

UNIVERSITY OF KWAZULU-NATAL

Howard College Campus

**An investigation into the knowledge and practice of securing
informed consent for surgery by health care workers in a selected
institution in KwaZulu-Natal**

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in

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Nursing(Critical Care and Trauma)

by

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DECLARATION

I declare that this study on investigation into **the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution in KwaZulu-Natal** is my own work. The sources that I have used or cited have been acknowledged by means of complete reference.

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Date: 13/03/2017

DEDICATION

This study is dedicated to my mother Kate Mukile Ngwenya, my lovely wife Simo Ngwenya, my sisters Simphiwe and Khulile Ngwenya, my Nephews Siyabonga Theko and Mlungisi Nkosi, my nieces Sanele Nkosi, Mmamogo and Okuhle Sebulele and my granddaughter Ntombenhle Theko.

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ABSTRACT

Background: Patients undergoing elective surgery experience fear and anxiety because they do not know what to expect and most of them lack knowledge about their legal rights as far as surgery is concerned. Pre-operative information should be provided by members of the multidisciplinary health team, for example the surgeon, anaesthetist, nurse and physiotherapist (Chetty and Ehlers, 2009) so that the patient can foster realistic post-operative expectations and co-operate in his/her wellness.

Problem statement: Illiteracy is found to be one of the problems faced by the patients globally, nationally and provincially. In developing African countries religious and cultural issues, uneducated and unsophisticated patient population, as well as pressure of work for health care workers, also pose serious challenges in conveying adequate information to the patient (Ezeome et al., 2011).

The purpose: The purpose of the study was an investigation into the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution.

Methods: A quantitative approach was taken, whereby orderly, disciplined procedures were used to acquire information. The researcher adopted census and convenient sampling. This study included 61 HCWs in the selected units or wards, 15 HCWs observed securing informed consent from the patients, and 31 signed consent forms covering a period of one month were reviewed retrospectively for completeness. A questionnaire with close ended questions for knowledge, and observation and record review checklists for practice were utilised for data collection.

Results: The return rate of 76.25 per cent (n=61) was achieved after three reminders through phone calls and visits. The study indicated that there was a discrepancy in the knowledge and practice of informed consent by surgeons. Though efforts were made to ensure understanding in terms of the use of layman's language, some important aspects of the information were not shared, for example, risks related to anaesthesia and surgery, adverse effects of blood transfusion, potential undesirable effects of surgery, ventilation (for patients who need ventilation after surgery), length of hospital stay for surgery, and other treatment options, for example, asking for a second opinion. In addition, health care workers sometimes displayed paternalistic attitudes towards patients, possibly relating to the patients' illiteracy and language barriers.

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ABBREVIATIONS

HCWs – Health Care Workers

Dept – Department

HPCSA- Health Professions Council of South Africa

Cinahl – Cumulative Index to Nursing and Allied Health Literature

Medline – Medical Literature online

DOH- Department of Health

CHAPTER 1: BACKGROUND TO THE STUDY

1.1 Introduction

The study established the knowledge and practice of securing informed consent in a selected institution in KwaZulu-Natal. This chapter is a synopsis of what informed or motivated this study through the background, problem statement and significance of the study. Furthermore, the study is introduced through the purpose, objectives and questions that this study addressed including operational definitions.

1.2 Background

1.2.1 The concept informed consent

Informed consent is a term that is used legally and is supported by jurisdiction and international law (Paterick et al., 2008). It is a complex process and may be unavoidably time-consuming (Moodley, 2011). It is also described as ‘voluntary authorisation by a patient or research subject, with full understanding of the benefits and risks involved for diagnostic procedures and for medical and surgical treatment’(Leclercq et al., 2010). Informed consent helps to recognise and respect a patient’s best interests by giving every patient the opportunity to decide freely what his/her best interests are in light of the planned procedure (Childers et al., 2009). The main purpose of informed consent before an intervention, as stated by Tayyab and Aurangzeb (2010), is to uphold and reinforce the concept of patient autonomy. Informed consent is also emphasized in research, however, research ethics are beyond the scope of this study except as part of the process of the research study.

Studies show that the informed consent requirement was initiated for the Nuremberg Trials following World War II (Schuman, 2012). This obligation was established after Nazi scientists in Germany carried out a number of involuntary and often deadly medical experiments on concentration camp prisoners (Schuman, 2012). The same author maintains that the United States found 23 of the Nazi scientists guilty of crimes against humankind and

sentenced seven to death and eight to different prison terms. As part of its final judgement, as stated by Schuman (2012), the tribunal of the United States disseminated a set of ten principles, later known as the Nuremberg Code, which provided the first global regulations for scientific research on human subjects. Later, in 1964, the World Medical Association (WMA) put in place international guidelines called the Declaration of Helsinki in order to provide guidelines for medical researchers (Schuman, 2012).

1.2.2 Importance of informed consent

Before subjecting patients to any investigation or treatment, health care workers need to obtain their agreement (Moodley, 2011). A health care worker should remain responsible for ensuring that before she/he starts any treatment or investigations, the patient has been given sufficient time to think and information to make an informed decision and has consented to the procedure or investigation (HPCSA, 2008). All healthcare workers are expected to work within their scope of practice; anyone failing to do so is answerable before the court of law or professional council (Republic of South Africa, 2005, section 50 (1) (b)).

Informed consent is needed prior to any examination, investigation or surgery (Fisher-Jeffes et al., 2007; Creedon, 2006). Legal and ethical principles generally require that valid consent must be obtained before starting an examination, treatment or physical investigation or providing personal care (Shannon and Scott, 2008). If surgery is undertaken lacking the patient's endorsement it would threaten their independence, and any surgical intervention or course of action could be considered a criminal fault in a court of law (Creedon, 2006, Lemaire, 2006). Legally, it is the primary duty of the responsible Health Care Workers to ensure that consent is obtained from a patient before an examination, treatment or surgery can commence (Health Professionals Council of South Africa, 2008, Creedon, 2006). This duty should not be delegated to a medical student, a clerk, or another health care worker, such as a nurse or intern (Moodley, 2011). Irabor and Omonzejele (2009) and Fisher-Jeffes et al. (2007), in their study analysis, state that information given by surgical trainees appear to be more often insufficient and or inappropriate than that given by experienced clinicians.

For emergency care and informed consent for surgery, some studies show that the culture in an emergency department is associated with time and moving patients as quickly as possible through the system using the triage system for rapid assessment and sorting (Sowney and Barr, 2007). Sowney and Barr (2007) state that health care workers working in emergency departments sometimes do not have time to gather information or time to spend with the patient because working in emergency requires speed. Patients are moved quickly to prevent injuries and complications such as death. The same author maintains that health care workers have a duty to act ethically to provide care and respect human rights in a safe manner based on fairness and justice. The focus in this study is both elective and emergency surgery.

1.2.3 Practice of securing informed consent

Therefore, before subjecting patients to any investigation or treatment, Health Care Workers need to obtain their agreement (Moodley, 2011). This is both an ethical and a legal requirement (Sowney and Barr, 2007). A patient can consent expressly to treatment, either orally or in writing, or can nod his/her head. In instances where a patient requires surgery, consent in writing is required. Both forms of consent (oral and written) are legally binding and constitute evidence that the patient agreed to the procedure (Moodley, 2011). The same author maintains that written consent shows better evidence that the patient consented to the planned procedure. The doctor should document in the notes the exact medical terms used during the informed consent process, to show evidence that an informed consent discussion has taken place in case of future disagreement or litigation where a patient is suing the physician or the hospital for malpractice (Paterick et al, 2008). She or he can also document which ways she/he used for the patient to sign consent, for example, she asked the nurse or an interpreter to explain the procedure or she/he did it by her/himself. It must also appear in the notes who signed the consent form: the patient, the spouse, the guardian if it is a child, the surrogate, the next of kin or the court (Health Professionals Council of South Africa, 2008). The consent form should contain the name of the physician involved (Paterick et al., 2008).

Every adult human being who is mentally competent has the right to say what should be done or not done with his/her own body (Shuman and Barnosky, 2011, Tayyab and Aurangzeb, 2010). This can be fostered through the process of informed consent. Schuman (2012) states that governments around the world have adopted a mixture of regulations that together impose this oldest and most universally accepted moral standards in research. Therefore, the South African government has guiding principles and policies in place that organise the practice of healthcare workers, to protect the public against medical carelessness, incompetence, immoral and unprofessional conducts (Health Professions Council of South Africa, 2008, Republic of South Africa, 2005, South African Parliament, 2003).

1.2.4 The importance of autonomy in the process of securing informed consent for surgery

Autonomy refers to a patient's right to self-determination without outside command, or intimidation (Moodley, 2011; Adedeji et al., 2009). This implies that the patient has the freedom to make decisions and choices about his/her own care without interference, even if those decisions are not in agreement with those of the health care team, provided that the individual is mentally competent and rational (Zerwekh and Garneau, 2014). Respect for autonomy in clinical practice is of great moral importance in our society (Paterick et al., 2008). The same authors maintain that the moral and legal responsibility of medical informed consent depends on the transmission of appropriate information to patients. The researcher believes that patients must not be forced to sign informed consent by any member of the health care team or by family members, friends or payers e.g. Medical aid.

From experience working in the Emergency Department, many health care workers show paternalistic attitudes towards the patient during the informed consent process. Patients are often given little information by the health care workers or none at all. Should the patient show interest by asking questions in knowing about his/her condition or refuse treatment, some health care workers become angry. Just because a patient refuses treatment does not in itself mean the patient is incompetent to make health care decisions. But whether they are considered competent or incompetent, patients have the right to refuse treatment, even those

that may be life-saving. Patericket al. (2008) maintain that physicians must allow for patients' questions about the proposed treatments, benefits and risks, and must answer these questions from the available medical literature and their professional practice or experience.

The Health Professional Council of South Africa (2008) states that if the patient is found to be incompetent to make health care decisions, a surrogate decision maker must speak for him/her. The same writer states that if no appropriate surrogate decision maker is available, the medical manager is expected to act in the best interests of the patient until a surrogate is found or appointed. Legally, it is generally accepted that complete informed consent includes a discussion of the following information:

- The nature of the disease and or procedure
- Reasonable alternatives to the proposed intervention
- The relevant risks, benefits, and uncertainties related to each alternative
- The consequences of doing nothing and possible outcome
- Assessment of patient understanding
- Acceptance of the intervention by the patient

(Naidoo, 2014;Tayyab and Aurangzeb, 2010;Laclercq, 2010; Health Professionals Council of South Africa, 2008; South African Parliament, 2003)

All this information must be disclosed by the HCW, in particular the surgeon, to ensure the patient his/her right to self-determination (Leclercq et al., 2010). Faghanipour et al. (2014) and Cainzos and Gonza´lez-Vinagre (2014) state that it is the responsibility of the surgeon to provide the patient with sufficient information to weigh the risks and benefits of the planned procedure. This is supported by Patericket al (2008) in his study, who also states that the physician involved in the proposed treatment should always discuss severe risks, such as death, paralysis, loss of cognition or loss of limb, even if the probability of occurrences is negligible. In such cases, the nurse is present and the role of the nurse in this process is that of a patient advocate (Bu and Jezewski, 2007). The nurse helps to facilitate the process of informed consent. She/he assesses the patient's understanding of what is going to occur during and after surgery, and to simplify any misunderstanding between the surgeon and the patient as far as informed consent is concerned (Creedon, 2006). This author also maintains

that for smooth running of the process, nurses need to be aware of cultural patterns and how they are influenced by social, political and economic factors in the society.

1.2.5 Barriers to informed consent process

Informed consent is compromised when language or cultural barriers are present (Pfaff, 2009, Schlemmer and Mash, 2006). Lemaire (2006) states that understanding of information is directly proportional to age and literacy level. Cainzos and González-Vinagre (2014), Fink et al. (2010) and Lemaire, (2006) maintain that a lower level of education is found to have a negative influence on understanding, memory and recall of information during the informed consent process. The results of a study by (Bhangu et al., 2008) show that DVDs and leaflets used can assist to inform patients about the proposed procedure. However, in this instance, this is not possible, since the selected institution receives patients from deep rural areas where most of the patients are illiterate and those who went to school did not make it beyond primary level , so it is difficult for them to understand the medical terminology used.

Also, most of them have no access to electricity to watch DVDs. Some studies show that being literate is important, especially when leaflets are being issued, as literate patients can easily read and understand about the proposed procedure and can more easily recall the information given and ask questions later for clarity (Johnson et al., 2011, Shekelle et al., 2013). The verbal communication used by the surgeon or interpreter to explain the planned procedure should be understood by the patient (Health Professions Council of South Africa, 2008). Trained interpreters may not be readily available in all health care settings, leaving the options of untrained bilingual staff or family members to facilitate communication (Creedon, 2006, Schlemmer and Mash, 2006).

In order for the patient's consent to be valid, he/she must be considered competent to make the decision at hand and his/her consent must be voluntary (Fisher-Jeffes et al., 2007, Sowney and Barr, 2007). When the patient and surgeon both agree on a course of treatment 'that is consent art' (Tayyab and Aurangzeb, 2010, Cainzos and Gonzalez-Vinagre, 2014). Consent discussions and forms should be witnessed (Ezeome and Marshall, 2009). The HPCSA (2008) states that patients have the right to information about the health care services

rendered and available to them. However, this literature maintains that these rights are often not observed or upheld by Health Care Workers. This has serious implications because providing the appropriate information to a surgical patient is dictated by law and may prevent litigation (Leclercq et al., 2010).

Determining incompetence and competence is a matter for the court and not a question of fact for the layperson. Ezeome and Marshall (2009) state that consent can be obtained from the patient, his/her relations, or a public authority, depending on the situation. Patients hold the right to information and any decision about his/her treatment, next of kin can give consent for minors and those without capacity (Ezeome and Marshall, 2009). Capacity means the ability to process information received and to communicate a meaningful response (Paterick et al., 2008). The same authors explain that decision-making capacity means the ability to understand the significant benefits, risks and alternatives to proposed health care and to make and communicate health care decisions. In situations where there is no one to sign for the patient, the most senior doctor (medical manager) of the institution can sign on behalf of the patient only if necessary to preserve life (Ezeome and Marshall, 2009). A court order may be needed in some special circumstances (Ezeome and Marshall, 2009 and Health Professionals Council of South Africa, 2008).

For example, any delay in the provision of the health service to the patient might lead to death or irreversible damage to his/her health (South Africa Parliament, 2003). Consent forms can also be signed by the surrogate who was chosen by the patient when not sick (Moodley, 2011). The researcher observed that patients from the referring hospitals come with consent already signed. Is this legal or ethical? HPCSA (2008) states that the surgeon going to execute an investigation or procedure should explain the procedure him/herself to the patient, the surrogate, guardian, family or friends, and/or next of kin.

1.2.6 The advocacy role of the nurse in the process of securing informed consent

In the midst of difficult decisions that patients and their families find themselves having to make, especially with regard to informed consent, advanced directives and treatment choices, the nurse is in a unique position, under the ethics of caring, to advocate for these health care users. In this role, the nurse ensures that patients' rights to self-determination and free choice are not violated. The purpose of advocacy by nurses is to ensure patients' access to health care, quality of care, awareness of the care that they receive, and its favourable and unfavourable effects, including an understanding of the alternatives to the proposed treatment (Pera & Tonder, revised by Oosthuizen and Van der Wal, 2011). In playing this advocacy role, the nurse interprets the health care environment for patients and protects them from abuse by other health care workers, even if it means taking the risk of contradicting the wishes of another, especially medical personnel or the organisation (Kelly, 2011). Zerwekh and Garneau (2014) further describe the advocacy role of the nurse as that of a learner and a change agent because the nurse needs knowledge of the system and the values of the health care user (culture brokering), including the power to change attitudes if she must advocate effectively for health care users. In cases where this advocacy role is not fulfilled, the above attributes are violated and patients are not protected at all. Bu and Jezewski (2007) maintain that patient advocates are sometimes accused of insubordination and suffer loss of reputation, friends and self-esteem, or are labelled as troublemakers or bad co-workers by nursing personnel or other colleagues. Therefore, the researcher wished to undertake the study in order to understand the system and thereby inform the role of the HCWs in as far as informed consent is concerned.

1.3 Problem statement

During peri-operative care, the information associated with a surgical procedure can be transmitted orally, in writing, by video or by computer technology (Lemaire, 2006). However, the use of leaflets, computer technology and video is not always possible in a society because there are people who are not well educated so their understanding is limited. Nowadays, patients are starting to be more aware of their rights, and the likelihood of litigation is high since the media have taken part in teaching the community about their

rights. This makes it even more important that patients be informed about their health status. This includes all the medical facts relating to their condition, and the proposed medical procedures, together with potential risks and benefits of each procedure, and alternative procedures, including the advantages and disadvantages of non-treatment, as well as the diagnosis, prognosis and progress of treatment (Moodley, 2011; Leclercq et al., 2010).

The researcher has observed that health care workers tend to adopt a paternalistic attitude by not telling the patient or protecting the patient from bad news, such as complications related to surgery. The law is clear in its requirement that information provided should extend to all significant complications of surgery, including those least likely to occur, and those related to non-surgical aspects of the treatment. Lemaire (2006) maintains that complete risk disclosure has been made a legal obligation in some countries, irrespective of the patient's personal preference.

In other legal environments, the patient has the right to refuse risk disclosure, but the surgeon should take a formal record of the patient's decision, to gain relative protection against legal action at some future time (Paterick et al., 2008). Failure to respect patient rights is a criminal offence and may lead to litigation. Patients have a right to sue the surgeon or the hospital for malpractice. Informed consent is meant to ensure that health care workers give patients the facts, thereby encouraging self-sufficiency and freedom of choice among patients (Childers et al., 2009, Shaha et al., 2013). During information disclosure, information should be offered as unmistakably as possible and consist of discussion of the findings, treatment options and substitute treatment, including non-surgical management and non-intervention (Cainzos and González-Vinagre, 2014; Leclercq et al., 2010; Shaha et al., 2013; Health Professionals Council of South Africa, 2008). From the researcher's experience of nine years, patients tend to be told to sign rather than receiving pre-counselling.

Shaha et al. (2013), in their study emphasise that information communicated to the patient should include a description of the procedure, clarification of the risks, benefits and latent consequences of the procedure, and discussion of choice. In one case, a physician was found guilty and charged for battery after he acted against the patient's wishes (the patient did not

consent) and removed a malignant tumour (Childers et al., 2009). Generally, the law protects the patient's right to informed consent by requiring the physician to disclose all pertinent information about risks and benefits of the procedure to the patient (Paterick et al., 2008: 313). This is supported by the South African Constitution (Republic of South Africa, 1996). The Constitution states that "everyone has the right to bodily and psychological integrity which includes the right to make decisions concerning reproduction, to security in and control over their body and not to be subjected to medical or scientific experiment without their informed consent" (Republic of South Africa, 1996: 8).

Illiteracy is found to be one of the problems faced by the patients globally, nationally and provincially. In developing African countries low literacy levels, religious and cultural interference, uneducated and unsophisticated patient population, as well as pressure of work for health care workers, pose serious challenges in conveying adequate information to the patient (Ezeome et al., 2011). The literature shows that understanding of information is directly related to age and education (Cainzos and González-Vinagre, 2014, Faghanipour et al., 2014). Having less education was found in most studies to have a negative influence on comprehension and memory. Recall of information was also negatively influenced by older age, low levels of education, and ethnic origin (Cainzos and González-Vinagre, 2014, Fink et al., 2010). This is supported by National South African Statistics for 2011, which show that only 28.4 per cent of South Africans over the age of 20 years had completed Grade 12, while only 33.8 per cent even got to high school and 8.6 per cent had no schooling at all, while only 12 per cent had a tertiary qualification (Statistics South Africa, 2012).

The biggest challenge to HCWs is dealing with patients and families from different cultures in which the principles of individual autonomy are not the main driving principles of decision making (Creedon, 2006). Therefore, the surgeon should regard each patient as a unique human being, regardless of cultural, religious, economic and social influences, and avoid alone making assumptions based on race, faith or family influences (Childers et al., 2009). Another issue about informed consent that needs to be considered by health care workers, is how a surgeon secures first-person consent from a married African woman, which is bound to be very different from how such consent is secured from a married European woman. This is

because the principle of autonomy, as it relates to a married European woman, applies differently to a married African woman (Irabor and Omonzejele, 2009).

Medical informed consent law requires disclosure of the risks of the alternatives to enable patients to make knowledgeable decisions (Health Professions Council of South Africa, 2008). Information must be presented in a language the patient can understand and treatment should not proceed until the physician (surgeon) believes the patient understands the risks and benefits and decides to proceed on the basis of that understanding (Paterick et al., 2008). The patient must not be cognitively impaired by medication such as premedication, or by personal emotional stress or external stress imposed by a family member or the physician. The researcher observed that patients are given medication such as morphine for pain, then asked to sign a consent form. One wonders whether a heavily sedated patient would be mentally competent to sign a valid consent. It is not clear in the literature where and when to give pre-operative information, and this issue is still debatable (Anderson and Wearne, 2007). Some physicians prefer to give pre-operative information during consultations in their rooms/clinics, during consultation as an outpatient, or during ward rounds.

Patients undergoing elective surgery experience fear and anxiety because they do not know what to expect and most of them lack knowledge about their legal rights as far as surgery is concerned. Therefore, pre-operative information should be provided by members of the multidisciplinary health team, for example the surgeon, anaesthetist, nurse and physiotherapist (Chetty and Ehlers, 2009) so that the patient can foster realistic post-operative expectations and co-operate in his/her wellness. Hence the need to investigate knowledge and practice of securing informed consent for surgery by health care workers in a selected institution.

1.5 Purpose of the study

The purpose of the study is to investigate the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution.

1.6 Objectives

The objectives of the study were to:

1. Describe the knowledge of the concept informed consent for surgery by Health Care Workers
2. Analyse the content of the pre-operative counselling given by Health Care Workers
3. Determine how the informed consent for surgery was secured in terms of:
 - 3.1 Timing of the pre-operative counselling
 - 3.2 Person charged with counselling
 - 3.3 Interpersonal relationship (HCWs to patient relationship) during pre-operative counselling

1.7 Research questions

1. What was the knowledge about informed consent for surgery among HCW in the context of the study?
2. What was the content of the pre-operative counselling given by HCW?
3. How was informed consent for surgery secured in relation to:
 - 3.1 When and how the pre-operative counselling was done or timed?
 - 3.2 Who the person charged with pre-op counselling was?
 - 3.3 How the person who secured consent interacted with the patient?

1.8 Significance of the study

As discussed in the background and problem statement, the ethical principles of securing consent for surgery are often not observed or upheld by Health Care Workers in their practice. The study hopes to raise awareness of the importance of adherence to ethical principles by health care workers when explaining a surgical procedure to the patient and to anticipate legal implications involved.

The findings may be used to help health care workers develop a plan of action, such as what information should be given to the patient pre-operatively and who should give the information, where and when. Nurse Managers and other policy makers may use the findings of this study to draft policies and guidelines for pre-operative patient care. Findings may be used to review, eliminate, add and strengthen the existing consent form in practice. The researcher also wishes to publish the results to support evidence-based practice.

1.9 Definitions of terms

1.9.1 Knowledge

Knowledge is specific information about something, the fact or condition of being aware of something (Finkelman and Carole, 2013). In this study knowledge means the awareness and understanding of the process of obtaining and explaining informed consent by the health care worker. This involves explanations of the surgical procedure to the patient as well as the importance of blood transfusion if necessary, of wearing identity tag, having drains and catheters and starving for some hours before the procedure (WHO, 2009; Health Professions Council of South Africa, 2008).

The researcher describes adequacy of knowledge in terms of a knowledge scale adapted from Basak, Petpichechian and Kitrungrrote (2014) as follows:

80% - 100%: good knowledge

60% - 70%: Satisfactory knowledge

Below 60%: is poor knowledge

1.9.2 Practice

Practice is the action or process of performing or doing something (Hanks, 2009). In this study it means what is done to secure informed consent in the practice setting. This includes exchange of information between the surgeon and the patient about the proposed or planned surgical procedure and the signing of informed consent forms. The patient must be given time and allowed to make informed decision before signing the informed consent forms and not rushed (Childers et al., 2009).

1.9.3 Health care workers

Health care worker means a person who by education, training, certification or licensure is qualified to and is engaged in providing health care, or an individual who has received special training or education in a health related field (Health Professions Council of South Africa, 2008). Health Care Workers in this study include Doctors and Professional Nurses. This includes following the scope of practice (practising as per training), not to harm patients and respecting patients rights (Health Professions Council of South Africa, 2008, Republic of South Africa, 2005).

1.9.4 Surgeon

Surgeon is someone who practices surgery or is a doctor who specializes in surgery, cuts someone open and fixes a problem (Ochieng et al., 2014; Menz et al., 2010). In this study a surgeon is any doctor (specialised or not) who routinely obtained informed consent and performed surgical procedures. This involves touching, manipulation, cutting of the skin, fixing of the bones, removing diseased tissues and treating illnesses (Canadian Orthopaedic Foundation, 2015).

1.9.5 Informed consent

It means to voluntarily agree or to give permission to the planned surgery or to allow someone to do something (Irabor and Omonzejele, 2009). In this study, informed consent occurs when someone (the patient, relatives, spouse, parent, etc.) is told by a health care worker about particular details relating to the procedure, such as benefits of the surgery, risks involved, alternative treatment if surgery is not performed and estimated time of recovery. The permission is given by the patient him or herself, or their spouse, family member, parent or legal guardian, to the surgeon to perform the proposed surgery with adequate and full awareness of associated facts as mentioned above (Ezeome and Marshall, 2009).

1.9.6 Pre-operative counselling

Pre-operative counselling is ‘an interactive process of providing information and explanations about surgical processes, expected patient behaviours, anticipated sensations and providing appropriate reassurance and therapeutic listening to patients who are about to undergo surgery’ (Lee, 2013). In this study pre-operative counselling means the patient is given information before she or he is taken to the operating theatre. Pre-operative counselling includes aspects such as preparation for surgery and medication, a review of the anatomy to be operated, and explanations of the medical devices patients will encounter in the hospital such as drains and catheters, and information on how to prevent complications (Chetty and Ehlers, 2009).

1.9.7 Interpersonal relations

Interpersonal relations is the social associations, connections, or affiliations between two or more people (Bryan et al., 2013). In this study Interpersonal relations mean the interactions between the Health Care Workers and the patient for pre-op counselling. The patient-doctor relationship becomes a true partnership, with shared decision making authority and responsibility for outcomes when the HCWs, as well as the patient, take medical informed consent seriously (Paterick et al., 2008).

1.9.8 Advocacy

Is the protection, promotion, and optimization of health and abilities, prevention of illness and injury, alleviation of suffering through the diagnosis and treatment of human response (Tomajan, 2012). In this study, advocacy involves a person who is mentally competent to represent the patient in case the patient is unable to make sound decisions for himself. This involves the mentally ill patient, the unconscious, children, severely injured patients and those who can't talk for themselves because of their social status, e.g. the unlearned and the poor (Health Professional Council of South Africa, 2008). The nurse may not necessarily sign for the patient but should ensure that the patient is represented by a legal, mentally competent person.

1.10 CONCLUSION

The chapter has covered the background to the study, the advocacy role of the nurse, autonomy as an important ethical principle involved in informed consent, the problem statement, the purpose of the study, research objectives, research questions, significance of the study, and definitions of terms.

The following chapter is a literature review, followed by chapter three, which discusses methodology, chapter four, the presentation of results and chapter five, which includes discussion, interpretation, conclusions, recommendations and limitations of the study.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Various literature searches were done for the purpose of the literature review, using the following data bases: Cinahl, Ebscohost, Science Direct, Pubmed, Medline and Google Scholar, from 2006 to date. Search terms used were: informed consent, surgery, surgeon, preoperative information and counselling. The purpose of the study was an investigation into the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution: the researcher wanted to know what, how and when information was given to the patient by the health care workers for them to make informed consent before surgery.

This chapter covers literature on the concept informed consent, the ethical principles underpinning informed consent, the practice of the process of securing informed consent, the in terms of content, of the information and purpose, who secures informed consent and who signs the informed consent. The conceptual model that guides the study was also presented in this chapter for application in chapter five where discussion of the study is presented.

2.2 Understanding the concept Informed Consent

Informed consent is a term that is used legally and is supported by jurisdiction and international law (Paterick et al., 2008). It is also described as voluntary authorisation by the patient or research participants with full understanding of the benefits and risks involved for diagnostic procedures and for medical and surgical treatment (Leclercq et al., 2010). Informed consent is a process requiring a competent health care worker, adequate transfer of information and consent. It is not just a signature on a piece of paper. Tayyab and Aurangzeb (2010) maintain that a genuine informed consent process requires disclosure, understanding, voluntariness, autonomy, authorisation, agreement, and then consent. Lemaire (2006) states that in the absence of informed consent from the patient, in theory, every surgical procedure could be considered a criminal offence.

Several writers (Tayyab and Aurangzeb, 2010, Health Professional Council of South Africa, 2008) maintain that legally, for successful informed consent and decision making, surgical management should commence with counselling whereby health care workers give information, which must include the following: the patient should have knowledge about the nature of diagnosis and procedure and the advantages and disadvantages of the planned procedure, get appropriate professional advice on options, and consent to harm or assumed risk and for the health care worker to start treatment.

2.2.1 Purpose of informed consent

Childers et al. (2009) maintain that informed consent assists in discovering and valuing patients' best interests, thereby giving the patient the opportunity to have a word freely about what his or her best interests are in light of the intended procedure and treatment. This is also supported by Tayyab and Aurangzeb (2010) who maintain that before surgery the patients are fully involved in decision making as part of the process, to give them an opportunity to say "no" and be presented with an alternative course of action where such exists. It also seeks to make out each patient's value system and their individual life aspiration and how these factors inform their decision-making (Childers et al., 2009). Another purpose mentioned by a surgeon in a study by Jamjoom et al., (2010), was to make certain that the patient is knowledgeable about all predictable problems and in addition to offer the health care workers greater security in a court of law.

2.3 Ethical principles underpinning the practice of securing informed consent

It is important for the health care workers to base their practice of securing informed consent on sound ethical principles. There are numerous ethical principles recognised and widely discussed in the literature in relation to informed consent for surgery, namely, autonomy, beneficence, non-maleficence, justice and veracity (Morton and Fontaine, 2009). Ethical principles are moral truths that guide deliberation and action, and provide guidance for thinking and acting in order to determine what should or should not be done in a particular situation. They may also be viewed as rules or codes of conduct or as generalisation that

provide a basis for reasoning (Beauchamp and Childress, 2013). Ethical principles mostly apply in nursing and health care in general including research but for the purposes of this study these principles will be applied to the process of securing informed consent for surgery.

Ethical principles are widely accepted codes based on humane aspects of society, in this case, the caring aspects of nursing that guide actions. They reflect what is in the best interests of the patient or health care user (White et al., 2011). While autonomy is the most important principle to be considered in decision making for any intervention, in particular, surgery, other principles are also involved, namely, beneficence, non-maleficence, justice and veracity (Moodley, 2011, Adedeji et al., 2009). Each of these principles is explained below.

2.3.1 Respect for autonomy

Respect for autonomy is an obligation to respect and not to interfere with, the choices and actions of autonomous individuals, for example, those capable of self-determination (Morton and Fontaine, 2009). It implies an individual who is master of himself or herself and can take actions, make free choices and decision making without constraint of another (Tangwa, 2009). The principle of respect for autonomy entails respecting the capacity of a person to be self-determining, to deliberate about actions and life choices, and to act on those deliberations without interference from others (Adedeji et al., 2009, Morton and Fontaine, 2009).

Respect for autonomy is binding on all health care workers and should be adhered to unless it is superseded by another obligation of equal or stronger claim (Morton and Fontaine, 2009). The same authors maintain that HCWs respect patients' autonomy by making sure that they receive all the information required to give informed consent. These authors continue that patients frequently have compromised autonomy and are unable to make decisions for themselves for some reason, such as their clinical status (mental handicap) or the possible effects of treatments they are receiving. In addition, the authors emphasise that when health care workers respect the autonomous choice of a patient it means that she or he should follow procedures for gaining consent before starting any procedure or intervention. Therefore, the

principles of autonomy as stated by Tangwa (2009) in the study, imply both the freedom of each individual to act and the obligation of others to respect that freedom.

2.3.2 Beneficence

Beneficence means doing well for the patient. An obligation to promote the welfare of others, to maximise benefits and minimise harm (Morton and Fontaine, 2009). This principle requires the HCW to act in a way that promotes patient welfare. It requires the provision of benefit as well as balancing of harms and benefits. For informed consent for the proposed interventions, the health care workers must give the patient information about the nature of the condition or procedure, the risks associated with the treatment or procedure and what will happen after the procedure. Zamanzadeh et al. (2015) argue that good care necessitates the health care provider to approach the patient in a holistic manner, taking into account patients' thoughts, emotions, customs and opinions, since this contributes to their recovery, happiness, and satisfaction.

Health care worker should act to benefit their patients, for example, they should make sure that any procedure undertaken is for the benefit of the patient or in the interest of the patient. During surgery no cotton wool, scissors or other instruments should be left inside the body cavities involved in surgery even if it is unintentional (Kim et al., 2015). Health care workers should make sure that before the procedure commences all equipment is ready for use for successful surgery (World Health Organization, 2009). In addition, they should make sure that the patient has an identity tag indicating the correct proposed procedure, the site to be operated, and the identity of the patient.

2.3.3 Non-maleficence

Morton and Fontaine (2009) state that non maleficence is an act of intentionally refraining from activities which might cause evil or harm to an individual. It is the act of not hurting or doing bad or avoiding harm as a result of doing well (Tangwa, 2009). This principle requires that health care workers play an advocacy role to protect those who cannot protect themselves. This protection from harm is particularly evident in such groups as children, the mentally incompetent, the unconscious, and those who are too weak to protect themselves. The nurse should protect the patient from malpractice such as the incorrect carrying out of procedure, doing a procedure for the wrong reasons such as research, or leaving equipment, such as abdominal swabs and scissors, inside the abdominal cavity.

Health care workers are expected to protect patients from harm by making sure that they receive the right information about surgery during the peri-operative period (Adedeji et al., 2009). In addition, the theatre nurse should make sure that after the operation all equipment used is counted and found correct to prevent reopening of the patient or having to do another operation (Kim et al., 2015, World Health Organization, 2009).

2.3.4 Justice

Justice means giving each one their due. It is the obligation of the HCW to be fair to all people (Tangwa, 2009). Morton and Fontaine (2009) define justice as the principle of fairness. Fairness requires that decisions about the distribution of health care be based on morally significant characteristics, and not on factors such as race, ethnicity, gender, social standing or religious beliefs (Morton and Fontaine, 2009). Justice combines individual rights and the common good. It also requires that each person be treated according to what is fair (Adedeji, 2009), for example, a poor patient requiring surgery should receive the same level of care as one with the same disease who has money. However, this is not possible in South Africa because there are many poor people who use public health care facilities where sometimes there is a shortage of equipment and staff (Scheffler, 2015). On the other hand, there are private hospitals that are competing with public hospitals and these hospitals are

used by those who have money because in private hospitals you are expected to pay for the care rendered (Coovadia, 2009).

Giving information in a way that is insensitive to language or communication or cultural barriers is another problem faced by the patient. For example, some patients could be operated upon without an understanding of the procedure because of the language used, but other patients may be assisted by an interpreter, which is a scarce resource in South Africa. However, nurses are used for interpretation, but they are often too busy, due to hospitals being short staffed, to find time to interpret properly. The poor and the rich are all entitled to equal service delivery, for example, the surgery performed for the rich individual should also be done for the poor, including receiving information preoperatively (Scheffler, 2015).

Patients have the right to be informed about their health status, including the medical facts about their condition, about the proposed medical procedures, together with the potential risks and benefits of each procedure, about alternatives to the proposed procedure, including the effect of non-treatment, and about the diagnosis, prognosis and progress of treatment (Laclercq et al., 2010 and Health Council Professional South Africa, 2008).

2.3.5 Veracity

Veracity is the duty to tell the truth and not to lie or deceive others (Morton and Fontaine, 2009). Veracity in health care settings refers to comprehensive, accurate and objective transmission of information (Kling, 2012). This implies that health care workers, after entering into a relationship with the patient, should tell the truth about the diagnosis, the procedure/therapy, the risks and the prognosis. Kling (2012) maintains that truth-telling applies both ways, when the two parties engage in a relationship the patient is also expected to tell the truth in the disclosure of information. This principle requires HCWs always to tell the truth, regardless of whether others want to hear the truth or not.

Health care workers should present information honestly and accurately, and respond honestly to any question that the patient asks and answer as fully as the patient wishes (Health Professionals Council of South Africa, 2008; Kling, 2012). The HCW should make sure the information given is not misleading to the patient. She or he must tell the patient what the patient wishes to know before deciding whether to consent to surgery or not. Health care workers should give details of the diagnosis, therapy, procedure, risks and other options if surgery is not performed (Health Professions Council of South Africa, 2008).

2.4 The practice of obtaining/securing informed consent

The international and South African laws prescribe who, when, and how the process of securing informed consent should be practiced (Health Professions Council of South Africa, 2008). This will be presented hereunder.

2.4.1 Who obtains or secures the informed consent?

A health care worker rendering treatment or conducting an investigation has the responsibility to discuss this treatment or investigation with the patient and obtain consent, since the consultant is the one who knows how the procedure is being done and understands the risks and benefits associated with it, as well as the treatment (Health Professions Council of South Africa, 2008).

Informed consent has to be prepared by the expert who is going to carry out the procedure (Jamjoom et al., 2011). These authors emphasise that this culture is supported by the widely practised customary policy that the duty of obtaining informed consent for a procedure in the end lies with the health care worker executing the procedure. Tayyab and Aurangzeb (2010) add that a senior doctor should take the consent since many members of the surgical team might not have sufficient knowledge to inform the patient properly. Where this is not possible, the consultant or the senior doctor may delegate the tasks to resident doctors or junior doctors or specialised nursing personnel (Health Professions Council of South Africa,

2008). However, many studies (Jamjoom et al., 2011; Tayyab and Aurangzeb, 2010; Irabor and Omenzejele, 2009; Lemaire, 2006) show that senior doctors/consultants are opposed to informed consent being completed by low ranking doctors who are not going to carry out the procedure. These studies further state that resident doctors are more capable of informing the patient of benefits of the surgical procedure than giving information about risks and alternatives.

A study conducted in Pakistan by Tayyab and Aurangzeb (2010) showed that consent was taken by junior doctors like trainee medical officers and house surgeons for most patients, which has far-reaching implications for the consent-taking process because it means that the surgeons were aware of the requirement for adequate consent as determined by the department of health (Tayyab and Aurangzeb, 2010). The same authors emphasise that the senior doctor should take the consent as other members of the surgical team might not have sufficient knowledge to inform the patient properly. When junior members of the surgical team took the consent the patient was not warned about specific complications and risks associated with surgery (Tayyab and Aurangzeb, 2010).

This shows commonsense, since a junior doctor may possibly not be competent to make available all the information required. Both KSA and UK surgeons are opposed to informed consent being prepared by a junior doctor who is not going to carry out the procedure (Jamjoom et al., 2010). The same authors maintain that surgeons from KSA accept that informed consent has to be made by the expert who is going to carry out the procedure. This is supported by the widely accepted policy that the duty of gaining informed consent for a procedure ultimately lies with the health care worker undertaking the procedure (Jamjoom, 2010; Health Professional Council of South Africa, 2008).

Sowney and Barr (2007) maintains that the husband or senior male family member is the one who gives or refuses consent. Consent may therefore be given by the patient herself after consultation with her husband, elders, or significant others in the family, for example, in some instances family members give proxy consent for patients (Ezome and Marshall, 2009). Empirical studies show that this practice is still exercised in some countries such as Nigeria,

Zimbabwe and South Africa (Irabor and Omonzejele, 2009). The cultural practice of respect for elders is a strong norm in most of Africa, and South Africa is no exception (Ezome and Marshall, 2009). The primary reason for this is that a bride price is paid for African women (Irabor and Omonzejele, 2009). The payment of the bride price has implications for obtaining first-person consent from this category of patients. This is because a woman gives up part of her autonomy to her husband and husband's family members on the payment of the bride-price (Ezeome and Marshall, 2009). This makes it difficult, especially in emergency cases, to obtain consent for surgery from a married woman, as the doctor has to wait for the husband or senior male member of the family to be present before surgery can be undertaken.

The South African Constitution (Republic of South Africa, 1996) states that everyone has the right to human dignity, freedom and privacy. Thus everyone has freedom of conscience, religion, thought, belief and opinion, which means that women have the right not to have their privacy of communication limited by their husbands or anyone else. However the attitude of subordinate position of women has not changed. From my experience of nine years, this belief is not held only by women, but by males too, who wait for their elder sibling or spouse to make decisions on their behalf.

2.4.2 Who signs the informed consent

The general practice in every culture is that informed consent for the operation is to be obtained from the patients themselves if they are of officially authorised age (18years and above) and mentally and physically competent, or else, informed consent for an operation is acquired from a permissible custodian, spouse, or next of kin (Jamjoom et al., 2011). When the patient is a minor or unconscious, the legal guardian, mother or father may sign the consent (Moodley, 2011). HPCSA (2008) states that for a mentally incompetent patient the health care workers may apply for consent for surgery in a court of law and, in order of priority, the patient, spouse, partner, parent, grandparent, brother or sister may sign the consent.

A dilemma exists regarding who should explain the procedure and sign the consent form when the patient is transferred from one institution to another, primary to secondary or tertiary institution. A question arises, is it the referral health care workers or receiving professionals in a tertiary hospital who are going to perform surgery or is it the surgeon who is responsible for providing the patient with sufficient information to weigh the risk and benefits of the proposed surgery? HPCSA (2008) states that the responsibility lies with the health care worker who is going to perform the surgery (the receiving doctor) to provide information and obtain consent as he/she is the one with an understanding of the treatment and procedure to be performed. To facilitate the process the nurse should assess the patient's understanding of what is to occur during and after surgery and clarify any misconceptions (Paterick et al., 2008). The role of the nurse in this process is that of patient advocate (Creedon, 2006). The nurse protects those who are vulnerable, such as the illiterate, the mentally ill, the aged, children or an unconscious patient.

In case of emergency, where there is no time to contact the family, the surgeon may operate upon the patient or in a state hospital the clinical or medical manager may sign the consent (Health Professions Council of South Africa, 2008). However, the surgeon should ensure that, in such a state of affairs, the informing process can still be continued after the operation, as part of the incomplete development of the physician-patient relationship (Childers et al., 2009). This author also states that the patient should be informed immediately after recovery about the importance of the treatment activities done.

2.4.3 Pre-operative information

Childers et al. (2009) maintain that information should be presented as clearly as possible. Patients have the right to be fully informed about the nature of the disease, the proposed surgery and its complications and their treatment, types of surgery, reason for the surgery, various options, alternatives, the effects of no treatment, anaesthesia and its complications, blood transfusion and its complications, rehabilitation, and who signs the consent form, post-operative complications and the management thereof (Leclercq et al., 2010). All this

information must be conveyed to patients by the health care workers to allow them their right to self-determination.

Statistics from a study by Chetty and Ehlers (2009) show that the surgeon, the ward nurses, the anaesthetist, and the operating theatre nurse are the ones who provide pre-operative information. The information relayed to the patient should be presented in a language that he/she understands, and where he/she cannot understand an interpreter may be used (Health Professions Council of South Africa, 2008). In another study by Wong et al. (2015) and Chetty and Ehlers (2009), the authors maintain that booklets, leaflets, diagrams and visual materials used to give preoperative patient information, allow patient to return to them for information at a later stage for better understanding.

Informed consent is often given by the patient during a pre-operative consultation with a consultant, a resident, and reinforced by a specialised nurse (Leclercq et al., 2010). However this is not always done or possible, due to staff shortages or negligence. Garretson (2004) states that to successfully implement a programme there may be a need for additional staff, which nurse/medical managers may be unable to provide or afford due to budgetary constraints. Lack of support from nurse managers, medical managers and other colleagues may block the progress of enthusiastic staff. Even the most dedicated nurse would encounter difficulties in trying to implement a programme without support from managers and peers. Evidence shows that lack of confidence may be another reason for reluctance to participate.

Responding to the psychological and information needs of patients requires self-confidence and sound clinical knowledge, and some staff may believe that they are not capable of meeting these challenges (Garretson, 2004). Another reason why pre-operative information programmes are not universal is lack of time and money in overcrowded and busy units or wards. In a study by Jamjoom et al. (2010) results show that Kingdom of Saudi Arabia (KSA) surgeons believe that facilitating informed consent is meaningless because making known information to the patient about imagined detrimental risks may stop the patient from going through with the recommended course of action.

This author still maintains that passing on information about severe but very rare complication to patients for the period of informed consent leads to information overload of which there is no guarantee that the patient will hang on to the information or correctly appreciate the risk of information given. When giving pre-operative information to the patient, the nurse should explain the operation, expectations for the immediate post-operative period and the mobilisation plan (Childers et al., 2009). Evaluating how well the patient understands the procedure is important. This could be done by asking the patient to explain in his/her own words what the operation entails in writing on the form where he/she signs consent for surgery (Childers et al., 2009). In a study by Chetty and Ehlers (2009), patients responded that post-operative nutrition, early ambulation, deep breathing and cough exercises were not addressed, therefore the information given was not adequate.

Kingdom of Saudi Arabia (KSA) and UK surgeons, in a study by Jamjoom et al. (2010), agree that complementary printed information has to be given to the patient for the period of informed consent. Printed information was found to be valuable as it educated the patient on a course of action to carry out in the calm of their own home and acted as a point of reference. However, written information alone proved inadequate to provide effective pre-operative information (Chetty and Ehlers, 2009). The same authors maintain that the patient should also be familiarised with the operation procedure by, for example, going to the waiting area, operating theatre, recovery room and ward/ intensive care unit.

2.4.3.1 Benefits of pre-operative information/education

In a study by Chetty and Ehlers (2009), results show that pre-operative information plays a significant role for the patient pre- and post-operatively. Pre-operatively, it decreases fear and anxiety, assists the patient to become more knowledgeable about the planned procedure, and allows health care workers to learn about the patient and to establish the relationship before the patient is transferred to theatre. Post-operatively, it decreases pain, shortens length of stay in the hospital, and increases patient satisfaction (Chetty and Ehlers, 2009). Rendering information about why patients should wear an identity tag, fast before surgery, wear a hospital gown, and have anaesthetists coming to see them, has the potential to reduce anxiety, increase patients' confidence, and enable them to take control of their health and wellbeing after the operation (Peate, 2015).

2.5 Conceptual framework

2.5.1 Definition

A conceptual framework is a logical grouping of related concepts created to draw together several different aspects that are relevant to a complex situation, such as the practice setting. In this study, for example, informed consent is a preoperative practice of patient preparation (Chinn and Kramer, 2011). It addresses phenomena of central interest to a discipline, for example, preoperative informed consent. Polit and Beck (2008) maintain that every study has a framework, which may be conceptual or theoretical, though these frameworks may not always be formal.

This study proposes to use the moral framework within which the steps of informed consent for ethical decision making are embedded (Childers et al., 2009). This framework prioritises the promotion of patient wellbeing and a respect for patient self-determination. The health care workers offer expert knowledge, recommendations and advice about medically accepted and available options, and the patient decides which options will best promote his or her life goals and values. Furthermore, the nurse must consider the context to facilitate this decision-making. The context may include the family system (e.g. nuclear family), the patient culture, ethics, gender issues, religion, spiritual affiliations and individual preferences. Ezeome and Marshall (2009) maintains that life in many parts of African countries such as Nigeria is still communal and the basic unit of existence is not the nuclear family but the extended family. Ezeome and Marshall (2009) states that Africans value family relations and use them much more than the western world in making decisions. The western have a good sense of autonomy and individual's right to decision making in the medical context.

Consent may be given by the patient only after he/she has consulted with his/her spouse, elders of the family, significant others in the family, and in some instances family members (e.g. father, brother, uncles) authorise consent for the patient (Ezeome and Marshall, 2009; Irabor and Omonzejele, 2009).

The same authors maintain that a competent patient has the authority to give informed consent and make sound medical decisions, and such decisions are often made within the nuclear family if a credible one exists, and in its absence, any adult extended family member can give consent and make emergency decisions for the family.

The most pertinent ethical principles that make up the moral framework for ethical decision making, in as far as informed consent is concerned, are autonomy, beneficence, non-maleficence, justice and veracity (Morton and Fontaine, 2009). These assist in analysing the moral conflict faced by practising nurses. Based on the moral framework, HCWs follow specific steps in the process of facilitating decision making by the patient. These steps include disclosure, patient understanding, and patient decision making (Childers et al., 2009).

2.5.2 Disclosure of information

Disclosure of information in this study means that the surgeon should clearly state in a language that is understood by the patient and discuss with the patient the diagnosis, risks, benefits, treatment options if any, other choices of treatment including nonsurgical intervention, and the proposed care available to him/her (Cainzos and González-Vinagre, 2014; Childers et al., 2009). The surgeon or HCWs should always tell the facts (selective truth-telling is not permissible) and the surgeon should make a frank admission of all the effects that are not well managed and other features that are not well understood by the medical profession or the surgeon (Childers et al., 2009).

2.5.3 Patient understanding

Patient understanding in this study means that the patient has understood the disseminated information relayed to him/her before making a decision. Here, the doctor answers questions asked by the patient. Participation of the patient in questioning the surgeon shows that the patient has understood the information given to her/him, or the doctor can ask the patient to repeat what she/he has just said to them (Childers et al., 2009). The same authors maintain

that the idea is not to question the patient, but to a certain extent to promote an open exchange of information and give the patient the confidence to participate and to ask essential questions. The surgeon should be aware and respect the patient because not all patients would like to ask or be asked questions, therefore, patients should be motivated to participate in the decision making (Childers et al, 2009).

2.5.4 Patient decision making

The patient should be given enough time to think and make informed decisions based on what was discussed with the physician, family and friends. This means time to think about the advantages and disadvantages and consequences of having or not having the operation (Childers et al, 2009). With this practice, it is essential to remember that the patient needs sufficient time to consider information, reflect on their values and concerns, and make an informed decision (Leng and Sharma, 2016).

Figure 2.1 depicts the three steps of securing informed consent, showing how the different components or steps of the process overlap, using arrows to signify their inter-relationship.

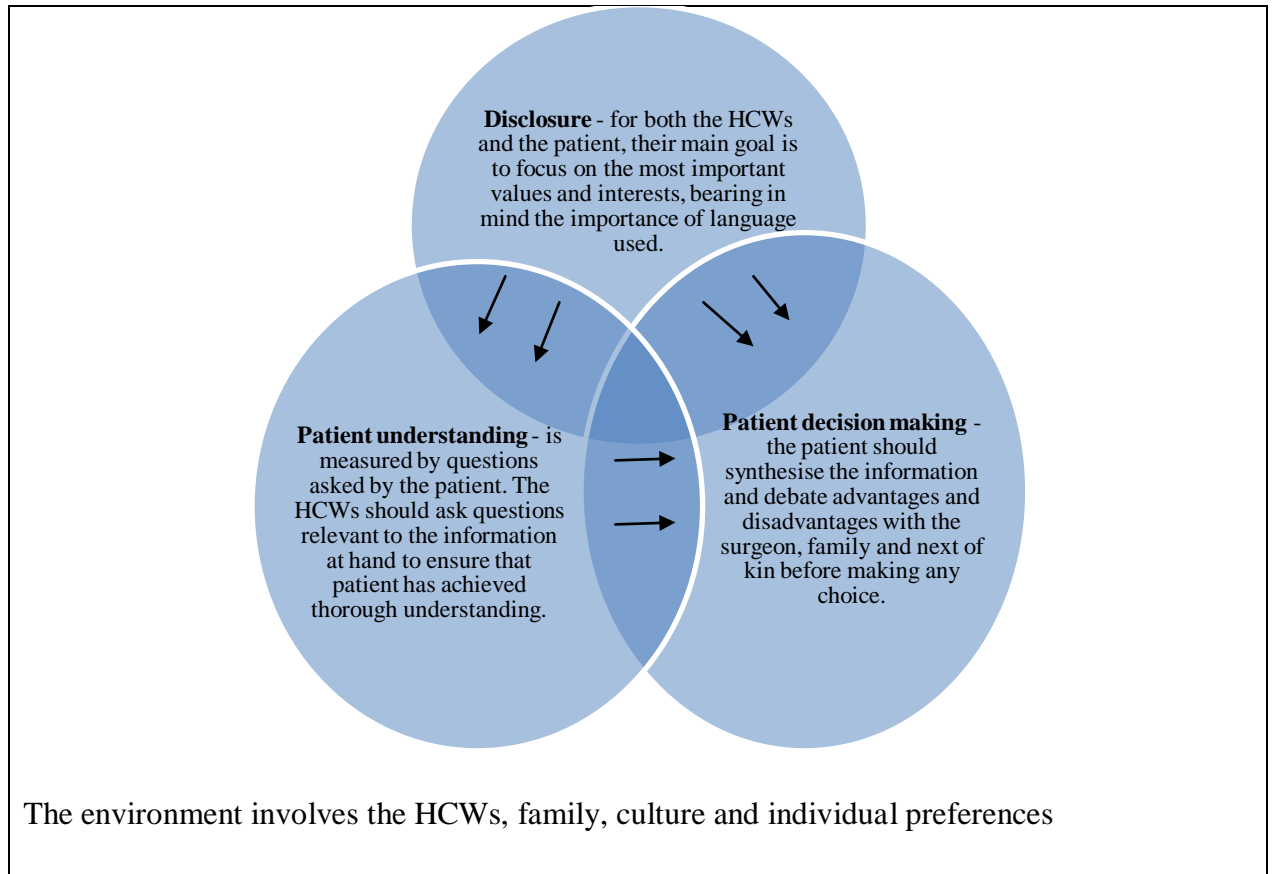


Figure 2.1: The three steps of securing informed consent (Childers, Lipsett and Pawlik, 2009)

This study seeks to determine whether the process of securing consent follows these steps, and considers the contextual issues mentioned above.

2.5 Conclusion

The literature review describes the concept informed consent according to various literature. This chapter also reveals the practice of securing informed consent including the widely accepted ethical principles that underpin the practice of obtaining informed consent such as, autonomy, non-maleficence, beneficence, justice and veracity. HCWs follow specific steps in the process of facilitating decision making by the patient. These steps include disclosure, patient understanding, and patient decision-making as described in the conceptual model underpinning this study. The next chapter is about methodology of this study.

CHAPTER 3: METHODOLOGY

3.1 INTRODUCTION

This chapter describes the methods used during the data collection process in order to achieve the set objectives. The information comprises the paradigm, research approach, research design, setting of the study, population of interest, sample, sampling methods, data collection instruments, data analysis, ethical considerations, reliability, validity, data management and a summary.

3.2 PARADIGM

This study was guided by the positivist paradigm, which suggests that reality is driven by real, natural causes. The researcher was independent from those being researched and objectivity and neutrality was emphasised in research, guided by this paradigm. The paradigm reduced the researched population into numbers, which were quantified into data that could be generalised into the study population (Polit and Beck, 2008).

3.3 RESEARCH APPROACH

A quantitative approach was adopted, whereby orderly, disciplined procedures were used to acquire information. In this approach, which is guided by the positivist paradigm, empirical evidence, which is grounded in objective reality, was gathered directly or indirectly using a structured instrument plan or tools as described by Burns and Grove (2009).

3.4 RESEARCH DESIGN

This was a cross sectional descriptive survey which examines the knowledge and practice of health care workers in securing informed consent. A survey is a non-experimental research design that obtains information about people's activities, beliefs, preferences and attitudes (Polit and Beck, 2008). Thus, the main objective of this study was to describe characteristics of persons, situations, and the frequency with which certain phenomena, such as informed consent, occur (Polit and Beck, 2008). The researcher observed, described and documented aspects of the process of securing or obtaining informed consent as it naturally occurred, as described by Polit and Beck (2008).

3.5 SETTING OF THE STUDY

The study was conducted in the selected hospital at Uthungulu District, in the north eastern area of KwaZulu-Natal. This hospital is a newly developing tertiary hospital used for semi-rural exposure for medical students and a referral hospital for 22 rural hospitals and a few district hospitals. The hospital is a 554 bed hospital. It provides District, Regional, and Tertiary services to communities from the Uthungulu, Umkhanyakude and Zululand Districts. It is situated in a suburb 5km away from Empangeni. Empangeni is about 20km from the Richards Bay Industrial area, harbour, beaches and airport. The units of interest for the study comprised surgical and orthopaedic clinics, eye clinic, female surgical and orthopaedics (ward G), male surgical (ward H), adult and paediatric burns unit, operating theatre, intensive care unit (ICU), emergency medicine unit and paediatric surgical ward. These units were included in the study because patients from these wards go for surgery.

3.6 POPULATION

The population is all the people or groups of people that are of interest to the researcher (Brink et al., 2006). Burns and Grove (2009) maintain that population is all the individuals, objects, or substances that meet the selection criteria for inclusion in a given universe. This

study defines population as consisting of a particular type of individuals or elements who are the focus of the research. The study investigated the knowledge and practice of securing informed consent among healthcare workers (HCWs) in the surgical department. Therefore the population consisted of 52 doctors in the surgical team, and 160 Professional Nurses, including consent forms from previous patients over a selected month.

3.7 SAMPLE SIZE

A sample is a group of people or things/objects that are chosen out of a larger number and are questioned or tested in order to obtain information about the larger group (Cambridge University Press, 2003). Brink (2006) states that a sample is part of a whole selected by the researcher to take part in the research study. This study included 61 HCWs working in the selected units or wards, 15 HCWs observed securing informed consent from the patients, and 31 signed consent forms over a selected month that were reviewed for completeness of documentation.

3.8 SAMPLING PROCESS/STRATEGY

Initially, the researcher intended to use probability or random sampling. Probability sampling implies that all elements in the population have an equal chance of being involved in the sample (Brink, 2006). However, due to depleted numbers of HCWs on self-administered questionnaire, and observations as well as depleted numbers of charts due to some missing files, the researcher had to change the sampling method to census and convenient sampling.

Census sampling is a study of every unit, everyone or everything, in a population. It is known as a complete enumeration, which means a complete count, while convenience sampling uses the most readily available or convenient group of people (Polit and Beck, 2008). Convenience sampling is a specific type of non-probability sampling method that relies on data collection from population members who are conveniently available to participate in the study (Burns and Grove, 2009). In other words the whole available population was recruited for the study.

3.8.1 Sampling for self-reported data and observations

The convenient sampling method was used, whereby all HCWs participated who were present in the surgical department during the sampling day and willing to participate in the study to determine knowledge and practice of informed consent, and willing to be observed securing the informed consent from patients.

a) Inclusion criteria

- All health care workers in the following categories present on the days of data collection:
 - Doctors: surgeons, medical and interns
 - Professional nurses: specialised and experienced
- HCWs who were involved in the pre-op counselling session on the days of data collection.
- All selected health care workers who volunteered and signed consent to complete the questionnaire
- All selected HCWs who volunteered and signed consent to be observed.

b) Exclusion criteria

All HCWs who were not in the selected categories, such as Enrolled Nurses and Nursing, Auxiliaries.

All HCWs who were not on duty, either on leave, day off, off sick or night duty.

All HCWs who refused to participate

3.8.2 Sampling for record review/document analysis

For document analysis the census sampling method was employed to analyse all consent forms that were completed over one month after surgery. This sampling strategy was adopted later because the charts were too few to select randomly due to some charts being missing.

Inclusion criteria:

- Available charts of patients who underwent surgery in the period between 20 October and 20 November 2015 in the records department of the selected hospital.

Exclusion criteria

- All charts that belonged to non-surgical patients in the Records Department of the selected institution.

3.9 DATA COLLECTION INSTRUMENTS

Three structured instruments/tools were utilised for data collection according to the type of data collected. A questionnaire (Appendix 1) was used for self-reported data on knowledge of the concept informed consent and some practice issues such as who obtains /secures the informed consent, who signs the informed consent and how the informed consent is signed. Two checklists (Appendix 2 and 3) were also used for document review and observation.

3.9.1 Self-reported questionnaire

A questionnaire had two sections, namely, section A and B as will be presented hereunder.

3.9.1.1 Section A: Demographics

The researcher used closed-ended questions of five items to determine the sex, marital status, race, including professional experience in months and years and occupational categories of the health care workers, both medical and nursing (Appendix 1). The latter items were the ones of importance in the study to further establish associations between demographics and the knowledge and practice of the participants.

3.9.1.2 Sections B: Knowledge and practice

The researcher used closed-ended questions to assess knowledge and practice of health care workers when securing informed consent (Appendix 1). The questionnaire was written in English only because HCWs are conversant with English and were trained in the same language. The participants were asked to choose and tick or circle the most appropriate answer to each question and to put the filled questionnaire into the sealed box. The researcher handed out the questionnaires to the participants and collected the questionnaires from a sealed box himself. The phone number for the researcher was given to the participants so that they could phone him if there was anything that they needed clarification on (Appendix 11 for the information about the scale of knowledge).

3.9.2 Observation checklist

An observation checklist of 22 criteria was used to assess knowledge and practice of health care workers when securing informed consent (Appendix 3). During the observation process the researcher ticked on the observation checklist whether or not the participant had covered each aspect in the observational tool related to the process of obtaining informed consent

3.9.3 Document analysis

The practice section was further assessed using the document checklist of 23 criteria to analyse the consent form signed by patients who had had surgery over the previous month (Appendix 2). The researcher ticked the criteria that the document revealed to have been observed during the process of obtaining consent in the selected month.

3.10 RELIABILITY

Brink (2006) maintains that reliability refers to the extent to which an instrument can be dependent upon to yield consistent results if used repeatedly over time on the same person (test retest) or if used by two researchers (inter-rater reliability) or if instruments are measuring the same construct as is the case in the current study. The criteria used to determine reliability were selection bias and internal consistency.

3.10.1 Selection bias

HCWs present and willing to participate were conveniently included in a self-administered questionnaire, record review and observational assessments of surgeons conducting pre-counselling sessions. This subjected the study to selection bias hence weakened the reliability of the study.

The checklists that are used in this study were existing instruments which were in the public domain in the South African context though they were developed in Australia. Unfortunately the developer(s) of this tool did not present the reliability and validity data on this tool. All the consent forms that were completed between 20 October and 20 November 2015 were assessed for completeness and it was assumed that there was nothing that could have influenced the performance of the HCWs during this month.

3.11 VALIDITY

According to Brink (2006), validity seeks to ascertain whether an instrument accurately measure what it is supposed to measure, given the context in which it is applied. The questionnaire was self-developed based on intensive literature review in relation to ethical and theoretical underpinnings of the concept informed consent, the practice of informed consent as reported in literature and as experienced by the researcher as a registered nurse of

nine years' experience predominantly in the surgical department of the hospital. The researcher gave the questionnaire to the supervisor and student colleagues who are at masters' level to check whether the contents of the instrument were in line with what the researcher proposed to test. A pilot test was conducted in the surgical unit of a hospital nearby due to the small number of the targeted population in the context under study. The pilot study yielded no discrepancies that warranted change in the tool. In addition the researcher ran a content validity test in which a comparison of objectives and the items in the questionnaire and checklists was made to establish if the researcher was measuring what he intended to measure (Table 3.1).

Table 3.1: Content validity of the instruments

Objectives	Questions
Describe the knowledge of the concept informed consent by HCWs	Questionnaire: questions A, B, C, D, E, F, G, J, K, L, M
Analyse the content of the preoperative counselling	Questionnaire: questions C, L Document review check-list: all items Observation check-list: all items
Identify the person that is charged with securing consent	Questionnaire: questions A, J Observation check-list
Establish the time allocated for preoperative counselling	Questionnaire questions: J,K
Determine how the informed consent is secured	Questionnaire: questions B, F, H, I, L Document review check-list Observation check-list

3.12 DATA COLLECTION PROCESS

3.12.1 Appointments and meetings with management

The researcher made appointments with the selected institution and held meetings with the management to explain the purpose and process of the study, confirm permission to conduct it (Appendix 6) and arrange a date and time for the visits. After explaining the purpose and process of the study, the researcher visited the institution for data collection.

3.12.2 Appointments with the participants

The researcher made appointments with the participants and explained to them both orally and in written form, the purpose and process of the study: how anonymity was going to be ensured and their right to withdraw from the study at any stage without penalty (see information sheet Appendix 11). Participants were given consent forms to sign as part of voluntary involvement (Appendix 12). Participants were seen during their tea and lunch breaks and after work to avoid disturbing them during working hours and disrupting ward routine.

3.12.3 Data collection

Data collection included three processes according to the type of data required, for example, knowledge using a self-administered questionnaire, practice using observation and record review.

3.12.3.1 Self-administered questionnaire

Questionnaires were given to each participant to answer the questions (Appendix 1). The instrument (questionnaires) was left behind to be filled in at home by HCWs to avoid disturbing them during working hours. The questionnaires were administered by the researcher and dropped into a sealed box by the participants. The completed questionnaires were collected by the researcher every second day in the afternoon.

3.12.3.2 Observations

Permission was sought from the participants and they were all made aware of the observations. HCWs research volunteers were observed engaged in informed consent seeking process in the outpatient department.

3.12.3.3 Record review

After securing permission from the institution and the records department, the researcher made an appointment with the records department to retrieve charts for analysis. Each chart was coded for anonymity. The chart review was done over three days.

3.13 DATA ANALYSIS

Quantitative data was analysed using the statistical package for social sciences, SPSS Version 21.

3.13.1 Descriptive statistics

Categorical data was coded, then summarised using frequencies and percentages. Graphs, tables and pie-charts were generated using the summarised statistics for presentation in the report.

3.13.2 Analytic statistics

Associations between independent and dependent variables were measured using the Pearson's chi-square test. All dependent variables were dichotomised into binary variables as "Correct response" or "Wrong response" before it was analysed against the independent

variables (profession of an individual, experience). *P-values* were used as a measure of statistical uncertainty.

For observations relations between independent and dependent variables were determined using the Pearson's chi-square test. Dependent variables were dichotomised into binary variables as "Yes observation" if done or "No observation" if not done before they were analysed for any association with the independent variables (profession of an individual, experience). *P-values*<0.05 were used as a measure of statistical uncertainty.

3.14 ETHICAL CONSIDERATIONS

3.14.1 Institutional Ethical Review Board for ethics clearance

This study was approved by the University of KwaZulu-Natal Humanities and Social Sciences Research Ethics Committee (Reference number: HSS/0417/015M) (Appendix 13).

The study was also registered with the School of Nursing and Public Health Research and Higher Degrees Committee as a research project for academic purposes. Evidence of registration of the study and ethical clearance are attached as appendices to this dissertation (Appendix 4).

3.14.2 Sensitisation of study

The researcher made appointments with the selected institution and held meetings with the management to explain the purpose of the study, seek permission to conduct it (Appendix 6) and arrange a date and time for the visits. After explaining the purpose of the study, the researcher visited the institution for data collection.

3.14.3 Participation in the study

Participation in the study observed the ethical principles of autonomy, beneficence and non-maleficence including veracity especially with observation.

3.14.3.1 Principle of autonomy

Permission was secured from the gatekeepers, namely, the Provincial Department of Health, and the participating hospital (Appendix 10 and 6).

Participants were made aware of their rights, potential risks to self-determination or free choice to participation in the research study.

Participation in the study was voluntary, and participants were free to withdraw at any time. The researcher explained the purpose of the study to the participants, both orally, and in written form: how anonymity was going to be ensured and their right to withdraw from the study at any stage without penalty (see information document: Appendix 11). Participants were given consent forms to sign as part of voluntary involvement (Appendix 12). Permission from the institution and the records department was secured with the knowledge that records were the institutional property. Participants were asked not to write their names on the questionnaire and were asked to drop the questionnaires into a sealed box and not to hand them directly to the researcher.

3.14.3.2 Beneficence and Non-maleficence as observed in the study process

Minimal risks such as the inconvenience of disrupting the participants' breaks and potential disruption of ward routine were acknowledged. To mitigate for these potential risks, the instrument (questionnaires) was left behind to be filled in at leisure by the HCWs. The confidentiality and anonymity of the participants were threatened especially with observations but HCWs who were observed conducting the informed consent seeking process in the outpatient department volunteered and were aware of the observation.

The questionnaires were handed out and collected by the researcher from the sealed box. Each reviewed chart was coded for anonymity. Participants were also told that the subsequent publications and reports would not identify the participants by name nor link any information to their names. Participants were reassured that the files would be kept under lock and key and soft copies would be stored on a password-controlled computer.

3.14.3.3 Veracity as a principle observed in the study

Participants were informed of the true purpose of the research including the whole process. The observed were made aware of being observed.

3.14.3.4. The principle of justice

The principle of justice in research is upheld by using probability sampling method which gives every population member a chance of being selected in the study. However, due to the small size of the population under study the census sampling which is a types of convenient sampling was used hence violating the principle of justice.

3.15 DATA MANAGEMENT

Hardcopies were kept under lock and key during the process of research, and will be kept in the supervisors' office cabinet in the Discipline of Nursing: School of Nursing and Public Health, UKZN for five years. Electronic data is kept in a password controlled PC and the password is known only to the researcher. At the end of the five-year period the documents will be destroyed by incineration. The study will be published in peer-reviewed journals in which no name of the participating institution nor of the respondents will appear. A summary of the study will be submitted to the involved institution as feedback.

3.16 CONCLUSION

This chapter explains how descriptive survey on knowledge and practice of securing informed consent for surgery among health care workers (HCWs) in the surgical department at a selected hospital in KZN province was designed and conducted. The study involved the collection of quantitative data from 61 conveniently selected HCWs using self-administered questionnaires, observation of HCWs conducting preoperative counselling (also conveniently selected) and a document review of 31 completed consent forms selected through census sampling. Reliability and validity of the tools were described. The collected information, which was all categorical data, was described, using frequencies, percentages, graphs, tables and pie-charts. Associations between independent and dependent variables were determined using Pearson's Chi square test. Ethical considerations and data management were presented according to the research policy of the university.

CHAPTER FOUR: PRESENTATION OF RESULTS

4.1 INTRODUCTION

This is a quantitative study which aimed to describe knowledge and practice of securing informed consent by health care workers in a selected referral hospital. This aim was achieved through describing the understanding of the concept informed consent by health care workers; analysing the content of the pre-operative counselling, identifying the person who is charged with securing the consent; establishing the time allocated for pre- operative counselling and the person charged with counselling and interpersonal relationships (HCW to patient relationship).

In this chapter, the quantitative data will be presented according to self-reported data (questionnaires), observations and record reviews. Eighty self-administered questionnaires were issued to 80 health care workers. Of these, 76.25 per cent (n=61) questionnaires were returned after three reminders through phone calls and visits.

Fifteen counselling sessions for consent before carrying out surgery were observed. Five counselling sessions were done by two surgeons, six sessions carried out by two medical officers and four sessions by two interns. Thirty-one (31) consent forms for elective surgery completed by patients over one month during previous procedures were also assessed for completeness. Further detail on the last two forms of data collection will be presented in the relevant sections.

4.2 PRESENTATION OF DATA

Data is presented according to the data sources such as, self-reported information from questionnaires, observations and record reviews.

4.2.1 Self-reported data

Self-reported data includes demographic information and knowledge of the concept of informed consent by participants, which was secured through questionnaires.

4.2.1.1 Demographic information

A total of 61 (100 per cent) healthcare workers, comprising 70.49 per cent (n=43) females and 29.51 per cent (n=18) males, participated in this study.

a) Profession and categories of the HCWs

Professionally experienced nurses constituted the largest [65.57 per cent (n=40)] proportion of the participants, followed by medical doctors, 16.39 per cent (n=10); professionally specialised nurses at 13.11 per cent (n=8); interns 3.28 per cent (n=2) and a surgeon 1.64 per cent (n=1). See Figure 4.1 below.

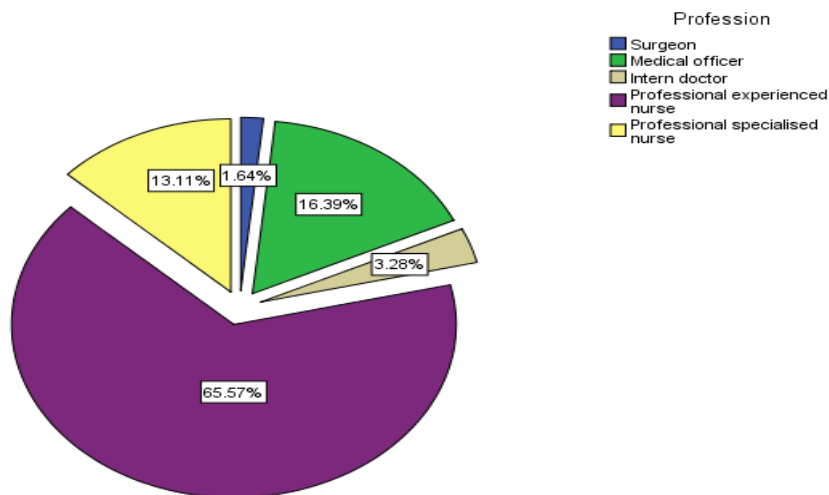


Figure 4.1: Proportion of participants according to their profession and categories (N=61)

b) Experience of participants

The bulk (86.89 per cent, n=53) of the participants had worked for more than 3 years, while 4.92 per cent (n=3) had worked for less than a year (Figure 4.2).

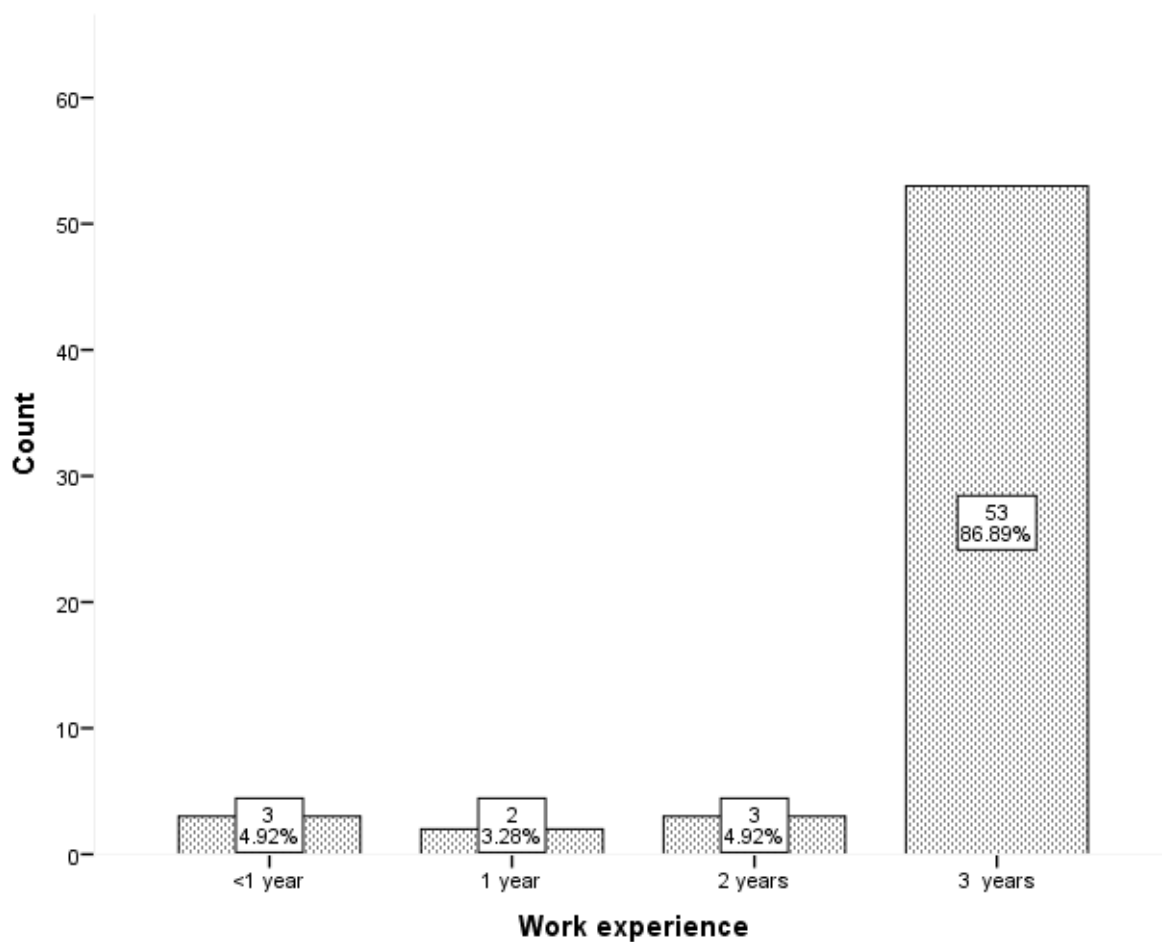


Figure 4.2: Work experience of participants

4.2.1. 2 Knowledge of the concept of informed consent by participants

a) Knowledge of the concept of informed consent

To determine the adequacy of knowledge, the researcher adapted the scale of Basak, Petpichechian and Kitrungrote (2014) as follows: Good (80-100 per cent), Satisfactory (60 per cent -79 per cent), Poor (below 60 per cent). The majority [81.97 per cent (n=50)] of the participants had a good knowledge of the concept of informed consent for surgery.

b) Knowledge of who is eligible to sign consent form

The respondents were less knowledgeable regarding who should sign a consent form for an unconscious patient brought to hospital accompanied by an under-aged (15-year-old) relative, with 72.13 per cent (n=44) of the participants giving an incorrect answer to the question. Close to half [47.54 per cent (n=29)] of the respondents did know that the health care worker (surgeon) had authority to perform procedures on patients without representatives to sign the consent form under certain circumstances. Similarly, 52.46 per cent (n=32) of the respondents gave an incorrect response to the question regarding who should sign the consent form in the case of illiterate/uneducated people (Table4.1). The South African National Health Act (South African Parliament, 2003) makes provision for surgeons to consent on behalf of mentally incompetent patients to an operation or medical treatment where such patients are unable to give the necessary consent and have not mandated anyone due to illness or other reasons (Health Professions Council of South Africa, 2008). There was an association between professional qualifications ($\chi^2=10.08$, $df=4$, $p=0.04$) and the response given as to who should sign the consent form for illiterate/uneducated people, with 60 per cent (n=40) of professional experienced nurses and 75 per cent (n=6) of professional specialised nurses failing to give the correct answer to the question.

Table 4.1: Knowledge of who is eligible to sign the informed consent form in surgery

Independent variable	Dependent variable	Character	Response		χ^2	df	P-value
			Correct	Wrong			
Knowledge on who signs the consent form	Profession	Surgeon	1	0	7.03	4	0.14
		Medical officer	5	5			
		Intern doctor	1	1			
		Professional experienced nurse	9	31			
		Professional specialised nurse	1	7			
	Total		17	44 (72.13%)			
				(27.87%)			
	Experience	<1 year	0	3	7.5	3	0.06
		1 year	2	0			
		2 years	0	3			
		3years	15	38			
		Total		17			
				(27.87%)			
Knowledge on authority of surgeon to perform surgery on patients without representative/s (Presumed authority)	Profession	Surgeon	1	0	4.86	4	0.30
		Medical officer	7	3			
		Intern doctor	2	0			
		Professional experienced nurse	18	22			
		Professional specialised nurse	4	4			
	Total		32	29 (47.54%)			
				(52.46%)			
	Experience	<1 year	3	0	5.22	3	0.16
		1 year	2	0			
		2 years	1	2			
		3years	26	27			
		Total		32			
				(52.46%)			

c) Knowledge of the contents of the consent form

The knowledge of what the consent form entails was almost equal [45 per cent (n=27) versus 55 per cent (n=33; $\chi^2 = 4.60$; $p=0.33$)] among the participants, and professional qualification and experience had no influence ($p>0.05$) on the outcome of the response. Refer to Table 4.2.

Table 4.2: Knowledge of what informed consent entails and how its comprehension is facilitated

Independent variable	Dependent variable	Character	Response		χ^2	d	P-value
			Correct	Wrong			
What does informed consent for surgery entail	Profession	Surgeon	0	1	4.60	4	0.33
		Medical officer	6	4			
		Intern doctor	2	0			
		Professional experienced nurse	16	23			
		Professional specialised nurse	3	5			
	Total		27 (45.00)	33 (55.00%)			
	Experience	<1 year	1	2	5.09	3	0.17
1 year		2	0				
2 years		0	3				
3years		24	28				
Total			27 (45.00%)	33 (55.00%)			
How can you facilitate comprehension of the informed consent form for surgery in uneducated/illiterates	Profession	Surgeon	1	0	10.08	4	0.04
		Medical officer	8	2			
		Intern doctor	2	0			
		Professional experienced nurse	16	24			
		Professional specialised nurse	2	6			
	Total		29 (47.54%)	32 (52.46%)			
	Experience	<1 year	1	2	2.70	3	0.44
1 year		2	0				
2 years		1	2				
3years		25	28				
Total			29 (47.54%)	32 (52.46%)			

d) Knowledge of the charge for contravention of the scope of practice of HCWs

Close to 61 per cent [60.66 per cent (n=37)] of the participants did not know what kind of charge would be made against health care workers who might have contravened the scope of practice. The level of knowledge on this question did not vary with professional qualifications ($\chi^2=5.06$, df=4, p=0.28) and experience levels ($\chi^2=3.65$, df=3, p=0.30) (Table 4.3).

Table 4.3: Knowledge of charge given to healthcare workers who neglected their scope of practice

Independent variable	Dependent variable	Character	Response		χ^2	df	P-value
			Correct	Wrong			
Knowledge of charge given to healthcare workers who neglected his/her scope of practice	Profession	Surgeon	1	0	5.06	4	0.28
		Medical officer	3	7			
		Intern doctor	0	2			
		Professional experienced nurse	15	25			
		Professional specialised nurse	5	3			
	Total		24 (39.34%)	37 (60.66%)			
	Experience	<1 year	0	3	3.65	3	0.30
		1 year	0	2			
		2 years	1	2			
		3years	23	30			
Total		24 (39.34%)	37 (60.66%)				

***Note that the number of respondents did not add up to 61 for that particular question**

e) Average knowledge Score per category

The average score for all 61 HCWs on knowledge of informed consent was as follows: Surgeons scored 84.6 per cent; Intern Doctors, 81 per cent; Medical Doctors, 70 per cent; Professional Specialised Nurses, 61.5 per cent and Professional Experienced Nurses, 58.8 per cent.

4.2.2 Data from observation of practice of obtaining informed consent

Observation included observation of practice before signing the consent, which entailed explanation of the procedure, content of the preoperative counselling, timing and duration of pre-op counselling including association between demographic characteristics and practice.

4.2.2.1 Practice before signing the consent

Fifteen HCWs were observed conducting preoperative counselling procedures.

a) Surgeon-patient interaction before counselling

Close to half [47 per cent (n=7)] of the surgeons did not introduce themselves to the patients and 60 per cent (n=9) of them did not ask the patients their preferred language. In spite of this, the surgeons tried to use layman's language in most cases [86.7 per cent, (n=13)] with a nurse present as an interpreter in all instances [100 per cent, (n=15)] (Table 4.4).

Table 4.4: Surgeon-patient interaction before counselling

Characteristic	Observation	
	Yes	No
Introducing her/himself	53.3% (8)	46.7% (7)
Greeting the patient	86.7% (13)	13.3% (2)
Ask about preferred language	40% (6)	60% (9)
Presence of an interpreter (nurse)	100% (15)	0% (0)
Use of layman's language	86.7% (13)	13.3% (2)
Establishment of patient age	100% (15)	0% (0)

4.2.2.2 Content of pre-op counselling

More than half [60 per cent (n=9)] of the surgeons did not inform their patients about alternative options available to the proposed surgery, 46.7 per cent (n=7) did not inform them about the risks associated with the surgery, and the same proportion did not inform the patients about their right to decision-making. In addition, all [100 per cent (n=15)] patients were not given a chance to enquire about a second opinion. In contrast, the nature of procedures and investigations involved was explained to all patients [100 per cent (n=15)] (Table 4.5).

Table 4.5: Content of the pre-op counselling

Characteristic	Observation	
	Yes	No
Nature of procedure explained	100% (15)	0%(0)
Investigation explained	100% (15)	0% (0)
Risk involved explained	53.3% (8)	46.7% (7)
Alternative options available explained to the patient	40% (6)	60% (9)
Patient given time to think about procedure	80% (12)	20% (3)
Patient allowed to ask for second opinion	0% (0)	100% (15)
Patient allowed to ask questions from surgeon	80%(12)	20% (3)
Were the patients asked about decision-making? (women only)	40% (6)	46.7% (7)*

***Note that the total for two responses did not add up to 15 because two participants were males**

4.2.2.3 Completeness of the content on the informed consent and adherence to ethical requirements in observed process of obtaining informed consent

The greatest proportion [93.3 per cent (n=14)] of the surgeons wrote their names on the consent forms and all patients (100 per cent) signed consent forms voluntarily. However, 13.3 per cent (n=2) of the surgeons did not record procedures on the patients' charts (Table 4.6).

Table 4.6: Completeness of consent form and adherence to ethical requirements in observed process of obtaining informed consent

Characteristic	Observation	
	Yes	No
Does the consent have surgeon's name?	93.3% (14)	6.7 (1)
Did the patient sign the consent form voluntarily?	100% (15)	0% (0)
Did the surgeon ask nurse to sign on his/her behalf?	0% (0)	100% (15)
Recording of the procedure in patient chart record?	86.7% (13)	13.3% (2)

Experience and professional qualifications had no influence ($p < 0.005$) on most of the above mentioned responses. However, there was a significant association ($\chi^2 = 8.47$, $df = 3$, $p = 0.037$) between work experience and introduction of HCWs to the patients, with most experienced HCWs [83.3 per cent (n=5)] comprising surgeons, not introducing themselves to the patients. Of the 5 surgeons, three quarters [75 per cent, (n=3)] of them had 4 years' experience, while all [100 per cent, (n=2)] surgeons with 5 years' experience also did not introduce themselves to the patients.

4.2.2.4 Timing of the pre-op counselling

The surgeons spent an average time of 23.73 minutes per patient with the shortest time spent with a patient being 12 minutes, while the greatest time spent was 43 minutes. The patient was asked to sign informed consent form immediately after the pre-op counselling session for the surgical procedure and no time was provided for the decision making process. The decision making and filling of the consent form must happen before the patients finish seeing

the HCW (doctor). The average time taken to the scheduled operation to take place ranged from hours to four days after the patient had signed the consent. Hundred percent (n=15) of the patients signed the informed consent immediately and seven percent (n=1) signed for her baby but requested to go home first to ask for permission from her husband. Twenty percent (n=3) of the patients had surgery the same day and forty six percent (n=7) were admitted overnight while thirty three percent (n=5) had surgery on the fourth day. Patients were not advised or reassured that they could still change their minds even though they had signed consent forms, for example within the day of operation to four days of scheduled surgery.

4.2.3 Data from record review/document review on the practice of obtaining informed consent

Thirty-one (31) consent forms for elective surgery completed over the previous months by patients undergoing procedures were assessed for completeness (Table 4.7) in the practice of obtaining informed consent. An amount of 19 percent [19.4 per cent, (n=6)] of the forms had been completed on the general risk section, while 12.9 per cent, (n=4) of them were completed on the specific risk section. The additional risk section was the least recorded section (3.2 per cent, n=1). Relevant treatment options were recorded on 6.5 per cent (n=2) of the consent forms. Only 19.4 per cent (n=6) of the doctors recorded their designation on the consent forms, and none of the consent forms were crossed (cancelled). See Table 4.7.

Table 4.7: Completeness of content of completed consent forms

Characteristic	Frequency (All 31)	%
Consent form identification and procedures		
Identification on each page	30	100*
Consent form procedures	31	100
Informing of patient of condition and risks		
Condition recorded in patient's own words	2	6.5
Condition described to the patients	29	93.5
Procedure described for patient	31	100
General risk recorded	6	19.4
Specific risks recorded	4	12.9
Recording of additional risks	1	3.2
Recording of relevant treatment options	2	6.5
Patient/substitute information		
Name of interpreter recorded	10	66.7*
Recording of patient/substitute decision-maker	31	100
Recording of patient/substitute decision-maker's signature	31	100
Recording of patient/substitute decision-maker's signature date	25	80.6
Recording of interpreter signature	10	76.9
Doctor's information		
Doctor's name printed	30	96.8
Doctor's designation printed	6	19.4
Doctor's signature appended	31	100
Crossed forms	0	0
Progress notes and nursing process on patient record form	31	100

*Note that the number of respondents did not add up to 31 on that particular question

4.3 CONCLUSION

In this chapter, data was presented according to the data sources used, namely, questionnaires, observations and a record review. Associations of practice and demographic characteristics of the participants on observation were also presented. The next chapter will present the discussion and interpretation of findings in the context of the existing literature and adopted conceptual framework, conclusions, recommendations and limitations of the study.

CHAPTER FIVE: DISCUSSION OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents a discussion of findings, conclusions and recommendations. The objectives of the study were: Describe the knowledge of the concept informed consent for surgery by health care workers; Analyse the content of preoperative counselling; Determine how the informed consent for surgery is secured in terms of: timing of the preoperative counselling, person charged with counselling, and interpersonal relationship (HCW to patient relationship).

The objectives were addressed using the conceptual framework as conceptualised by Childers et al. (2009). This framework categorises the approach to informed consent into disclosure, patient understanding and patient decision making.

5.2 Discussion of overall findings

The discussion of findings will utilise the above categories to place the findings in context. Other literature will be cited for the same purpose.

5.2.1 Disclosure of information

Disclosure involves ensuring that the patient understands the concept informed consent and has adequate information before consenting to the surgical procedure.

5.2.1.1 Knowledge on informed consent

The conceptual framework suggests that the surgeon discusses with the patient the diagnosis, risks, benefits, treatment options if any, other choices of treatment, including non-surgical intervention, and proposed care available to him/her. However, it is important for health care workers to have adequate knowledge of informed consent in order to be able to carry out this aspect.

Overall, this study demonstrated that some health care workers were not aware of, or were ignorant of most components of the consent form for surgery. This is demonstrated by their knowledge scores which seem to be influenced by their qualifications (Surgeons scored 84.6 per cent, Intern Doctors 81 per cent, Medical Doctors 70 per cent, Professional Specialised Nurses 61.5 per cent and Professional Experienced Nurses 58.8 per cent). Yet the informed consent course of action provides a unique opportunity for HCWs to interact with a patient and allow him/her to put into effect the right of self-determination (Irabor and Omonzejele, 2009). A study conducted in Iran noted that patients do not receive enough information during the process of providing their informed consent; in other words, their consent is not “informed” as much as necessary (Childers et al., 2009). This is in agreement with a study by Fisher-Jeffes et al. (2007), where they noted that knowledge of the consent form was low among clinicians.

The worldwide practice amongst all background is that informed consent must be obtained from the patients themselves if they are of acceptable age and are competent to make their own decisions (Jamjoom et al., 2010). In situations of diminished capacity resulting from conditions such as cognitive dysfunction or psychiatric illness, or legal incompetence, the decision will have to be made by a legally appointed representative who is capable of making decisions for the patient (Leclercq et al., 2010). It was of concern to note that, in this study, most (72 per cent) respondents were not aware that, even if the patient is brought to hospital by an under-aged person, the under-aged person should be informed of what needs to be done to his/her relative prior to the surgery, despite the fact that s/he is legally incompetent. A number of studies have focused on the competency of children aged 9, 14, 18 and 21 using

hypothetical treatment dilemmas, and found that 14-year-olds did not differ from adults in their competency to make treatment decisions (Weithorn and Campbell, 1982 cited in Fisher-Jeffes, 2007). In 1985, Lord Fraser, in the Gillick ruling, established that children of 16 years of age, who are capable of fully understanding the implications of their decisions, can give valid consent (Fisher-Jeffes et al., 2007). Thus children who have reached 16 years of age are considered, in law, to be experienced enough to give consent.

In South Africa, a child may consent to the performance of a surgical operation on him or her, or on his or her child, if: the child is over the age of 12 years, and the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation; and the child is duly assisted by his or her parent or guardian (Mahery et al., 2010). In the case of surgery for children over 12 who have sufficient maturity, the parents need to assist the child to reach a decision. Mahery (2010) states that if the parent refuses to assist the child and to sign the consent form, then the surgery cannot be performed unless ministerial or court-ordered consent is obtained to overrule the parent's refusal to assist.

Also of concern was the observation that half (52 per cent, n=32) of the health care workers were not aware of who should sign the consent form if the patient is illiterate/uneducated. This may be because HCWs sense that not much will be gained by trying to describe detailed operation procedures to an illiterate person who entirely trusts that the HCW does not desire his/her impairment. In support of this theory, a study conducted in Nigeria (Irabor and Omonzejele, 2009) noted that explaining and not explaining a consent form to illiterate people was the same because they would end up agreeing to put their thumb print on the appropriate line. Thus a signed informed consent form may only really serve as legal justification when complications crop up for a limited number of educated people (Irabor and Omonzejele, 2009).

The level of ignorance about practice was high among both nursing participants (professional experienced nurses 60 per cent and 75 per cent professional specialised nurses). In concurrence, a study carried out in the United Kingdom which considered knowledge of

capacity to consent to or refuse medical treatment, observed that the performance of doctors was generally better than that of non-doctors (Fisher-Jeffes et al., 2007). The same study noted that 58 per cent of psychiatrists, 34 per cent of geriatricians, 20 per cent of general practitioners and 15 per cent of students correctly answered questions on capacity to consent to or to refuse medical treatment (Fisher-Jeffes et al., 2007). A study conducted in Uganda (Ochieng et al., 2014) found that there was a big variation among respondents as to when the consent should be sought, indicating that there was a discrepancy in the knowledge and practice of informed consent by surgeons.

There is no doubt that informed consent is a process in which the surgeon plays a very important part. This task has been called “the skill of attaining informed consent in the clinical setting” (Childers et al., 2009). The same authors further assert that all surgeons, including those in training, must be acquainted with this skill, and, in their opinion, informed consent should be fundamental for day-to-day practice. Contrary to the assertion by Childers et al. (2009), half of the health care workers did not know what constitutes a valid consent form in the current study. This finding was not peculiar to this study, as a previous study researching the knowledge of consent practice in HCWs noted that the performance of doctors was generally better than that of non-doctors (Fisher-Jeffes et al., 2007). However, what is more encouraging, is that at least 75 per cent of respondents knew how to prepare for surgery, who is responsible for getting the consent form and who should sign it.

The most failed question was what course of action should be taken against a health care worker who neglects his/her scope of practice, with almost all respondents failing the question. The code of practice in surgery is that all patients should have a consent form signed by them if legally competent, prior to any procedure being performed on them (Leclercq et al., 2010). Thus, in the absence of an informed consent being signed, health care workers may be indicted for battery or negligence if the aftermath of treatment does not meet the patient’s expectations, or should complications arise (Sherlock and Brownie, 2014).

Sometimes legal steps are taken against HCWs if the outcome of treatment does not meet the patient's expectations, or should complications occur. These legal steps are normally taken by those who are aware of their rights and able to meet the financial costs of a law suit. The most probable reason why most nurses could have failed that question badly may be that the consent form is the duty of the doctor. Although in this study, nurses and junior doctors did not know what course of action should be taken against a health care worker who neglects his/her scope of practice, another study (Ochieng et al., 2014) noted that sometimes nurses obtained informed consent from patients when doctors were busy.

5.2.1.2 Practice

Practice was mainly established through observations and chart review.

a) Observations

Surgeon-patient engagement is a crucial stage before explaining the procedure to be conducted on a patient. Informed consent should be sought from the patient by the surgeon before operating on him/her, and this is a continuous process that begins as soon as the surgeon meets the patient, and should continue after the operation to expedite the patient's understanding of the procedure. Benefits, anticipated risks and risks of the operation and the post-operative follow-up period should all be explained to the patient (Ochieng et al., 2014). In the current study, half of the surgeons did not greet the patients. Crowded hospitals and busy schedules appear to be the main factors discouraging surgeons from interacting with their patients sufficiently (Faghanipour et al., 2014). Childers et al. (2009) mentioned that surgeons tended to refrain from long talks with patients due to their busy schedule or other factors. Irabor and Omonzejele (2009) stated that many surgeons were not aware that it is a unique opportunity to interact with a patient and allow him/her to exercise the right of self-determination.

The clinician has a moral and legal duty to ensure that patients fully understand what is being done to them or else any operation can count as physical assault, which could result in liability for damages (Khan et al., 2013). In this study, more than 46 per cent (7) of patients were not informed about the risks involved. Similarly, Faghanipour et al. (2014) found, in a study conducted in Iran that, while participants obtained information about the nature of their disease, justification for surgery and the general nature of the surgical procedure, they were, nevertheless, not informed about the complications, risks, other options, length of stay and follow-up after discharge. Similarly, a study carried out in Australia (Larobina et al., 2007) found that 80 per cent of patients considered it very important to be informed of all risks of surgery, rather than only the major complications (20 per cent).

During the consent form discussion, the surgeon is supposed to explain the procedure, the risks involved and alternatives to the procedure to the patient, and it is during this process that the patient is allowed questions and is allowed to ask for a second opinion, and is also able to engage in a discussion for surgery (Cainzos and Gonzalez-Vinagre, 2014, Childers et al., 2009). However, in practice, this is not the case. A study conducted in Pakistan (Tayyab and Aurangzeb, 2010) showed that no information was provided to 69.3 per cent of patients regarding surgical risks, and 75 per cent of patients received no information on the risks of anaesthesia. In this study, all (100 per cent, n=15) patients were not given a chance to request a second opinion. In contrast, the nature of the procedures and investigations involved was explained to all patients (100 per cent, n=15).

This study also found that the majority of patients were not informed about the general and additional risks associated with the surgery they would be undergoing. A study by Larobina et al. (2007) in Australia noted almost all patients (80 per cent) regarded the doctor as obliged to inform them of all risks of surgery. Patient and non-related factors influence the information the surgeons give to their patients during informed consent. Jamjoom et al. (2011) noted the following dynamics as influencing patient-doctor interaction: the patient's gender, timing of the surgery, medical presentation whether emergency or elective, qualifications and background of the patient, availability of financial support for treatment, difficulty and length of surgery, age of the patient, and how active the surgeon was at the time. This is supported by Childers et al., (2009) who assert that selective truth-telling must be avoided, and all potential hazards and risks, controlled or not well controlled, should be disclosed.

b) Document review

There were a high number of omissions in the completion of information on the archived forms. For instance, only 6.5 per cent of the forms had information on the diagnosis recorded in patients' own words. Similarly, a study done in the United Kingdom (Leng and Sharma, 2016) found that there was no (0 per cent) recording of additional procedures like blood transfusion, drains or application of splints in 2013, however, this changed to 7.5 per cent in 2014. In Africa, Ezeome et al (2011) observed the same in Nigeria, where none of the consent forms made provision for documentation of patients' permission for blood transfusion, tissue disposal, awareness of the risks of not undergoing the prescribed treatment, and the risks of anaesthesia. Nevertheless, they observed a slight change in provision for four other requirements: interpreter, signature of anaesthetists, alternatives to the procedure to be mentioned, and answering of the patient's questions, which were completed on less than 10 per cent of the forms. This trend was consistent with a study in Uganda, where it was found that informed consent administration and documentation for surgical care was inadequate at university teaching hospitals (Ochieng et al., 2014). It is thus recommended that all the consent forms should have the patient's name and signature, patient's authorisation of the procedure, permission for anaesthesia, and permission for additional procedures, if needed during the surgery (Ezeome et al., 2011).

Although the use of a consent form does not eliminate possible allegations that the patient did not understand the form, or was not given sufficient time to comprehend the nature of the procedure, these allegations are considerably weakened by the proper use of a comprehensive form. In a court of law it is difficult to prove whether a patient wasn't given information about a procedure and its complications, or whether it was simply a case of forgotten details (Khan et al., 2013).

Risk management goals may be met by listing the complications on the informed consent form that the patient signs and providing a copy of the form to the patient. Other reasons to document risks and complications are: the significant decline in information remembered over time, the extended time for litigation to conclude, and the potential of increasing the patients' understanding of the procedure and complications (Naidoo, 2014).

The current study also found that (<20 per cent) of patients were not informed about the general, specific and additional risks associated with the surgery they would be undergoing. The issue of not informing patients about the risks associated with treatment is not unique to surgery, but is also common in other fields of therapy like blood transfusion. For instance, a study conducted in Canada (Rock et al., 2007) on whether a treating physician had discussed the risks, benefits, and alternatives of blood transfusion with the patient, found that 75 percent of patients had not been informed about these issues. The remainder who had been informed (25 percent) were found mainly in the anaesthesia or pre-admission notes (14.7 per cent) (Rock et al., 2007). Yet such information gives a patient the option to select an alternative treatment, and, in the current study, only 6.5 per cent of forms had that information recorded. Khan et al. (2013) emphasised that it is a moral and legal duty of a clinician to utilise all possible resources to ensure that patients fully understand what is being done to them otherwise any operation can count as physical assault, which could be liable for damages. To reinforce the importance of consent form documentation, Leigh (2006, in Khan, 2013: 140), a solicitor, put it like this: "I regularly advise doctors that their skills are for their patient and their notes are for themselves. My words fall on ears which are as deaf as the surgical patient."

The doctor's designation indicates who accessed the patients' information, and in this study, less than 20 per cent of the doctors did not mention their designation. However, it is encouraging to note that in this study, most (96.8 per cent) doctors printed their names on the consent forms, contrary to a study carried out in the United Kingdom (Leng and Sharma, 2016), where 46 per cent of consent forms had doctors' names printed on them in 2013, and the number declined to 13 per cent in 2014. It was very interesting to note that in the current study, all the doctors entered their signatures on the consent forms and the counselling session was recorded by all nurses involved in the nursing process.

Although a specific standard operating procedure addresses responsibility for documentation, clearer identification of the responsible individual and further education would help improve this situation in the hospital (Rock et al., 2007). The same authors, in their study conducted in Canada, state that providing information and documentation is a time-consuming process but, whether it be via a written consent form or a note on a chart, there is now a requirement in many jurisdictions for documenting that an exchange of information on practice has occurred.

5.2.2 Patient understanding

Patient understanding in this study means that the patient has understood the information relayed to him/her before making a decision. A proper informed consent process requires information (from doctor to patient) and comprehension (by the patient) (Irabor and Omonzejele, 2009). Here, the doctor answers questions asked by the patient. In the current study twenty percent of patients were not given the opportunity to ask questions of the surgeon. Yet to make certain that the patient understood, the surgeon needs to give an opportunity to the patient to repeat in their own words their perception of the rationale, dangers, and advantages of the procedure (Childers et al, 2009). Participation of the patient in questioning the surgeon shows that the patient has understood the information given to him or her. The idea is not to question the patient but rather to give him/her confidence for open communication of information and to encourage the patient to play a part and to ask questions (Cainzos and Gonza´lez-Vinagre, 2014). Surgeons should be aware and respect the patient’s choice not to ask or be asked questions, as some patients prefer not to enquire. Patients will possibly understand the information offered, but a number of patients may choose not to take a decision and desire to rely only on their surgeon’s advice. However, patients should be encouraged to be more active participants in the decision-making process (Cainzos and Gonza´lez-Vinagre, 2014; Childers et al., 2009).

Traditionally, surgeons have relied almost entirely on their own judgement about patient diagnosis, need for information and treatment (Moodley, 2011). For example, in some cultures, there is still a cultural belief that doctors know best and patients often entrust their physician with making medical decisions (Faghanipour et al., 2014).

Some doctors withhold information from patients when they think the information could harm them (Tabak et al., 2013). Yet others use dishonesty in clinical practice under certain circumstances (Kling, 2012). Hence, the researcher sensed paternalistic attitudes among some of the health care workers, especially with illiterate patients. This may be because HCWs think that it would be a futile exercise to explain to a person who would not understand anyway (Irabor and Omonzejele, 2009). This behaviour could also be related to patient numbers which result in overcrowding. Faghanipour (2014) concurs that crowded teaching hospitals and busy schedules appear to be the essential factors discouraging the surgeons from informing their patients adequately.

Mabuza et al. (2014) maintain that it is common practice in South Africa for healthcare workers who do not speak the patient's first language to make use of nurse interpreters. The use of a nurse interpreter and the local language are important to facilitate comprehension. Most (60 per cent) HCWs did not ask patients what language they preferred, while knowing the language spoken by the patient might be crucial, as language barriers negatively affect direct healthcare delivery (Escobedo et al., 2007). These authors observed that language barriers disturbed the doctor-patient relationship, and that patients who did not speak the same language as the doctor had a high rate of non-adherence to medications and to appointments with their doctors. While the current study was conducted in a predominantly isiZulu-speaking community, it should be borne in mind that South Africa is a multi-lingual country with eleven official languages. The National Health Act (South African Parliament, 2003, Chapter 2 Section 6) states that information on informed consent forms must be provided in a language that the patient understands and in a manner that takes into account the patient's literacy level (Naidoo, 2014). Hence, knowing the patient's preferred language is crucial, so as to use a language understood by each patient, thus giving him/her the right of self-determination. It has been recommended that healthcare practitioners have at least a minimum understanding of their patients' languages and culture so as to facilitate effective communication (Mabuza et al., 2014).

The current study revealed that the HCW are not practising as expected in terms of securing consent for surgery in contravention of the assertions by authors such as Ochieng et al., (2014) and Bal and Choma, (2012) who argue that securing informed consent is a process of dialogue between the patient and the provider.

5.2.3 Patient decision

The patient should be given enough time to think and make informed decisions based on what was discussed with the physician, family and friends (Childers et al., 2009). The same author maintains that this includes time to think about the risks, benefits and consequences of having and not having the operation. In the current study at least 80 per cent of patients had an opportunity to think about the procedure, as opposed to 46.7 per cent of patients who were not informed of the risk involved. With this process, it is very important to remember that patients need adequate time to process information, reflect on their values and interest and make informed decisions (Wancata and Hinshaw, 2016). The literature does not say to what extent the surgeon should divulge information to the patients (Bal and Choma, 2012). The average time taken for consultation was 23.7(24) minutes for each patient, with the shortest time taken being 12 minutes and the longest 43 minutes. In the current study each patient was given informed consent form and asked to sign immediately after the surgeon had explained the surgical procedure (pre-op counselling session). The surgeon (HCW) verbally asked the patient to think about the proposed procedure while handing over the informed consent form to the patient for him or her to sign. No time was given to patients for decision making. The decision making and signing had to happen before the patients finish the consultations with the HCWs. Some surgical procedure was schedule for the very same day but later. Other patients were admitted overnight to be prepared in the ward for theatre the following day, while others were given two to three days to stay in the hospital after pre-op counselling sessions and signing of the consent form. Patients were not advised or reassured that they could still change their minds even when they had signed consent forms. In one case a child who was to be admitted for four days, the mother asked for permission to go home to ask for permission first from her husband before the child was operated upon. The mother's options for decision making were still limited because the HCW wanted the answer within a specific time and had initiated the need for the decision making time herself.

Childers et al. (2009) indicated that the progression of informed consent would possibly be best facilitated over the course of frequent pre-operative appointments, during which an adequate amount of time could be allocated for the surgeon and patient to attain a joint understanding of the patient's best interests.

Patient understanding in this study means that the patient has understood the information relayed to him/her before she/he makes a decision. Here, the doctor answers questions asked by the patient. Participation of the patient in questioning the surgeon shows that patient has understood the information given to him, or the doctor himself can ask the patient to repeat what she/he has just said to them. The idea is not to test their knowledge but rather to encourage an open dialogue on the information given and encourage the patient to contribute and to ask relevant questions. However, some patients, especially the illiterate tend to trust the HCWs to an extent of agreeing with whatever the HCW recommends.

5.2.4 Conclusions

The study indicated that there was a discrepancy in the knowledge and practice of informed consent by surgeons. Though efforts were made to ensure understanding in terms of the use of layman's language, some important aspects of the information were not shared, for example, risks related to anaesthesia and surgery, adverse effects of blood transfusion, potential undesirable effects of surgery, ventilation (for patients who need ventilation after surgery), length of hospital stay for surgery, and other therapy options, for example, asking for a second opinion. In addition, health care workers sometimes displayed paternalistic attitudes towards patients, possibly relating to the patients' illiteracy and language barriers. Statistics in South Africa show that only 28.4 per cent of South Africans over the age of 20 years have completed Grade 12, only 33.8 per cent even made it to high school and 8.6 per cent had no schooling at all, while only 12 per cent have a tertiary qualification (Statistics South Africa, 2012). Half of the healthcare workers in the current study did not know what constitutes a valid consent form. Meanwhile, at least half of the healthcare workers knew the best time for discussing the consent form. In spite of this, the current study shows that further education about consent is required. Identifying which aspects of an informed consent are most neglected will help improve the process of providing information to patients.

A study conducted on patient rights in Iran (Faghanipour et al., 2014) revealed that three major factors causing the violation of patients' rights are: patients' unawareness of their rights, the unresponsiveness of the monitoring system, and a shortage of human resources, time and facilities, particularly in teaching hospitals. Patients do not understand technological terms in their mother tongue. While they may give "informed consent", its validity must be questioned because of the patient's lack of comprehension of what is being consented to. With over 2 000 languages in Africa, the problem is not limited to South Africa or to isiZulu, but applies to other countries and languages as well (Jack et al., 2014). The consent processes used may fulfil the obligation of information disclosure, but may not have addressed the ethical considerations of understanding and ability of the patient to make decisions that are in his or her best interests (Jack et al., 2014. 17).

5.3 Recommendations

Recommendations are offered in relation to practice, education, management and future research.

5.3.1 Recommendations according to practice

Considering these findings, the researcher recommends that surgeons and other health care workers should try to provide patients with more information regarding the surgical procedure, type of anaesthesia, potential complications of surgery, potential risks of surgery, alternative therapy options, length of hospital stay for surgery, postsurgical follow-up, and costs of therapy, in a manner comprehensible to the patients, to ensure that their consent is informed. In this way, the informed consent will be truly reliable. The researcher proposes the use of multiple methods to improve the informed consent process, such as translating informed consent forms into isiZulu for the purposes of this study, the use of video recordings and social media for educational purposes, issuing supplementary written material (in simplified language), using computer-based educational tools, having structured discussions, use of pictures, decision aids and repeat back methods.

5.3.2 Recommendations according to education

The researcher suggests that the educational curricula of surgical residents and nursing students should emphasise the importance of informed consent. Informed consent and dilemmas surrounding it, must be used as concrete examples for teaching ethos and professional practice. This issue could also be included in continuing educational plans for physicians and all health care workers in the surgical ward as well. Moreover, the researcher recommends that health care users should be educated and become aware of their right to receive information about their treatment, via different media. Faghanipour et al. (2014) state that public awareness of patients' rights and modifying the structure of monitoring systems will help ensure patients' rights.

Recommendations made as a result of the 2013 audit of consent form completion in the United Kingdom included incorporating the consent process into the junior doctor departmental orientation programme and teaching, as well as increasing awareness of departmental efforts to increase standards (Leng and Sharma, 2016). As reinforcement to junior doctors, it should be emphasised that the written consent form is a medico-legal document, and that the use of legible handwriting, together with their signature and full name in block letters is important for proper documentation (Wong et al., 2015).

5.3.3 Recommendation to management and policy-makers

The researcher proposes that managers increase awareness and emphasis on the bill of rights and associated documents such as *Batho Pele* (People first) for HCWs. One study recommended that different techniques be used to improve patient understanding, for example, increasing discussion time to 15–30 minutes, providing patient information leaflets, multimedia presentations, visual aids, the Internet, structured informed consent platforms and repeat back methods to ensure understanding (Mulsow et al., 2012). Ongoing in-service education is the key to successful implementation of the informed consent process.

5.3.4 Recommendations for future research

The intention of this study was to investigate the knowledge and practice of securing informed consent for surgery by HCWs in a selected institution, because it impacts on their trainees' knowledge and practice. To my knowledge, there has not been any systematic review of documents, self-reported information (questionnaires), or observations conducted regarding informed consent practice for surgery. The researcher proposes that other researchers could develop procedure-specific consent forms that detail particular risks, benefits and alternatives. The researcher also proposes that more studies be conducted on patients with mental disabilities or a lack of capacity as far as informed consent is concerned. Further studies can also be carried out to assess the level of knowledge of patients about their rights in relation to the use of informed consent form.

5.4 Limitations of the study

This study did not include HCWs working in the psychiatric ward and family medicine inpatient and outpatient departments. The researcher did not involve HCWs who were on leave, sick leave, maternity leave and those working on night duty, but only those who were working during the day at the time of data collection. The findings may be biased, because the results will be generalised to the whole population, whereas not everyone participated in the study such as medical students, nursing students, nursing assistants and staff nurses.

The participants in the observation were aware of them being observed. Therefore they may have been tempted to alter their behaviour to impress the researcher (Al-Natour, 2011).

5.5 Conclusion

The intention of this study was to investigate the knowledge and practice of securing informed consent for surgery by HCWs in a selected institution, because it impacts on their trainees' knowledge and practice. The study proposes that managers put more emphasis on the bill of rights and associated documents such as *Batho Pele* (People First) for HCWs. Management of institutions could use the following strategies: leaflets, multimedia presentations, patient decision aids, the Internet, structured informed consent platforms, and repeat back, to provide the patient with information prior to surgery.

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APPENDICES

Appendix 1

Questionnaire: English

Section A

Tick or circle your response in the box (√)

Demographic data

1. Sex

Male

Female

2. Work experience

1. Months

2. 1Year

3. 2years

3. 3years and above

3. Marital status

1. Married

2. Single

3. Widow

4. Separated

5. Cohabitation

4. Race

1. African

2. Indian

3. White

4. Coloured

5. Category

1. Doctor – surgeon

2. Professional Nurse - experienced nurse

- Registrar- specialized nurse

- Medical officer

- Intern

Section B

QUESTIONNAIRE: INFORMED CONSENT

Please read the following Scenarios and circle the most appropriate answers

Patient V, a 22 year old patient from Mseleni Hospital is transferred to your unit in an ambulance with Acute Abdomen. He is critically ill, unconscious accompanied by his 15 year old brother. It is immediately decided that Mr V be prepared for emergency surgery.

A. In preparation for surgery, Dr S, the surgeon asks:

1. The referring doctor to send the patient with a consent from his hospital
2. The brother to sign the consent on his brother's behalf
3. The nurses to locate the parents or older sibling to come and sign while he liaises with the medical manager to act on the patient's behalf.
4. The nurses to get Mr V's right thumb print on the consent form

B. The surgeon further asks:

1. The referring doctor to explain to the brother about the surgery before transfer to the operating theatre
2. The intern on call in Emergency Department to explain the surgery to the brother while he gets ready
3. The nurses in the Emergency Department to explain the surgery to the brother that is to be done while he gets ready in theatre
4. the brother to his office to explain the surgery much against the intern who feels this is a dire emergency and needs to be rushed to theatre

C. Dr S in his discussion with Mr V's brother discloses

- i. The nature of the proposed procedure
- ii. All the benefits to the brother before he lets anyone sign
- iii. Reasonable alternatives to the proposed intervention
- iv. All the benefits and risks involved in the surgery before he lets anyone sign
- v. All the benefits, risks and uncertainties related to each alternative before he lets anyone sign

1. i, ii and iii
2. ii, iii and IV
3. i, ii and IV
4. i, iii and v

D. The surgeon tells the nurses that since this an emergency he will take the consent to be presumed. This means

- i. The information has been given already by the referring doctor
- ii. Surrogate decision maker is not available
- iii. The patient is unconscious and incompetent
- iv. For the well-being of the patient, he may need to act on behalf of the patient since his life is at stake

1. I, and ii
2. I and iii
3. iii and iv
4. ii and iv

E. An informed consent is valid if the following is done **except**

1. The uneducated is allowed to choose to provide his Right Thumb Print rather than ask someone else to sign for her
2. It is given voluntarily
3. The patient is mentally competent
4. Understanding of the patient is assessed before letting him/her sign

F. The informed consent for the child is signed by

1. His/her parents
2. His/her older siblings
3. The child himself or herself if they can understand
4. Medical manager

G. Informed consent is often required for

- i. Surgery
- ii. Anaesthesia
- iii. Visiting
- iv. Investigations
- v. Research

1. i, ii, iii, V
2. ii, iii, IV and V
3. i, ii, IV and V
4. ii, iii, IV and V

H. In the course of his stay in hospital Mr V undergoes another operation. Dr S, the surgeon uses the consent signed for the first operation. This is called a

1. A referral consent
2. A blanket consent
3. Presumed consent
4. Opt in Consent

I. Comprehension can be facilitated for the uneducated/illiterate patients in an informed consent discussion by:

- i. Use of simple non-technical language
- ii. Use of interpreters
- iii. Use of visual Aids
- iv. Establishing understanding at the end of discussion
- v. Use of Right Thumb Print for signature

1. i, ii, iii, and V
2. ii, iii, IV and V
3. i, ii, iii, and IV
4. i, iii, IV and V

J. Enrolled Nursing Assistant B working in operating theatre fetches a patient for evacuation of products of conception. On arrival in theatre he discovers that the patient has no consent and gives a consent form to the patient to sign. When the patient is under General Anaesthesia the Accident and Emergency sister phones to say it is the wrong patient. This nurse needs to be charged with:

- i. Wrong identification of the patient
- ii. Subjecting the patient to General Anaesthesia for nothing
- iii. Failure to secure informed consent
- iv. Acting beyond his scope

1. i, ii and iii,
2. i, ii and iv
3. ii, iii and iv
4. i, iii, and iv

K. The best time to discuss informed consent for surgery is

- i. Immediately before surgery
 - ii. In the outpatient before the patient is admitted
 - iii. When investigations on the diagnosis have been completed
 - iv. Before giving pre-medication
 - v. When the Operating theatre staff comes to fetch the patient
1. i and ii
 2. ii and iii
 3. iii, and IV
 4. iv and v

L. Informed consent is signed when

- i. Disclosure about the intervention, it alternatives and outcomes of both have been discussed
 - ii. Question and answer session has been created
 - iii. Understanding by patient is assessed
 - iv. The patient has accepted the proposed intervention
 - v. Disclosure only is provided
1. I, ii, iii iv and v
 2. ii, iii, iv and v
 3. I, ii, iii and iv
 4. I, iii, iv and v

M. Who is responsible for obtaining informed consent?

1. The Ward Doctor
2. The Referring Doctor
3. The Intern Doctor
4. The Surgeon going to perform the procedure
5. The Nurse

Appendix 2

Document Review

CHECKLIST FOR ANALYSIS OF THE INFORMED CONSENT FOR SURGERY

Item	Yes	No	N/A
1. Is there a consent form present?			
2. Is the consent form procedure specific?			
3. Is there patient identification on each page?			
4. Has the communication/cultural needs been identified?			
5. Has the condition been recorded in patients' own words?			
6. Has the condition been described for the patient?			
7. Has the procedure been described for the patient?			
8. Are the general risks recorded?			
9. Are the specific risks recorded?			
10. Are any additional risks/complications recorded?			
11. Are there any other relevant treatment options recorded?			
12. Has the name of the patient/substitute decision maker been recorded?			
13. Has the signature of the patient/substitute decision maker been recorded?			
14. Has the date of the patient's/substitute decision maker's signature been recorded?			
15. Has the name of the interpreter been recorded?			
16. Has the signature of the interpreter been recorded?			

17. Has the doctor printed or his/her name?			
18. What is the designation of the doctor?			
19. Has the date of the doctor's signature been recorded?			
20. Has any crossing out been made to the form?			
21. If so, is it initialled?			
22. Any record on patient chart: progress notes, nursing process notes?			
23. Any further comments?			

Queensland Health policy Statement: <http://www.health.qld.gov.au/informedconsent>

Appendix 3

Observation Checklist

Date completing checklist/...../.....

Name of Observer..... Signature of Observer.....

Time session began/..... AM/PM Time session finished.....

Observation Checklist tool

Item	Yes	No
1. Did the surgeon greet the patient?		
2. Did the surgeon introduce him/herself to the patient?		
3. Did the surgeon ask about the language preferred by the patient?		
4. Is the name of the surgeon or consenter written in the consent form?		
5. Did the surgeon explain the nature of the procedure?		
6. Did the surgeon explain about the investigations?		
7. Did the surgeon explain about disadvantage and advantage of the procedure?		
8. Did the surgeon explain about the risk involved when doing the procedure?		
9. Did the surgeon explain alternative treatment options available?		
10. Did the surgeon give patient time to think about the planned procedure?		
11. Did the surgeon ask for further questions?		
12. Did the surgeon explain what will happen should they identify new problems while operating?		
13. Did the surgeon allow the patient to ask for second opinion?		
14. Did the surgeon allow time for questions from the patient?		
15. Did the patient sign the consent form voluntarily?		
16. Was the patient forced to sign the consent form?		
17. Was a note written in the patient charts or record regarding his/her consent to the planned procedure?		
18. Did the surgeon use lay language and avoid using scientific words that the patient did not understand?		
19. Was a bilingual interpreter present?		
20. Did the surgeon establish the age of the patient?		
21. Did the surgeon ask about decision making (especially for woman)?		

22. Did the surgeon ask the nurse to sign on his behalf after the counselling session?		
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www.ouhsc.edu/.../901-c_informedconsentobservationchecklist.pdf

Appendix 4

17 April 2015



Student No: 210527940

Dear Mr Jabulane Ngwenya,

MASTER OF NURSING (CRITICAL CARE AND TRAUMA)

Title: "An investigation into the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution."

Supervisor: Prof BR Bhengu

The above-mentioned ethics application was considered and the protocol has been approved for the Master of Nursing coursework degree by the Academic Leader of Research and Higher Degrees. The ethics application together with the protocol has been forwarded to the Humanities and Social Sciences Research Ethics Committee for review.

Please note:

- The study may not begin without the full approval of the Humanities and Social Sciences Research Ethics Committee.

Yours sincerely

A handwritten signature in black ink, appearing to read "Carol Dhanraj".

Carol Dhanraj
School of Nursing and Public Health
Postgraduate Administration

cc: Ms C Ngcobo
Prof BR Bhengu

Postgraduate Administration

School of Nursing and Public Health

University of KwaZulu-Natal

Postal Address: University of KZN, Durban, 4041, South Africa

Founding Campuses

- Edgewood
- Howards
- Medunsa
- Pietermaritzburg
- Westville

Appendix 5



7 Woodlands Rd
GLENWOOD
DURBAN
4001
083 415 2531

28 November 2016

Reg. No. 2006/156780/23

Jabulane Ngwenya

EDITING OF RESEARCH DISSERTATION OF JABULANE NGWENYA

I have an MA in English from University of Natal (now UKZN) and have been performing editing services through my company for eleven years. My company regularly edits the research dissertations, articles and theses of the School of Nursing, Environmental Studies and various other schools and disciplines at the University of KwaZulu-Natal and other institutions, as well as editing for publishing firms and private individuals on contract.

I hereby confirm that Shirley Moon edited the research dissertation of **Jabulane Ngwenya** titled "An investigation into the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution" on behalf of WordWeavers cc and commented on the anomalies she was unable to rectify in the MS Word Track Changes and review mode by insertion of comment balloons prior to returning the document to the author. Corrections were made in respect of grammar, punctuation, spelling, syntax, tense, referencing and language usage as well as to sense and flow. A guideline and comments were also supplied.

I trust that the document will prove acceptable in terms of editing criteria.

Yours faithfully

C Eberle

Catherine P. Eberle (MA: University of Natal)

Appendix 6

University of KwaZulu-Natal
Howard College School of Nursing
Desmond Clearance Building Floor 5
Durban
4041
23 February 2015

Hospital Manager
Ngwelezana Hospital
Private Bag X 20021
Empangeni3880

Dear Sir / Madam

Request for permission to conduct a research study

I Jabulane.G. Ngwenya masters student in Nursing (Critical Care & Trauma), University of KwaZulu-Natal request to conduct a study in the above mentioned institution. **Title of the study: An investigation into the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution.** The purpose of the study is to establish knowledge and practice of securing informed consent for surgery by health care workers. The study will be conducted during the month of March 2015 to December 2015. The researcher promises to show respect and protect the rights of the participants.

Your positive response to my request will have much appreciation. Thanks.

Yours faithfully

J.G. Ngwenya (Mr)

Student

B.R Bhengu (Prof)

Supervisor

Appendix 7



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

NGWELEZANA HOSPITAL
OFFICE OF THE MEDICAL MANAGER
Private Bag X20021, Empangeni 3880
Thanduyise Road, Ngwelezana Township
Empangeni, 3880
Tel: 035 - 9017273, Fax: 035 - 7941883
www.kznhealth.gov.za

Enquiries: Dr. A. Modiba.
Telephone: (035) 9017273

27th February 2015

Dear Mr JG Ngwenya

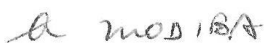
RE: PERMISSION TO CONDUCT RESEARCH AT NGWELEZANA HOSPITAL

I have pleasure in informing you that the permission has been granted to you by the institution to conduct research in: "An Investigation into the Knowledge and Practice of Securing Informed Consent by Health Care Workers in a Selected Hospital".

Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Please ensure this office is informed before you commence your research.
4. The Facility will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to the Facility.

Sincerely,



Dr A. Modiba.
Medical Manager
Ngwelezana Hospital

MEDICAL SUPERINTENDENT
NGWELEZANE HOSPITAL
PRIVATE BAG X20021
EMPANGENI 3880

uMnyango Wezempilo . Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope

Appendix 8



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Thanduyise Road, Ngwelezana Township, EMPANGENI, 3838
Private Bag X20021, EMPANGENI, 3838
Tel: 035 901 7105 Fax: 035 794 1883 Email Thandeka, Khanyile @kznhealth.gov.za

NGWELEZANA TERTIARY HOSPITAL
Office of the Chief Executive Officer

07/12/2015

Reference: NgweR-07/11/2015
Enquiries: Dr V N Khanyile.

Mr JG Ngwenya 210527940.

University of Kwa Zulu -Natal

School of Nursing and Public Health

Howard College Campus

Dear Mr Ngwenya

Permission to conduct research at Ngwelezana hospital.

Research title: "The investigation into the knowledge and practice of securing informed consent for surgery by health care workers (HCW) in a selected institution".

Protocol reference number: HSS/0417/015M

I hereby confirm receipt of relevant documents with respect to the above research which includes the approval of your study by the Provincial Health Departments Research Committee and you academic Institutional research ethics committee.

You may commence with your research at your earliest convenience.

Please report to the office of the Medical manager when you are ready.

I wish you all the best with your research.

Yours Faithfully

Dr TT Khanyile

Chief Executive Officer

Fighting Disease, Fighting Poverty, Giving Hope

Appendix 9



11 August 2015

Health Research & Knowledge Management sub-component

KwaZulu-Natal Department of Health

10-103 Langalibalele Street

Private Bag x9051

Pietermaritzburg

3200

Email: hrkm@kznhealth.gov.za

Dear Sir / Madam

Request for permission to conduct a research study.

I Jabulane G Ngwenya masters student in Nursing (Critical Care & Trauma), University of KwaZulu-Natal request to conduct a study at Ngwelezana Hospital. **Title of the study: An investigation into the knowledge and practice of securing informed consent for surgery by health care workers.** The purpose of the study is to establish knowledge and practice of securing informed consent for surgery by health care workers. I wish to collect the data during the month of September 2015 to December 2015. The researcher promises to show respect and protect the rights of the participants as indicated in the proposal.

Please find attached the proposal, questionnaire, checklist, information sheet and informed consent form.

School of Nursing and Public Health

Postal Address: University of KwaZulu-Natal, School of Nursing and Public Health, Howard Campus, Private Bag X 54001, Durban, 4000

Telephone: +27 (0) 31 2602499 Facsimile: +27 (0) 31 2601543 Website: www.ukzn.ac.za

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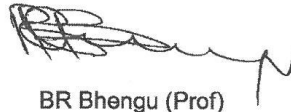
Your positive response to my request will have much appreciation. Thanks.

Yours faithfully



J.G. Ngwenya (Mr)

Student



BR Bhengu (Prof)

Supervisor

Appendix 10



health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address: 330 Langalibalele Street, Pietermaritzburg
Postal Address: Private Bag X9051
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3782
Email:
www.kznhealth.gov.za

DIRECTORATE:

Health Research & Knowledge
Management

Reference: 314/15
KZ_2015RP26_222

Date: 10 November 2015

Dear Prof B. Bhengu
Email: bhengub2@ukzn.ac.za

Approval of research

1. The research proposal titled 'The investigation into the knowledge and practice of securing informed consent for surgery by Health Care Workers (HCWs) in a selected institution' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at Ngwelezana Hospital.

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge

Chairperson, Health Research Committee

Date: 10/11/15

Appendix 11

Information Document

Introduction

You are invited to participate in a research study on an investigation into the knowledge and practice of securing informed consent by health care workers in a selected hospital in KwaZulu-Natal. The purpose of the study is to assess' knowledge and practice of securing informed consent for surgery by health care workers in order to provide holistic approach and care and increase our clinical knowledge and practices when explaining a surgical procedure to the patient. This research is part of the requirement for the masters' degree in Critical Care and Trauma Nursing which the researcher is currently studying for at the University of KwaZulu-Natal.

Information about participant's involvement in the study.

The study consists of a questionnaire which we ask you to choose the most appropriate one answer from each question.

Duration of the response

Your participation requires about 15 – 30 minutes in total.

Benefits

Your participation will directly contribute to the research for masters in nursing and contribute to the knowledge and practice of health care workers. There is no price or gift to be given for participating in this study.

Participation

Your participation in this study is voluntary and you have the right to withdraw from it if you wish at any stage without any penalties. The researcher will appreciate returning of fully completed questionnaire.

Confidentiality

The study is anonymous. Your name will not appear or written on the questionnaire for privacy, anonymity and confidentiality. No information will be pass on to any party for any reason without you being informed.

Project members

The researcher Jabulane.G. Ngwenya, Master of Nursing (Critical Care and Trauma Nursing) post graduate student at the School of Nursing, University of KwaZulu-Natal, 5th Floor Desmond Clarence Building, Howard College Campus. Contact no. 0725304626. Email address: jabulanegngwenya@gmail.com

Supervisor. Professor B.R. Bhengu, University of KwaZulu-Natal Howard College, School of Nursing. Contact no. 031 260 1134, Fax number: 031 260 1543. Email: bhengub2@ukzn.ac.za

Should you be unhappy or unclear with anything in the process of the study you can contact the research office in the University of KwaZulu-Natal. Contact details ass follows: Mr Premlall Mohun, Human and Social Science Research office, University of KwaZulu-Natal, Govan Mbeki Building, Westville Campus. Contact no. 031 260 4557, Email: HsrecHealthsciences@ukzn.ac.za

Appendix 12

Informed Consent Document

Consent to participate in research

The purpose of the study is the investigation into the knowledge and practice of securing informed consent for surgery by health care workers in a selected institution.

1. I have read and understand the above mentioned information and agree to participate in this study.
2. Terms and conditions involved about the study were explained to me.
3. I also understand that I can withdraw from the study at any given time should I wish to do so.
4. I have been informed that my participation will directly contribute to the knowledge and practice of HCW's.
5. I understand there is no price or gift to be given for participating in this study.
6. I have been told that my participation requires about 15-30 minutes.
7. I have been informed that my name will not appear on the questionnaire to protect my identity and for security reasons.
8. I have been provided with contact numbers to phone for clarity and if I have questions to ask.

Participant's signature Date.....

Signature of researcher..... Date

Appendix 13



5 May 2015

Mr Jabulane Goodman Ngwenya 210527940
School of Nursing and Public Health
Howard College Campus

Dear Mr Ngwenya

Protocol reference number: HSS/0417/015M
Project title: The investigation into the knowledge and practice of securing informed consent for surgery by Health Care Workers (HCWs) in a selected institution

Full Approval – Expedited Application

In response to your application received on 23 April 2015, the Humanities & Social Sciences Research Ethics Committee has considered the abovementioned application and the protocol have been granted **FULL APPROVAL**.

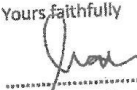
Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment/modification prior to its implementation. In case you have further queries, please quote the above reference number.

PLEASE NOTE: Research data should be securely stored in the discipline/department for a period of 5 years.

The ethical clearance certificate is only valid for a period of 3 years from the date of issue. Thereafter Recertification must be applied for on an annual basis.

I take this opportunity of wishing you everything of the best with your study.

Yours faithfully


.....
Dr Shenuka Singh (Chair)
Humanities & Social Sciences Research Ethics Committee

/pm

Cc Supervisor: Professor BR Bhengu
Cc Academic Leader Research: Professor M Mars
Cc School Administrator: Ms Caroline Dhanraj

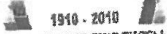
Humanities & Social Sciences Research Ethics Committee

Dr Shenuka Singh (Chair)

Westville Campus, Govan Mbeki Building

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Telephone: +27 (0) 31 260 3587/8350/4557 Facsimile: +27 (0) 31 260 4609 Email: ximban@ukzn.ac.za / anymam@ukzn.ac.za / mohunp@ukzn.ac.za
Website: www.ukzn.ac.za


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