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Informed consent for peripheral nerve blocks in patients presenting for upper limb surgery: documentation and patients' knowledge

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine in Anaesthesiology, Johannesburg, 2016.

Declaration

I, Adriaan Willem Buitenweg, declare that this research report is my own work. It is submitted for the admission to the degree of Master of Medicine in Anaesthesiology in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

……..

15th day of March 2016

Abstract

Peripheral nerve blocks for upper limb surgery are commonly performed procedures that are considered very safe but may be associated with significant distress, serious and life threatening complications.

The informed consent process, including its documentation, is an ethical and legal requirement to ensure that patients have full knowledge of the possible consequences, risks and benefits of the procedure for which they are granting permission.

Numerous previous studies have shown that informed consent is often not obtained and that if attained is often inadequate and poorly documented.

The aim of this study was to evaluate the adequacy of the informed consent process among patients receiving peripheral nerve blocks for upper limb surgery at the Chris Hani Baragwanath Academic Hospital Hand Unit.

Patients receiving peripheral nerve blocks for upper limb surgery between September 2014 and March 2015 were approached for inclusion in the study. Patients were asked to complete a survey questionnaire and the patients' records were then reviewed to determine if consent was documented.

It was found that only 20% of patients had adequate knowledge of the peripheral nerve blocks they had received, and only 44% of these patients had documented consent. None of the patients in the study had documented consent that was adequate according to the standard set out by the HPCSA.

This study revealed that patients receiving peripheral nerve blocks for upper limb surgery at the CHBAH Hands Unit currently do not have adequate knowledge regarding the blocks and that documentation of informed consent is inadequate if present at all. 68% of patients requested that an information leaflet be developed and provided to them as part of the informed consent process.

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Chapter 1: Overview

1.1 Introduction

In this chapter, an overview of the study will be presented which describes the background, problem statement, aim, objectives, research assumptions, location of the study, ethical considerations, research methodology, significance of study and validity and reliability.

1.2 Background

The last decade has seen an exponential growth in the field of regional anaesthesia (peripheral nerve blocks), specifically ultrasound-guided techniques (1). The main advantages of ultrasound guidance over peripheral nerve stimulation are higher success rates and quicker insertion, even for novices (2-4). A better general safety profile with ultrasound techniques has not been proven in trials (5, 6), but greater safety has been demonstrated for specific types of peripheral nerve blocks with regard to specific complications (2, 7). Some experts advocate ultrasound guided techniques as the gold standard (8). Peripheral nerve blocks are now being performed faster and with more ease (2-4), with the perception that they are safer (8), making them more common in daily practice (1). The development of education for peripheral nerve blocks also reflects this growth spurt (1, 9).

With the exponential growth of the use of peripheral nerve blocks, it follows that attention needs to be paid to the informed consent process regarding these peripheral nerve blocks and their complications (10). Some of the complications of peripheral nerve blocks are life threatening, but very rare. On the other hand, some are transient, but can be distressing (2).

Informed consent is firstly a matter of sound ethical practice and a human right and secondly, it is a legal requirement. Since informed consent was introduced into medical practice in 1957 (11), it has been incorporated into the legal systems of several countries, including the United States of America (USA), Canada, Australia

and South Africa (12, 13). Just as there is growth in the field of peripheral nerve blocks (1), there is on-going focus and continual development of human rights, especially in South Africa. The Patients' Rights Charter (14) mentions the "many decades" of "denial or violation of fundamental human rights, including rights to health care services". It stipulates, amongst other things, the need for patient participation in decision making and the need for informed consent. Better counselling (during the informed consent process) and greater care in communication is emphasised in all spheres of training and practice (15-18).

It has been proven that recall of information after the informed consent process is a problem. Affleck et al (19) found that only 36% of patients recalled more than two complications of epidural analgesia. Sanchini et al (20) found that 38% of patients enlisted in a clinical trial did not remember that they were involved in a trial and only 40% of patients were able to report some potential side effects. If a patient, therefore, is not able to report knowledge relevant to informed consent, it might not reflect on the quality of the informed consent process, but rather the poor recall of the patient (20).

The issue of documentation of consent is riddled with uncertainty, especially in the field of anaesthesia (10). Where no specific consent was taken for anaesthesia previously, it is now regarded as a compulsory requirement by medical defence organisations (21), the Health Professions Council of South Africa (HPCSA) (22) and practicing anaesthetists (10). Uncertainty regarding the exact extent of detail necessary during the informed consent process sees some practitioners recording increasing amounts of detail (16). Recommendations, guidelines and information sheets have been produced by several international and local institutions, all erring on the side of including more, rather than less information (23-28). These aids could make the counselling process much less daunting and more standardised, and can decrease litigation against the medical profession (15, 16).

Even though the need for obtaining informed consent is appreciated by most doctors, it is well known that informed consent is mostly not taken and/or documented correctly, for both surgical procedures and anaesthesia, nationally and internationally (29-31).

1.3 Problem statement

Patients need to receive adequate counselling regarding procedures such as peripheral nerve blocks of the upper limb. This is done to ensure sound ethical practice by providing patients with enough knowledge, through counselling, to make an informed decision. Furthermore, adequate counselling lessens pre-operative anxiety (32) and avoids possible litigation resulting from poor communication (15, 16).

It is vital, with increasing focus on human rights and increasing litigation against doctors, that documentation of informed consent and counselling practises be assessed. It was not known whether informed consent was adequately documented for patients at the Chris Hani Baragwanath Academic Hospital (CHBAH) Hand Unit before upper limb peripheral nerve blocks, and whether patients have adequate knowledge following the informed consent process.

1.4 Aim and objectives

1.4.1 Aim

The aim of this study was to describe the documentation of informed consent and patients' knowledge and perceptions of peripheral nerve blocks following the informed consent process, in patients who presented for upper limb surgery at the CHBAH Hand Unit.

1.4.2 Objectives

The objectives for this study were to:

- describe the documentation of informed consent
- describe the adequacy of documentation of informed consent according to the HPCSA standard
- describe the patient's knowledge of peripheral nerve blocks for upper limb surgery
- describe the patient's perception of the informed consent process.

1.5 Research assumptions

The following definitions were used in this study.

Informed consent: is a process and not just a form signed by the patient. The process conveys information to potential patients with active discourse between the patient and the doctor in order to obtain the patient's voluntary agreement to the anaesthesia.

Informed consent documentation: was an anaesthetist's note in the patient's record or a completed consent for anaesthesia section on the CHBAH "Consent to operate" form (Appendix A).

Adequate informed consent documentation: according to the HPCSA (22) "Health care practitioners must use the patient's case notes or the consent form to detail the key elements of the discussion with the patient, including the nature of information provided, specific requests by the patient, and details of the scope of the consent given."

Knowledge: as it relates to peripheral nerve blocks in this study, refers to the recall of the procedural events, benefits and risks related to this procedure.

Adequate knowledge: implied that the patient answered "Yes" to 10 (59%) of the knowledge questions. This is based on a similar study by Sanchini et al (20).

Anaesthetist: This included interns, medical officers, registrars and specialist anaesthetists working in the Department of Anaesthesiology at the study hospital.

1.6 Location of the study

This study was conducted at the CHBAH in Soweto, Johannesburg, which has 2888 beds. CHBAH, a central hospital, is affiliated to the University of the Witwatersrand. This public hospital accepts referrals from many clinics and secondary level hospitals

in the Gauteng province, as well as from other major referral centres in South Africa and beyond.

The Hand Unit is a multidisciplinary unit where peripheral nerve blocks are usually done by the anaesthetists, but are occasionally done by the orthopaedic surgeons.

1.7 Ethical considerations

Permission to conduct this study was obtained from the relevant authorities (Appendix B, C and D).

The researcher and a trained field worker invited post-operative patients who had upper limb surgery under peripheral nerve block, with a Ramsey score of ≤ 2, to participate in this study. Those who agreed were given an information letter and written consent was obtained (Appendix E).

The study was conducted in adherence to the principles of the Declaration of Helsinki (33) and the South African Good Clinical Practice Guidelines (34).

1.8 Research methodology

1.8.1 Study design

This was a prospective, descriptive, contextual research design.

1.8.2 Study population

The study included patients who had undergone a peripheral nerve block for upper limb surgery at the CHBAH Hand Unit, as well as the relevant patient records.

1.8.3 Study sample

Patients were recruited between September 2014 and March 2015. Convenience sampling was used in this study. Inclusion and exclusion criteria for the study were defined. A total of 59 patients were included in this study.

1.8.4 Data collection

A draft questionnaire was developed after an extensive literature review and reviewed by three specialist anaesthetists with a special interest in peripheral nerve blocks.

The proposed data collection period was from September 2014 to March 2015. The researcher and a trained field worker were responsible for assisting patients in completing the questionnaire. Some patients had procedures done to their dominant hand and the researcher or field worker had to fill in their questionnaire as they indicated their answers.

The data was entered into a Microsoft Excel ® spreadsheet.

1.8.5 Data analysis

Descriptive statistics were used to analyse the data in this study.

1.9 Significance of study

Informed consent for a peripheral nerve block is compulsory. This study aimed to describe the documentation of informed consent and patients' knowledge and perceptions of peripheral nerve blocks, following the informed consent process. This would give insight into ethical practice, respect of human rights and the risk the department is exposed to with regard to litigation, which is on the increase, both in the number of claims, and the amount of money per claim (35, 36). Furthermore, sufficient information has been shown to lessen pre-operative anxiety (32). The results of this study may change the informed consent process in the Department of Anaesthesiology.

1.10 Validity and reliability of study

Measures were taken to ensure the validity and reliability of this study.

1.11 Study outline

The following chapters are presented in this study.

Chapter 1: Overview
Chapter 2: Literature review
Chapter 3: Research methodology
Chapter 4: Results and discussion
Chapter 5: Summary, limitations, recommendations and conclusion

1.12 Summary

In this chapter an overview of the study was provided. A review of the literature is presented in Chapter 2.

Chapter 2: Literature review

2.1 Introduction

This literature review will start by discussing matters pertaining to brachial plexus blocks. The anatomy of the nerves relevant to the procedure will be explained. Next, consideration will be given to the techniques used to perform brachial plexus blocks. A short summary of the history and development of the techniques is put forward. Following this, the complications of brachial plexus blocks are discussed in more detail, due to the fact that the complications largely necessitate the need for the process of informed consent.

When discussing the process and documentation of informed consent, its history and development (focussing on the ethical basis), then integration into legislation, followed by the guidelines that resulted, and finally the documentation is reviewed.

2.2 Brachial plexus blocks

In order to understand the complications of peripheral nerve blocks of the upper limb, an understanding of the relevant anatomy and techniques used are briefly discussed.

2.2.1 Anatomy

Innervation of the upper limb is via the brachial plexus, which originates where the cervical spinal nerves exit the spinal cord. This is illustrated in Figure 2.1 with a diagram from Netter (37). The ventral rami of these nerves, from C5 to T1 level, join to form the trunks of the brachial plexus. The roots of C5 and 6 form the superior, C7 the middle and C8 and T1 the inferior trunk. These three trunks lie between the anterior and middle scalene muscles. Of the terminal branches that exit the plexus at the level of these roots and trunks, only the suprascapular nerve carries afferent, sensory signals, from the glenohumeral joint.

All the trunks divide into anterior and posterior divisions. The divisions combine again to form the cords. The posterior divisions all combine to form the posterior

cord, the anterior division of the inferior trunk forms the medial cord, and the anterior divisions of the superior and middle trunks form the lateral cord. Several nerves supplying sensory innervation branch off from the cords and the cords themselves then become terminal branches. (38)

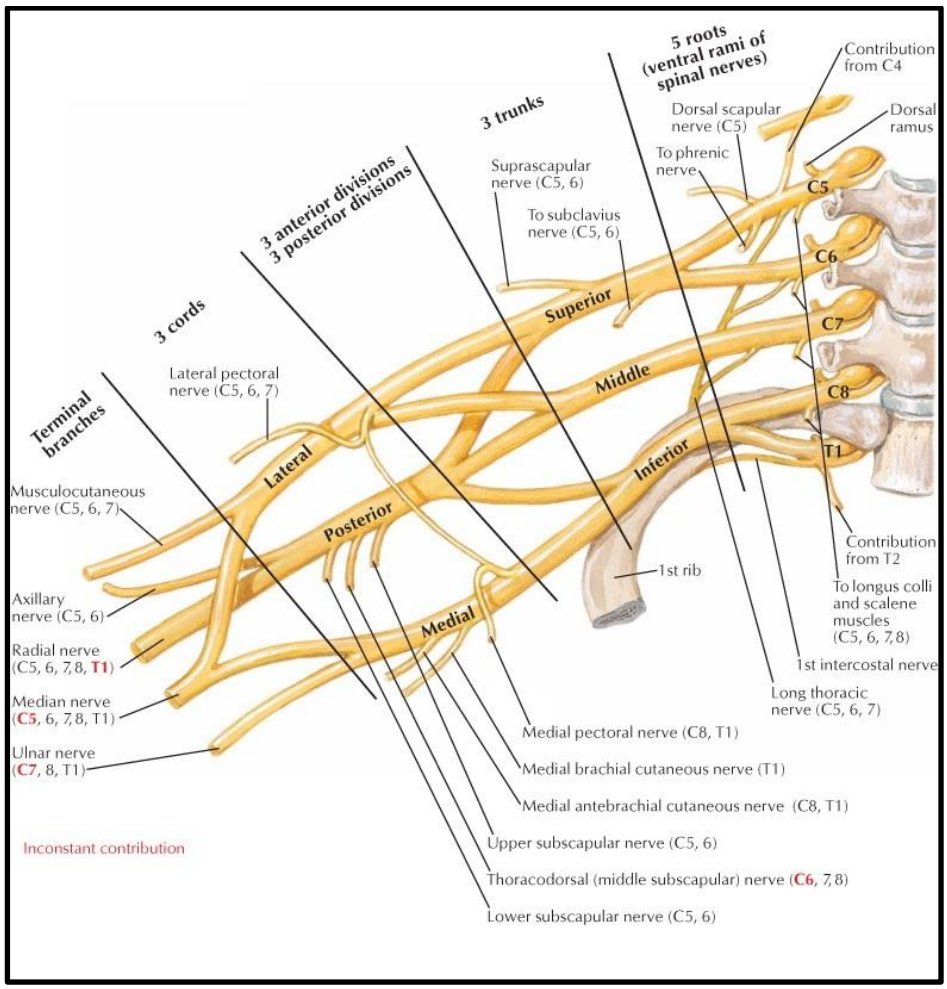


Figure 2.1 Anatomy of the brachial plexus (37)

The lateral cord gives off the lateral pectoral nerve which innervates the glenohumeral joint. The lateral cord then continues to become the musculocutaneous nerve which innervates the elbow, proximal radioulnar joint and the skin overlying the brachioradialis muscle. The lateral cord also joins a branch from the medial cord to form the median nerve that supplies the elbow and all joints distal to it, the skin of the lateral half of the palm and the palmar surface of the thumb, index, middle and medial aspect of the ring finger. (38)

The posterior cord terminates in the axillary nerve, innervating the glenohumeral and acromioclavicular joint and the skin over the deltoid; and the radial nerve, innervating the posterior arm, posterior forearm, elbow, radioulnar joint, wrist and dorsum of hand over the thumb, index, middle and ring finger (proximal to the distal interphalangeal joint). (38)

The medial cord gives off the medial brachial and antebrachial cutaneous nerves that innervate the medial aspect of the arm and forearm respectively. The cord then terminates in the ulnar and median nerves. The ulnar nerve supplies sensation to the medial half of the palm and the palmar and dorsal surface of the ring and little fingers. The medial cord also gives off a branch that joins the lateral cord to form the median nerve, as discussed above. (38)

2.2.2 Technique

Regional anaesthesia is defined as “the selective numbing of a specific nerve distribution or region of the body to facilitate surgery” (39). This is done by injecting local anaesthetic agents in close proximity to the nerve or nerve group percutaneously, either by using a needle for a single injection or by threading a catheter for serial or continuous administration of local anaesthetics. Regional anaesthesia of the brachial plexus can be done at several different levels. Current techniques advocate peripheral nerve stimulation or ultrasound visualisation of the needle to ensure accurate positioning. The axillary block can also be performed “blind”, without the abovementioned aids, as a trans-arterial technique. (40)

The first peripheral nerve block was done in 1885 by Halsted. In 1911, Hirschel described the axillary approach and in the same year Kulenkampff (41) described the supraclavicular approach. Bazy described the infraclavicular approach in 1914 and Etienne followed in 1925 with the interscalene approach. Many different techniques have since been described for interscalene, supraclavicular, infraclavicular and axillary approaches. (40)

2.2.3 Complications

The complications of brachial plexus blocks range from minor or transient to life threatening. These include:

- pneumothorax
- systemic local anaesthetic toxicity
- accidental intrathecal or epidural injection
- paraesthesia
- nerve injury
- vascular puncture
- haematoma
- phrenic nerve involvement with hemidiaphragmatic paralysis
- Horner's syndrome
- hoarseness (40).

The incidence of unsuccessful blocks requiring general anaesthesia or intravenous analgesia is reported to be 0 to 14% (4, 5).

Pneumothorax due to peripheral nerve block of the upper limb is very rare. In four large case studies (5, 42-44), including 2639 , 5526 , 2301 and 16 382 patients respectively, assessing the risks of all block types, not a single pneumothorax was described in the patients that received interscalene, periclavicular or axillary blocks. A case review specifically assessing supraclavicular blocks in 510 patients also reported no pneumothorax (45). Two review articles (3, 6) analysing randomised controlled trials involving all block types also found no pneumothorax in any of the studies. A single pneumothorax from an interscalene block occurred in only one prospective study including 520 patients (46).

Systemic local anaesthetic toxicity is the most troublesome complication of peripheral nerve blocks. It is acute, potentially life threatening and more common than other life threatening complications of peripheral nerve blocks of the upper limb, such as a pneumothorax. Only transient symptoms such as seizures have been described for peripheral nerve blocks of the upper limb and no report of deaths could be found in the literature. While no mention of such complications are made in a

case review (45) and a study (47) investigating only upper limb blocks, others report an incidence of 0 to 0,2% (46, 48). In case reviews and studies investigating all block types, but specifying occurrence for upper limb blocks, 0,012 to 0,174% is reported (42-44). These incidences are slightly higher than for blocks in general, which have an incidence of 0,011 to 0,098% (5, 42-44).

Accidental intrathecal or epidural injection is a theoretical possibility, but this has not been described for peripheral nerve blocks of the upper limb (42, 43). Only three reports for lumbar plexus blocks were found where epidural spread of local anaesthetic was thought to be the cause of serious complications (44).

Paraesthesia during insertion of a block or shortly thereafter is a known complication. Neurological symptoms, especially paraesthesia, at 7 to 10 days after insertion is quoted as being between 0 and 14% (4, 46, 49) in studies investigating all blocks and two studies looking specifically at upper limb blocks did not report any paraesthesia (4, 48).

Paraesthesia at the last follow-up of patients in nine studies (4, 5, 42-47, 49), done at 6, 9 or 12 months, confirmed that permanent nerve damage due to a peripheral nerve block is much more rare than paraesthesia during insertion of the block. Of these studies, the ones that assessed all block types (5, 42-44) reported an incidence of 0,0069 to 0,055%. In the studies that assessed all block types but specified incidences for upper limb blocks, the incidence was 0 to 0,12% (42, 43, 49) and in blocks looking specifically at upper limb blocks the incidence was 0 to 0,2% (4, 45-47).

Vascular puncture may lead to inadvertent local anaesthetic injection into an artery and is reported to occur in 0 to 0,6% of patients receiving peripheral nerve blocks of the upper limb (45-47). Haematoma is a theoretical possibility, but was not encountered in large case reviews assessing all block types (42, 43).

Phrenic nerve involvement with hemidiaphragmatic paralysis also resolves with block resolution, with the diaphragmatic involvement not causing distress in healthy individuals. Most studies (3, 42-44, 46) do not mention this complication, because it

is mostly asymptomatic, but some studies have quoted incidences of 1 to 2,5% where patients with respiratory symptoms were investigated and hemidiaphragmatic paralysis was found to be present (4, 45).

Horner's syndrome is common following peripheral nerve blocks of the upper limb, especially interscalene and supraclavicular blocks. Interscalene blocks are associated with incidences of 18,5% (50) and supraclavicular blocks up to 50% (7, 45, 48), depending on the technique used. Infraclavicular blocks are reported to have an occurrence of 5% (48). No record of this complication during axillary blocks could be found. Some case reviews (42-44) and studies (4, 46) do not mention this as a complication. Horner's syndrome resolves with the resolution of the block.

Hoarseness, due to involvement of the recurrent laryngeal nerve, has been reported as a complication of peripheral nerve blocks of the upper limb (51). This resolves with resolution of the block.

2.3 Informed consent

2.3.1 Origins and development

Historically, decision making with regard to patient treatment saw a paternalistic approach being employed. Hippocrates said a physician should "conceal most things from the patient while [he is] attending to him… revealing nothing of the patient's future or present condition." Withholding information from the patient was believed to prevent patient distress. This absence of communication was not a manifestation of absence of ethical orientation in practice however, as the Hippocratic oath dictated that a doctor will "prescribe regimens for the good of [his] patients according to [his] ability and [his] judgment and never do harm to anyone…" This omission of communication with the patient was continued through the medieval period, where doctors believed that they were extensions of God. They did not think it necessary to discuss the patients' condition with them. (52)

Even when the 1847 American Medical Association's Code of Medical Ethics (53) was published, it read:

> "The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions as to their fitness, to influence his attention to them."

Therefore, for the most part of history, patients were neither *informed* about their condition, nor was *consent* sought from them for treatment or procedures. Later, assent was sought from patients. This first form of obtaining patient approval was practiced in the early 1900s, but it was not a legal requirement and no minimum standard for the amount of information that had to be disclosed to the patient had been set (52).

Formal informed consent was required to conduct research on humans long before informed consent was required in clinical practice. It is commonly believed that the Nuremberg Code of 1947 was the first ethical guideline requiring informed consent for research (54). It seems, however, that the Prussian Government first sought informed consent from research volunteers as early as 1900 (55), referred to as the Berlin Code (54). Informed consent was also required according to the Guidelines for Human Experimentation of 1931, drawn up by the (Weimer) German Government (54). Ghooi (54) accused the authors of the Nuremburg Code of plagiarism, due to its striking resemblance to these 1931 guidelines. The World Medical Association Declaration of Helsinki was developed in 1964 and is based on the Nuremberg Code, and is regularly updated. The Declaration of Helsinki of 2013 is currently used as the authorative ethical guideline in research (54). Here too, informed consent is required for research (33).

Only in 1957 was the concept of formal informed consent introduced into clinical practice following the case of *Salgo versus the Leland Stanford, Jr. University Board of Trustees* (11) in the USA, where Mr Salgo was left paralysed after aortography. It is therefore a concept introduced by the legal system and not a product of medical ethics discussions. Justice Bray ruled that "a physician violates his duty to his patient

if he withholds any facts which are necessary to form [the] basis of an intelligent consent by [a] patient to a proposed treatment…" This meant that, for the first time, patients had to be given enough information to make a decision about their proposed treatment, and had to give permission for such treatment to commence.

This concept of informed consent drew a lot of criticism from Katz (56), a psychiatrist with a special interested in the process of informed consent, because it is idealistic and not easily interpreted and implemented in practice. Katz compared informed consent to a fairy tale:

> "Fairy tales are so appealing because ultimately they reduce complex human encounters to enchanting simplicity. In listening to them we suspend judgment and believe that once upon a time it was, and maybe even today it is, possible to utter magic words or perform magic deeds which transform frogs into princes or punish greedy fishermen's wives. The phrase "informed consent" evokes the same magic expectations. Its protagonists often convey that once kissed by the doctrine, frog-patients will become autonomous princes. Its antagonists warn that all the gold of good medical care which physicians now so magnanimously bestow on patients will turn to worthless metal if the curse of informed consent were to remain with us."

Court rulings in the 1960s and 1970s in the USA brought about some evolution of the concept of informed consent in an attempt to clarify aspects of informed consent in practice. The cardinal concern of all these cases is the issue of exactly how much information a patient needs to be given to enable them to make an informed decision. This question remains a point of concern to this day. (10) In the case of *Natanson versus Kline of 1960* (57), where Ms Natanson suffered disabling burns after cobalt irradiation for breast cancer, the court ruled that a patient needs to be counselled with the same effort as "a reasonable practitioner would make under the same or similar circumstances". This idea became known as the "reasonable doctor standard" (10, 52).

In contrast, in the 1972 case of *Canterbury versus Spence (58)*, where Mr Canterbury was partially paralysed by thoracic spinal surgery, the court ruled that the extent of disclosure should be based on what is material to the patient and not on the "reasonable doctor standard". This principle is called the "reasonable patient standard" (10, 52). The latest principle is referred to as the "subjective patient standard", where patients are told as much information as they themselves deem necessary (10, 52). Studies in the last 20 years have debated how to judge exactly how much information each individual patient wants to hear (59, 60). Other studies suggest that patients who may have requested minimal counselling and found it adequate, may not be considered informed enough to make an informed decision (61). The suggestion then, is to rather give more, than less information. Garden et al (59) showed that patients may perceive minimal amounts of information during the counselling process as adequate, but may later realise that it was inadequate when a more detailed counselling process is undertaken. A similar situation may occur when a patient is comfortable with minimal information being divulged during the counselling process, but claims to have wanted more information after a complication occurs that they were not counselled about (15, 16). Much uncertainty still remains about exactly how much information to impart onto patients before they are able to give truly informed consent. (10, 52)

2.3.2 Integration of informed consent into legislation

Informed consent consists of two aspects, the ethical base of the process and the legal application. Although they are not the same thing, they cannot be separated.

As Murray (12) explains, informed consent has been incorporated into the legal system of most common law countries by means of precedence set in court rulings. This is true for the USA for the case of *Salgo versus the Leland Stanford, Jr. University Board of Trustees* (11) which has already been mentioned. Different states in the USA have different statutes that all specify that informed consent is essential (62). *Rogers v Whitaker* (63), where Ms Whitaker lost vision in her left eye following surgery to her already blind right eye, was the landmark case for Australia according to Murray (12). Similarly, the *Kueper versus McMullin* (64) case, where a dentist left a broken drill bit in a patient's tooth without telling the patient, was the

landmark case for Canada (12). Canada is also the only country identified that has since developed an entire Act dedicated to informed consent (65).

In the United Kingdom of Great Britain and Northern Ireland (UK) courts, informed consent was not recognised as a doctrine. The *Bolam* test was adopted after the case of *Bolam versus Friern Hospital Management Committee (66),* where the patient received electroconvulsant therapy without a muscle relaxant, and the violent movement caused an acetabular fracture. The Bolam test "may be formulated as a rule that a doctor is not negligent if he acts in accordance with a practice adopted at the time as proper by a responsible body of respectable medical opinion" (66). The *Bolam* test was altered slightly with the case of *Hunter versus Hanley (67),* where a hypodermic needle broke off while the patient received an injection, and it then stated that "a doctor is not negligent if he acts in accordance with a practice adopted at the time as proper by a responsible body of respectable medical opinion." This was seen as proof of a standard of care to be expected and it has been argued to be more correctly phrased as "sufficient consent", rather than "informed consent". (12)

As can be seen in court cases that followed, the *Bolam* test practically had much the same implication as the "reasonable doctor standard": In the *Smith versus Tunbridge Wells Health Authority* (68) case, Mr Smith suffered from impotence following rectal surgery, and in the *McAllister versus Lewisham (69)* case where the patient was left with a hemiplegia after brain surgery. It is important to note that with the *Bolam* test, emphasis was still placed on both counselling the patient and obtaining consent. With doctors supplying more and more information to patients, the expected standard of counselling is always on the rise, and the legal requirements for adequate counselling are rising in parallel. The important difference in countries following a "reasonable patient standard" doctrine, is that the medical profession is setting its own high standards and they are not being set by the courts. (12) The UK has, however, also moved to a more patient orientated approach after *Sidaway versus Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital (70),* when Ms Sidaway was left paralysed after spinal surgery.

South African law has also embraced the concept of informed consent. The National Health Act No 61 of 2003 (13) has separate sections dealing with a patient's rights to have full knowledge of their condition, consent to treatment and participate in decision making. The Patient's Rights Charter (14) also includes sections on participation in decision-making, informed consent and refusal of treatment.

2.3.3 Guidelines, documentation of consent and information sheets

Several governing bodies and institutions, both internationally and locally, have issued guidelines and information sheets to assist practitioners in maintaining a high quality of care for their patients, including high ethical standards involving informed consent.

International

The World Federation of Societies of Anaesthesiologists (WFSA) produced the "International Standards for a Safe Practice of Anaesthesia" (71) that advocates the use of the World Health Organisation (WHO) "Surgical Safety Checklist" (72). This checklist requires the staff in theatre to confirm that informed consent has been given, but includes informed consent for the surgery and not the anaesthesia. A specific need for consent for anaesthesia is not mentioned in these standards.

In Canada, The Health Care Consent Act of 1996 (amended 2012) (65) deals widely with the aspects of informed consent. Clear exclusions as to who does not need to give consent are defined, with no anaesthesia related procedure being excluded. Voluntariness, discussing other treatment options and the risks of not accepting any treatment are all issues that are discussed. A definition of the amount of information required to constitute *informed* consent is also given, clearly following the 'reasonable patient' standard. It is clearly stated in the act that consent may be expressed or implied, but no mention of documentation of the consent is made. The Canadian Medical Association developed "The Basics of Informed Consent" (73) that upholds the same high standards set out in the act. In addition, it also advises that the process of informed consent be documented, suggesting that detailed documentation should be done. The Canadian Anesthesiologists' Society "Guidelines to the Practice of Anaesthesia" (74) does not mention the issue of

informed consent, but in line with WFSA it advises the use of the WHO “Surgical Safety Checklist” (72).

The American Medical Association produced the “Fundamental Elements of the Patient-Physician Relationship” (75) that deals with the core ethical issues of patient autonomy and the mutually respectful alliance. The American Medical Association also produced a document titled “Informed consent” (62) which details the elements of informed consent (voluntariness, capacity and information supplied) and advocates both “full disclosure” and “timely and thorough documentation” of the process. The American Society of Anesthesiologists “Basic Standard for Pre-Anesthesia Care” (76) also clearly expresses the need for documentation of informed consent for anaesthesia.

The Australian and New Zealand College of Anaesthetists has extensive material available for both anaesthetists and patients. Not only did they produce “Recommendations for the Pre-Anaesthesia Consultation” (77) that requires informed consent to be given for anaesthesia related procedures, but also issued “Guidelines on Consent for Anaesthesia or Sedation” (78). This document deals specifically with the elements of consent, the documentation of consent, standard consent forms and information sheets. Australian and New Zealand College of Anaesthetists has a website with large amounts of printable information for patients, dealing with topics like “what is anaesthesia”, “types of anaesthesia”, “what to expect”, “different procedures” and “frequently asked questions” (79).

The UK has the most extensive and specific guidelines with regards to consent for anaesthesia related procedures. The Association of Anaesthetists of Great Britain and Ireland has published a booklet on “Consent for Anaesthesia” (23). This booklet deals broadly with the importance of consent, capacity or incapacity and voluntariness, information and the process of consent, documentation, qualified consent, advance decisions and special circumstances (even extending to Braille information sheets for blind patients). Of all the international guidelines and standards, this booklet best reflects the current practice of rather giving too much information than too little. This reflects the requirements set out by the General Medical Council in “Consent: patients and doctors making decisions together” (80),

which requires written consent for anaesthesia, which would meet the requirements for when an “investigation or treatment is complex or involves significant risks”. Furthermore, the Association of Anaesthetists of Great Britain and Ireland and the Royal College of Anaesthetists has developed several information sheets for patients, e.g. “You and your anaesthetic” (28) and “Anaesthesia explained” (24) which can be downloaded or printed.

South Africa

With regard to informed consent in general (not specifically for anaesthetists), the HPCSA has a booklet titled “Seeking patients’ informed consent: The ethical considerations” (22). This booklet elaborates on the concerns dealt with in the National Health Act and Patient’s Rights Charter. It states clearly that a comprehensive informed consent process must take place, but due to a “reasonable patient approach”, unfortunately, room for interpretation is still left, as can be seen from the following extract:

> “The amount of information that must be given to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes.”

This booklet also states clearly that detailed documentation of informed consent should take place if “the treatment or procedure is complex or involves significant risks and/or side effects”, a category into which anaesthesia related procedures would fall. Even though room for interpretation is left with the statement about how much information to disclose to a patient, an attempt is made to delineate the detail required when documenting the process, although some aspects are addressed:

> “Health care practitioners must use the patient's case notes or the consent form to detail the key elements of the discussion with the patient, including the nature of information provided, specific requests by the patient, and details of the scope of the consent given.”

The South African Society of Anaesthesiologists (SASA) has issued practice guidelines which contain a section dealing with informed consent (25). Due to the nature of the organisation, it is more focussed on anaesthesia related procedures and allows for more detailed descriptions. These guidelines also err on the side of giving too much rather than too little information, in keeping with current, worldwide trends and the HPCSA guidelines. It does, however, advise practitioners not to bombard patients with details about “rare and uncommon outcomes that will incur undue anxiety”, provided that they do not have “catastrophic outcomes”. Specific mention is also made of the fact that informed consent needs to be taken for “major plexus anaesthesia”.

Many aids to the informed consent process are available in South Africa. SASA has developed an information sheets for epidural anaesthesia (27) and for peripheral nerve blocks of the upper limb (26). These serve as documentation of informed consent, as the patient can sign at the bottom of this sheet. The Anaesthesiologists Independent Practitioner Association developed the “Anaesthetic Consent Form”, which details some particulars of the informed consent process. The patient can sign at the bottom of the page. Discovery Health has a procedure information guide regarding local anaesthetics (81) that can be given to a patient to read before consent is taken. The public hospitals use the “Consent to Operate” form which has a small section where the anaesthetist can document the type of anaesthesia, but no space is available to document particulars like anaesthesia options discussed or complications discussed.

2.3.4 Litigation

Patients have also, in general, become better informed through social media and self-research (16, 35). Patients are realising what they are entitled to and exactly where doctors’ conduct is found to be wanting. Therefore, litigation against doctors is on the increase, both in the number of claims, and the amount of money per claim. The Medical Protection Society of South Africa (MPS) reports settling its highest claim ever in 2012 and also that the number of cases reported increased by 30% from 2006 to 2010. (35) The Gauteng Department of Health suffered claims of R 573 million between 2009 and 2010 (82). Most notably, cases are being settled not because complications occur, but because patients were not made aware of the

possibility that these defensible complications could occur (18, 83). The internet, television and radio has no shortage of law firms, advertising their expertise in malpractice claims, now also working on a “no win, no fees” basis. In a country with high unemployment rates (25,2% or ±4,6 million people) (84), financial compensation without the risk of unaffordable attorney’s fees could be a powerful incentive for patients to take legal action.

Instead of focussing on a comprehensive informed consent process, clinicians are sometimes more concerned about having a signed document that confirms that informed consent was obtained. In a court of law, however, the signed form could be of questionable value. Court rulings regarding the extent of validity of the signed form vary, with some courts (85, 86) arguing that a signed form means informed consent was obtained correctly, and the onus is on the patient to prove that this is not the case. Other courts argue that the documentation of consent is “not sufficient evidence that informed consent had been obtained” (85). “Foundational Principles of South African Medical Law” authors Carstens and Pearmain (87) liken written informed consent to the black box of an aeroplane, when there has been a mishap, everyone tries to find this in an attempt to establish what went wrong. There is, however, no clear view on the value of written consent forms as far as the courts are concerned.

2.3.5 Recall of information by patients

The ability of patients to recall information that was imparted during the informed consent process remains a problem. Varying results have been found in studies that have investigated this problem, but differences in methodology, objectives and demographics make the results difficult to compare.

Cheng et al (88) found good levels of recall with more than 88% recall of three serious side-effects by participating patients following regional anaesthesia for caesarean section. This study was done in Australia, a developed country, and even though most patients had not completed high school, all patients were either still at school, or had higher education. The authors do, however, claim that the level of education did not impact on the recall patients seemed to have reported. The methodology of this study involved prompting the patients for answers.

These results are in stark contrast to another study done by Affleck et al (19) in a developed country (USA) where demographics were not reported, but 63% of patients were unable to recall more than two complications following epidural analgesia.

Sanchini et al (20) investigated recall of patients who underwent a thorough informed consent process for enrolment in a trial and found that only 38% of patients remembered that they were enlisted, and only 40% of patients could recall some potential side-effects of the medication they were taking. This study was done in Italy, in a population where most patients had only completed primary school education. They concluded that comprehension and recall following counselling improved if the patients had a higher level of education and/or received more, rather than less information. Comprehension and recall decreased with an increase in age.

2.4 Summary

In this chapter an overview of the literature was provided. Chapter 3 will contain the methodology of the study.

Chapter 3: Research methodology

3.1 Introduction

In this chapter the problem statement, aims and objectives, ethical considerations, research methodology and the validity and reliability are discussed.

3.2 Problem statement

Patients need to receive adequate counselling regarding procedures such as peripheral nerve blocks of the upper limb. This is done to ensure sound ethical practice by providing patients with enough knowledge, through counselling, to make an informed decision. Furthermore, adequate counselling lessens pre-operative anxiety (32) and avoids possible litigation resulting from poor communication (15, 16).

It is vital, with increasing focus on human rights and increasing litigation against doctors, that documentation of informed consent and counselling practises be assessed. It was not known whether informed consent was adequately documented for patients at the CHBAH Hand Unit before upper limb peripheral nerve blocks, and whether patients have adequate knowledge following the informed consent process.

3.3 Aim and objectives

3.3.1 Aim

The aim of this study was to describe the documentation of informed consent and patients' knowledge and perceptions of peripheral nerve blocks following the informed consent process, in patients who presented for upper limb surgery at the CHBAH Hand Unit.

3.3.2 Objectives

The objectives for this study were to:

- describe the documentation of informed consent
- describe the adequacy of documentation of informed consent according to the HPCSA standard
- describe the patient's knowledge of peripheral nerve blocks for upper limb surgery
- describe the patient's perception of the informed consent process.

3.4 Ethical considerations

Approval to conduct this study was obtained from the Human Research Ethics Committee (Medical) (Appendix B) and the Post Graduate Committee (Appendix D), Faculty of Health Sciences of the University of the Witwatersrand.

Approval was obtained from the CHBAH Medical Advisory Committee (Appendix C) to conduct research in the hospital and specifically, to conduct interviews with post-operative patients in the wards.

The researcher and a trained field worker invited post-operative patients who had upper limb surgery under peripheral nerve block, with a Ramsey score of ≤ 2, to participate in this study. Those who agreed were given an information letter and written consent was obtained (Appendix E).

After completing the questionnaire, patients were given the opportunity to ask questions and discuss the content of the questionnaire. The researcher or field worker provided any further education on the procedural events and risks of peripheral nerve blocks that the patient required.

The completed questionnaire was placed into a sealed box, separate from the consent form and only the researcher and supervisors had access to the data to protect patient confidentiality. Anonymity could not be ensured as the researcher or

field worker assisted patients who had procedures done to their dominant hand, to complete the questionnaire.

Only the researcher and supervisors have access to the collected data. The data will be kept in a secure cupboard for a period of six years after the completion of this study.

The study was conducted in adherence to the principles of the Declaration of Helsinki (33) and the South African Good Clinical Practice Guidelines (34).

3.5 Research methodology

3.5.1 Study design

A prospective, descriptive, contextual research design was undertaken.

Prospective studies measure variables during the course of the study (89). The variables for this study were measured at the time the study took place.

The descriptive design employed in this study saw one sample being used to describe the variables as they occur naturally, where there is no manipulation of the research variables and no attempt to determine the relationship between variables (90). This is a descriptive study in that the documentation of informed consent and patients' knowledge and perception of informed consent was described.

Contextual studies separate certain components from the larger context (91). This study examined the documentation of informed consent and patients' knowledge and perception of informed consent for peripheral nerve blocks in patients who presented for upper limb surgery at the CHBAH Hand Unit.

3.5.2 Study population

The study included patients who had undergone a peripheral nerve block for upper limb surgery at the CHBAH Hand Unit, as well as the relevant patient records.

3.5.3 Study sample

Sample size

Patients were recruited between September 2014 and March 2015. A total of 59 patients were included in this study.

Sampling method

Convenience sampling is a process whereby the researcher gathers conveniently accessible data (89). A convenience sampling method was used in this study. On the days that the researcher or a field worker was available, all patients who met the criteria were included.

3.5.4 Inclusion and exclusion criteria

In this study the following inclusion and exclusion criteria were used.

Inclusion criteria:

- patients, 18 years and older, who had undergone upper limb surgery under peripheral nerve block
- patients who gave informed consent to participate in the study.

Exclusion criteria:

- patients who could not adequately communicate in English
- patients with a Ramsey score > 2
- patients who were health care workers, with knowledge of the procedure
- patients who had records that were incomplete, missing or illegible.

3.5.5 Data collection

Data collection sheet for documentation of informed consent

A data collection sheet (Appendix F) was compiled by the researcher and requested the following information:

- study number
- was informed consent documented
- where was informed consent documented
- was documentation of informed consent adequate according to HPCSA
- language of informed consent process
- language of documentation of informed consent process
- consent obtained verbally or in writing
- type of block performed.

Development of questionnaire

A draft questionnaire was developed by the researcher after an extensive review of the literature. The draft questionnaire was reviewed by three experienced specialist anaesthetists with more than 10 years of anaesthetic experience and who have a special interest in the field of peripheral nerve blocks. The questionnaire was written in easily understandable English and any unfamiliar words or statements were clarified by the researcher or field worker at the time of data collection.

The final questionnaire (Appendix G) addressed the following aspects:

- demographics
- whether the patient has previously had a peripheral nerve block of the upper limb
- knowledge of the peripheral nerve block procedure
- knowledge of other anaesthetic options
- knowledge of complications of the peripheral nerve block
- the source of information with regard to the peripheral nerve block
- voluntariness
- patient perception of the informed consent process.

The questionnaire consisted of 24 questions, 19 knowledge questions (including 8 questions related to the procedure and purpose of the peripheral nerve block of the upper limb, and 11 questions related to complications) and 5 questions regarding perception. The questions were answered by selecting either “Yes”, “No” or “Unsure”.

Data collection

The data collection period was from September 2014 to March 2015.

An Australian medical student doing an elective was recruited as a field worker to assist with data collection from February to March 2015. The background of the study as well as the aims, objectives and methodology was discussed and a copy of the protocol provided. The field worker accompanied the researcher to collect data for a day to orientate him.

Due to the researcher and the field worker’s clinical commitments, data was collected at the end of working days, as well as pre- and post-call.

Data collection proved difficult as patients were discharged home from the recovery room. Few patients were available in hospital for recruitment at any particular point in time, especially in the ward at the end of a working day.

The researcher or field worker approached patients with a Ramsey score of ≤ 2 in the post-operative wards. Those patients interested in participating were provided with an information sheet and informed consent (Appendix E) was obtained.

The researcher or field worker was responsible for assisting patients in completing the questionnaire, as well as the collection and storage of the data generated.

All curtains were drawn around the patient’s bed to protect their privacy. Each completed questionnaire was placed into a sealed box, separate from the consent form, to protect patient confidentiality.

The data was entered into a Microsoft Excel ® spreadsheet.

3.5.6 Data analysis

Descriptive statistics were used. Categorical data was summarised using frequencies and percentages. Means and standard deviations were used to describe normally distributed continuous data and medians and interquartile ranges were used if the data was not normally distributed. The Kolmogorov-Smirnov (KS) value was used to describe the distribution of the continuous data. Data was analysed using GraphPAD InSTAT®.

3.6 Validity and reliability of study

Botma et al (90) state that “validity indicates whether the conclusions of the study are justified based on the design and interpretation”. It also states that “reliability represents the consistency of the measure achieved.”

The validity and reliability was optimised by the following means.

- The face and content validity of the questionnaire was optimised by developing it after an extensive literature review and review by three specialist anaesthetists with a special interest in peripheral nerve blocks.
- Simple English was used in the questionnaire and when communicating with patients verbally.
- The researcher and a trained field worker were the only people collecting the data, ensuring a standard approach and were present to assist with questions regarding the questionnaire.
- Data was analysed in consultation with a bio-statistician.
- Excel spreadsheet entries and data was cross checked for accuracy.
- Questionnaires were only completed by patients who were not sedated (including the effects of analgesia) as assessed by a Ramsey score of ≤ 2.

3.7 Summary

In this chapter the research methodology was presented. The following chapter contains the results and discussion.

Chapter 4: Results and discussion

4.1 Introduction

In this chapter the results of the study, according to the objectives, and the discussion are presented. The objectives of the study were to:

- describe the documentation of informed consent
- describe the adequacy of documentation of informed consent according to the HPCSA standard
- describe the patient's knowledge of peripheral nerve blocks for upper limb surgery
- describe the patient's perception of the informed consent process.

4.2 Results

Percentages are rounded off to the nearest whole number and may therefore not add up to 100%. Continuous variables are reported as means and standard deviations for all normally distributed data. In addition, the median and interquartile range are reported for data that is not normally distributed. Continuous data was assessed for normality using the Kolmogorov-Smirnov (KS) test and this will also be reported.

4.2.1 Sample realisation

Questionnaires were handed out to all patients meeting the inclusion criteria between September 2014 and March 2015. A total of 61 questionnaires were completed by the patients, however 2 were excluded from the study as they were incomplete, leaving 59 completed questionnaires.

4.2.2 Demographics

Most of the patients included in the study were male (n=41, 69%), had completed primary school (n=33, 56%) and were between the ages of 18 and 29 (n=26, 44%). The demographics of the patients included in the study are displayed in Table 4.1.

Table 4.1 Demographics of patients

Demographics	Number	Percentage
n=59	**(n)**	**(%)**
Gender		
Male	41	69
Female	18	31
Level of education		
Did not complete primary school	4	7
Completed primary school	33	56
Completed high school	21	36
Completed tertiary education	1	2
Age groups (in years)		
18-29	26	44
30-39	10	17
40-49	14	24
50-59	4	7
60-69	5	8
Type of block		
Coracoid	39	66
Axillary	19	32
Supraclavicular	1	2
Received previous upper limb blocks		
Yes	7	12
No	51	86
Unsure	1	2

4.2.3 Objective: to describe the documentation of informed consent

Documentation of informed consent was found to be present for 26 (44%) of the patients and the remaining 33 (56%) had no documentation of informed consent.

Consent could be documented in the patient's file (including the anaesthetic record), or on the "Consent for Operation" form only. Presence of documentation and the location of the notes are indicated in Figure 4.1.

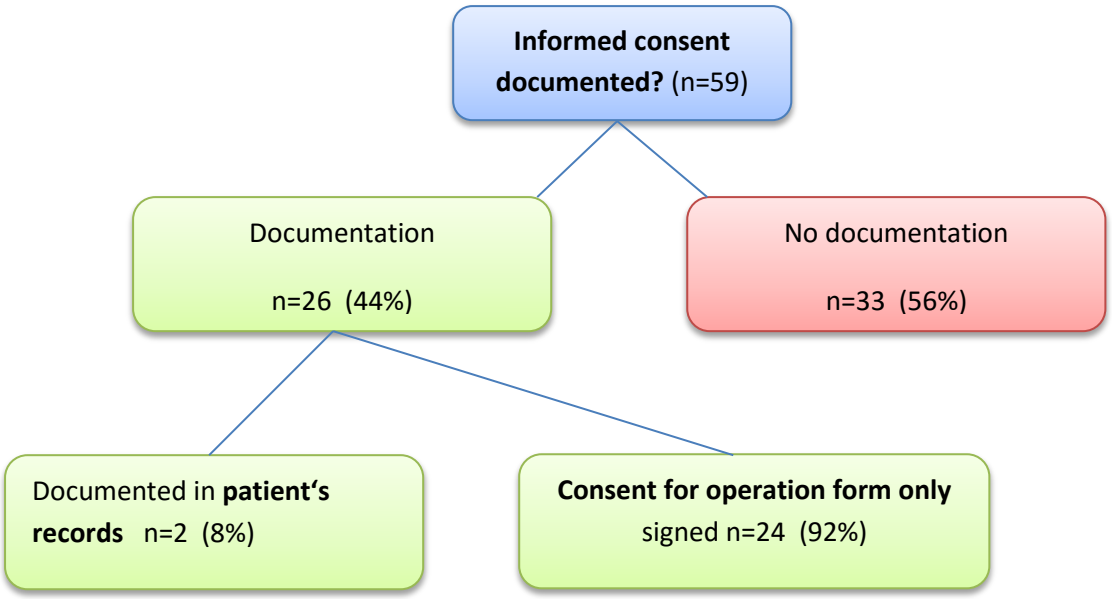


Figure 4.1 Documentation of informed consent

Of the 59 patients in the study only 2 (3%) had documentation of informed consent with notes in the patient's records and 24 (41%) of all the patients had only a signed "Consent for Operation" form.

Information regarding the procedure and complications were given verbally to all 59 patients. The language in which this was done is shown in Table 4.2, as is the language of documentation.

Table 4.2 Language of informed consent process and documentation

	Number (n)	Percentage (%)
Language conducted		
English	57	97
Sotho	1	2
Zulu	1	2
Language of documentation of informed consent		
English	26	100

4.2.4 Objective: to describe the adequacy of documentation of informed consent according to the HPCSA standard

None of the documentation of informed consent in this study was adequate according to the HPCSA standard as defined in the research assumptions.

4.2.5 Objective: to describe the patient's knowledge of peripheral nerve blocks for upper limb surgery

Overall knowledge

Adequate knowledge implied that the patient answered "Yes" to 10 (59%) of the 19 questions listed as questions 1 to 19 of the study questionnaire. Of the 59 patients included, 12 (20%) had adequate knowledge of the peripheral nerve block that they had received for upper limb surgery, while 47 (80%) did not.

The data for these 19 questions was normally distributed (KS=0.1362, p>0.10). The mean score for these questions that assessed adequate knowledge was 8 (SD=3,98) which is 42%. Figure 4.2 shows the number of patients for each score out of 19.

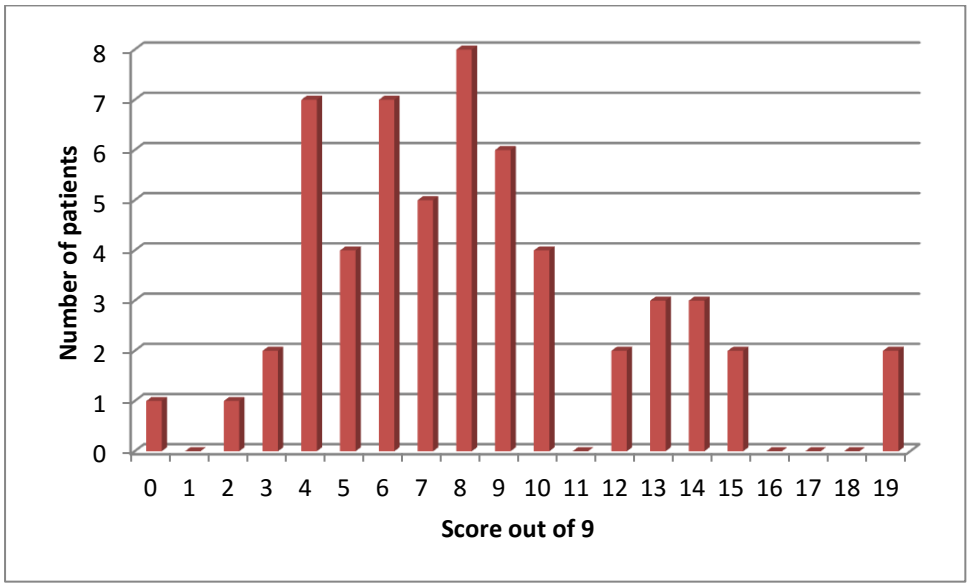


Figure 4.2 Overall knowledge scores for upper limb blocks

Knowledge of procedure and purpose

For the eight questions (1 to 3 and 15 to 19) of the questionnaire that assessed knowledge regarding the procedure and purpose of the peripheral nerve block of the upper limb and the informed consent process, the data was normally distributed

(KS=0.1344, p>0.10). The mean score for these questions was 4,76 (SD=1,82) which is 60%. The majority (n=14) of patients scored 4 out of 8. Figure 4.3 shows the number of patients for each score out of 8.

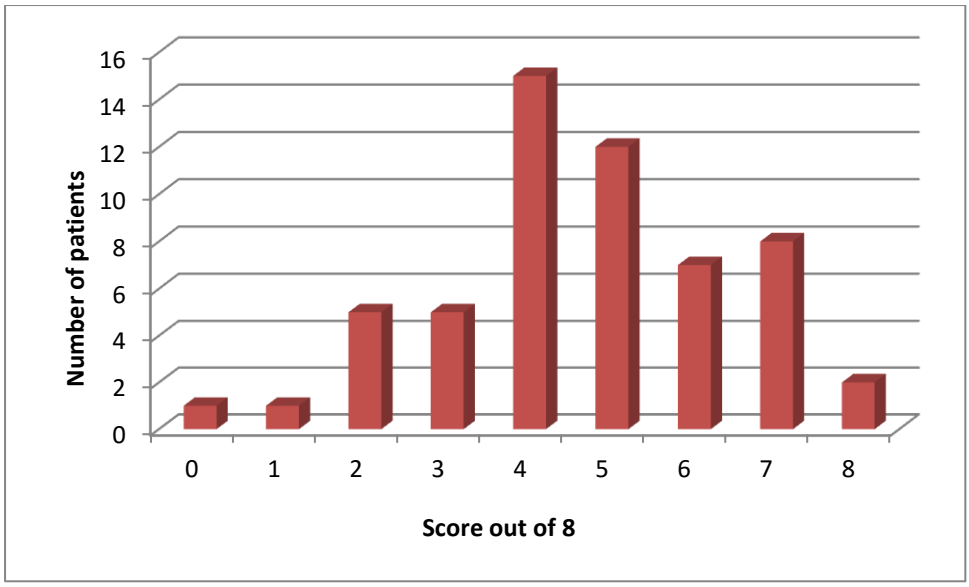


Figure 4.3 Knowledge scores for procedure and purpose of upper limb blocks

Knowledge of complications

For questions 4 to 14 of the study questionnaire that assessed knowledge regarding complications that could arise following an attempt to perform a peripheral nerve block of the upper limb, the data was not normally distributed (KS=0.1941, p=0.0234). The median score was 2 out of 11 (IQR=1-5). Figure 4.4 shows the number of patients for each score out of 11.

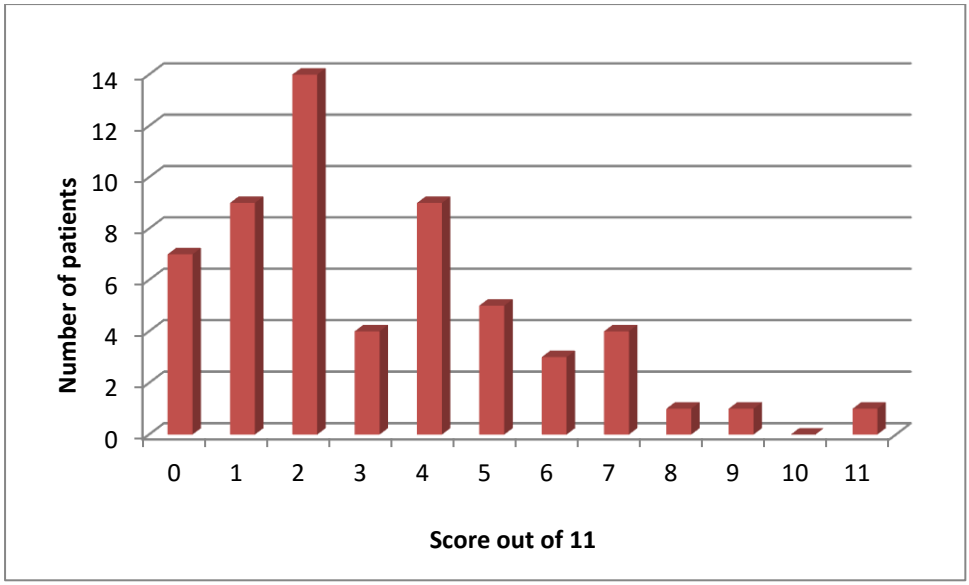


Figure 4.4 Knowledge scores for complications of upper limb blocks

4.2.6 Objective: to describe the patient's perception of the informed consent process

Fifty one (86%) patients identified the health care worker who took consent for the peripheral nerve block of the upper limb as an anaesthetist, while 7 (12%) identified them as a surgeon and 1 (2%) patient indicated that he/she was counselled by a nurse.

Questions 21 to 24 of the study questionnaire addressed:

- whether patients felt forced to undergo a peripheral nerve block of the upper limb
- were happy with the information they had received regarding the block before the procedure
- whether enough time was spent giving them information regarding the block
- whether they would have liked an information sheet about the block before the procedure.

Most patients did not feel forced (n=50, 85%), were happy with the information provided (n=43, 73%), felt that enough time was spent giving them information

(n=33, 56%), but would have liked an information sheet (n=40, 68%). These results are shown in Figure 4.5.

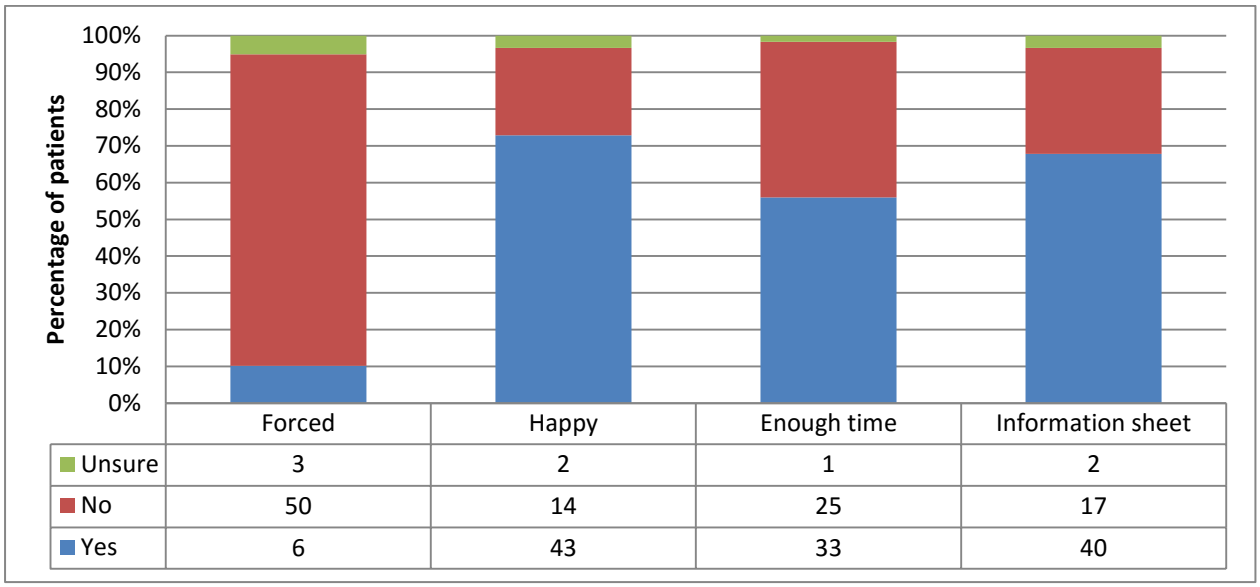


Figure 4.5 Patient perceptions regarding the informed consent process

4.3 Discussion

This study served to shed light on the documentation of informed consent and patients' knowledge and perceptions of peripheral nerve blocks following the informed consent process, in patients who presented for upper limb surgery at the CHBAH Hand Unit.

It was expected that the documentation of informed consent for peripheral nerve blocks of the upper limb at the CHBAH Hand Unit would have been incomplete. This is in keeping with other South African doctors' attitudes towards the informed consent process according to Naidu (29), who found that 84% of doctors advocate documentation of informed consent, but only 38% complied with this requirement. Our study showed similar results, as only 26 (44%) of the patients had documented informed consent present.

No documented consent was found for 33 (56%) of patients. It would appear that all patients gave verbal consent, but this is inadequate. In only two of the 26 cases where documentation of informed consent was present, did the anaesthetists make

notes in the patients' records. This is a total of 3% of the 59 patients included in the study. In the other 24 cases (41% of all cases) the "Consent for Operation" form was merely signed, which is not adequate according to the HPCSA, but was defined as adequate for this study because that is what is considered standard practice at the study hospital. A culture of detailed notes with regard to informed consent does not prevail among the health care workers at the CHBAH Hand Unit at present.

These findings are of concern, because documentation of informed consent falls short of the requirements set out by the HPCSA (22). In accordance with these requirements, it is suggested by medical defence councils (21) and other practising anaesthetists (10), that detailed documentation of the informed consent process be practised. The standard of information required by the HPCSA is reflected in the information sheet that SASA (26) has made available for peripheral nerve blocks of the upper limb, but this was not used by any of the health care workers in this study.

Only 12 (20%) patients had adequate knowledge of the peripheral nerve block they had received. Recall of information following the informed consent process has mostly been found to be poor. Affleck et al (19) showed that only 37% of patients in a developed country (USA), receiving epidural anaesthesia during labour, could recall three of the thirteen risk factors they were told about. Sanchini et al (20) conducted a study in Italy, in a population with levels of education that are comparable to those found in our study, where most patients (56%) only completed primary school. In their study, 40% of patients were able to recall some potential side effects, but this is double the number of patients with adequate knowledge found in our study. Poor recall may therefore not be the only factor to consider when faced with the inadequate knowledge that patients had, and it has to be acknowledged that poor counselling may have contributed. However, Sanchini et al (20) is of the opinion that the level of education of a patient may play a role in the extent of their comprehension of the information during the informed consent process and this could have impacted our study.

The language in which the informed consent process took place could play a role in the comprehension of the information received by the patient. It is interesting to note that only 2 (3%) of the patients reported being counselled in a language other than

English, despite the majority of patients and some doctors in the Department of Anaesthesiology speaking African languages as their home language.

Patients scored much better in questions related to the procedure and purpose of the blocks than in questions related to complications, and had knowledge about why they needed to have the blocks or whether alternatives to the blocks were available to them. The mean score for these questions was 4,76 (SD=1,82) out of 8, which was 60%. In contrast, patients knew less about the complications that could occur following a peripheral nerve block of the upper limb. The mean score for these questions was 3.3 (SD=2.7) out of 11, which was 30%. Sanchini et al (20) also noted that patients are familiar with the procedures of the proposed treatment after treatment initiation and therefore report good knowledge on this aspect, but lack knowledge about more specific details such as complications that were not encountered . This could be a reflection of post-operative knowledge stemming from the experience of the procedure and not of the pre-operative knowledge gained from the informed consent process. This would also fit in with the scenario where patients are not adequately counselled but told that they “quickly need an injection to take the pain away”.

The doctors who took consent for the peripheral nerve block were identified as anaesthetists by 51 (86%) of patients, while 7 (12%) identified the doctor as the surgeon and 1 (2%) patient indicated that he/she was counselled by a nurse. As nurses are not the health care professionals that do the blocks, they are not allowed to take informed consent for such procedures (22). It is more likely that the anaesthetist or surgeon who counselled the patient was thought to be a nurse, indicating that he/she possibly did not introduce him-/herself adequately.

Litigation following adverse outcomes is heavily influenced by patient perceptions (15, 16). In the event of an adverse outcome, poor pre-operative knowledge of the complication that occurred could be blamed on what the patient may have perceived as a poor informed consent process.

Despite so many patients not having adequate knowledge of the peripheral nerve blocks that they had received, 43 (73%) patients were happy with the information they had received about the block before the operation and 33 (56%) felt that

enough time was spent giving them information. This could reflect the fact that most people do not feel that an extensive amount of information is required for an adequate informed consent process. This was found by El-Sayeh (61), in a study where 83% of patients requesting minimal information during the informed consent process, were happy with the amount of information they had received. Garden et al (59) also found that at least 65% of patients presenting for cardiac surgery, felt that an adequate informed consent process had taken place, despite the fact that a minimal amount information had been divulged (59).

Unfortunately, in our study 14 (24%) patients were not happy with the information they had received and 25 (42%) did not feel that enough time was spent giving them information, which leaves the study hospital with patients who may feel that their human rights were violated and who may be more inclined to pursue legal recourse if complications occur (15, 16). This is also a common scenario as found by Jawaid et al (30), where 97% of patients were not given enough information regarding the proposed anaesthetic technique, 60% were not given the chance to ask questions and 51% were unhappy with the information they had received before the procedure.

It is possible that patients may have perceived the information they received during the informed consent process as adequate, but may still come to realise that it was inadequate should a complication arise from the peripheral nerve block.

4.4 Summary

In this chapter the results and discussion were presented. Chapter 5 contains a summary of the study, the limitations, recommendations and a conclusion.

Chapter 5: Study summary, limitations, recommendations and conclusion

5.1 Introduction

In this chapter, a summary of the study, limitations pertaining to the study, recommendations regarding changes in practice and future research and a conclusion will be presented.

5.2 Study summary

5.2.1 Aim

The aim of this study was to describe the documentation of informed consent and patients' knowledge and perceptions of peripheral nerve blocks following the informed consent process, in patients who presented for upper limb surgery at the CHBAH Hand Unit.

5.2.2 Objectives

The objectives for this study were to:

- describe the documentation of informed consent
- describe the adequacy of documentation of informed consent according to the HPCSA standard
- describe the patient's knowledge of peripheral nerve blocks for upper limb surgery
- describe the patient's perception of the informed consent process.

5.2.3 Methodology

This was a prospective, descriptive, contextual study. A convenience sampling method was used and 59 patients were included in the study. A data collection sheet and questionnaire were compiled by the researcher in order to capture information regarding the documentation of informed consent process, and patients' knowledge and perception of the informed consent process. The data collection period was from

September 2014 to March 2015. The researcher and a field worker assisted patients in completing the questionnaire. Some patients had procedures done to their dominant hand and the researcher and field worker had to fill in their questionnaire as they indicated their answers. The data was entered into a Microsoft Excel ® spreadsheet and analysed using descriptive statistics.

5.2.4 Results

It was found that only 26 (44%) patients had documented consent, with most (n=24, 41%) patient merely having a signed “Consent for Operation” form and only 2 (3%) having documentation elsewhere in the records. None of the patients had documented informed consent that is adequate according to the HPCSA standard.

Only 12 (20%) of patients had adequate knowledge about the peripheral nerve block they had received. For questions pertaining to the procedure and purpose of the peripheral nerve block, patients had a mean score of 4,76 out of 8 (SD=1,82) which is 60%. In contrast, patients did worse for questions pertaining to complications related to peripheral nerve blocks of the upper limb, with a median score of 2 out of 11 (Q1=1, Q3=5).

Fifty one (86%) patients identified the health care worker who took consent for the peripheral nerve block as an anaesthetist, while 7 (12%) identified them as a surgeon and 1 (2%) patient indicated that he/she was counselled by a nurse.

Most patients did not feel forced (n=50, 85%), were happy with the information provided (n=43, 73%), felt that enough time was spent giving them information (n=33, 56%), but would have liked an information sheet (n=40, 68%).

5.3 Limitations

Limitations to this study included the fact that the patients may not have been well educated and that English may not have been their first language. Even though every attempt was made to have simple English in the questionnaire, this may have influenced patients’ comprehension of the questions, but the researcher or field worker was present during questionnaire completion to clarify concepts or words.

Patients may have completed the questionnaire with the level of knowledge they had post-operatively, instead of recalling their pre-operative knowledge of the peripheral nerve block. Questions were asked in a manner that should have elicited answers of pre-operative knowledge.

Knowledge of the study being conducted among practising anaesthetists may have influenced the quality of the informed consent process that they conducted with patients. The convenience sampling method used did, however, make timing of data collection unpredictable.

The study is contextual in nature and was conducted among patients at the CHBAH Hand Unit. Results may possibly not be reliably extrapolated to other departments, hospitals or a larger population. This is confounded by the fact that convenience sampling was used and sampling bias may have occurred.

The study sample was determined by the number of available patients receiving peripheral nerve blocks of the upper limb during the period September 2014 to March 2015. Limitations included the fact that patients were discharged home from the recovery room. Data was collected at the end of working days as well as pre- and post-call, when most patients had left hospital already and could therefore not be interviewed. Despite the help of a field worker, only 59 patients could be recruited.

5.4 Recommendations

5.4.1 Clinical practice

The following recommendations are suggested for clinical practice:

- more diligent documentation of the informed consent process, utilising a format that meets the HPCSA standards
- the implementation of an information sheet for patient to read before presenting to theatre, empowering them with more knowledge regarding the treatment they consent to.

5.4.2 Further research

The following recommendations are suggested for further research.

- Describing the change of opinion that patients may experience concerning the amount of information they regard as sufficient to make an informed decision, once they have been in the unfortunate position of having developed a complication.
- A follow-up study could be done once an information sheet has been established at the study hospital, to investigate whether there has been a change in the patients' knowledge regarding peripheral nerve blocks of the upper limb and whether their perception of the informed consent process has changed.

5.5 Conclusion

In conclusion, this study found that at the CHBAH Hand unit, documentation of informed consent is not done consistently. All documentation of informed consent that is done, does not meet the standard required by the HPCSA. Patients' knowledge regarding the peripheral nerve blocks they receive is also inadequate.

Patients' perceptions of the informed consent process regarding peripheral nerve blocks of the upper limb are that they mostly do not feel forced to undergo the procedure, feel happy with the information that they receive, feel that enough time is spent giving them information, but would like an information sheet before the procedure.

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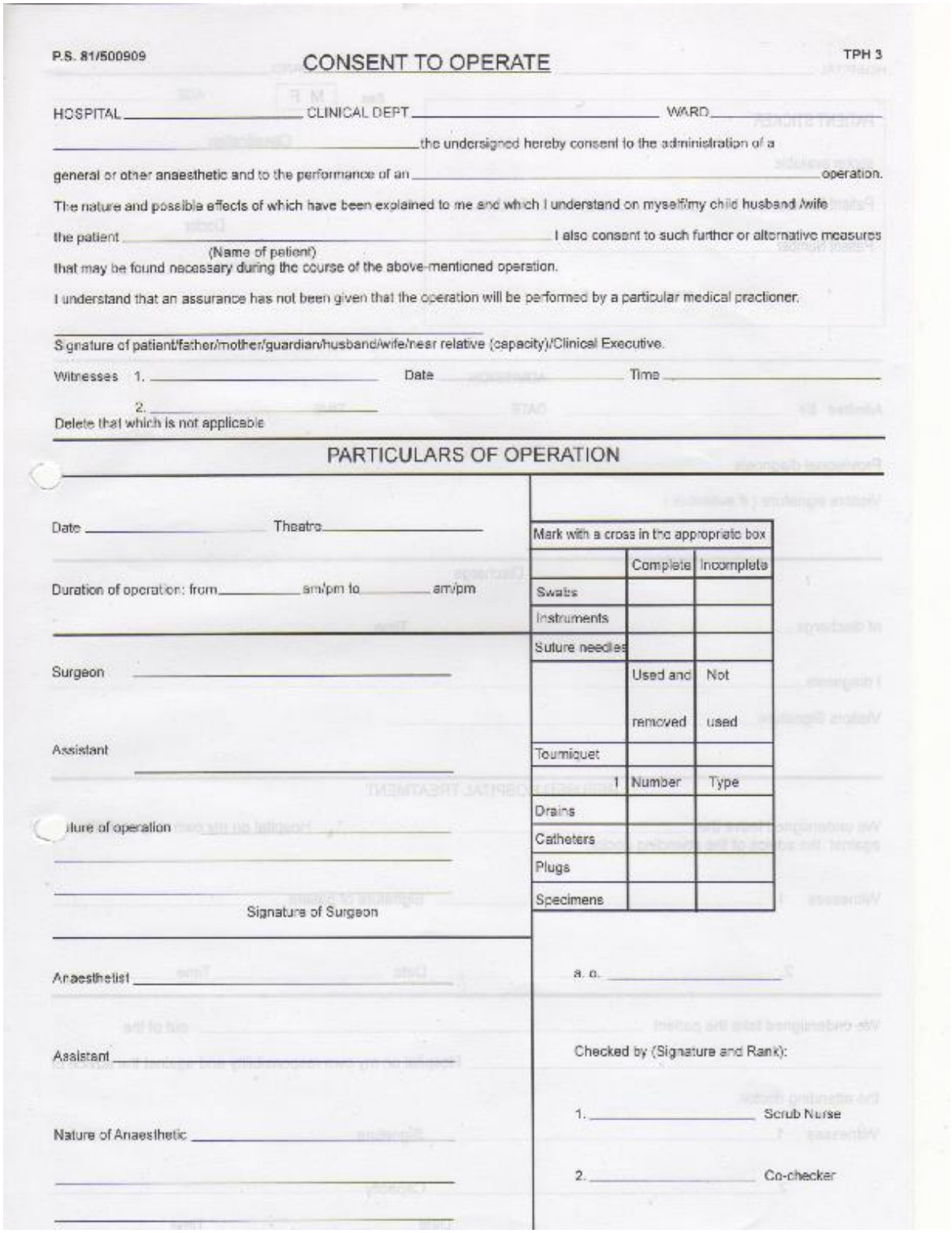
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Appendix A: "Consent to Operate" form



P.S. 81/500909

CONSENT TO OPERATE

TPH 3

HOSPITAL _____ CLINICAL DEPT _____ WARD _____

_____ the undersigned hereby consent to the administration of a general or other anaesthetic and to the performance of an _____ operation.

The nature and possible effects of which have been explained to me and which I understand on myself/my child husband /wife the patient _____ I also consent to such further or alternative measures

(Name of patient)

that may be found necessary during the course of the above-mentioned operation.

I understand that an assurance has not been given that the operation will be performed by a particular medical practioner.

_____

Signature of patient/father/mother/guardian/husband/wife/near relative (capacity)/Clinical Executive.

Witnesses 1. _____ Date _____ Time _____

2. _____

Delete that which is not applicable

PARTICULARS OF OPERATION

Date _____ Theatre _____

Duration of operation: from _____ am/pm to _____ am/pm

Surgeon _____

Assistant _____

lure of operation _____

_____

_____

Signature of Surgeon

Anaesthetist _____

Assistant _____

Nature of Anaesthetic _____

_____

_____

Mark with a cross in the appropriate box		
	Complete	Incomplete
Swabs		
Instruments		
Suture needles		
	Used and removed	Not used
Tourniquet		
1	Number	Type
Drains		
Catheters		
Plugs		
Specimens		

a. o. _____

Checked by (Signature and Rank):

1. _____ Scrub Nurse

2. _____ Co-checker

Appendix B: Ethics approval

R14/49 Dr Adriaan Willem Buitenweg/Prof EE Oosthuizen

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130707

NAME: (Principal Investigator)	Dr Adriaan Willem Buitenweg/Prof EE Oosthuizen
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital Rahima Moosa Hospital
PROJECT TITLE:	Informed Consent for Peripheral Nerve Blocks in Patients Presenting for Upper Limb Surgery: Documentation and Patients' Knowledge
DATE CONSIDERED:	26/07/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof EE Oosthuizen
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	20/09/2013

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C: CHBAH Medical Advisory Committee

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 25 February 2014

TITLE OF PROJECT: Informed consent for peripheral nerve blocks in patients presenting for upper limb surgery: documentation and patients' knowledge.

UNIVERSITY: Witwatersrand

Principal Investigator: AW Buitenweg

Department: Anaesthesiology

Supervisor (If relevant): J Wagner

Permission Head Department (where research conducted): Yes

Date of start of proposed study: February 2014
Date of completion of data collection: March 2015

he Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 25 February 2014

.....
Approved/Not Approved
Hospital Management
Date: 21/02/14

Appendix D: Postgraduate Committee approval

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

19 March 2014
Person No: 775915
PAG

Dr AW Buitenweg
PO Box 605
Kruger Adorp
1740
South Africa

Dear Dr Buitenweg

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Informed consent for peripheral nerve blocks in patients presenting for upper limb surgery: Documentation and patients' knowledge* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix E: Patient information letter

Informed consent for peripheral nerve blocks in patients presenting for upper limb surgery: documentation and patients' knowledge

Hello, my name is Adriaan Buitenweg. I am a doctor who is studying further at the University of the Witwatersrand to become a specialist anaesthetist. An anaesthetist is a doctor who gives patients medicines that make them sleep or special injections to take their pain away during an operation. As part of my studies I am doing a research study and I would like to invite you to take part.

I am trying to learn more about how much patients knew about the injection they received in their neck, shoulder or arm before they went in for the operation.

If you agree to be in this study, I will ask you questions about the injection you had in your neck, shoulder or arm. I am trying to find out how much information about the injection the doctor gave you before you went for your operation. I will be available to help you to fill in the questionnaire. This should not take longer than 10 minutes.

After you have filled in the questionnaire, you can ask questions about the study, the injection or the operation that you have had. We can talk for as long as you like. If you have a question later that you didn't think of at the time, you can contact me on my phone.

The Human Research Ethics Committee (*number*) and the Postgraduate Committee of the University of the Witwatersrand have approved my study.

I do not believe that you will be hurt or upset by being in this study. If you take part in the study and believe that you have been hurt or upset in any way, you may stop taking part in the study. I will not tell anyone anything that you have told me, or show anyone your questionnaire. You will not write your name on the questionnaire and

once I place it in the sealed box, I will not be able to tell which questionnaire belonged to you.

If you decide to be in this study, it will probably help you to learn more about the injection that you were given in your neck, shoulder or arm. It will also show me important ways to teach other patients coming for the same operation as you, about the injection in the neck, shoulder or arm.

If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop. Your doctors will continue to treat you whether or not you participate in this study.

For more information you may call me on (011) 488 4397. You may also contact Prof Cleaton-Jones, chair of the Human Research Ethics Committee, at (011) 717 1234.

Signing your name on the consent form means that you agree to be in this study, so please make sure that you have understood this letter. This letter is yours to keep.

Thank you very much for your time!

Regards

Adriaan Buitenweg

CONSENT TO PARTICIPATE IN RESEARCH

I, _____, give my consent to participate in the study '**Informed consent for peripheral nerve blocks in patients presenting for upper limb surgery: documentation and patients' knowledge**'. I have read and understand the contents of information sheet. I have been given the opportunity to ask questions.

_____ _____

Signature of Subject Date

Appendix F: Data collection sheet

Study number	Documentation of informed consent (Y/N)	Where consent was documented	Adequate documentation by HPCSA standard (Y/N)	Language of informed consent process	Language of documentation of informed consent	Consent obtained verbally or in writing	Type of block

Appendix G: Questionnaire

Please think back to the information you got about the injection before the operation when giving your answers!

My age (in years) is between:

18 – 29	30 – 39	40 – 49	50 – 59	60 – 69	70 - 80

I am:

Male	Female

My highest level of education is:

Did not complete primary school	Completed primary school	Completed high school	Completed tertiary education

Have you had the injection before, before today? ☐ ☐ ☐

Before the operation, I was told:	**Yes**	**No**	**Unsure**
1. About "the injection".	☐	☐	☐
2. Why I need to have "the injection".	☐	☐	☐
3. About other choices, other than the injection.	☐	☐	☐

I was told about the following problems (complications) that may happen because of the injection:	**Yes**	**No**	**Unsure**
4. Difficulty in breathing due to a collapsed lung.	☐	☐	☐
5. "The injection" may not work and I may need medication in the drip, or even need to sleep.	☐	☐	☐
6. I may have pins and needles, strange feeling or a numb spot In my arm or hand for many days after "the injection".	☐	☐	☐
7. I may not be able to feel part of my arm or hand, or may not be able to move a part of my arm or my arm may feel weak for several weeks or months.	☐	☐	☐
8. I might never again be able to feel with a part of my arm or hand, or may not be able to move a part of my arm or hand, after "the injection".	☐	☐	☐

9. The doctor might accidently go through a blood vessel with the needle when doing “the injection”. ☐ ☐ ☐

10. I may have fits (falling sickness), a strange feeling in my lips, confusion or even die, after the “the injection”. ☐ ☐ ☐

11. I may have a drooping eyelid for a short while after “the injection”. ☐ ☐ ☐

12. I may have a hoarse voice for a short while after “the injection”. ☐ ☐ ☐

13. I may have shortness of breath after “the injection”. ☐ ☐ ☐

14. “The injection” may go into the wrong place and may cause me to lose consciousness (faint). ☐ ☐ ☐

Before the operation, I was told:	**Yes**	**No**	**Unsure**
15. About the risks of having the “the injection”.	☐	☐	☐
16. That my arm & hand will be numb for many hours.	☐	☐	☐
17. That I can sleep for the operation.	☐	☐	☐
18. That I may refuse the operation.	☐	☐	☐
19. That I must go to a doctor if my arm does not work normally after a few hours.	☐	☐	☐

20. I was told about the injection by:

Anaesthetist, the doctor that gave the injection	Surgeon, the doctor who did the operation	Nurse	Other patients	Someone else	Nobody

	Yes	**No**	**Unsure**
21. I feel that I was forced into choosing “the injection”.	☐	☐	☐
22. I am happy with the information that I received about “the injection” before the operation.	☐	☐	☐
23. I feel that enough time was spent giving me information about “the injection” before the operation.	☐	☐	☐
24. I would have liked to receive an information sheet about “the injection” before the operation.	☐	☐	☐

Thank you for filling in this questionnaire!