IONM carry a risk of varying degrees of intraoperative deficit. The deficit may all be clinically different depending on the structure that is involved. In spinal surgery there is a risk of complete or partial paralysis and in neurosurgery there is a risk of paralysis of the

limbs or cranial-nerve supplied muscles, including swallowing and movement of the face. It is important that the person performing and giving feedback during IONM is knowledgeable the clinical aspects of neurology/neurosurgery. This ensures that an appreciation of the function affects the patient, but also that preoperative assessment of these nerves and muscles allows for appropriate monitoring. When a person is not registered with the HPCSA there is no guarantee that the person has the clinical or ethical knowledge to make important medical decisions and therefore remains unethical.

Clinical examination

The person performing IONM has a responsibility to evaluate the patient preoperatively in order to identify which modalities need monitoring in order to achieve the maximum benefit of IONM. Firstly, non-healthcare professionals cannot perform a clinical examination given their lack of knowledge and experience. Secondly, for a non-healthcare professional to examine a patient is inherently wrong as the person does not hold the credentials that would support the exercising of clinical skills. Without adequate clinical knowledge the patient cannot be properly examined and therefore adequate IONM neuromonitoring cannot be guaranteed. Armed with the clinical history and physical examination the persons performing IONM can create an individualised plan with the aim of maximizing benefit. Based on the complexity of the case the IONM team may review preoperative imaging and discuss the potential risks and possible changes in responses that may occur during the procedure. Also, a discussion of specific stimulators (for stimulating neural structures) and modalities needs to take place with the surgeon in order to determine its relevance in the procedure. Using the incorrect equipment during the procedure can adversely affect the procedure and could result in possible harm. These are all important aspects that need to be done by a healthcare professional that is governed by the HPCSA as this ensures that the person giving advice has the appropriate knowledge. A lack of communication with the patient and with the surgeon can both lead to harm. Not properly communicating a deficit to the surgeon can leave a patient with an intraoperative deficit. Not having adequate knowledge of the procedure and clinical examination can lead to the harm. This can not only cause physical harm but also psychological harm. In summary, a lack in knowledge in clinical medicine could adversely affect the surgical procedure and result in harm to the patient. This highlights why persons performing IONM should be healthcare professionals registered with the HPCSA.

Lack of experience and trust

Unregulated persons pose a potential harm as they may report an intraoperative deficit due to inexperience which would dissuade the surgeon from continuing with the operation. This translates to diminishing possible benefit and it can also result in the surgeon losing confidence in his surgical abilities. When IONM is performed by persons not adequately registered with the HPCSA or adequately trained there is a risk of incorrect information arising from those persons. Repeated instances of this not only puts risk upon the patient but also translates to surgeons and societies losing trust in its potential benefit. The potential loss in benefit is therefore not only direct but also serves as an indirect disadvantage of IONM within South Africa. Surgeons that aren't aware of the necessary regulations may be putting patients at risk due to a false sense of protection resulting from an inexperienced, unregistered person performing the IONM.

In South Africa, IONM is not regulated nor is any international qualification or certificate recognised by the HPCSA for a proof of competency. There is also potential harm posed to adequately trained and registered IONM specialists, with unregistered persons degrading the field of IONM by supplying incorrect intraoperative feedback. Continued advancement of the field serves to not only give the surgeon confidence in the procedure and in IONM but also serves to make surgeries safer.

Beneficence requires that persons wishing to perform IONM should be registered with the HPCSA, because it binds them to aspects such as trust and understanding why experience plays a role in IONM. Incorrect advice given to the surgical team can diminish the trust upon the field and a false sense of protection is given to patients when an unexperienced person, not registered with the HPCSA performs IONM. A lack of trust translates to the surgeon not utilizing IONM to its full potential and therefore puts at risk, the possibility of harm and diminished beneficence.

Clinical application and cost

IONM can be viewed as a very attractive tool for surgeons, with promise of making surgeries safer. In South Africa, IONM is driven by disability and not by preventing harm. How unregistered companies advertise IONM determines is use. It is often advertised as a tool for reducing disability and therefore medicolegal risk. It is important that surgeons understand when and how IONM should be used in order to receive the most amount of benefit from it. I will claim that IONM has been over advertised, without an evidence-based approach that would determine the most amount of benefit from IONM. This has been a topic of conversation, with surgeons questioning the benefit of IONM in certain procedures. This has been particularly discussed within the field of thyroid and parathyroid surgery – which will be discussed later in this chapter.

In a study by Angelos (2012), the author reviewed the literature surrounding the ethical and medicolegal issues in neuromonitoring during thyroid and parathyroid surgery (27). The author stated that there were few discussions regarding the ethical issues in neuromonitoring during thyroid and parathyroid surgery, and the reason was that "few ethical issues can be proven on the basis of traditional surgical trials". It was also stated that instead, ethical issues must be identified by careful deliberation and clinical experience (27). This is an important aspect of my research report as it highlights that IONM – as an extension of the surgery, should also be subject to investigation of ethical issues. Another important statement was made, indicating that the identification of ethical issues themselves may not resolve them, however, by increasing awareness it may encourage physicians and patients to adopt strategies that may limit the occurrence of unethical behaviour (27). In the setting of thyroid and parathyroid surgery, the literature fails to prove that IONM significantly reduces the rates of intraoperative nerve injury. The only use that IONM truly has is "reducing risks of bilateral recurrent laryngeal nerve injury" (27).

IONM has grown in popularity as a technology to prevent injury, however, this has been proven otherwise in the setting of thyroid and parathyroid surgery. This type of IONM is often marketed as being a modality to 'prevent' injury, however, this is unethical practice. The application of IONM must be appropriate in order to guarantee benefit. Companies aggressively advertising IONM may be due to IONM companies wanting more cases to be

performed in order to generate income. After all, a significant interest is to increase profit. This form of advertising is business-orientated and not patient-orientated and therefore is ethically questionable.

When registered with the HPCSA healthcare professionals are bound to performing procedures that benefit their patients. Without registration, non-healthcare professionals act unethically when suggesting IONM serves to benefit the patient. Their motivation is driven by the soul goal of generating more income by maintaining a relationship with the surgeon and this is viewed as unacceptable within healthcare. These companies create and maintain their relationship with surgeons by establishing personal relationships with these surgeons through advertising a truly beneficial service with questionable motives. This is generally known within healthcare in South Africa, as the HPCSA has published strict guidelines for advertising. Under the guidelines of HPCSA, "A practitioner shall be allowed to advertise his/her services or permit, sanction or acquiesce to such advertisement: Provided that the advertisement is not unprofessional, untruthful, deceptive or misleading or causes consumers unwarranted anxiety that may be suffering from any health condition" (28). When persons perform IONM without being registered with the HPCSA these guidelines are undermined, and since these persons are not registered with the HPCSA they do not have to follow these guidelines. According to these guidelines, when advertising IONM whilst not being registered with the HPCSA is not permissible, given the act is deceptive and misleading. Moreover, these guidelines state that:

> "A practitioner shall not canvas or tout or allow canvassing or touting to be done for patients on his/her behalf. For the sake of clarity Council regards:
>
> - Canvassing is a conduct by a practitioner which draws attention, either verbally or by means of printed or electronic media, to one's personal qualities, superior knowledge, quality of service, professional guarantees or best practice. For example, "I am the best Physiotherapist in town."
> - Touting is a conduct which draws attention, either verbally or by means of other media, to your product offering by employing guarantees or material benefits outside the categories of professional services or items.
> - Touting or canvassing encompasses the definitions above practiced by a third party in a practitioner's professional space. An example of canvassing

> would be informing the public that there is free Wi-Fi at the consulting rooms to use while waiting for consultation since it falls outside the services rendered by the healthcare practitioner (28)."

A company, such as those that provide IONM are contradicting these guidelines since they firstly, do not fall under persons performing a medical procedure, secondly, they undermine traditional advertising guidelines, by touting surgeons (indirectly patients) to a service that is both 'rare' and 'specialised' and having a large work force that allows for 'the best possible service'. On websites, these companies market themselves as "Intra-operative Neurophysiological Nerve Monitoring Specialists" (29), and this is misleading to the public and to surgeons, as it implies a particular degree of skill and speciality that cannot be guaranteed. Therefore, persons registered with the HPCSA would have to abide by strict advertising guidelines set out by the HPCSA. To not abide by these rules would not ensure the best ethical practice.

Misleading surgeons

Surgeons are misled into thinking that IONM is a preventative measure, however, this is misleading and therefore arguably unethical. In particular scenarios, IONM may simply be a decision-making tool, in order to guide the surgery in a specific direction. In the context of possible benefit of IONM in the setting of thyroid and parathyroid surgery, the patient should be informed that IONM will only provide information that will be used to determine if only one or both thyroid lobes will be removed. In the setting of a thyroid and parathyroid surgery, if the IONM team and surgeon decide to only remove one thyroid lobe the patient must wake up from the surgery knowing why this was done.

It is important that the IONM team inform the surgeon of limitations of IONM and to ignore this would be unethical. The IONM team have an ethical duty to inform the surgeon of how IONM is utilized in every case. If the IONM equipment is not utilized correctly in thyroid and parathyroid surgeries this would be unethical both on the IONM team and surgeon's behalf. This highlights the benefits and limitations that IONM in only surgery, however, there are numerous cases, each with its own benefits and limitations. It would be financially beneficial for persons not registered with the HPCSA and employed by a company to not divulge evidence that would otherwise result in IONM not being used. This results in

IONM not being used for beneficence but has rather turned into a tool that misleads surgeons and patients into a false sense of protection. Persons registered with the HPCSA follow ethical guidelines that would not allow for such practice. Also, if a person registered with the HPCSA were to conduct themselves in this manner they could be prosecuted. Registration with the HPCSA therefore tries to ensure good ethical practice and those that do not act in an ethical manner can be scrutinized. This is absent when persons are not registered with the HPCSA.

False training resulting in harm and lack of beneficence

In South Africa IONM does not receive a lot of attention in the academic and educational setting. This perhaps has also influenced unethical practice of IONM – the lack of knowledge pertaining to the field. Surgeons of various disciplines qualify from their surgical speciality without significant exposure to IONM. This is inherently flawed as academic setting is where surgeons should learn aspects of beneficence and non-maleficence – in particular, pertaining to IONM. Those that do receive exposure to IONM in their training often do not understand the limitations and intricacies of IONM.

As mentioned previously it is important to understand these aspects as it ultimately affects the outcome and therefore the benefit of IONM. Therefore, without this knowledge it puts at risk, the very purpose of IONM – benefit and preventing harm. Surgeons qualify from academic institutions without experience in IONM and therefore are subject to being informed by the person performing the IONM. Although it remains a discussion as to who is responsible for teaching surgeons the intricacies of IONM it would be unacceptable for persons not registered with the HPCSA (non-healthcare workers), to give surgical advice and training – since IONM is an extension of the surgery. When IONM is engaged and embraced by the healthcare professionals most suited for the performing of IONM then the field of IONM can flourish, with the engagement with the surgical team and educational advancement to improve the field, translating into maximum benefit. As it stands persons not registered with the HPCSA give surgeons advice that may or not be correct, however, the surgeon views the person as an expert – without having any credentials to support their claims. This can directly affect the safety of patients and result in possible harm and diminished beneficence and therefore is unethical.

Medical representatives and harm

The persons currently working for IONM companies can be viewed as company representatives as their lack of credentials confirm they are not healthcare professionals. The South African medical technology industry association (SAMED) state that "company representatives may not provide clinical diagnostic advice, surgical advice or recommend treatment, even as a result of a direct request from the surgeon, operating staff, or any other healthcare professional" (30). This serves not only to protect the patient from a non-healthcare worker influencing the decisions that ultimately affect outcome, but also prevents incorrect information being relayed to the surgeon. There may also be a legal aspect, with companies opting to not give advice as it affects their involvement which can ultimately make them liable for particular aspects of the surgery. IONM companies and non-registered persons performing IONM have simply chosen to ignore this legal aspect and this puts the patient as risk. Surgeons that have become used to receiving clinical information from company representatives may simply accept information received. Given that receiving clinical information from an unregulated person is inherently flawed, company representatives should not be given the responsibility of making decisions that could ultimately benefit or harm the patient. Medical representatives performing IONM is thus unethical due to non-healthcare professionals possibly influencing medical decisions and therefore the safety of patients.

Legal harm

To practice IONM and not fall within the HCPSA's regulations would result in the person performing IONM to be void of any responsibility. To be void of responsibility would mean there is no obligation to make decisions that would benefit the patient and in South Africa, the surgeon takes responsibility of all aspects of the patient, irrespective of the influence from the IONM team (personal experience). This is flawed and poses a risk of harm to the patient as mentioned previously, to be void of responsibility means that there is no ethical or legal obligation to ensure the best outcome for the patient. When there is no risk of responsibility there is a risk of laxed need to provide the best care possible and therefore this minimizes the possible benefit that IONM attempts to achieve. When a person is registered with the HPCSA, they are given the responsibility to provide care under the specific scope they are assigned with. The healthcare professional in return, gets paid a fee for the service provided. Moreover, the healthcare professional also obtains gratification for the service provided. This is because the healthcare professional is driven by various

ethical principles that ensures the best benefit for the patient and this translates to accepting these principles as a tool used to make decisions.

There is a great amount of respect and gratification that one obtains when performing IONM, as it ultimately affects the patient's outcome. To prevent intraoperative injury is a great achievement, one that holds high, the essence of healthcare – non-maleficence and beneficence. Only a healthcare professional, registered with the HPCSA can embrace ethical principles and hold dear to them, the relational goal to prevent harm. Persons performing IONM without registration with the HPCSA makes them void of all legal responsibility and therefore there is no obligation to prevent intraoperative injury and therefore can result in harm and no guarantee of beneficence. This further emphasises that the person performing the IONM has no obligation to prevent harm, therefore making it unethical practice.

Professionalism

To perform IONM without being registered with the HPCSA would be to undermine the most basic ethical principles. People registered with the HCPCSA hold closely, the professionalism that allows for the best interest of the patient to be in mind. It is this very professionalism that make persons understand that IONM is an intricate medical procedure that goes beyond simply providing feedback received from neurophysiological tracings. When there is a lack of responsibility on the side of the IONM team, there is a lack in responsibility, and a lack of ethical principles that would serve to guide in decision-making in order to promote patient benefit.

When a healthcare professional is found to be performing an act which is deemed unethical, an ethical proceeding may take place and serves to not only reprimand the professional, but also serves to protect the patient. This also applies in the legal spaces. Without professionalism, the field of IONM may never be put under scrutiny and therefore would never improve. Professionalism strengthen the field on legal and ethical grounds. This will unravel ethical issues that take place and makes patients and surgeons more aware of ethical injustices. Healthcare professionals, bound by the principle of professionalism, enables

good ethical practice which translate to good medical practice, with an emphasis on beneficence. The absence of registration with the HPCSA ignores these fundamental principles and is therefore unethical.

Medical judgement

Beneficence is balanced against the potential risk and cost involved. The standard of care is the standard that healthcare professionals should express, and medical judgement is a big aspect of this. It is the idea that healthcare professionals with the same knowledge and skills should give their patients the best possible care and is derived from proper training, competent skills and diligent practice (31). When there is no standard of care in IONM it is difficult to grade the potential risk due to inexperience, lack of regulation or lack of knowledge. It is important that healthcare professionals make decisions based on their best judgement, however when persons perform IONM without regulation there is no way to assess that persons 'best judgement'. It may be difficult for a patient to understand the benefit that IONM holds and therefore it falls upon the healthcare professional to weigh up the interests of the patient in order to decide whether IONM is beneficial. The lack of registration with the HPCSA makes it impossible to assess whether the person performing the IONM is using their best judgement with regards to the safety of patients. This would allow for potential harm and diminished beneficence.

Self-criticism

In order to continuously provide the best possible care that will benefit a patient the person providing the service must continuously learn from their mistakes. Mistakes are inevitable but it is important that a professional stay self-critical and acknowledges their limitations (21). When errors are driven by fear or legal exposure the opportunity for self-improvement is lost. Persons that are not registered with the HPCSA and are employed by companies are performing IONM out of fear of losing their job or losing the business of the surgeon, not out of concern for the benefit for the patient. To identify one's limitations is to admit that humans are fallible and by learning from mistakes it minimizes the likelihood of the mistake repeating (21). However, it would be unacceptable for unregistered persons to learn from their mistakes by using patients as guinea pigs. Moreover, the environment that these employees get placed in does not allow one's mistakes to be shared with colleagues. This is not only unacceptable for the patient as benefit is diminished, but also that there is no

opportunity for learning. In a healthcare setting, where the patient's well-being is a shared concern by healthcare professionals, sharing of mistakes is acceptable if the person responsible is showing an adequate amount of expertise in the scenario. This is because ultimately, continuous learning among colleagues improves the field. In the setting of a company, with no real healthcare workers there can be no expert opinion these conversations cannot take place. This diminishes the potential for improved learning and ultimately attenuates beneficence.

Chapter 4 – Justice

In this chapter I will address the aspects of justice and how it relates to IONM in South Africa. Various aspects of justice will be discussed as it is an ethical principle that is affected by persons performing IONM without being registered with the HPCSA. I will argue that when persons practice IONM without registration, this creates a number of ethical conflicts.

The principle of justice

Justice refers to non-exploitation and reasonableness. It demands that treatment be fair, equitable and appropriate in light of what is owed and due to persons (32). It is therefore important to define what are the injustices that occur when persons not registered with the HPCSA perform IONM. The author will address will apply the principle of justice in a claim that to perform IONM without being registered with the HPCSA undermines justice. An act can be unjust when a system does not distribute burden fairly (32). I will describe the injustices that are present within the spaces of IONM in healthcare by addressing the responsibility of healthcare professionals towards IONM, moral status, universalizability of IONM, the demand of IONM, distribution of resources, rights based justice, legal justice and responsibility to society. I will argue that justice is undermined when persons performing IONM, do so without registration with the HPCSA.

Forms of justice

In the realms of healthcare, Gillon (1994) described three forms of justice, including: (1) distributive justice, which describes the fair distribution of scarce resources, (2) rights based justice, which describes respect for persons rights, and (3) legal justice, which

pertains to respecting morally acceptable laws (33). Below I use these forms of injustice to frame the injustice that results from non-registered IONM-P practising IONM.

Distributive justice

In IONM the fair distribution of scarce resources is of particular importance. To extend on this, IONM is an open market at this stage and doctors, whether in the private or public healthcare sector, decide whether IONM is necessary. In rural areas it is unlikely that complex neurosurgical surgeries that require IONM will be performed. Where surgeries requiring IONM are performed the service may simply not be available. Complex surgeries are often performed at an academic hospital, where IONM may be offered by private companies or clinical neurophysiology technologists. Clinical neurophysiology technologists that provide IONM are commonly based in the private healthcare sector, having most of their IONM training done after they have completed their degree in clinical neurophysiology. This has unfortunately left the private sector lacking persons experienced in IONM. Clinical neurophysiology technologists are also not able to work for a public hospital which they are not employed at as this leads to some legal complications, with indemnification not being present. It is for this reason that qualified healthcare professionals are hesitant to perform IONM in the public healthcare sector. IONM companies are more likely to provide an IONM service in the public healthcare sector due to their lack in need for legal or ethical cooperation and being a company, they are easily reimbursed for the IONM products they use during the surgery and do not have a concern over charging professional fees. Although the diminished presence of registered healthcare professionals performing IONM in the public healthcare sector is a continued concern, this should not result in private IONM companies not registered with the HPCSA being able to exploit this. Not only is this a legal and ethical concern for the reasons mentioned in the above chapters, but also that persons are not able to provide a medical procedure (IONM) within a public hospital without being employed by that hospital. This is to ensure that only qualified healthcare professionals perform medical procedures on patients. This is of public concern given the exploitation of the public healthcare sector but also that persons in the public healthcare sector are also at risk. Therefore, persons performing IONM in the public healthcare sector pose a particular risk to patients.

In the private sector the practice of IONM is especially simple. This is because IONM companies have been allowed to perform IONM without being questioned. This is because IONM companies, with an exceptional marketing strategy and large amount of staff members, provide a 'reliable IONM service'. This outlines that poorer people in the public healthcare sector, are at an even greater risk from potentially unscrupulous unregulated IONM persons.

Rights based justice

Rights based justice refers to adhering to persons fundamental rights (33). These rights may be conventional, which are derived from society's values or natural which refer those of morals. Natural rights as a form of justice refers to respecting basic human rights, with a violation of these rights being immoral (15). Conventional rights, which are based on society's views, are made of the values of the persons that make up the society (15). For example, a society's view on abortion as permissible or not. In South Africa, basic human rights such as the right to access information is violated when a person performs IONM without being registered with the HPCSA (34). This is because not all the information regarding the necessity of registration with the HPCSA is not disclosed, nor is the correct performing of IONM guaranteed, and since this practice is still questionable, it would be important to disclose this. Also, the right to dignity is also undermined, with practice of IONM without being registered with the HPCSA would contradict societal acceptance of such practice within the constitution (34). The right to healthcare is also restricted as performing IONM without the proper registration does not constitute a medical procedure as IONM is not performed by a healthcare professional recognised by the HPCSA (34).

Internationally, the United Nations Educational, Scientific and Cultural Organization (UNESCO) has set out a rights-based approach in order to unify education, science and culture (35). Under one of its rights – right to enjoy the benefits of science progress and its application, it is stated that ethics science, science of society and science for a sustainable future is important to every country. The ethics of science involves promoting international reflection on the ethics of life sciences. This would contradict the internationally recognised practice of IONM, with healthcare professionals performing IONM that follow strict regulations governing IONM professionals. Science is a collective endeavour and it ensures good healthcare. The right to benefiting from healthcare is undermined when persons

perform IONM without being registered with the HPCSA because it does not serve to benefit society in a sustainable, ethical manner (35).

Legal justice

Legal justice, as a form of justice regulated by laws and legislator are undermined when a person performs IONM without being registered with the HPCSA. These laws that would otherwise need to be abided to are ignored. In the South African setting the company providing the service has no healthcare professional that abides by laws and regulations that would ensure proper legal and ethical practice. Laws and regulations allow healthcare professionals to be held responsible for negligence and without persons needing to be registered with the HPCSA means these persons are excluded from legal or ethical scrutiny by society.

Societal responsibility

In ethics of IONM there remains a large social responsibility by healthcare professionals. Companies and persons not registered with the HPCSA have shaped the practice of IONM in South Africa and therefore have set a standard for how IONM should be performed – irrespective of how ethical it is. This has been performed by persons that do not necessarily have any ethical and legal foundation and therefore lacks the integral components of proper practice in healthcare. This is true because persons that perform IONM without being registered with the HPCSA may not have any formal medical training and do not qualify as healthcare professionals. Medical training which would equip the person with the adequate knowledge and skills to ensure the best practice in order to adhere to their society responsibilities. In the larger scheme of things this appears a dire problem that puts at risk, the population of patients needing IONM since healthcare persons that respect and apply practices that assist with their society responsibility are absent.

When IONM is performed without any ethical and legal backbone it appears unreasonable to allow it, and it has been left to companies and persons not registered with the HPCSA to determine their own competency. This is a complete disregard the social responsibility to be a healthcare professional. This is how the practice of IONM has developed and has morphed into ‘normal practice’ and can be viewed as ethically justified given the

responsibility of IONM has been given to these persons not registered with the HPCSA. This is far from how IONM is expected to be practiced, with healthcare professionals having the social responsibility to perform medical procedures such as IONM. When scrutinized, one can see that the responsibility that healthcare professionals must provide is undermined by persons performing IONM without registration the HPCSA.

Societal duty

As the demand of IONM increases in South Africa there has been a societal duty for healthcare professionals to keep up with the demand. Afterall, this would be in the best interest of the population. Indeed, if we lived in such a world then demand would have been met and unethical practice such as the one that the author is addressing, wouldn't exist. However, there are simply not enough professionals to keep up with the demand. This is fuelled by IONM companies marketing IONM as a tool to be used in numerous cases – even with cases where it has not been scientifically validated. This not only skews the perception of IONM to the public but has also resulted in a market which is fuelled by the desire to prevent harm. It is a desire because the efficacy of IONM is overexaggerated by IONM companies in order to increase their number of cases. This has put an immense amount of pressure on the field of clinical neurophysiology. Not only to train more qualified persons, but to also win back the public's perception of IONM. IONM companies not registered with the HPCSA has made IONM an attractive service to 'serve the public', however, this has resulted in an overall misuse of IONM – one that cannot be sustained by the healthcare system.

Efficacy and cost

For the past two decades there has been an increasing analysis of balancing quality with efficacy of procedures and the component of cost effectiveness (23). Evidence-based research has allowed disciplines to assess the balance of efficacy versus cost effectiveness (23). This has led to studies being developed in order to assess whether IONM assists or is a handicap to surgery. In the past it was simpler to have prospective, blinded, controlled studies assessing outcome. However, when there is a serious risk of intraoperative deficit surgeons would opt for IONM, even if its efficacy may not scientifically sound. This is done for various ethical reasons (23). This is supported by IONM having proved its

effectiveness in particular cases as long as the person performing the IONM is experienced Given the controversies regarding the efficacy of IONM in certain cases, it would be unacceptable for non-healthcare professionals to perform such a complex procedure.

The question of efficacy is further complicated by persons not registered with the HPCSA performing IONM, whereby questioning the very efficacy the field of IONM tries to prove and protect. To accept persons performing IONM without registration is to also accept that efficacy provided by simply being a healthcare professional is absent and therefore we can accept that IONM is not always going to guarantee a good clinical outcome given the lack of regulation and qualifications. A counter argument to this would be that bad medicine is better than no medicine, but this would have little ethical and legal grounds in the setting of IONM. It should be unacceptable for persons performing IONM to be free of regulation as it will result in further undermining patient's respect, inflicting harm and resulting in injustices. Simply put, IONM is a costly procedure and when you have persons not registered with the HPCSA performing the IONM then the measuring efficacy becomes impossible and calls into question the balance of cost versus efficacy. The act becomes an injustice towards the patient and medical system when the efficacy cannot be guaranteed and therefore a service, which is supposed to have great efficacy which relies on experienced healthcare professionals, is undermined by persons not registered with the HPCSA.

In conclusion, various forms of justice are undermined when persons perform IONM without being registered with the HPCSA. Society and the healthcare system are exploited by persons employed by companies that are not registered with the HPCSA, with a false promise of benefitting society, when in fact, various injustices take place. These persons perform an act that is not reasonable based on societal values and undermine several justice-based rights outlined nationally and internationally. Healthcare professionals performing IONM have a duty as a part of society to practice in an ethical manner in order to promote beneficence and reduce harm. When persons are not registered with the HPCSA there is no societal duty given that these persons are not governed by values of a healthcare professional. Moreover, the public sector is more at risk of injustice, with companies taking advantage of a struggling public healthcare sector. The overuse of IONM fuelled by IONM has put an immense amount of pressure on the field of clinical neurophysiology as its

permissibility is now dictated by the lack of qualified persons registered with the HPCSA and not its efficacy.

Chapter 5 – Laws, regulations and guidelines pertaining to intraoperative neuromonitoring

This chapter will be dedicated to discussing the regulatory and legal aspects of performing IONM without being registered with the HPCSA. Quite often the ethical and legal aspects in medicine go hand in hand and therefore the chapter will address the legal aspects with support from ethical sources. I will define the legal aspects of IONM in South Africa and include the legal risks when persons perform IONM without being registered with the HPCSA. Also, I will include its permissibility, current practice, surgeon-opinion versus legal reality.

Legal aspects of IONM

Assessing the legal aspects of IONM consist first of defining what IONM is within the healthcare. As previously mentioned, in 2008 the House of Delegates of the AMA stated that the interpretation of IONM constitutes the practice of medicine and therefore the persons interpreting the IONM data needs to demonstrate a particular degree of competence within the field (2). In South Africa, who should perform and interpret IONM data is still an unanswered question. Without a proper standard of care and no way of determining competency within South Africa, the legal aspects remain open for discussion (3). To my knowledge there have been no documented legal cases which involve IONM in South Africa. This may represent IONM being performed adequately or that the persons performing IONM have not been held responsible for intraoperative deficits.

Although all IONM cases should be recorded for medico-legal reasons, there may still be an argument as to who should be the expert witness to assess the case. If we allow unregulated persons to continue IONM, over time, unregulated persons would be viewed as the experts in the field. This would further result in unethical practice and this would mean that IONM would be corrupt at its core. As mentioned previously, the person monitoring may not even know whether their decision is the correct one, as they are only

acting on the experience they have. Experience that was possessed without even having been taught adequately.

Health Professions Act

The Health Professions Act addresses who can practice within South Africa. From a legal point of view, the practice of IONM without registration is in contravention of the Health Professions Act, 56 of 1974 (36). Under section 17 of act 56 of 1974 "(1) No person shall be entitled to practise within the Republic [of South Africa] unless he or she is registered in terms of this act" and under section 17(1)(b)(iii) a person may not "[give] advice in regard to such defects, illnesses or deficiencies unless he or she is registered in terms of this Act" (36). The HPCSA defines a practitioner as "a person registered in terms of the Act [Health Professions Act 56 of 1974]. Since the interpretative aspect of IONM involves giving feedback for possible intraoperative defects it would be in contravention of the Health Professions Act. The interpretative aspect of IONM may ultimately lead to an intervention that directly affects patient-outcome and therefore in the South African context it would also be permissible to accept the interpretative and interventional components of IONM as a medical procedure. Since IONM can be accepted as a medical procedure, it should be provided by a healthcare professional governed by the HPCSA Persons performing IONM without registration with the HPCSA is thus in contravention of the Health Professions Act of South Africa.

The Health Professions Act, 56 of 1974 also allows for the establishment of professional boards in order to deal with issues of unprofessionalism. "Professional boards sets, maintains and applies fair standards of professional conduct and practice in order to effectively protect the interests of the public" and have the power to institute a disciplinary proceeding regarding unprofessional conduct against any person registered with the HPCSA (37), however there remains little power over unregistered persons. The HPCSA and its respective boards are entities put into place to protect the public and discipline healthcare professionals that deviate from the legal and ethical duties. A person that is not registered with the HPCSA does not have to abide by rules and regulations set out by the governing body and is free to practice in any way they see fit. Persons performing IONM without being registered with the HPCSA are not bound by any the HPCSA and healthcare boards and therefore, along with no guarantee of following a specific scope of practice,

also don't have the right from the HPCSA to practice the profession of clinical neurophysiology and IONM.

Opinion versus legal reality

There may be different opinions regarding the legal aspects of IONM and who remains responsible for any deficit that may occur. When an intraoperative deficit occurs, many would agree that the person performing the IONM should also be questioned, as to their involvement and possible negligence that may have affected the procedure. On the other end of the spectrum some surgeons acknowledge that IONM is just an extension of their skills and therefore all legal responsibility is placed on the surgeon, irrespective of the input from the IONM team. As mentioned previously the latter perspective is flawed given that there may be no need for regulation regarding whom should perform IONM since the decisions made by the person performing the IONM influences the outcome of the patient. This may not be apparent to the persons performing IONM without being registered with the HPCSA as it benefits them financially, with little attention being placed on performing a service that has ethical and legal grounds. When IONM is performed with a strong ethical and legal foundation then proper steps are taken to provide the best possible service because from a legal viewpoint no healthcare professional wishes to be sued for negligence, and from an ethical perspective, healthcare professionals pride themselves on acknowledging the correct practice of IONM in order to provide benefit from surgeries. When surgeons accept all responsibility of the surgery including on behalf on the IONM team, it is perceived as unethical as the surgeon is not acknowledging the need for expertise in IONM, nor are they accepting that IONM can be a medical procedure that is subject to negligence. The practice is unethical, and the surgeon performs an unethical act when accepting legal responsibility of the IONM team. When surgeons accept all legal responsibility of the IONM team they, and the IONM team (absence of responsibility), are acting unethically and poses a legal risk.

South African medical technology association

The South African medical technology association (SAMED) compiled the Company Representative in the Clinical Environment (CRICE) course in order to address the responsibilities and guidelines for company representatives in medical theatres in South Africa. There are a number of terms conferred upon representatives and the guidelines were

published to prevent harm, ensure confidentiality and mitigate against liability (38). The guidelines include advising on technical questions related to the operating of company products consistent with the instructions and labelling of the product. The representative may not provide diagnostic advice or recommendations on treatment even on request by the surgeon or other healthcare professional. Products may not be applied directly to a patient even if they hold the appropriate licensing/certification. This is considered the responsibility of a healthcare professional. Also, the representative may not have physical contact with the patient. The representative may not provide patient care or provide a medical service even if they have the appropriate licensing or certifications (39). This highlights that a representative of a company should provide advice regarding the preparation, assembly and use of instrumentation, devices or products (39). A common argument to the use of representatives in surgical cases is due to a lack in staff. This may also be the reason why non-healthcare professionals are performing IONM, however, this is a poor excuse as it conflicts with various legal and ethical standards. When non-healthcare professionals perform IONM they are performing an invasive procedure by placing needles in the skin of patients while they are under anaesthetic. This is unsettling as it implies that any person can perform an invasive medical procedure and undermines what is means to be a healthcare professional with values which include performing a procedure for which you were trained and can perform.

Reasonable person rule

Claims of negligence often rely on the "reasonable person rule" whereby the "The hypothetical reasonable person provides an objective standard by which the conduct of others is judged" (40). In medicine, a healthcare professional performs procedures and treats a patient based on acquired skills, experience and education and then they are judged based on what other reasonably skilled professionals would do (40). If there were to be an interoperative deficit while IONM is performed and the IONM team were to accept legal responsibility the reasonable person rule will be used to judge all the persons involved in the surgery in order to determine the extent to which party played towards the deficit. In this way the surgeon and the IONM team can be judged based on what other reasonable persons would have done in a similar situation.

Due to there being no standard of care or practice the surgeon becomes more liable as the unregistered person performing the IONM cannot be judged against others with similar skill and education since no standard exists. This is due to the absence of regulations that would have otherwise conferred the responsibility of performing IONM, and therefore the field of IONM has become subject to persons not registered with the HPCSA performing IONM, irrespective of educational background or experience. Moreover, there is no governing body that has laid down requirements for performing IONM in South Africa and this results in unregulated practice. This highlights the importance of setting a standard of what educational and regulatory prerequisites should be required to perform IONM.

When setting a standard, persons will have to gain experience and knowledge in order to meet some sort of standard of care. Currently the average person performing IONM may have no formal registration at the HPCSA nor any formal training and this puts the patient at risk as the possibility of giving false information to the surgical team and the possibility of negligence comes into question.

Negligence

It is important to highlight why negligence play such a major role in IONM and how persons not registered with the HPCSA can play a role in communicating false information to the surgical team. A false-negative in IONM occurs when the IONM team report that all neural structures are intact, when in fact a neural structure is being or is compromised (41). A false-positive occurs when the IONM team incorrectly reports a compromised neural structure (41). False-negatives and false-positives are both a looming problem in IONM and a large amount of false-positives can dissuade the surgeon from continuing the surgery, resulting in the surgical procedure being aborted. In cases of tumor removal procedures, an unnecessary amount of false-positives can cause the surgeon to lose confidence in his ability to continue and incomplete resection of the tumor can occur. This is detrimental to the patient and therefore IONM can have a significant influence on the surgical procedure.

The difficulty lies in determining whether something reported by the IONM is false-positive or simply a true-positive (a compromised neural structure was reported correctly) since the surgeon will always opt to follow the advice of the IONM team. If the patient

were to wake up with a deficit after the surgeon had chosen to ignore the warnings by the IONM team then this may be viewed as a form of negligence. This has been observed in a legal case (42). False-negatives result in a patient having a neurological deficit after the IONM team reported no IONM changes (41). This has been reported to occur during IONM and is unavoidable; however, who is to say whether a false-negative was an unavoidable occurrence of whether it was a user fault. When a false-negative occurs then a surgeon will often view it as an unavoidable incident, but it is unsettling when the false-negative occurs when the person performing the IONM is not a healthcare professional with credible qualifications. The same would apply to false-positive results where numerous false deficits would be reported by a non-healthcare professional registered with the proper governing bodies.

IONM in the courtroom

When an intraoperative injury occurs, IONM can be viewed as a double-edged sword in the courtroom (43). Negligence on the part of the person performing IONM and the surgeon needs to be addressed since IONM is being performed by persons that are not registered with the HPCSA and may not be properly trained. It is arguably impossible to prove negligence on the part of a person performing IONM while not being registered with the HPCSA since there is no standard against which negligence can be proved. As the use of IONM increases so does the risk of lawsuits of healthcare professionals and hospital (44). For the plaintiff negligence can be in the form of a failure to use IONM, ignoring IONM warnings and incorrect reporting by IONM (43).

In the event of an intraoperative deficit, failure to use IONM can be viewed as a form of negligence by the surgeon; however, a surgeon may have lost all their confidence in IONM if the person performing IONM have given incorrect information on numerous occasions. It is unlikely that this argument will hold up in court because there are adequately trained healthcare professionals (registered with the HPCSA) to perform IONM.

Companies providing IONM dominate the field and therefore surgeons may simply be unaware of the properly trained IONM personnel. When ignoring the IONM team's warning, the same might apply. The surgeon may simply not have confidence in the IONM

team since the number of false-positive warnings may deter the surgeon from following the instructions of the IONM team. When there is a possibility of a false-positive that needs to be ignored due to acknowledgement of the false-positive, then the surgeon and the IONM team need to discuss this in order to decide whether to continue. These complex decisions are being performed by persons that are not healthcare professionals registered with the HPCSA and therefore their level of skill comes into question.

IONM can also be viewed as a form of 'defensive medicine', where the surgeon is exculpated from responsibility and the liability is shifted towards the IONM team. Surgeons may believe they are legally free of liability simply because there is someone performing IONM; however, there is no guarantee of efficacy when a non-healthcare professional performs IONM. Even in court the presence of IONM during a case may mean that the surgeon was not liable for not using IONM, but the act can still be negligent when the surgeon allowed a non-healthcare professional to perform the IONM. This puts the surgeon at particular risk because they may assume that either the person monitoring is a healthcare professional or that is simply not necessary for a non-healthcare professional to perform IONM.

Standard of care

There are several legal cases where the surgeon opted not to use IONM and an intraoperative deficit occurred. The court stated that IONM should be the standard of care in spinal surgeries (43). This was stated in the case of *Kingsley v. Pinto* (45), where a patient was left paraplegic after a T3-S1 fusion. Kingsley contended that IONM would have warned Dr Pinto of the deficit and steps could have been taken to reverse the injury (45).

In another case of *Nissen v. Johnson* (46), the court attempted to determine whether IONM could have prevented damage to the plaintiff's cervical spine. It was stated by the plaintiff that IONM could have alerted the surgeon to a sharp object damaging the spinal cord. Although it was found that there was no malice in the case the court alluded to the fact that IONM could constitute a standard of care for cases like this. With its increased popularity and international legal cases pointing to IONM as a standard of care for spinal surgeries then South Africa may soon adopt the same outlook.

In the case of *Vaccaro v. St. Vincent's Medical Center,* the court stated that there can be negligence within IONM, with negligent monitoring constituting a deviation from standard of care (47). This statement makes it apparent that the USA is in the process of deliberating whether IONM should constitute a legal standard of care (43). Standard of care is the "care most people would exercise under the same or similar circumstances" (47). Within healthcare, professionals "should exercise at least the skill, knowledge, and care normally possessed and exercised by other members of their profession" in order to meet the standard of care (43).

In South Africa there is currently no formal standard of care. This relates to both the standard of care for IONM pertaining to particular surgeries, and the standard of care that the person performing IONM should have. When persons perform IONM without registration with the HPCSA it makes the legal aspect more complicated than it already is. In order to address the issue of standard of care within IONM one first must legally decide whom should perform IONM and one of the criteria should at least include that the person performing IONM be governed by some form of professions council, namely the HPCSA. Since IONM falls within the realms of a medical procedure it should legally be performed by a healthcare professional and the only way to be a healthcare professional is to be registered with a medical council such as the HPCSA. Legally the patient is put at risk when a person performs IONM within being registered with the HPCSA since the person performing the IONM cannot be judged as a healthcare professional that should display a specific set of skills and knowledge to perform IONM.

As mentioned previously it is difficult to assess the standard of care in South Africa when none has been established. It is for this reason that surgeons automatically deviate from the standard of care when they make use of a person to perform IONM without being registered with the HPCSA since the efficacy of IONM performed by non-healthcare workers cannot be determined. This becomes apparent when determining whether there was a causal link between the act or omission that resulted in injury to the patient, and to what extent does IONM influence the causal link. A specific act or omission can be directly influenced by the feedback provided by the person performing IONM but whether the feedback was a

form of negligence will most likely not be determined. This is most likely because the standard of care is often determined by an expert testimony. Given that IONM cases get performed by non-healthcare workers there is a possibility that the expert testimony will be delivered by an unregistered person. This for obvious reasons cannot be allowed due to IONM falling into the realms of an expert medical procedure.

Scope of practice

Practicing within your scope of practice is particularly important within IONM and clinical neurophysiology. It is important that persons performing IONM should be registered with the HPCSA and their duties should fall within their scope of practice. Generally, the job responsibilities of clinical technologists specialising in neurophysiology include: "The performance of electrophysiological [clinical neurophysiological] procedures, as well as tests on the brain, nervous system and muscular systems of the patient" (11). The HPCSA reported one of its biggest contributors to malpractice was related to scope of practice. This highlights that persons in South Africa can practice outside their scope of practice with little obstruction from governing bodies. IONM is just one of many fields that are subject to persons performing a procedure that they simply should not be performing, or it is subject to another healthcare professional working outside their scope of practice.

Conclusion

The regulatory systems surrounding IONM are extremely fragmented, with various ethical dilemmas when practicing IONM without being a healthcare professional and not being registered with the HPCSA. This research report outlines that injustices that occur when that performing IONM without registration with the HPCSA. Problems regarding autonomy and respect for persons arise, with patients remaining inadequately informed and therefore undermining their autonomy by affecting their access to information in order to make an informed decision. There is no doubt that the respect for fellow persons is lost when non-healthcare professionals perform IONM as the respect for inherent value as humans is diminished when performing IONM without being registered with the appropriate governing body.

Without being registered with the HPCSA, persons may not have the best interest of the patient in mind and may not have previous experience in healthcare that would have

otherwise groomed a healthcare professional to have values that assisted with caring for a patient. In South Africa there is no standard of care guidelines regarding the use of IONM in certain surgeries not set out for its actual practice. This has resulted in various ethical and legal questions being raised. As IONM continues to be performed by unregistered persons it loses its value of being a reputable medical procedure that carries weight as an important medical intervention in healthcare that aims to prevent harm and facilitate beneficence. There is also a form of deception when persons perform IONM without being registered with the HPCSA since there is a false sense of skill that is given to the patient and the surgeon.

Regarding beneficence and non-maleficence there are concerns about ensuring patient safety. When IONM is performed without the proper regulations there is no guarantee of its practice being effective and further emphasizes no establishment of a standard of care. Also, determining the degree of beneficence and non-maleficence for every surgical case takes a specific set of skill and knowledge – which is not guaranteed when persons perform IONM without being registered with the HPCSA. These discussions are often done between healthcare professionals in order to plan the management of every patient. When persons not registered with the HPCSA involve themselves in these discussions it undermines the very principles of being a healthcare professional. To utilize values supported by ethical principles instils upon healthcare professionals, the ability to make decisions that ensure the patient's best interests are in mind.

Compared to developed countries, South Africa is lagging in terms of its regulations in IONM. The practice of IONM in South Africa is conflicting, with various people performing IONM without being registered with the HPCSA. Unified regulations and guidelines are needed to improve the field of IONM and therefore healthcare. In South Africa, the need for proper regulations becomes apparent as the popularity of IONM increases. The technical, interpretative and interventional responsibilities of IONM should be laid out in order to establish the duties placed upon various members of the IONM team. International guidelines do exist, but they have not been adopted by South Africa and there is no guarantee that these guidelines will be able to function within the South African context. This may be due to a lack of educational courses in IONM and the lack of healthcare professionals available to perform the IONM.

In term of justice there has been an increase in need for IONM and therefore there has been increased exploitation of the field. As the popularity of IONM increases there has been increased attention on the field. With simple analysis one can see that the current practice of IONM cannot become the gold standard and cannot be allowed to be nationalised to become common practice that could be accepted by society.

Recommendations

Legal aspects

The legal aspects of IONM in South Africa are unclear, with little to no information regarding IONM in the legal spheres. It seems that IONM has not received the legal standing that is expected, and it appears that IONM is not considered a significant factor in legal cases or the persons that perform the IONM are less likely to be held liable. Persons performing IONM ought to be registered with the HCPSA because they need to be judged according to the standards of a healthcare professional and a reliable IONM professional. There should be a balance in responsibility between all the active participants in the surgical case. However, IONM should not be used as a form of defensive medicine, making the surgeon less liable given that IONM is used as a tool to reduce medical liability and not to reduce the risk of intraoperative injury.

Education and Training of IONM and key competences

A positive solution to this problem could include devising an academic program that would allow persons to gain the knowledge to perform IONM and allow for registration with the HPCSA. This program, that can be offered by an accredited university linked to an academic hospital can be offered given there are already existing physiologists, doctors and technologists available to teach. This would promote good ethical practice and skilled professionals that act in alignment with common ethical standards.

Regulation including Professional Registration with HPCSA

It is important to note that the identification of ethical issues themselves may not resolve them. However, awareness of ethical issues may encourage surgeons and society to adopt strategies that may limit the occurrence of unethical behaviour. To this end, the over-

arching recommendation of this report is thus that any person wishing to perform IONM ought to be registered with the HPCSA in order to be in accordance with good ethical practice that would result in respecting patient's, preventing harm, improving beneficence and improving justice. Moreover, registration with the HPCSA would also reduce the legal complications associated with non-registration.

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