INFORMED CONSENT: A POST-OPERATIVE ASSESSMENT

by

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DECLARATION

I declare that the research report hereby submitted as compliance with the requirements for the degree Magister Societatis Scientiae in Nursing to the University of the Free State is my own independent work and has not previously been submitted by me to another university. I further cede copyright of this research report in favour of the University of the Free State.

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The researcher hereby acknowledges the financial contribution of the School of Nursing, University of the Free State towards this study. Without this assistance the study would not have been possible.

DEDICATION

This work is dedicated to my Heavenly Father, without His strength and mighty power none of this would have been possible. Thank You Lord, for saving, guarding and protecting me through this season in my life.

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I wish to express my sincere gratitude to:

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“Dedicate some of your life to others. Your dedication will not be a sacrifice; it will be an exhilarating experience.”

Thomas Dooley

SUMMARY

The researcher's observation that patients do not always understand what they are consenting to was confirmed by various sources. According to Northouse and Northouse (1998: 270) and the South African Department of Health (2006: 11) patients' lack of comprehension in the process of informed consent is a general phenomenon taking place in every hospital setting due to factors such as lack of interpersonal relationships between the health care professional and the patient cultural practices as well as language.

A quantitative, descriptive study design was used to describe the process of obtaining informed consent prior to a surgical procedure in a hospital in the Northern Cape. Specific objectives were to: (1) describe the current practice of obtaining informed consent prior to a surgical procedure or an operation; and (2) make recommendations to relevant stakeholders for the purpose of improving the process of informed consent for an operation or procedure and thus the quality of health care.

A structured interview, based on a questionnaire, was used to gather information using convenient sampling as the primary sampling method because it was feasible and affordable. A pretest was done before the main data collection process, but the results were not included in the final results. Data collection took place over a period of 90 days and included 150 participants who all met the inclusion criteria determined by the researcher.

The researcher was assisted by a biostatistician who made use of Statistical Analyses Software (SAS) in order to analyze the data. Descriptive statistics namely means and standard deviations or medians and percentiles were calculated for continuous data. Frequencies and percentages were calculated for categorical data, and the analysis was done by a biostatistician. The researcher organized the study results according to tenets of capacity to consent to give meaning to the data and make it easy to understand. Figures

and tables were used to present the large amount of detailed information concisely and clearly. More than one third of the sample was vulnerable due to their low educational level and unawareness of their rights as patients. Unfortunately no effort was made to ensure that they fully comprehended what they were consenting to.

Recommendations focused on strategies to improve understanding by patients and to inform patients of their rights and responsibilities.

OPSOMMING

Die observasie van die navorser dat pasiënte nie altyd verstaan waarvoor hul toestemming gee nie, was bevestig deur verskeie bronne. Volgens Northouse en Northouse (1998: 270) en die Suid-Afrikaanse Departement van Gesondheid (2006: 11) is pasiënte se gebrek aan begrip tydens die proses van ingeligte toestemming ‘n algemene verskynsel wat plaasvind in elke hospitaal opset as gevolg van faktore soos gebrek aan interpersoonlike verhoudinge tussen die gesondheidssorgpraktisyn en die pasiënt se kulturele praktyke asook tale.

‘n Kwantitatiewe, beskrywende studie ontwerp was gebruik om die verkrygingsproses van ingeligte toestemming voor ‘n chirurgiese prosedure in ‘n hospitaal in die Noordkaap te beskryf. Spesifieke objektiewe was om: (1) die huidige verkrygingspraktyk van ingeligte toestemming voor ‘n chirurgiese prosedure of operasie te beskryf; en (2) aanbevelings te maak aan relevante aandeelhouers om die proses van ingeligte toestemming vir ‘n operasie of prosedure te verbeter, en dus die kwaliteit van gesondheid.

‘n Gestruktureerde onderhoud gebaseer op ‘n vraelys was gebruik om inligting in te samel, deur die gebruik van die gemaklikheidstoetsing as die primêre toetsingsmetode omdat dit uitvoerbaar en bekostigbaar was. ‘n Voorondersoek was voor die hoof data-insamelingsproses gedoen, maar die uitslae was nie by die finale resultate ingesluit nie. Data-insameling het plaasgevind oor ‘n periode van 90 dae en het 150 deelnemers ingesluit wat almal die insluitingskriteria bereik het, wat deur die navorser bepaal is.

Die navorser was bygestaan deur ‘n biostatistikus wie gebruik gemaak het van Statistiese Analise Sagteware (SAS) om die data te ontleed. Beskrywende statistieke naamlik middeletoetse en standaard afwykings of mediane en persentuele was bereken vir ononderbroke data. Frekwensies en persentasies was bereken vir kategoriese data. Die analise was gedoen deur

die biostatistikus. Die navorser het die studie resultate volgens beginsels van kapasiteit om toestemming georganiseer, om betekenis aan die data te lewer en dit verstaanbaar te maak. Figure en tabelle was gebruik om die groot hoeveelheid gedetailleerde inligting bondig en duidelik te presenteer. Meer as een derde van die steekproef was kwesbaar as gevolg van hul lae onderrigvlak en onbewustheid van hul regte as pasiënte. Ongelukkig was geen poging aangewend om te verseker dat hul verstaan waarvoor hul toestemming verleen nie.

Aanbevelings het gefokus op strategieë wat pasiënt verstandhouding verbeter en om hul in te lig van hul regte en verantwoordelikhede.

LIST OF ABBREVIATIONS

BICEP	The Brief Informed Consent Evaluation Protocol
CANSA	Cancer Association of South Africa
CEO	Chief Executive Officer
CD	Compact Disc
DC	District of Columbia
DENOSA	Democratic Nursing Organization of South Africa
DoH	Department of Health
DVD	Digital Versatile/Video Disc
GP	General Practitioner
HIV	Human Immune Deficiency Virus
HSRC	Human Science Research Council
MRC	South African Medical Research Council
REC	Research Ethics Committee
RN	Registered Nurse
SANAC	South African National Aids Council
SANC	South African Nursing Council
SAS	Statistical Analyses Software
UFS	University of the Free State
UK	United Kingdom
WHO	World Health Organization

GLOSSARY

Assault: Medical informed consent laws in South Africa has stated that: (1) assault is defined as the unlawful, intentional, application of force, against the body of another (or the threat thereof); (2) false or negligent representation by a health care practitioner may result in a claim of assault; and (3) in the case of no 'informed consent,' and thus services rendered, constituted assault against the bodily integrity of the patient, therefore the doctor/hospital may incur liability for (a) breach of contract; (b) civil or criminal assault (a violation of bodily integrity); (c) civil or criminal iniuria (a violation of dignity/privacy), or (d) negligence, as the case may be (Oldwage v Louwrens, 2000; Castell v De Greeff, 1994).

Caring: From a nursing perspective caring is viewed as the art of nursing, "*the way of being the comportment of the nurse in the sacred dance of healing with the client. In this meaning, caring becomes the ground of practice"* (Smith, 1999: 20).

Competency: "Autonomous individuals, who are capable of understanding and weighing the benefits and risks of a proposed study [surgical procedure or operation], are competent to give consent" (Burns & Grove, 2005: 196). However, patients with a mental or terminal illness, decreased consciousness or confinement to an institution might not be legally competent to participate in the research study (American Association of Critical-Care Nurses, 2006: Online). Competency is therefore a characteristic that is legally determined.

Comprehension: It is very important for the patient not only to have the information given to them by the healthcare practitioner but also to understand that information. Therefore the information should be in the patient's own language at his or her level of understanding and in his or her vocabulary – not in technical language or professional jargon (Pedroni & Pimple, 2001: 6).

Operational definition: Comprehension will be measured by means of a structured interview. (See Addendum F).

Consent Document / Form: "A written form, tape recording, or videotape used to document a subject's agreement to participate in a study" (Burns & Grove, 2005: 731). The hospital consent document / form will be use as standard procedure by the surgeon or nurse practitioner to obtain consent from the patient for a procedure or operation.

Dignity: Dignity can be considered as an other-regarding value that means respecting the dignity of others and as a self-directed value that means respecting one's own dignity or self-respect. Respect for the dignity of others is given more attention as the respect for one's own dignity. Dignity should subjectively be considered as something that include individual differences and eccentricities, and objectively as the basis of human rights (Gallagher, 2004: 587-588).

Disclosure of essential information: It is when the health care practitioner discloses specific information to each patient including: the description of a procedure or operation; description of risks and discomforts; description of benefits; disclosure of alternatives; assurance of anonymity and confidentiality; offer to answer questions; noncoercive disclaimer and option to withdraw (Burns & Grove, 2005: 193-194).

Health care provider: Means any person providing health services in terms of any law, including in terms of the: 1) Allied Health Professions Act, 1982; Health Professions Act, 1974; Nursing Act, 1978; Pharmacy Act, 1974; and Dental Technicians Act, 1979 (South Africa. National Health act 2003: 10).

Health worker: Means any person who is involve in the provision of health services to a user, but does not include a healthcare provider (South Africa. National Health act 2003: 12).

Informed Consent: "The prospective subject's agreement to voluntarily participate in a surgical procedure or operation, which is reached after assimilation of essential information about the surgical procedure or operation" (Burns & Grove, 2005: 739), as in the case of an adult, they have capacity to give valid consent to clinical interventions, provided they are sane and sober (South African Medical Research Council, 2002: 9)

Moral competence: Moral competence can be defined as the individual's capacity to recognize their feelings in a particular situation as they influence what is good or bad, reflect on these feelings, make a decision, and act in a manner that is beneficial to patients (Jormsri, Kunaviktikul, Ketefian & Chaowalit, 2005: 586).

Patient: Is a person who is physically or mentally ill or who is undergoing treatment for physical or mental illness (Blackwell's Dictionary of Nursing, 1997: 500). In this study, it refers to the people admitted to a public hospital in the Northern Cape for general surgery, but for the purpose of this study, the researcher will refer to a patient as a participant.

Respect: As a noun *"respect"* is defined as *"a feeling of admiration for somebody or something because of their good qualities or achievements."* As a verb, to respect is *"to have a very good opinion of somebody or something"* (Oxford Advanced Learner's Dictionary, 2010: 1245)

Voluntarism: "Means that the prospective subject has decided to take part in a study of his or her own volition without coercion or any undue influence" (Burns & Grove, 2005: 196).

INDEX

CHAPTER 2: Literature review

CHAPTER 3: Methodology

LISTS OF FIGURES

LISTS OF TABLES

LIST OF ADDENDUMS

CHAPTER 1

Overview of the study

1.1 INTRODUCTION

After completion of his studies in General Nursing Science at Henrietta Stockdale Nursing College (Kimberley), the researcher immediately started with clinical practice in a private hospital in Kimberley. He worked as a Registered Nurse (RN) in the Emergency Unit where different procedures are performed on a daily basis and where patients are prepared for theatre in specific situations. Usually the standard practice in hospital is that patients have to give informed consent prior to a procedure or an operation, but the researcher came across situations where consent was not obtained for a specific procedure or an operation, or where the proper procedure was not followed. Although it is the right of an individual not to be subjected to medical or scientific procedures without their informed consent (South Africa. Bill of Rights, 1996:2), the researcher also experienced that many patients who did give consent, had no comprehension of the procedure or operation for which they consented. And since it is the duty of the physician to promote and safeguard the health of the people and that the physician's knowledge and conscience are dedicated to the fulfillment of this duty (World Medical Association. Declaration of Helsinki, 2001: Online). Those situations interested the researcher so much that he decided to do a study on patients' comprehension of informed consent to a procedure or an operation. Thus, the researcher would start to explain the importance of informed consent for a procedure or an operation.

Informed consent is an essential component of a procedure or an operation, especially when it involves human beings. This phenomenon involves *'informing'* which is the transmission of essential information from the health

care practitioner to the patient, and *'consent'* which is the agreement of the patient after proper consultation (Burns & Grove, 2005. 193).

Informed consent is also an ethical issue and legal doctrine, which is essential for the conduct of ethical research on human beings (Burns & Grove, 2005: 193) or for the performing of procedures and operations.

Lastly, informed consent requires health professionals to provide information to patients to make an informal decision, that is why health care professionals should take the time to inform patients about treatment procedures, to ensure they understand (Northouse & Northouse, 1998: 266).

1.2 PROBLEM STATEMENT

The researcher's interpretation of ethical practice is that the principles of informed consent in research should apply to all treatment procedures. Informed consent was formally defined in the first principle of the Nuremberg Code (1947: Online) as

"The voluntary consent of human subject is absolutely essential. … This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision" (Levine, 1986: 425).

Four elements were identified in the Nuremberg Code, which will be discussed hereafter.

1.2.1 The elements of informed consent

The elements of informed consent include the following: (1) disclosure of essential information; (2) comprehension of consent information; (3) competency and decision-making capacity; and (4) voluntary consent (Burns & Grove, 2005: 193). Each of these four elements will be discussed briefly.

1.2.1.1 Disclosure of Essential Information

The healthcare practitioner disclose specific information to each patient including: the description of a procedure or operation; description of risks and discomforts; description of benefits; disclosure of alternatives; assurance of anonymity and confidentiality; offer to answer questions; noncoercive disclaimer and option to withdraw (Burns & Grove, 2005: 193-194).

The consent documents must be written in lay language and any technical jargon avoided (University of Washington. School of Medicine, 2008: Online). The diverse culture of the patients should also be considered to avoid conflict between the practitioner and the patients. Healthcare practitioners must take the role of a teacher in taking time to ensure that patients understand the critical information clearly. The amount of information will greatly depend on the patient's knowledge of the procedure or the operation (Molyneux, Peshu & Marsh, 2004: 2547).

Meade (1999: 134) says that the technical design of a consent document such as its specificity, conciseness and terminology used is very important and also the information it contains such as its "Purpose, Benefits and Risks" for the comprehension of a patient. Comprehension of consent information can lead to consenting or refusing to treatment regarding risks or benefits involve (Molyneux *et al.,* 2004: 2551).

1.2.1.2 Comprehension of Consent Information

When focusing on the element, comprehension, it's clear that patients do not fully understand the information given to them by health care professionals to constitute an inform consent regarding a treatment or research process (Northouse & Northouse, 1998: 269).

It is also very important for the patient not only to have the information given to them by the health care practitioner but also to understand that information (Pedroni & Pimple, 2001: 6). A full discussion on the comprehension of consent information will be held later in the study.

1.2.1.3 Competency to Give Consent

The patient must be competent to give consent for a procedure or operation. If the patient is not competent due to mental status, disease, or emergency, a designated surrogate may provide consent if it is in the patient's best interest (University of Washington. School of Medicine, 2008: Online).

1.2.1.3.1 Decision-making capacity

There are four generally recognized elements of decision-making capacity namely: understanding, appreciation, reasoning and expression of a choice (Appelbaum & Grisso cited in Eyler & Jeste, 2006: 555). The researcher will briefly describe each of these elements.

Understanding refers to a person's ability to comprehend information relevant to the treatment process and it is also most widely assessed of the four elements.

Another important element of the decision-making capacity is appreciation which means that an individual appreciate the consent-related information given to them if they understand the relevance of the presented details to his or her own situation.

Reasoning refers to a person's ability to manipulate presented information, especially to weigh the stated risks and benefits against alternative courses of action.

Expression of a choice refers to an individual's ability to indicate in a clear and consistent manner his or her decision about treatment.

1.2.1.4 Voluntary Consent

The patient's decision to consent must be voluntary, free of any coercion or promotion of benefits that is unlikely from the procedure or operation (University of Washington. School of Medicine, 2008: Online).

The presentation of the consent information can take place either orally or in writing although an oral presentation would provide opportunities for broader discussions and questions. It is also important that the health care practitioner should avoid biased language that might influence the patient's decision to participate (Polit & Beck, 2008: 177).

Patients should not feel forced, obligated or threatened to sign consent if they do not fully understand the information in the consent document (Molyneux *et al.,* 2004: 2548). They have the right to autonomy and self-determination (Northouse & Northouse, 1998: 266) to form an informed consent and if that is not upheld, these human rights are violated. Studies have shown that the research participants' levels of comprehension after receiving consent information are low (Kitching, 1990: 298; Gauld, 1981: 556).

Obtaining informed consent might be difficult at times, especially engaging disadvantaged and vulnerable patients where literacy and education opportunities are inadequate and where there are language and cultural barriers. However informed consent must be achieved through the use of cultural acceptable practices including the use of the patient's language of choice in both research and the treatment process (South Africa. Department of Health, 2006: 11).

The patient's lack of comprehension in the process of informed consent is a general phenomenon taking place in every hospital setting due to factors such as lack of interpersonal relationships between the health care professional and the patient (Northouse & Northouse, 1998: 270), cultural practices as well as language (South Africa. Department of Health, 2006: 11).

1.3 AIM

The aim of the study is to describe the process of obtaining informed consent prior to a surgical procedure or an operation.

1.4 OBJECTIVES

The objectives of this study are to:

- Describe the current practice of obtaining informed consent prior to a surgical procedure or an operation; and
- Make recommendations to relevant stakeholders for the purpose of improving the process of informed consent for an operation or procedure and thus the quality of health care.

1.5 CONCEPT CLARIFICATION

In a conceptual definition, a set of concepts defines another concept. The definition conveys the general theoretical meaning of the concepts, and uses words to describe its properties (Brink, 2006: 86).

An operational definition assigns meaning to a variable and describes the activities required to measure it. In other words, it describes how the variable under study is to be observed and measured (Brink, 2006: 87). Definitions of concepts specified to this study will follow in alphabetic order.

Competency: “Autonomous individuals, who are capable of understanding and weighing the benefits and risks of a proposed study [surgical procedure or operation], are competent to give consent” (Burns & Grove, 2005: 196). However, patients with a mental or terminal illness, decreased consciousness or confinement to an institution might not be legally competent to participate in the research study (American Association of Critical-Care Nurses, 2006: Online). Competency is therefore a characteristic that is legally determined.

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Voluntarism: "Means that the prospective subject has decided to take part in a study of his or her own volition without coercion or any undue influence" (Burns & Grove, 2005: 196).

1.6 RESEARCH DESIGN

For the purpose of this study a quantitative, descriptive study design will be used to examine characteristics of a single sample. A quantitative approach allows the researcher to analyze data using numerical information through statistical procedures (Polit, Beck & Hungler, 2001: 472). In this instance, the study involves using a structured interview as research technique to gather numerical information.

The descriptive research design describes a situation accurately and carefully as it takes place in the natural environment (Uys & Basson, 2005: 38). This process involves the identification of a phenomenon of interest and the variables within the phenomenon, the development of conceptual and operational definitions of the variables, and the description of the variables. The latter leads to an interpretation of the theoretical meaning of the findings and provides new information of the variables and the study population. This design is critically important for acquiring knowledge in an area in which little research has been conducted (Burns & Grove, 2005: 232-233).

The descriptive research design also identifies problems with current practice, justifies current practice, making judgments, or determining what others in similar situations are doing (Burns & Grove, 2005: 232). A descriptive research design also sometimes provides an origin for hypothesis or theory development (Polit & Beck, 2008: 274).

In general, a research design provides greater control in examining a research problem and thus improves the validity of a study (Burns & Grove, 2005: 231). Therefore the methodological challenge will be to design a study that will provide the strongest possible evidence to answer the research question in the presence of other challenges (Polit & Beck, 2008: 248).

1.7 RESEARCH TECHNIQUES

Uys and Basson (2005: 55) refer to a research technique as a method by which the researcher can obtain primary information, thus a structured interview will be used to gather that information for this study. During an interview, the researcher will obtain information from the participant through verbal communication. The content is similar to a questionnaire with the possible responses to questions carefully designed by the researcher (Polit & Beck, 2008: 414).

Structured data collection is a fixed rather than flexible approach of gathering information. Both the researcher and the participant are constrained during the collection of structured data. To enhance objectivity and reduce biases, constraints are imposed to advance consistency in what is asked and how answers are reported (Polit & Beck, 2008: 414).

In structured interviews, the researcher has increasing amount of control over the content of the interview. The questions that will be asked will be designed in a specified order by the researcher before the initiation of data collection. In some cases the researcher will be allowed to further explain the meaning of the question or modify the way in which the question has been asked so that the participant can better understand it. With a structured interview, data collection will be possible from participants that are very ill, illiterate or unable to express themselves (Burns & Grove, 2005: 396-397).

1.8 POPULATION

A population consists of elements, which are individual units that can be a person, event, behaviour, or any other single unit of a study. When elements are persons, they are referred to as participants who in this instance are patients. The population also known as the target population; are those participants who undergo a general surgical procedure at a public hospital in the Northern Cape. The accessible population is the portion of the general surgical patients[1] (target population) who are booked for general surgery to which the researcher has reasonable access, and the sample will be obtained from the accessible population (See Table 1.1) (Burns & Grove, 2005: 341-342).

TABLE 1.1: Booked general surgical cases for January – December 2009

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
43	41	44	60	51	46	66	57	65	60	84	27

1.9 SAMPLING

According to Burns and Grove (2005: 341), sampling involves selecting a group of people, events, behaviours, or other elements from a given population with which to conduct a study. A sampling plan defines the process making the sample selections; and sample denotes the selected group of people or elements included in a study. The study focuses on the process of obtaining informed consent, prior to an operation or procedure, in a general surgical ward, in a public hospital in the Northern Cape. For the researcher to be able to conduct an assessment of that nature, the appropriate sample would be to use surgical patients in a general surgical ward in a public hospital in the Northern Cape.

[1] See Annexure A for general surgical admission statistics.

1.9.1 Convenience Sampling (Nonprobability Sampling)

Convenience sampling entails using the patients booked for operations or procedures in the general surgical unit, which are the most conveniently available people as study participants (Polit & Beck, 2005: 341). According to the population statistics of 2009, the researcher will be able to select approximately 53 participants per month. Therefore, the researcher aims to have 150 participants over a period of three months for the study, as the sample for the structured interview, using the convenience sampling method.

Participants that will be included in the research study are those who had an operation or a surgical procedure at a public hospital in the Northern Cape, and who stayed at least one night after the procedure. Also those who are older than 18 years booked for a surgical procedure or operation will be considered. Others that will be excluded are the ones suffering from pain; or those who are under sedation; or those who have a decreased level of consciousness or a psychiatric co-morbidity (American Association of Critical-Care Nurses, 2006: Online). The structured interview will only be conducted on discharge of the participant.

1.10 PRETEST

A pretest is also known as the trial administration of a newly developed instrument to identify flaws or assess time requirements (Polit & Beck, 2008: 762). The items of the structured interview will be tested, by interviewing 10 participants drawn from the target population. Data gathered during the pretest will not be included in the final study. The researcher himself will do the pretest as well as the data collection. Questions such as, “Are there any statements that confused you? Or did you understand the question?” will be asked on concluding the structured interview, to determine if participants understood the questions asked.

The pretest answers will give an idea if questions need to be rephrased or excluded. The researcher will keep in mind that if the pretest fails to suggest

any changes, it probably indicates a flaw in the pretest rather than a problem free item (Streiner & Norman, 2003: 65-66).

1.11 DATA COLLECTION

Reasons for data collection in this study are to generate numerical data to address the research objectives. To collect data, the researcher first needs to obtain permission from the identified hospital in writing where the study will take place, and from the potential participants to ensure that their human rights are protected (Burns & Grove, 2005: 42).

According to Uys and Basson (2005: 103) the researcher has the following responsibilities prior to, during or upon completion of data-collection.

The researcher will first obtain written consent from the identified hospital where the study will be conducted, as well as approval from the Ethics Committee of the Faculty of Health Science at the nearest university. Before the interview, participants will be informed verbally and in writing of the purpose and nature of the study, the nature of the questions and the type of response to be expected of them (Uys & Basson, 2005: 103). The researcher will review the hospital consent documents to determine whether the participants had consented to the procedures or operations and whether that was recorded. The researcher will also review the detail information that was recorded and who gave that information to the participant.

Consent will be obtained from the participants to ensure that their human rights are protected. The researcher will ensure prior to data collection that there is a private area available to conduct the interviews to ensure privacy and confidentiality of the participants (Burns & Grove, 2005: 42).

The researcher will conduct the interviews, which will ensure that professionalism and respect for human dignity prevail. He will obtain an admission list on a daily basis of the patients booked for procedures and operations in the general surgical ward during the period of data collection. Data will be collected on the day of the participants' discharge from hospital to

ensure consistency in the data collection process and to avoid conflict between the participants and the health care practitioners prior to the procedure or an operation. The researcher would not expect of participants to provide information when they are disinclined to do so, or to act in any way contrary to their beliefs or principles (Uys & Basson, 2005: 103). Confidentiality of participant's information will be maintained because the researcher will not make any data regarding the participants available to others (Polit & Beck, 2008: 180). Data collection will take place over a period of 90 days from 01June 2011 to 31 August 2011. An estimate of five structured interviews per day needs to be completed. The pre-test will indicate if this estimation is possible (Uys & Basson, 2005: 105).

After conclusion of the structured interview the coding of questionnaires will be done by the researcher as soon as possible (Burns & Grove, 2005: 42). The completed questionnaires will be kept in a safe place by the researcher for a period of three years where after it will be destroyed.

1.12 VALIDITY

Burns and Grove (2005: 376) refer to the validity of an instrument as the determination of the extent to which the instrument actually reflects the abstract constant being examined. Face validity means that an instrument looks valid or appears to measure the content – although it is no longer considered acceptable evidence for validity, it still determines the willingness of the participants to answer the questions asked by the researcher (Burns & Grove, 2005: 376-377).

Content validity will be enhanced by three sources namely: the literature, content experts, and representatives of the relevant population. The researcher will do an extensive literature review by making use of electronic sources, books and journals. All the questions in the questionnaire will be based on the literature review. A panel of experts will critique the question formulation as well as the content covered by the questionnaire.

1.13 RELIABILITY

Polit and Beck (2008: 452) refer to an instrument's reliability as the consistency with which it measures the target population – thus the reliability of the structured interview will be the major criteria for assessing its quality and adequacy. The questionnaires will be completed by the researcher instead of fieldworkers, which gives more reliability to the measurement method. Because one person, namely the researcher will gather the data, consistency will be enhanced. He is familiar with the interview structure and is knowledgeable on how to record answers consistently. He will also try to ensure, that all the questions are answered by all the participants.

1.14 ETHICAL CONSIDERATIONS

Researchers are guided by three fundamental ethical principles, namely, respect for persons, beneficence and justice. These principles are based on the human rights that need to be protected in research, namely, the right to self-determination, to fair selection and treatment, to privacy and confidentiality, to be protected from discomfort and harm, and informed consent (Brink, 2006: 31). A discussion of these rights follows.

1.14.1 The right to self-determination

The participants will have the right to decide voluntarily whether to participate in the study, without risking unfair treatment. They will also have the right to ask questions, to give information, or to withdraw from the study at any time. No participant will be forced or coerced, which involves threats of penalties for failing to participate, or rewards for agreeing to participate (Polit & Beck, 2008: 171-172).

1.14.2 The right to fair selection and treatment

The convenient sampling method as mentioned previously in the study will ensure that no participant will be treated unfairly in the selection process. All participants in the study will be treated with the respect they deserve, for their beliefs, habits and lifestyles, as they are from different backgrounds and

cultures. They will be treated in a non-prejudicial manner, whether they decline or withdraw, after agreeing to participate in the study (Polit & Beck, 2008: 173-174). The researcher will make use of two languages, namely English and Afrikaans, because the majority of the population in this region of the country is competent in these languages.

1.14.3 The right to privacy and confidentiality

The researcher will ensure that the participants' privacy is maintained all through the study and that information regarding them will be kept strictly confidential (Polit & Beck, 2008: 174). The names of the participants will be kept strictly confidential and the information given by the participants will not be shared with the health care practitioners, to enhance complete confidentiality.

1.14.4 The right to be protected from discomfort and harm

No physical or physiological harm will be inflicted because the study involves no innovation therapy or treatment. No psychological or emotional harm will be inflicted because the study will not be more intrusive than it needs to be. No social or economic harm or discomfort will be caused. The structured interviews will be conducted by the researcher in a private place (Polit & Beck, 2008: 170).

1.14.5 Informed consent

The researcher will make use of informed consent as mechanism to ensure that the participants' rights are protected (Brink, 2006: 35), (See Addendum F) and therefore will take the following action:

- The researcher will design a consent document that will be used to obtain consent from the patients to participate in the study.
- The researcher will clearly define to the participants what their role is in the study to ensure that they understand their status in the study.
- Participants will be informed of the study goals and what type of data will be collected.

- The structured interview method will be described to them and the estimated time commitment from them. Information on who is funding the study and its academic requirements will be shared.
- The researcher will explain the convenient sampling method and how many participants will participate in the study.
- The participants will be informed if there is any possibility of harm or discomfort is to be experienced.
- The benefits of what the study will mean for quality of patient care and for the hospital will be discussed. Mention will be made that no stipend will be given to any participants for participating in the study.
- The researcher will ensure that the participants' privacy and confidentiality are protected at all times.
- The researcher will also indicate that participation is strictly voluntary and that failure to do so will not influence their treatment process in hospital.
- The participants will also be informed that even after consenting to the study, they will have the right to withdraw from the study or withhold information from the researcher.
- The researcher will provide information to the participants whom they can contact if they have further questions, comments or complaints (Polit & Beck, 2008: 176-177).

1.14.6 Dissemination of Results

The research study will be made available to the hospital management because they will directly benefit from the study and the patient indirectly. The hospital management is responsible for quality assurance and implementing of best practices, therefore the results of the study can be used to improve services. It means that the hospital management will have the power to influence future situations based on the results.

1.14.7 Benefits/Risks

There will be no direct benefit, but the results may benefit future patients. No risks, physical or social harm are foreseen. It will take their time, but some may even see it as a benefit, as the interview may relieve their boredom while waiting for discharge from hospital.

1.14.8 Remuneration

Participants will not receive a stipend from the researcher because participation will not involve any financial strain. The interviews will not be time-consuming or tedious therefore no incentives will be necessary (Polit & Beck, 2008: 175).

1.14.9 Publication

The researcher will ensure during publication that the participants' identity is kept in strict confidence and potential risks will be limited at all costs (Polit & Beck, 2008: 174-175).

1.15 DATA ANALYSIS

Uys and Basson (2005: 109) referred to descriptive statistics as statistics that are used for describing the data and include techniques whereby information is sorted, arranged, collected and presented in a scientific manner.

Descriptive statistics namely means and standard deviations or medians and percentiles will be calculated for continuous data. Frequencies and percentages will be calculated for categorical data. The analysis will be done by a biostatistician at Department of Biostatistics, University of the Free State (UFS).

1.16 VALUE OF STUDY

The study will be relevant to three groups namely: the health care practitioners that include the general surgeons and nurses, the policy-makers who are the hospital management, and the study population who are the patients.

Thus the study might demonstrate usefulness in three broad respects such as:

- Contribution to existing knowledge.
- The hospital management (policy-maker), health care practitioners and health care practices might find usefulness and meaning in the study.
- The results of the study might be generalized to relevant groups in other settings who stand to benefit from it.

The results might also contribute to theoretical knowledge of the profession. Furthermore, the results will be disseminated orally in community meetings and conferences for public scrutiny and critique. It will also be published in peer-reviewed journals for health care practitioners to use as theoretical information and research methodology (De Vos, Strydom, Fouché & Delport, 2005: 115-116).

1.17 TIME SCHEDULE

The researcher makes use of an accurate estimation of the activities to be performed, the resources and the possible hindrances because time and money are absolutely important in research (Uys & Basson, 2005: 101). It is also important to identify the sequence of activities necessary to execute the study, the persons responsible for carrying out each activity and the anticipated dates for commencing and completing each specific activity (De Vos *et al.,* 2005: 119). See Addendum B for a schematic illustration of the time schedule for the proposed study.

1.18 BUDGET

The administration component translates the time schedule into monetary values by providing a detailed budget. The budget identifies the resources required to accomplish the activities described in the time schedule and estimates the cost of each activity (De Vos *et al.,* 2005: 119). The researcher

will be responsible for all expenditure involved in the study. See Addendum C for a detail illustration of the budget for the proposed study.

1.19 STUDY OUTLINE

The study will be presented as outlined below:

- Chapter 1: Overview of the study;
- Chapter 2: Literature Review;
- Chapter 3: Methodology;
- Chapter 4: Data analysis, results and findings; and
- Chapter 5: Recommendations, limitations and conclusions.

1.20 CONCLUSION

The chapter provided a general background for the proposed study by identifying the phenomenon to be investigated and how this phenomenon will be valuable to health care. In this study the aim is to describe the process of obtaining informed consent prior to a surgical procedure or an operation. And the objectives are to: (1) describe the current practice of obtaining informed consent prior to a surgical procedure or an operation; and (2) make recommendations to relevant stakeholders for the purpose of improving the process of informed consent for an operations or procedure and thus the quality of health care. Additional to that, a research plan was designed that identified the major elements of the study, which include the research problem, framework, and the proposed methods to conduct the study. The following chapter however will start by describing the values of nursing to illustrate the role of the nurse in the process of obtaining informed in relation to that of the physician.

CHAPTER 2
Literature review

2.1 INTRODUCTION

Originally, nursing was viewed as a female dominated profession, therefore undervalued through the gender segregation (Klaich, 1990: 18). Viewed from this historical perspective, the evolution of nurse's professional identity in relation to female identity may be understood. Therefore, nurses of today have such difficulty in gaining recognition for the importance of caring in society where caring is undervalued (Ohlen & Segesten, 1998: 723).

According to Pera and Van Tonder (2005: 3), *"Nursing is a caring and inherently moral enterprise, and nursing practice is characterized by its long and noteworthy moral tradition."* This profession also teaches its practitioners to advocate the wellbeing of patients and their families with compassion, commitment, confidence, competence and a deep sense of moral awareness. The primary task of caring for those in need is best associated with the nursing profession because unlike any other profession or discipline, nursing practitioners have closer contact with patients and their families. Nurses are trained to respect human life, to protect human dignity and to maintain a person- centred approach in nursing (Pera & Van Tonder, 2005: 3).

Smith (1999: 19) contends that, *"no other discipline is developing knowledge related to how the quality of relationships facilitates health, healing, and the quality of life. This knowledge, generated within nursing will be essential for other disciplines in which caring relationships are also the foundation of their practice."*

Nurses (and others) can use their artistic skills as an opportunity to create and appreciate imagined possibilities in furthering a caring relationship with patients (Carper, 1978: 14). These artistic experiences allow spirits to connect with each other at much deeper levels (Lewis, 2003: 38).

Like in nursing, the care for human beings within many disciplines reflects values associated with caring and healing connected to persons, environments, relationships, dialogue, healing, choice, experiential process, behaviours, and economics (Lakomy in Gaut, 1993: 189). Roach (1997: 14) believes, for nurses not to care is almost as if they lose their being, because through their caring, they become more authentic human beings. The loss of nurses' caring can be identified not only in **their** interaction with patients, but in the nurse's own being (Lewis, 2003: 39).

2.2 CARING

In nursing, caring is the most basic **value** of all the professional values. Fowler and Levine-Ariff (1987: 138) argues that caring is the starting point of all other values inherent in the nurse-patient relationship. They also believe that caring, which is both a traditional and contemporary value, is the cornerstone of the moral art of nursing.

Smith (1999: 20) believes that from a nursing perspective, caring is viewed as the **art** of nursing*, "the way of being the comportment of the nurse in the sacred dance of healing with the client. In this meaning, caring becomes the ground of practice."* Therefore, Lewis (2003: 41) acknowledges that, *"the ground of nursing practice can be rooted in a soulful caring consciousness that integrates caring as being and that reaches infinitely beyond conscious knowing."*

Caring is part of the very nature of being human and should **not only be viewed as a professional attribute**. It represents a whole range of ethical, moral and religious concepts and principles, and does not only represent the present continuous form of the verb *'to care'* (Van der Wal in Pera & Van Tonder, 2005: 14), meaning as an action, procedure or technique, because it neglects other senses of the word such as *"caring as a virtue or quality of human character"* (Gaut, 1979: 79). Griffin (1980: 261) believes that the nursing action is motivated and energized by the emotional element of the caring activity, thus allowing one to call it caring. However, the importance of

caring is about doing something at the right time, in the right place when the unabled person needs it the most (Gendron in Leininger & Watson, 1990: 280).

It is evident that caring is an **ethic** because caring is based on knowledge, skills, experience and values, is culturally situated and is ultimately aimed at doing what is good and right, which is similar to that of ethics (American Association of Colleges of Nursing, 1998: 12). Bevis (in Leininger, 1981: 49) believes that only positive things can come from caring because of its nature. Not only for nursing, but also for many other health care services, caring is the central ethic (Klimeck in Leininger & Watson, 1990: 178). Although other health care services tend to focus rather on their characteristic professional knowledge and skill rather than caring (American Association of Colleges of Nursing, 1998: 14).

Caring is regarded as a commitment that entails **respect** for all persons and that patients should be respected as individuals because they matter as persons (Bandman & Bandman, 2002: 13).

Fry (1988: 48) argues that caring (1) is vitally important in directing the behaviour of nurses and other health professionals; (2) is an *'universal attitude'* that is acceptable across many generations and cultures; (3) identifies certain behaviours that are associated with perfectness in human behaviour; and (4) has a high regard for others. Further, caring does not only involve carrying out nursing procedures, but is based on an *"attitude of nurturing, and helping one another grow"* (Lindberg, Hunter & Kruszewski, 1990: 5).

Caring is the foundation of all nursing that is moral and focused on the wellbeing of patients (Pera & Van Tonder, 2005: 6). It includes growth and helping the patient to realize their optimal potential without neglecting them in the process (Van der Wal in Pera & Van Tonder, 2005: 15). Watson (1985: 54) argues that human care *"consists of transpersonal human to human attempts to protect, enhance, and preserve humanity by helping a person find meaning in illness, suffering, pain, and existence; to help another gain self-*

knowledge, control, and self-healing in which a sense of inner harmony is restored regardless of the external circumstances."

Van der Wal (in Pera & Van Tonder, 2005: 17) says this in summary, caring:

- *Humanizes science and technical procedure;*
- *Determines the quality of the connectedness (intentionality) between subject and object;*
- *Brings about true job satisfaction; and*
- *Accompanies curing and oversees healing.*

Caring for patients is not business but rather requires compassion, judgment, and advocacy because the nurse have the moral right and legal duty to advocate for patients (Integrated Health Service Plan, 2009: 1). Nurses who provide direct-care know that patients are not just another product, and that *"traditional nursing values of compassion and individualized patient care honour the humanity of patients. Nurses are both individually and collectively impelled and inspired by these values to advocate for patients at the bedside, at the bargaining table, and in the political arena"* (Integrated Health Service Plan, 2009: 2).

Nursing is a caring profession; therefore caring is described as professional behaviour that uses both art and science to address all dimensions of the patient in nursing practice. Caring *"encompasses the nurse's empathy for and connection with the patient as well as the ability to translate these affective characteristics into compassionate, sensitive, appropriate care"* (American Association of Colleges of Nursing, 1998: 8). The foundation for caring professional practice is provided by the professional values (Fahrenwald, Bassett, Tschetter, Carson, White & Winterboer, 2005: 47). Values integration must ensure that caring will be the foundation for the future nursing workforce and through the application of value-based behaviour, actualizes this caring (Fahrenwald *et al.,* 2005: 51).

The most significant attributes of caring are compassion, competence, confidence, conscience and commitment which corresponds to the image of the professional nurse (Roach, 1997: 183), while characteristics of the

excellent nurse are found to be competence, compassion and courage (Kilkus, 1993: 1324).

2.3 MORAL COMPETENCE

Society expects competent nursing practice for the pursuit of health care, forcing the nursing profession to require increasing competence of its practitioners at all levels. These levels might only be achieved through emphasizing and assessment of nursing practice-based competence among nurses (Jormsri *et al.,* 2005: 582). Competence is defined as a person's ability to meet the requirements of a job by producing quality outcomes (Zhang, Luk, Arther & Wong, 2001: 467). According to Parsons (2000: 29), competence refers to the knowledge and skills required in a profession as well as the ability to apply those knowledge and skills and therefore it goes further than just knowing; but requires doing. In order for an individual to achieve competence, he/she should have an up to date knowledge base and the ability to achieve desired outcomes through the performance of defined skills (LaDuke, 2002: 165).

Nursing competence is defined as *"the possession of basic nursing skills, including: (1) clinical competence – assessment and intervention skills, clinical judgment, and technical skills; (2) general competence – communication, critical thinking, and problem solving skills; and (3) moral competence – the individual's ability to live in a manner consistent with a personal moral code and role responsibilities"* (Lenburg, 2000: 11).

Moral competence can be defined as the individual's capacity to recognize their feelings in a particular situation as they influence what is good or bad, reflect on these feelings, make a decision, and act in a manner that is beneficial to patients. Therefore, moral competence can be seen as a combination of three dimensions: *"(1) moral perception as an affective dimension requires the individual's awareness of values and the expression of those values in clearly communicated messages about the same; (2) moral judgment as a cognitive dimension entailing the individual's choice of the*

value over another based on logical reasoning and critical thinking; and (3) moral behaviour as a behavioural dimension involving the individual's application of values to action by being willing to receive public affirmation for the choice, and consistent repetition of the same" (Jormsri *et al.,* 2005: 586). For these reasons, nurse practitioners not only depend on technical knowledge and skills but also on values, beliefs and ethics, assisting them in their decision-making process.

Taylor (1995: 1) argues that modern society expects nurses to be aware of moral competence to help them work through ethical issues they encounter in their daily practice. Further, nurses who are morally competent can be trusted to put patient's interests first; they can be accountable for themselves, the patients, the caregiving team and society; and they can be an effective patient advocate and mediator of ethical conflict among patients, significant others, health care team members, and other interested parties (Jormsri *et al.,* 2005: 583).

Scanlon and Glover (1995: 1516) believe that commitment to and familiarity with nursing values are prerequisites for moral competence in nursing practice. Nurse practitioners' values derive from familial and religious upbringing as well as work experience in nursing. Nursing values influences nurses' views of goals, strategies, and actions, which also serves as a guide when engaging in ethical competent practice and in confronting contemporary ethical challenges. Normally, nurse practitioners' life experiences consists of their ordinary life and practice made up by nursing knowledge which is embedded in beliefs, values and traditions, religious and cultural observances, and other relevant episodes of life (Will, 2001: 107). Considering all these concepts, the acquirement of nursing values takes place through personal, social and professional experience (Fry, 1994: 12).

2.3.1 Personal values

Personal values are the representation of nurses' beliefs of what it means to be and act as a good nurse. Most nurses use their personal values as resources in their ethical decision-making. Families, religious figures and friends have the greatest influence on ethical decision-making; these

influences are driven by personal values and beliefs (Blancett & Sullivan, 1993: 9-10). Scanlon and Fleming (1989: 978) argue that the process of determining, assessing and exploring personal values, and then identifying the impact of these values on nursing practice are vitally important when dealing with ethical issues. Also these values that consists of goals, attitudes, interests, feelings, convictions and beliefs accepted by nurses, guide their thinking, action and interactions with patients (Fagermoen, 1997: 435).

2.3.2 Social values

Social values are complex standards that guide individual conduct in many ways, for example, directing an individual to take a particular position in a specific social situation. At the same time, social circumstances, including religion, culture, politics and economic considerations, have an impact and form an individual's value system. Social values therefore soften personal values (Jormsri *et al.,* 2005: 584).

Leddy and Perry (1993: 75) believe that social values are also constructed through socialization of the nurse, for example, when the student nurse is practising in the clinic and in the school of nursing, the same process will continue in their professional life after completion of their basic and advanced education.

Through the process of socialization, the nurse is also confronted with social problems of both him/herself and the patient. Social problems are defined by the objectivist as *"any condition that has been identified by scientific enquiry and values as harmful to society and human wellbeing"* (Goode, 1997: 56), meaning that the objectivist acknowledges the public or people's concern, but views the concrete threat or condition more important, problematic and theoretically interesting. As a result, the objectivist sees the existence of a social problem as an objective fact, of which the concrete damage it causes in society can be measured by the undesirable conditions. The constructivist on the other hand, views the public or people's concern as important, problematic and interesting from a theoretical point of view. Therefore, regards the threat or condition as a given fact (Du Toit & Van Staden, 2005: 199-200).

Against this background, South Africa is apparently confronted by many social problems, for example, substance abuse, poverty, suicide, prostitution, divorce, rape, juvenile delinquency, domestic violence, abortion, corruption etc. Alarmingly, many high profile leaders are guilty of some of these behaviours, and thus contribute to the moral decay in the country. For example, Jacob Zuma, the President of South Africa, who has been divorced from Nkosazana Dlamini Zuma in June 1998, having four children between them. He also had the following charges against him, (1) in 2003, corruption and fraud; (2) in 2005, charge of rape; and (3) in 2006, he failed to disclose his assets after taking office as president. Also some other controversial issues such as, in 2006, during the rape trial, he stated in court that he took a shower after having unprotected sex with a HIV-infected woman, to cut the risk of contracting HIV, whilst he was the head of the National Aids Council of South Africa (SANAC). In 2009, he had a child out of wedlock, and clearly through both these acts, he put the health of his other spouses at risk because culturally, he is a polygamist (Wikipedia, 2011: Online). Through the process of socialization and development of acceptable social behaviour these examples influence the population of the country and contribute to existing social problems. Social values influence the development of personal values and indirectly professional identity.

2.3.3 Professional Identity

Professional identity is viewed as having a direct connection to everyday nursing practice, and it represents the nurse's philosophy of nursing, in other words, the nurse's conception of what it means to be and act as a nurse. As such it serves as a basic frame of reference in nursing practice when dealing with relevant problems, goals and approaches. More precisely, *"professional identity is defined as the values and beliefs held by the nurse that guide his/her thinking, actions and interaction with the patient"* (Fagermoen, 1997: 435).

Ohlen and Segesten (1998: 721-722) holds that professional identity is also regarded as an essential part of the nurse's personal identity, and a precondition for the development of a professional identity is the existence of

a personal identity. Professional identity is described as having the feeling similar to a person who can practise nursing with both skill and responsibility, and it also implies the nurse's awareness of personal resources and limitations. The nurse's professional identity refers to two aspects which are: (1) the commonality of the nursing profession; and (2) the special way the nurse utilizes this commonality within the profession. Hence, the concept, nurse professional identity can be approached from either the common goals which all nurses have, or from the nurse's self-perception as a professional. Professional identity is the perception of the individual nurse of him/herself in the context of nursing practice. The development of a nurse professional identity is viewed as a process of balancing between external and internal attributes of professionalism. The central personal motivating factors in this process consist of will, insight and ability.

Furthermore, Ohlen and Segesten (1998: 724) believe that the nurse has not reached genuine professional identity until he/she has experienced the inception, infancy and growth of the development of trust, autonomy, initiative and industry. The development of professional identity is a continuing process, and the possibility of strengthening identity and abilities to reach progress, will always exist (Bunkers, 1992: 154).

Fagermoen (1997: 435) and Mannahan (1989: 593) argue that social interaction and self-reflection are essential processes through which self-formation and consequently professional identity emerges. The internalization of values is an important part of this process because for the individual to become a social being, also involves the development as a moral being. Socialization into the nursing profession occurs amongst others through professional development activities to internalize professional values.

From the literature review, it emerges that concepts of self-esteem, self-image and role of the nurse are closely related to the concept of professional identity of the nurse. Professionalism is also closely related, but professional identity is rather an antecedent of professionalism (Fagermoen, 1997: 434).

As a precondition for a strong and therapeutic relationship with a patient, a nurse should have a positive self-image, which is a reflection of the

professional identity. Career advancement and advanced education help nurses to develop a more positive self-image, and professionalism, scientific approach, empathy and discernment are seen as underlying dimensions of the nurses' professional selves (Porter & Porter, 1991: 208). Fagermoen (1997: 434) argues that *"professional attitudes or professionalism is seen as a framework used by professionals in identifying their work in a social role context; thus, the emphasis of professionals' value commitments is specifically on the professional status of their work."*

Nurses' role responsibilities are considered as a product of a well-developed professional identity, which assists the nurse to care for the whole person and meet their human needs. The nurses' roles also include that of a change agent, patient advocate and contributor to the profession (Leddy & Perry, 1993: 75). Nurses' roles are also regarded as bureaucratic, professional and service roles (Kinney, 1985: 170).

From the perspective of moral philosophy, values such as respect for human dignity, autonomy and justice are considered to be of moral nature (Beauchamp & Childress, 1989: 58). Thus, the nurse who is acting in the interest of the patient's wellbeing is actualizing moral values. In addition, working as a nurse is important for the individual too, and it provides for realization of self-oriented values.

Fagermoen (1997: 436) argues that both moral and work values are the basis upon which the specific nature of identity generates. Fagermoen thus suggests that there are institutionalized sets of values inherent in nursing which becomes the basis for each individual when developing their value commitments regarding nurses' work and morality. Hence, values are inherent in developing and sustaining professional identity and are expressed in nurses' performance and interactions with others in reaching the desired goals for each one. In addition, providing nursing care is a form of self-presentation through which nurses express their values and communicate their personal meanings (Katims, 1993: 269). Various authors view respect as the pivotal value (Beauchamp and Childress, 1989: 73; Downie & Telfer, 1970: preface).

2.4 RESPECT

According to the Oxford Advanced Learner's Dictionary (2010: 1245), the noun *"respect"* is defined as *"a feeling of admiration for somebody or something because of their good qualities or achievements."* As a verb, to respect is *"to have a very good opinion of somebody or something."*

Concepts like admiration, esteem and deference are sometimes used synonymously with respect (Kelly in Leininger, 1990: 74). Respect is distinguished from these concepts on the basis of its quality as an ethical principle, whereas these concepts have no association with ethics or morality. In addition, while deference, esteem or admiration may depend on circumstance, respect is considered a right rather than a reward for a particular behaviour or personal characteristic.

Respect is viewed as the central moral attitude from which all other moral principles are explained, therefore considered to be the primary ethical principle (Downie & Telfer, 1970: 33-34). Rokeach (1979: 69) views respect as a human value that addresses justice, honour and human dignity. Respect is considered a humanity principle that acknowledges human beings as autonomous agents who naturally have inherent intrinsic value (Milner, 1986: 86). Levine (1977: 846-847) considers respect to be the core value of human rights that honours other's freedom of choice, worthiness as humans and opportunity for equality. Values of human dignity, intrinsic worthiness, autonomy, individual uniqueness and self-determination reflect in these definitions of respect. As a nursing ethic, respect *"is not the display of one's moral rectitude in times of crises, but is the day-by-day expression of one's commitment to other persons and the ways in which human beings relate to one another in their daily interactions"*

Kelly (in Leininger, 1990: 75) considers respect as both an antecedent and prerequisite to caring as an ethic, and not only a component of caring. Meaning, respect to caring is a major distinguishing feature. As an essential

component of the caring process, respect is considered to have its origin from a deep interest in humanity.

From a caregiver's perspective, respect is demonstrated through the **interaction** with patients by acknowledging their presence, uniqueness and individuality by means of empathy, support and acceptance of a person's unique cultural heritage and the capacity to show regard and consideration to their cultural orientation (Forrest, 1989: 815). Leininger (1989: 251) believes that respect for a person's cultural rights suggests respect for their basic human rights.

Caring and respect **share** in many ways conceptual characteristics. General caring may be differentiated from respect based on *"conceptual quality and degree of abstraction,"* where respect is considered one component within the broader concept of caring. While caring is considered a nursing ethic, the ethic of respect cross the boundaries of nursing to have influences at all levels of society and while caring requires a degree of knowledge about an individual patient, respect for another human being does not (Browne, 1993: 213).

Respect is also associated with the concept of presence. Presence involves the nurse's communication of a deep sense of availability to the patient (Gardner, 1985: 316). Browne (1993: 213) stated that respect appears to be the unnoticed component of presence and the element that is responsible for the formation of presence. Respect, however, has an unconditional nature while presence is conditional on circumstance and situational context. Therefore, as a nursing ethic, respect must occur without exception in all interactions with patients.

The concept of humanized care is also closely related to respect (Howard, Davis, Pope & Ruzek, 1977: 12). Respect forms the basis for many conditions necessary for humanized care that is characterized by viewing patients as unique, autonomous, irreplaceable, whole persons with inherent worthiness during activities such as shared decision-making through reciprocal relations with patients (Browne, 1993: 213).

The concept of confirmation also has relations to respect and its attributes share similarities to those of presence. Confirmation involves having one's state of being acknowledged and legitimated through the caregiver's actions that promote personal growth and personal healing. Respect in its primary form transpires as a differentiated characteristic of the general concept of confirmation and thereby preserving a person's dignity (Drew, 1986: 39).

2.5 DIGNITY

Dignity can be considered as an other-regarding value that means respecting the dignity of others and as a self-directed value that means respecting one's own dignity or self-respect. Respect for the dignity of others is given more attention as the respect for one's own dignity. Dignity should subjectively be considered as something that includes acknowledgement of individual differences and eccentricities, and objectively as the basis of human rights (Gallagher, 2004: 587-588).

Dignity seems to be both a duty and a right in professional codes and in human rights frameworks. The South African Nursing Council Draft Charter of Nursing Practice, Code of Conduct and Ethics of Nursing (2004: Online) states: *"Nurses must respect, uphold and safeguard the right of healthcare users to privacy, confidentiality and dignity."*

The United Nations' Universal Declaration of Human Rights (1948: Online) states that: *"All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."*

The Constitution of the Republic of South Africa (1996: 6) states under human dignity that: *"Everyone has inherent dignity and the right to have their dignity respected and protected."*

Mairis (1994: 947) stated that: *"Dignity exists when an individual is capable of exerting control over his or her behaviour, surroundings and the way in which he or she is treated by others. He or she should be capable of understanding*

information and making decisions. He or she should feel comfortable with his or her physical and psychosocial status quo."

Haddock (1996: 924) stated that: *"dignity is the ability to feel important and valuable in relation to others, communicate this to others, and be treated as such by others, in context which are perceived as threatening. Dignity is a dynamic subjective belief but also has a shared meaning among humanity."*

2.5.1 Dignity and nursing practice

The researcher often found the concepts *'dignity'* and *'respect'* together, which are considered as two fundamental professional values. Although there are many professional values, these two are significant. As previously mentioned, dignity can be considered as an other-regarding value – a person benefits others, and as a self-regarding value – a person mostly benefits himself or herself. Respect has also been discussed both in itself – how nurses should show respect, and as respect-for – as dignity, autonomy, privacy and so on. Respect for one's own dignity refers to the judgment and recognition of one's own value and worth, both as a human being and a professional (Gallagher, 2004: 591).

Jormsri *et al.* (2005: 590) suggest that respect for dignity, human values and rights are important for maintaining or promoting nursing values, and respect for other's dignity and humanity is important, because everyone has their own values. They further suggest that respect for persons is regarded in two ways: as individual autonomy and self-determination; and as interdependence and interconnectedness. Dehumanization of patients often occurs when nursing care takes place without respect (McGee, 1994: 681). Jacobs (2001: 17) views respect for human dignity as the essence of caring in nursing. Human dignity also applies in interventions such as maintenance of safety, provision of privacy, sensitivity to ethnic and cultural differences, and professional accountability (Fahrenwald *et al.,* 2005: 47).

2.6 ETHICS IN NURSING PRACTICE

More than a century ago, the nursing profession had a concern for ethics in nursing. Therefore an oath was introduced in the form of the Nightingale Pledge for nurses completing their training (Pera & Van Tonder, 2005: 3). According to Fowler (1989: 955) nursing ethics is a social ethic, which is not confined to bedside nursing but rather focused on the enduring of ideal service. Nurses are often confronted by divergent moral beliefs in their daily practice. They often find themselves in conflict situations between the values systems of patients, health care institutions, and other health care professionals and are required to make moral decisions and bear the consequences of such decisions (Hamric, 2000: 199-201; Dierckx de Casterlé, Janssen & Grypdonck, 1996: 330; Rodney & Starzomski, 1993: 23-26; Ericksen, 1989: 23-24). Moral decision-making is based on morality.

Morality often refers to the *'norms of conduct'*, which is very often upheld and adhered to by individuals and groups of people. Therefore, a moral rule's violation may cause a group's disapproval leading to mistrust or hostility (Pera & Van Tonder, 2005: 5; Jormsri *et al.,* 2005: 591). Thompson and Thompson (1992: 5) refer to morals as the *'ought's'* and *'ought nots'* of life meaning *'what we should or should not do.'*

Generally, members of a particular society widely share norms about right and wrong human conduct. These norms form a firm social agreement and encompass standards of conduct, which include moral principles, rules, rights and virtues (Pera & Van Tonder, 2005: 5; Jormsri *et al.,* 2005: 591; Zhang *et al.,* 2001: 468; Lenburg, 2000: 11; Taylor, 1995: 2). Beauchamp and Childress (2001: 3-5) refer to this notion that all morally serious persons share a *'common morality'*. This is the same in most professions that contain professional morality with standards of conduct that are acknowledged by those professionals who are serious about their moral responsibilities. While morality seems to be group oriented, values are more individually oriented.

A value is defined as a position that a person has taken, which is expressed through conduct, feelings, imagination, and knowledge, and is connected to a person's identity and lifestyle. There are two types of values, which develop

from *"association with other people, from life experiences, from the environment and from within the self."* These are known as intrinsic and extrinsic values (Steele & Harmon, 1983: 1-2).

Tschudin (1993:2) believes that values are connected to the meaning of life. According to Steele and Harmon (1983: 1), *"a value is an affective disposition towards a person, an object or an idea and represents a way of life."* Values are formed through association with other people, through specific experiences and also relate to our identity (Jormsri *et al.,* 2005: 586; Will, 2001: 107; Blancett & Sullivan, 1993: 9-10).

According to Pera and Van Tonder (2005: 8), *"values arise from cultural and ethnic backgrounds, family traditions, peer group ideas and practices, as well as political, educational and religious philosophies."* Since the primary goal of nursing is to provide the best care for each patient, nurses constantly have to make ethical decisions regarding patient care. Pera and Van Tonder (2005: 7-8) further argue that, *"the knowledge of self contributes to ethical decision-making and nursing practice,"* therefore it is important for nurses to know themselves as individuals, what they believe in and what they value. However, nurses should never impose their own values on patients, since patients have their own decision-making capabilities based on relevant information (Thompson & Thompson, 1992: 75-76).

It is absolute important for nurses to know and understand their own value system since these values influences the nurse-patient relationship and professional nursing practice (Borawski, 1994: 17-18; Blancett & Sullivan, 1993: 9-10; Scanlon & Fleming, 1989: 978). Thompson and Thompson (1990: 20) argues that both the nurse and patient enters into a mutual agreement, namely to care for the patient with respect and dignity and to support their right to self-determination. Meaning, that value ethics plays a fundamental role in nursing ethics.

Wright (1987: 7) believes that ethical decision-making is influenced by values in three ways. Firstly, *'values frame the problem,'* meaning, we identify or fail to identify a problem, based on the values we bring to a situation. Secondly, *'values provide alternatives for the resolution of a problem.'* Thirdly, *values*

direct judgments,' meaning that the judgment and resolution of a problem are directed by the values we wish to uphold or promote. Therefore, it is important to recognize the role of values in ethical decision-making to ensure that important values are not overlooked when a decision is made.

Ethics has several meanings, which is often used to refer to a particular group of individuals' practices or beliefs. Or the group's expected standard and behaviour as described in their code of professional conduct. It *also "refers to a philosophical method of enquiry, which enables us to understand the moral dimensions of human conduct."* Therefore, ethics can be seen as an activity or a *'particular method of enquiry'* a person undertakes in reaction to certain questions regarding human welfare (Creasia & Parker, 1991: 149). According to Tschudin (1993: preface) ethics is closely related to nursing because nursing and caring is synonymous and caring is unavoidably an ethical value.

Fowler and Levine-Ariff (1987: 186) argue that because of nursing's distinctive concepts and caring function, its own particular means of expression, it has a distinctive nursing ethic. This unique nursing ethic is often expressed in codes of ethics.

2.6.1 Codes of ethics

Weis and Schank (2000: 201) state that professional values are standards for action, providing a framework for the evaluation of nurses' behaviour. Nurses in practice, consistently make decisions that define and maintain a certain ethic. They maintain that a professional code of ethics is a way of understanding professional commitments: a statement of values and a claim of goals. These professional values become the foundation for standards of practice, producing an equivalent shift in professional identity and behaviour (Weiss and Schank, 1991: 50).

Various codes or pledges contain common guidelines that help nurses when making ethical decisions. Similar to other professions, nursing has its own professional code of ethics that contain rules and moral standards applicable to nursing conduct. Although some codes that address specific issues are unclear on matters of etiquette or broad statements, most do not give

guidance on conduct to the nurse practitioner in specific situations. Nursing codes serve both as a guide for members of the profession and a declaration to the public they serve (Pera & Van Tonder, 2005: 6).

Like other established professions, the nursing profession often tends to clearly define the moral standards guiding their professional conduct. Professions greatly depend on its members' integrity to carry out their work in the best interest of whom they serve. Although codes of ethics cannot provide answers to all moral dilemmas in daily practice because of their limitations, it does provide a framework for governing professional practice, which include: general rights, duties, values, and policies (Thompson, Melia & Boyd, 1988: 57-58).

The South African Nursing Council Draft Charter of Nursing Practice, Code of Conduct and Ethics of Nursing represent a set of ideals, of which the interpretation and application are central to practice. The Code also provides guidelines for nursing practice throughout the country. It is considered a hallmark of professionalism; it states that a nurse has an obligation to individuals, to society and the country, to the profession, to nursing co-workers and workers in other fields, and to the self (SANC, 2004: Online). Professional values are therefore seen as the fundamental values providing direction for nursing practice.

According to the SANC Draft Charter of Nursing Practice, Code of Conduct and Ethics of Nursing (2004: Online), the following values are fundamental to nursing:

Respect for the healthcare user as a total being i.e.

Respect for his or her:

- *Body, psyche, spirit*
- *Individuality, beliefs and traditions*
- *Privacy and the right to confidentiality*
- *Right to decision making regarding his or her care*
- *Possessions*

- *Vulnerability, being conscious or unconscious, in the absence of the necessary strength, will or knowledge*

Respect for all aspects of human life including:

- *The value of life*
- *The beginning and end of life*
- *The vulnerability of life*
- *The quality of life*

Commitment to:

- *Accountability for safe practice*
- *Compassionate involvement*
- *Personal integrity*

Although there are good guidelines and codes, it does not guarantee that professional people will adhere to those guidelines. For example, it was alleged that the former Minister of Health, Manto Tshabalala-Msimang was convicted of theft by the Lobatse Magistrate's Court of stealing a patient's possessions and hospital equipment, whilst she was still a Medical Superintendent at the Athlone Hospital in Botswana in the mid 1970's (Solomon, 2011: Online). Other examples are, the deaths of 29 neonatal babies at the Cecilia Makiwane Hospital in East London, in January 2011 (Business live, 2011: Online), and the National Public Servant strike in 2010 in which many nurses participated and members of The National Defence Force had to work in hospitals, looking after patients (Seria & Cohen, 2010: Online).

Similar to nursing practice in South Africa, the practice of medicine in Western democratic countries has undergone a radical transformation over the past four decades. In the relationship and practices between medical professionals and their patients, ethical consciousness and sensitivity now occupy a central place. Ethical codes, principles, and committees have been established to serve as formidable watchdogs to protect medical patients from potential abuses, and to provide oversight over medical decisions and practices. This transformation has led to a heightened recognition and respect for patients' rights of self-determination and autonomy from the traditional paternalistic,

general belief that *'doctors know best'* (Frimpong-Mansoh, 2008: 106; Kluge, 2007: 411; van Kleffens, van Baarsen & van Leeuwen, 2004: 2326; American Nurses Association, 2001: Online; United Nations, 1948: Online).

Globally in medical practice, obtaining competent individual patients' (or their designated proxy's) voluntary informed consent is now, in principle, a fundamental ethical requirement. The South African Constitution act 1996 (Act No. 108 of 1996), in particular, section 12 (2) of the Bill of Rights maintains that *"Everyone has the right to bodily and psychological integrity, which includes the right (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiment without their informed consent."*

2.7 ELEMENTS OF INFORMED CONSENT

The term *'informed consent'* may be described as an interactive process between patients and doctor that allows the patient to make an informed decision regarding his or her treatment. There are medico-legally four essential elements which constitutes the validity of informed consent: (1) disclosure of essential information, (2) the patient's comprehension of the consent information, (3) the patient's competency to give consent, and (4) the voluntary nature of consent without any influence or coercion from other parties including health professionals or relatives (Ashraff, Malawa, Dolan & Khanduja, 2006: 140; Burns & Grove, 2005: 193).

Informed consent is essentially a legal doctrine, because it is designed partially out of recognition of a patient's right to self-determination and partially out of the doctor's duty to give the patient sufficient information to make an 'informed' choice. It is also considered to be the process whereby explicit communication of information is provided relevant to the decision of whether or not to have a particular treatment (Dyer & Bloch, 1987: 12). Informed consent also implies that it is the patient's right to confirm or deny consent based on an explorative procedure or treatment and the knowledge of suspected risks (Usher & Holmes, 1997: 50).

The patient's right to practice self-determination is protected by legislation. Also, the patient's decision on whether to consent or refuse a procedure, is based on their right to receive sufficient information in order to make an informed choice. The individual responsible for performing the procedure or operation must explain to the patient the nature of the procedure, benefits, alternatives, and the risks and complications. Therefore, the most important part of informed consent is not the consent document, but rather the discussions between physician and patient (Fiesta, 1999: 6).

Informed consent is also a legal prerequisite to any surgical procedure and not only an important ethical consideration. It is well documented that much of the information given to the patient during a consultation, is often forgotten and/or misunderstood (Ley, 1972: 23). It has also been shown that the patient has forgotten the information that was discussed with the doctor, within five minutes of departing from the consultation room (Kitching, 1990: 298). Of all the information given, the patient only remembers approximately 20%. However, if there is additional visual or written information, this may be increased to 50% (Gauld, 1981: 556). If there is inadequate communication between the doctor and the patient, complaints and legal actions may follow as a consequence (Green, 1996: 49). In the past, doctors were concerned that too much information might increase anxiety; therefore they withheld information from patients. However, studies have shown that patients are keen to receive more information (Weinman, 1990: 304; Mayberry & Mayberry, 1996: 205-208).

2.7.1 Disclosure of essential information

Informed consent cannot be endorsed without disclosure of sufficient information that enable patients to make a decision that aligns with their value system, personality, religion, and other ways of life. The patient's right to have information regarding their medical diagnosis and treatment, is based on their right to autonomy; therefore the right to informed consent is of legal nature. Some of the advantages of information disclosure include patient's compliance to treatment, a better doctor-patient relationship, and a better outcome (Kitamura, 2005: 627). In addition to that, the benefits of relevant

disclose information to patients, were recognized by clinicians for a very long time. They often believed that the disclosure of information *"may endanger patients' psychological health and lead to self-destructive behaviour"* (Bamford, Lamont, Eccles, Robinson, May & Bond, 2004: 151). However, Miller and Mangan (1983: 223) suggest that when a patient receives detailed information before a frightening medical procedure, the patient becomes more accepting of the procedure, leading to reduced anxiety and increased adjustment during and after procedure. Thus, disclosure of information can benefit a patient's wellbeing who desires this information in order to exercise their autonomous decision-making which is also supported by the notion that informed consent can lead to improved conditions in patients.

Azoulay *et al.* (2005: 987) suggested that both the patient and family members' levels of psychological distress are reduced when they have received detailed information. For example, family members of patients in intensive care units, will report more post-traumatic stress reaction if they felt that incomplete information was given, that they could not understand what was imparted and that insufficient time was spent to share information about their loved ones.

Some researchers believe that education plays an important role in forming patients' attitudes towards medical information – which includes direct and indirect medical education, which should **start at the beginning** of the therapeutic relationship. This **educational process** may include a number of things, for example, the doctor's encouragement for that patient's participation in decision-making, self-help groups, inpatient and outpatient education such as leaflets, videotapes, lectures, postal or emails, etc. Such activities make patients more aware of the importance and relevance of medical information, as well as persuading the patients to take part in planning their own treatment (Helgeson, Cohen, Schulz & Yasko, 1999: 344). Although written information is certainly useful and advisable, it still does not replace the importance of the doctor-patient verbal communication and discussion. It does not matter **when** the patient receives the information, in other words, whether the patient received the information a month ago at a counselling session or just before the patient is sedated for the procedure. Furthermore, the patient would also

want to know who would be doing the procedure or operation, whether it will be a consultant, trainee (under supervision), etc. They also want to know the **years of experience** and technical skills of the doctor, including the doctor's personal success and complications rate (Ladas, 2006: 187).

When treatment is recommended for a patient, the health care practitioner should obtain informed consent from the patient, especially if the treatment is invasive. According to Fish (2004: 449) and Rado (2008: 504), five distinct components that **should be addressed** when in consultation with a patient before medical or surgical treatment are:

- *"The diagnosis or nature of the specific condition that requires treatment.*
- *The purpose and distinct nature of the treatment.*
- *Risks and potential complications associated with the proposed treatment(s).*
- *All reasonable alternative treatments or procedures, and a discussion of their relative risks and benefits, including the option of taking no action.*
- *The probability of success of the proposed treatment(s)."*

There are **exceptions to the rule of disclosure** where the provider does not need to disclose information to the patient. These four situations are discussed hereunder.

"A life- or limb-threatening emergency." The health care provider may administer emergency treatment without the patient's consent unless he has reason to believe that the patient would refuse such treatment.

*"When disclosing information could threaten the patient or cause her harm or suffering."*The primary duty of the provider is to do what is best for the patient and to avoid harm to the patient. What is known as *'therapeutic privilege,'* is the right to withhold information under these circumstances, but Dimond (1991: 26) warns that disciplinary action might follow against the nurse for challenging this *'therapeutic privilege'* because the nurse does not have a legal right to countermand these instructions.

"When the patient chooses not to hear all the information." A patient may wish not to participate in decision-making or in some aspects of his/her care.

Therefore, the patient should sign a waiver giving up his/her right to a full disclosure. The health care provider should respect the patient's autonomy by withholding information and discuss the procedure with the patient's family if the patient does not want a full explanation.

"When the patient has prior knowledge." The health care provider does not need to disclose information that is considered common knowledge, and the patient may need only a review of what is involved before he/she signs the consent form, if the patient had this type of procedure before (Zucker, Boyle, Jefferson & Ratliff, 2010: 25; Wegmann, 2009: 25; Rado, 2008: 504-505; Fish, 2004: 449-450; South Africa. National Health act 2003: 20; Dunn, 1999: 42).

A reasonable patient would also want to have a clear explanation of whether he/she may **withdraw consent** at any time prior to the procedure or operation. It is therefore important that this information should be given to a patient in clear **understandable** terms, which is easy for the patient to understand (Ladas, 2006: 187).

The healthcare practitioner should provide the patient with information and assurances that would allow a patient to sign the informed consent document, but once the document is signed the patient must be certain of the following:

- That the procedure or operation was explained to them in terms and a language they understand by the clinician primarily responsible for their care;
- That their particular concerns were adequately discussed;
- The clinician primarily responsible for their treatment and his team will continue to explain to the best of their ability and knowledge, what will happen before, during and after the procedure or treatment;
- Although the treatment might be different to anything the patient had imagined, the clinician and his team will continue to answer the questions of the patient, their family member(s) and/or care(s) to the best of their knowledge and ability as the treatment process continues (Little, Jordens, McGrath, Montgomery, Lipworth & Kerridge, 2008: 627).

There are different situations in which the consent process might not be as straight forward as explained so far, and one of them would be the *'implied consent.'* Implied consent is described by Quallich (2005: 49) as the type of consent that allows the health care provider to proceed with treatment if the need arises, as long as the possibility of additional treatment was discussed as part of the initial consent. Although implied consent can also be seen as failure to refuse treatment or intervention, and that much of the routine nursing care would fall under this concept as long as there is a rational explanation for the action. Moskop (2007: 47) argues that if consent is implied, it is not necessary for the physician to provide explicit information (as in common, safe procedures) or to provide explicit consent (as in emergencies).

Researchers argue that informed consent may be omitted when emergency treatment is needed to prevent death or other serious harm (Berg, Appelbaum, Lidz & Parker, 2001: 76; Faden, Beauchamp & King, 1986: 36; Rozovsky, 1984: 88). It is believed that consent in such situations is *'implied'* or *'presumed'* – it presumed that any particular patient would consent to treatment under the same circumstances, as any reasonable person would in an emergency if they were able to do so (Berg *et al.,* 2001: 76). Faden *et al.* (1986: 36) however caution that these terms may be misleading and explain by saying that the implication that consent in an emergency is 'implied,' is based on a standard of the reasonable person and not a particular individual. This language and strategy is evasive; because it claims that consent has been obtained when in fact no authorization has occurred. Moskop (2007: 47) argues that limited time prevents actual consent taking place in genuine emergency situations, and that treatment is believed to be justified by the presumption that patients would, if they had the time, consent to emergency treatment to prevent death or serious injury.

Over the years as the laws and ethics of informed consent evolved in some countries, several different disclosure standards were adopted to guide physicians in determining how much information they must provide to patients. In this process, it was identified that these disclosure standards also provide guidance about **what information** need not be disclosed in order to obtain informed consent. It is generally believed that information that is widely

known to the average patient or that include minor risks that is unlikely to occur, does not have to be provided by the physician (Berg *et al.,* 2001: 57). It is further argued that consent requirements can therefore be described from *'formal and explicit to informal and implicit.'* That means that some procedures require a formal consent process because of its intensity and the major risks involved. With these procedures explicit disclosure of the major risks and explicit consent by the patient takes place, which is usually documented by a signed consent form. There are safe and common procedures that do not require any explicit disclosure of information further than a simple mention of the procedure, because the information is widely known to the general public, or that the procedure include minor risks that are unlikely to occur. The patient's verbal agreement or even his/her silent cooperation with the procedure may be enough to indicate consent. The patient is still giving his/her actual authorization for a procedure in these informal consent processes. However, it might be described as ***'implied,'*** because the process is informal and does not require explicit disclosure of information (Moskop, 2007: 47).

Furthermore, implied consent can also be classified as *'blanket'* consent, in situations where the patient comes to the emergency department for treatment, or when patients register for admission to hospital, signing a consent form agreeing to all *'indicated'* or *'necessary'* treatments, and sometimes acceptance of responsibility for payment of hospital accounts. However, this blanket consent does not replace the informed consent for any specific procedure, unless the procedure is an emergency or the procedure is so common and safe that no disclosure of explicit information is required (Easton, Graber, Monnahan & Hughes, 2007: 35).

The next situation is where a competent patient waives his/her right to specific information and to give explicit consent in turn to be totally dependent on the provider's judgment and recommendation (Coulson, Glasser & Liang, 2002: 1365). However, the patient should still be informed by the provider of the information regarding the treatment procedure, in order for them to reconsider their decision. Although the patient may waive the right to be informed, the provider has a responsibility to **continuously** present opportunities to discuss

the ongoing treatment (Quallich, 2005: 50). It is therefore important that the patient understands that he/she has the right to informed consent, but explicitly declines to exercise that right (Moskop, 2007: 47).

Another situation is the *'refusal to consent'*, when even a competent adult patient's decision or choice of treatment is likely to result in death, they still have the right to determine what happens to them (Quallich, 2005: 50). The researcher holds that the patient must still be provided with all the relevant information a *'reasonable person'* would have received in order for the patient to say that he/she has been informed but still refused the proposed treatment. The patient's refusal makes it either very difficult for the health care practitioner to document, that a clear discussion had taken place, and that the patient is competent.

It is unlawful when surgery is performed without the informed consent of the patient, and that consent for any medical procedure is required from a competent, adequately informed adult patient (South Africa. National Health act 2003: 20-22). Consent is valid and provides a defence to the claim of assault, if the patient has been informed in broad terms of the nature of the procedure. In addition, as previously mentioned, the care provider has the duty to provide a patient with information of the **nature, risks, consequences and alternative associated with the proposed therapy**, and if anyone fails to disclose the requisite standard, it may result in a claim of assault. The patient is enabled by this ideal of informed consent to be part of the decision-making process so that they **can decide for themselves as to what course they should adopt** (Chester v Afshar, 2005; Oldwage v Louwrens, 2000; Castell v De Greeff, 1994). This is based on the ethical principle of respect for patient autonomy, which is also acknowledged by law (South Africa. National Health act 2003: 20-22; O'Neill, 2003: 4; South Africa. Promotion of Access to Information act 2000; South Africa. The Constitution of the Republic of South Africa, 1996; Veatch, 1989: 175). **When information regarding the proposed treatment is made available to the patient, the imbalance of power between the informed and experienced doctor and the vulnerable patient is addressed** (Johnston & Holt, 2006: 147). Jones (1999, 103) argues that when the standard of disclosure is linked to the doctor's duty

rather than to the patient's need for information, it allows disclosure of information to become a *'medico-legal'* practice issue rather than good medical practice. Although health care professionals are of the opinion that in some cases *'good medical practice'* leads to the duty to disclose, some argue that therapeutic privilege has been recognized by the law as justification for non-disclosure resulting from the duty to do no harm. The physician's primary duty is to do what is beneficial for the patient; therefore the general purpose of the privilege is that it frees physicians from a legal requirement, which would force them to violate that primary duty (Meisel, 1979: 413).

The therapeutic privilege is defined as *"... withholding of information by the clinician during the consent process in the belief that disclosure of this information would lead to the harm or suffering of the patient"* (Etchells, Sharpe, Burgess & Singer, 1996: 387). This means, that the information that a competent patient ordinarily would be told, is deliberately withheld, as perceived by the health care professional, for the patient's benefit (Johnston & Holt, 2006: 146). Meisel (1973: 1037-1038) argues that a patient experiences emotional distress with almost every encounter and that it is quite normal if a patient is upset if the serious risks of a proposed treatment is disclosed, although it is still not clear that being upset necessarily interferes with the patient's ability to engage in rationale decision-making. But Côté (2000: 199) gives direction by saying that when the patient gets upset it does not necessarily translate into harm, which would ultimately suggest the inclusion of the therapeutic privilege. In addition, there is no justification in introducing the therapeutic privilege in situations where the health care professional is of the opinion that the patient would make an inappropriate decision by refusing treatment, when objectively decided by the health care provider to be in the patient's best interest. Thus, manipulation of information allows the health care professional to substitute his/her judgment for that of the patient, to achieve the best result for the patient effectively (Johnston & Holt, 2006: 148). Veatch (1989: 170) says that moral judgment should be made by the health care practitioner of whether or not to disclose a diagnosis, or risks of a treatment or procedure while doing so, the possible harm and benefits, both

physical and psychological should be considered, and the option that is most likely to benefit the patient selected.

There is an assumption that the physician cares not only for the patient's physiological health but for their psychological and moral wellbeing (Barber, 1980: 37). There might be clashes between the duty to revere the best interest of the patient and his/her welfare as a whole, and the patient's right to choose treatment based on adequate information. It would either not be fair to consider the provision of information separately, in terms of the rights of the patient, which might lead to the exclusion of the ethical and social dimension of medical treatment that might potentially harm the doctor-patient relationship (Hanna, 1998: 143). ***"The key to understanding how distressed a patient would be if informed of diagnosis or risks of a treatment, and then whether that harm justifies non-disclosure under the therapeutic privilege doctrine, lies in the core values of dialogue, reciprocity and communication skills"*** (Johnston & Holt, 2006: 149). It is not lack of disclosure, but rather the manner of disclosure, that is important in the provision of relevant and adequate information (Johnston & Holt, 2006: 149). Meisel (1979, 413) argues that the idea that patients make their decisions about treatment, which are enhanced by disclosure of information, is all an illusion. He believes that a physician will always disclose information in such a way as to assure that the patient agrees to the treatment. When consent is merely a ritualistic legal procedure, it does not serve to respect the autonomy of the patient. Furthermore, many patients will feel intimidated by this huge amount of information that they may fail to see the relevance of the information. Patients reported that they were *"unwilling or unable to question professionals, primarily because they felt disempowered by the forms of etiquette that govern the surgeon-patient relationship, which they felt cast patients in the role of non-experts and doctors in the role of unchallengeable experts"*(Habiba, Jackson, Akkad, Kenyon & Dixon-Woods, 2004: 422).

2.7.2 Comprehension of consent information

Given that the informed consent is an ongoing process, the health care practitioner must ensure that the patient is always fully informed. According to

Golec (2004: 15), it is the health care institution's responsibility to ensure that the informed consent form is truly readable, because lengthy consent forms and low readability contribute to poor comprehension. Furthermore, informed consent forms **containing information of innumerable risks, no matter how small the procedure or operation, can be as harmful as too little information. Additionally, pages and pages of theoretical information can be intimidating and overwhelming to the patient.**

Besides the form, it is important for the health care practitioner or doctor to evaluate informed consent practices. Generally in the traditional setting, the patient is presented with a lengthy legal document to read. Thereafter, an oral explanation of the procedure or operation follows, along with, presumably, a conversation with the patient about concerns and to assess understanding. Issues that might influence the information conveyed to the patient are the following: the presentation style of the doctor, the daily workload of the doctor, the doctor's or patient's mood that day, or language or cultural barriers (Brady, 2003: 36). As a result, the presentation of the consent information is inconsistent and may be inadequate.

Hochhauser (2003: 10) argues that the patient's attitudes and perceptions might also influence the informed consent process. If the patient does not ask questions, it simply means full comprehension or utter confusion but signifies that the patient is unaware of what they do not know. He further argues that it is unreasonable to expect patients to fully understand their medical condition or treatment options due to the technicality and complexity of medicine. In some cases patients might be intimidated by the situation, they sometimes do not want to risk embarrassment by asking for clarification or might simply consent to satisfy the doctor (Brady, 2003: 36). These are all attitudes and beliefs that lead to uninformed consent. Refusal for the procedure or operation to take place does not indicate full understanding either. Therefore, regardless of the patient's decision, full comprehension, must still be assessed by the doctor in some manner after the procedure or operation is explained to ensure that the patient is making an informed decision (Jaynes, 2005: 106).

Jaynes (2005: 106) argues that several methods can be used to foster understanding of complex information in a way that may be more easily understood by the patient. These methods include the use of technology and educational materials such as DVDs, brochures, and Web sites. The use of multimedia to convey information may increase comprehension for those patients who have difficulty with the written word. Although it would be difficult to accurately assess a patient's understanding of the consent information, there are steps that can be taken to ensure that a reasonable understanding is present. Very often, doctors rely on verbal assurance from the patient, however, this may not reflect the actuality. Therefore, a brief interview can be used to identify any misunderstandings. In the interview, the patient may be asked to describe the procedure or operation, or answer simple open-ended questions, which may reveal the patient's comprehension of the consent information. Further, documentation of the answers will provide verification that a truly informed consent was obtained. Alternatively, the nurse practitioner can also be used to question the patient to further assess understanding, and this interview should also be documented. It is therefore important that health care practitioners should take whatever measures necessary to ensure that the informed consent form represents true understanding and not just a signed form.

According to Flory and Emanuel (2004: 1599), patients in general may understand only 30% to 81% of information in a standard consent-form. Such poor comprehension is due to the complexity of most consent and privacy documents, which are often written at too advanced a level for their intended audience (Breese, Burman, Rietmeijer & Lezotte, 2004: 897-898). In addition, a number of factors can adversely affect consent comprehension such as old age, cognitive impairment, low educational attainment, and poor literacy skills (Joffe, Cook, Cleary, Clark & Weeks, 2001a: 1772).

With specific focus on low literacy, which is an important barrier to informed participation in a procedure or operation, some organizations have made recommendations to improve the informed consent process, especially for those patients with limited literacy skills (Campbell, Goldman, Boccia & Skinner, 2004: 205). They suggest that **consent documents should be**

written at an eighth grade reading level or lower. In addition, the consent document should be relatively short, clearly organized information with subheadings, illustrated, and written in active voice with straightforward vocabulary (Kripalani, Bengtzen, Henderson & Jacobson, 2008: 13). They believe that patients prefer material that is presented in a simplified format and that several prior studies of enhanced consent forms have demonstrated improved understanding. Other research has shown that when a patient receives both written and verbal information, they having a better recall of information than written or verbal information alone (Flory & Emanuel, 2004: 1598; Andrus & Roth, 2002: 300). A study that was based on the *'teach-back of key information'* has also shown that in comparison to those patients who read at below a third-grade level, patients reading at a fourth- to eight-grade level had approximately twice the odds of comprehension, and those reading at a high school level demonstrated more than four times the odds of comprehension (Kripalani *et al.,* 2008: 17). These findings suggest that patients with limited literacy skills should be considered a vulnerable population and that special consideration should be given to their protection during procedures or operations. Therefore, additional steps should be taken to ensure comprehension of consent information among those patients with limited literacy skills (Denny & Grady, 2007: 384).

Kripalani *et al.* (2008: 17) suggest that the **teach-back method** is preferred to confirm understanding of consent information, and its use is advocated by the National Quality Forum in Washington, DC, the Agency for Healthcare Research and Quality, and other groups. They further suggest that this specific method is a feasible and generalized approach that could be adopted in most healthcare institutions to help assess the patients' comprehension of the consent information. Healthcare practitioners should ask patients to describe their understanding of the purpose, risks, and benefits of the procedure or operation. Moreover, by asking the patient to teach-back the procedure or operation information, allows the doctor to find out in real time how well the patient understood the material or information. Misconceptions can be clarified immediately, and patients can be asked again to teach-back the information to ensure their comprehension (Schillinger, Piette, Grumbach,

Wang, Wilson, Daher, Leong-Grotz, Castro & Bindman, 2003: 83). This approach is called the **teach-to-goal strategy,** a method used to ensure that understanding of information is achieved (Raich, Plomer & Coyne, 2001: 437).

According to Kripalani *et al.* (2008: 17), it is unclear how often teach-back methods or teach-to-goal strategies are used in the informed consent process, but available data suggest their use is uncommon. A study done by principal investigators shows that only 20% used open-ended questions to assess understanding, for example, *"Tell me in your own words the purpose of this procedure or operation,"* while 80% used closed-ended questions such as, *"Do you understand?"* (Raich *et al.,* 2001: 437). The latter is clearly inadequate given that many patients subject themselves to procedures or operations and consider themselves informed but demonstrated poor performance on tests or interviews that assess their understanding of the procedure or operation (Joffe *et al.,* 2001a: 1772). According to the National Quality Forum (2003: Online), in order to facilitate comprehension and assess understanding of consent information prior to a procedure or operation, additional measures must be taken, especially in groups with limited literacy skills and other vulnerable populations.

Competency to give consent is just as important in the informed consent process and will be discussed hereafter.

2.7.3 Competency to give consent

The core meaning of competence can be defined as *"the ability to perform a task"* (Beauchamp & Childress, 2001: 70). While a person might not be considered competent to make a complex health decision, that person might very well be considered competent to decide on a wide range of issues, for instance on what to buy or cook. Such specific competence may also vary over time (Brock & Buchanan, 1990: 18-20). According to Beauchamp and Childress (2001: 71), a person **is competent** to make decisions if they have the capacity to understand the information regarding the proposed treatment, to make a decision about the information based on their values, to intend a certain outcome, and to communicate freely their wishes to the caregivers or investigators. In medical contexts, a patient is usually considered competent if

able to understand the information regarding a therapeutic or research procedure, to carefully think about the major risks and benefits of the procedure, and to make a value judgment in light of this deliberation (Beauchamp & Childress, 2001: 72). According to these conditions, people's decision-making capacity varies. There is no definite answer to how defective these abilities have to be, or how the different abilities should be balanced against each other for an individual to be considered not competent (Baeroe, 2010: 90).

If competence to consent could be treated as an equivalent to *'criminal responsibility'* or ***'legal competence,'*** for which there are clear legal regulations, court precedents as well as extensive literature, it would be easy to ignore such neglect. But, unfortunately their subjects are different and cannot be treated the same. *"Criminal responsibility describes the ability to respect legal binding standards which protect the legal interests of others,"* which is not an aspect of the competence to consent. The latter rather involves the capacity to handle one's own legal interests rationally, of which the guidelines are not dictated by legally binding standards. The researcher further argues that, ***"legal competence describes, in simple terms, the ability to take on contractual obligations."*** On the one side, a certain agreement can be observed between the competence to informed consent and the legal competence, which concerns the handling of one's own interests. On the other side, legal competence implies that an individual can assess contractual obligations that are sometimes assumed for long periods of time. Whereas competency to informed consent does not imply any contractual obligations for those giving consent, consent may be revoked (Amelung, 2000: 1-2).

It is important to understand what the outcome is when somebody is judged to be **incompetent** to give informed consent. This is an unquestionable issue that persons who have been declared **incapable** shall not decide on their own about the effect on their legal interests. The researcher further argues that it is because of **paternalistic** care that the patients' right to decide on their own about their legal interests is denied, unless there is reason to believe that they are incapable of doing so in a rational way and without causing harm to

themselves. Fundamentally, this is the idea behind the competence to consent. More specifically, the **competence** to consent is defined as *"a person's ability to arrive at a reasonable decision about the implementation and sacrifice of his own legal interests"* (Pearce, 2009: 48; Lidz, 2006: 537; Amelung, 2000: 5).

Consent can be seen as an **assent** that includes **sacrifice**, for example, a person who gives consent to an operation, sacrifices his freedom from bodily harm. It is further believed that a reasonable human being makes such a sacrifice only if it is to his own benefit. Thus implying that a rational decision about consent, is always a **cost-benefit decision** with the benefit overriding the cost. In order for the patient to establish whether there is an overriding benefit, he first has to assess both the cost and the benefit, which makes a **value system** inevitable. The *'objective'* system which is provided by the lawmaker or physician evaluates the reasonableness of a consent or refusal, which implies that the patient is forced to adopt a value system that is not his own. The *'subjective'* value system of the patient, which includes the right to give consent, a tool of self-determination and meant to avoid coercion; may be authoritative in giving informed consent (Lidz, 2006, 540; Joffe *et al.,* 2001a: 1772; Amelung, 2000: 5; Schaefer, Krantz, Wichman, Masur, Reed & Vinicky, 1996: 262; Penman, Holland, Bahna, Morrow, Schmale, Derogatis, Carnrike, & Cherry: 1984: 850).

The ability to make a cost-benefit analysis of the planned treatment according to his own value system is the first basic requirement the patient has to fulfil in order to be competent. There might be a twofold reason for the lack of this ability. On the one hand, patients are prevented by certain mental disorders from establishing a consistent value system for a fixed period of time. The patient will change his mind from yes to no, in an instant. This patient would probably not be considered competent to give informed consent. On the other hand, some patients suffer from mental illness that may distort their value systems. These are, for example, defects leading to overestimating ideas or addictions that cause the patient to want to be in situations he would never have felt attracted to when in a sound mental state. The term distorted is just as well applicable to the still undeveloped value system of a minor who is

trying to cope with problems specific to his age, e.g. a youth who agrees to test his courage in order to be sufficiently accepted among his peers (Amelung, 2000: 6; Kitamura & Kitamura, 2000: 245; Kitamura, Tomoda, Tsukada, Tanaka, Kawakami, Mishima & Kitamura: 1998: 224).

Consent given is also based on relevant facts, and not only out of a decision based on values. A patient must know the relevant facts and causal implications or understand them after having been informed, in order to arrive at a reasonable decision on whether or not to give consent. As a consequence of this, it is essential that the patient duly understands the facts. For example, a person who gives consent to a kidney operation must know the nature of the kidney as well as the malfunctioning, which is to be corrected. However, it is just as vital for the patient to be able to comprehend future causal implications, i.e. prognoses. On the one hand, a patient who gives consent to a kidney operation must be aware of the consequences that may occur in case he refuses the operation, whereas on the other hand, he should also know about the risks and restrictions of the treatment. In cases of insufficient intelligence caused by mental defect or senile dementia, understanding facts and causal implications may be lacking. The patient's cognitive capacity may be absolutely sufficient for simple medical procedures, while insufficient for more complicated procedures. Therefore, the decision depends on the actual case of whether a patient is competent to give informed consent. Even if a patient is not competent to give consent to a complicated operation, for example, a brain operation, the same patient may definitely have the capacity to give consent to a simple operation, for example, an appendectomy (Rado, 2008: 517; Eyler & Jeste, 2006: 565; Iltis, 2006: 186-187; Wilkinson, 2001: 345-346; Amelung, 2000: 6-7).

Giving consent is also primarily the decision to be made in a conflict situation, and not only implies making a decision on the basis of values and facts. This is evident with every occurrence of consent to medical treatment. Almost every person would prefer to avoid making a decision about whether or not his abdominal cavity should be opened. If a person consents to such a procedure, it is usually only for the reason that indisposition, pain or even death could be avoided. In other words, a patient who appears perfectly

rational consents to an operation like this only if the operation is indispensable to cure an illness or to prevent death. Therefore, if there are no other milder alternatives to attain this goal, the treatment is indispensable. This is yet another ability that a person giving consent has to display. Besides being capable of making an assessment on the basis of his own value system as well as understanding the relevant facts, the patient must also be able to comprehend alternatives to the planned operation as well as to evaluate them in accordance with his own value system. For example, a medicated treatment, which takes longer and has more severe side effects, might be an alternative to an operation. If a patient is not capable of comprehending such alternatives he cannot be considered competent, since the decision for or against is then no longer a reasonable conclusion but the result of blindness (Eyler & Jeste, 2006: 556; Quallich, 2005: 49; Akkad, Jackson, Kenyon, Dixon-Woods, Taub & Habiba, 2004: 1133; Whitney, McGuire & McCullough, 2004: 55; Amelung, 2000: 7). Competence to consent is very often counteracted by the individual's lack of self-determination, therefore a competence assessment needs to be done.

Competence assessment is a process that involves complex and variable factors, which in some cases makes it difficult to find a single measure to assess the patient's competence. The patient's concept of quality of life, his or her life experience, cultural and religious beliefs, desired input from others, beliefs in one's own potential impact on health outcomes and considerations for others, are individual variables which have been shown to influence patient's decision-making (Moye, Gurrera, Karel, Edelstein & O'Connell, 2006: 1055). All such individual variables need to be recognized by the clinician in each patient and their impact on the individuals' decision-making distinguished from incompetence. Moreover, individuals might differ in how information is processed and reasoning is carried out. The examining clinicians must be able to identify any of these contingent individual variables, in order to provide an accurate determination of individual competence. Because it takes time and experience to become a skilled interpreter who is able to capture every individual variable that might be of importance, we must assume that clinicians do not always grasp the whole picture of the relative

competence of an individual, which might affect the way competence is assessed. Also, the outcome of this process of identification will depend on the physician's ability to make a connection between the presumed benefits of the proposed treatment and the patient's idea of what is best for them (Baeroe, 2010: 90). Further, Baeroe (2010: 91) suggests that people are generally treated as if they possess decision-making competence, and only when there is a suspicion that someone lacks the necessary competence to make a significant decision, a competence assessment is usually carried out. It means that such suspicion is usually aroused for formerly competent individuals when healthcare workers or proxies do not feel the patient's choice is in his best interest. Consequently a patient's right to self-determination is conditioned by the right of others to review this very right.

By the growing number of elderly person with a high prevalence of both (chronic) illnesses and cognitive decline, the need for an instrument to assess competence to consent to treatment will presumably increase. The search for a single test of competency or gold standard within clinical practice is comparable with the search for a *'Holy Grail.'* The physician, an instrument, and/or a family member are assumed to be the three potential judges in clinical practice to give valid and reliable judgments about a patient's competency to consent to treatment; but all three judgments have their strengths and weaknesses (Vellinga, Smit, van Leeuwen, van Tilburg & Jonker, 2004: 645).

First, physicians are directly confronted in everyday practice with competency, and patients' decision-making capacity, are often (implicitly) assessed by them. Based on the physicians' clinical experience, they can make a judgment and weigh their impression of the patients' decision-making capacity along with other clinical and contextual information (Grisso, Appelbaum & Hill-Fotouhi, 1997: 1419). Although physicians are regarded as the *'gold standard'* various studies have demonstrated low interrater reliability therefore the ability of physicians to give reliable judgments are questioned (Vellinga *et al.,* 2004: 646; Kim, Caine, Currier, Leibovici & Ryan, 2001: 716; Kitamura and Kitamura, 2000: 245-247).

Second, many instruments have been developed to assess decision-making capacity (Vellinga *et al.,* 2004: 646; Schmand, Gouwenberg, Smit & Jonker, 1999: 81; Kitamura *et al.,* 1998: 224; Grisso, *et al.,* 1997: 1415). These instruments help to make a more objective judgment about decisional abilities of the patient because of its clearly described standards. The patient's ability to – evidence a choice, understand relevant information, reason about the choice, and appreciate the situation, are the four standards with a legal origin which is evaluated by most instruments. Although the use of clear standards raises the reliability of judgments, instruments cannot take into account contextual information of the specific choice. Therefore, instruments that make use of the four standards leave aside emotions and personal values, factors that presumably play a significant role in competency as well (Vellinga *et al.,* 2004: 646).

Third, it is rare that the family is mentioned in the competency judgment as a possible factor. To evaluate the competency judgments of family members, two important arguments can be given. First, the shared history between the patient and their family may be expected to direct the family's impression of the patient's competency. With this knowledge of shared experiences, family members can test whether the patient's arguments are true or false. Secondly, the involvement of family members could shift the frame of reference from a legal orientation to one based on common knowledge (Vellinga *et al.,* 2004: 646; Kuczewski, 1996: 30; Berlin & Canaan, 1991: 354; Appelbaum & Grisso, 1988: 1635). It is further believed that in the family judgment, emotions or personal values may be better represented than in those of physicians or instruments. Although it has been argued that family members should have a more central role in medical decision-making, the entwining relationship between family and patients may often lead to invalid judgments of competency (Vellinga *et al.,* 2004: 646; Kuczewski, 1996: 30; Blustein, 1993: 6; Lindemann, 1992: 11). Some studies have shown that physicians are prohibited by privacy laws to discuss specifics of a patient's condition with family members even when that discussion would seem to be in the patient's best interest. For that reason, physicians should be encouraged when they believe it to be necessary, to talk with their competent patients

about including a family member in discussions. The physician should make a note of this discussion in the patient's chart, and if the patient consents to that, the physician should have the patient complete and sign any forms required (Zucker *et al.,* 2010: 26).

It is acknowledged that if a child is not mature or unable to comprehend the benefits, risks and social implications of an operation, they have not attained their own competence and therefore the parent or guardian of the child has to take decisions on their behalf (South Africa. Children's act 2005: 90). Although, it is not only children whom need other people to speak on their behalf.

There are patients who have lost the capacity to relate to others, whose desired treatment and care options rely on the people who treat them to know and articulate those desires. This is where the importance of family and relatives come in. They are the ones who can relate a desired health programme to the treating physician in the form of an advanced treatment directive, and still preserve their independence. They can at least ensure that the holistic attitude towards care is preserved, and it is important to understand that based on people's personal circumstances, they will make different choices. A holistic approach necessitates that health providers communicate effectively and sensitively with the family and relatives, but most importantly with the patient themselves if possible. However, there are situations where the patient wishes to refuse a certain treatment or care action, but are judged to be legally incompetent to do so. Therefore, when a patient is deemed to be incompetent, certain measures can be taken to deliver care, which the patient may not wish to receive. These measures include a specific element of the capacity issue, which state that each element of care and treatment has to be examined when a patient is judged not to have the legal capacity to make their own decisions. The healthcare practitioner cannot simply say that the patient has or does not have capacity, they have to ascertain capacity for each element of care or treatment (Fullbrook, 2007: 746-747). Baeroe (2010: 87) argues that the healthcare practitioner needs to ascertain that all measures are taken to ensure

respectful treatment of these vulnerable patients, otherwise the autonomy of the patient is threatened.

2.7.4 Voluntary consent

Beauchamp and Childress (2001: 93) argue that *"a person acts voluntarily to the degree that he or she wills the action without being under the control of another's influence."* The different influences in healthcare that might render an act non-autonomous, are unclear. Patients cannot be expected to recognize whether they are exposed to deliberate or unintentional lack of information, limited choices, deception, manipulation or even coercion. Threats to patients can be presented in subtle ways, for example, *'This is the only treatment we can offer,'* which means, *'You get this or nothing.'* From this perspective, the boundaries between coercion, manipulation and persuasion can be unclear. Theoretically, healthcare practitioners may have difficulty in recognizing forces that affect their suggestions of care, for example, the influence of pharmaceutical companies or incentives introduced by healthcare authorities. Healthcare practitioners may become a channel for manipulation of such influences, rather than manipulative agents in themselves; nevertheless, the patients' choices are affected. Patients may either reject or voluntarily endorse any distorting influence that can impact on their decision-making, if able to recognize these influences. Non-competent individuals, however, are vulnerable in at least two ways namely they are not given the chance to make a decision regarding their wellbeing or their opposition to manipulation or coercion may be ignored (Baeroe, 2010: 89).

Both Rhodes (2005: 12) and Miller (2005: 34) argue that there has been undue emphasis on informed consent as an **event**. Sears (2005: 47) argues that informed consent should be understood; and implemented as a contextual **process** rather than just as an event or as a signed document. Rhodes (2005: 12) identifies, yet understates the importance of **context** in making informed and careful decisions about healthcare treatment. Sears (2005: 47) holds that respect for autonomy means respecting the right of the autonomous individual to make choices as well as the context in which those choices are to be made. The researcher further holds that *"one can be*

autonomous, yet be exquisitely vulnerable to contextual influences" and that *"vulnerability is often **situational** rather than categorical."* However, we may lose sight of how we all are vulnerable in different ways at different times if we rely on the identification and protection of vulnerable groups in categorical ways alone. The key to ensure voluntary and informed consent is to ensure a context that allows the optimal absorption of information and weighing of choices. Recognizing the importance of context also requires that informed consent should be viewed as a continuous process as priorities and vulnerabilities change over time (Berry, Dodd, Hinds & Ferrell, 1996: 508-509).

Frimpong-Mansoh (2008: 104) argues that it seems that it would not be **ethically and culturally** feasible to apply the principle of voluntary informed consent in African communitarian culture, given that the principle is putatively rooted in individualistic values, especially the rights of autonomy and self-determination. An effort to protect medical patients from potential abuses by medical practitioners involves the development of the ethical principle of voluntary informed consent. But the ineffective implementation of the principle in African cultural and healthcare systems is evident by the increasing failure to protect healthcare users in Africa from potential exploitation and abuses.

Frimpong-Mansoh (2008: 106) holds that global application of voluntary informed consent remains a contested area despite its centrality and widespread acceptance in international codes and conventions as a fundamental ethical guideline and requirement of research involving human subjects. Some scholars have argued that a perception of **imperialistic globalization of Western values** is created by the global application of the principle (Macklin, 2004: 4). Others believe that the voluntary informed consent principle is rooted in individualistic values, for example the rights of self-determination and autonomy of the individual, in which the individual patients are the primary focus of ethically sound medical decisions. This means that the rights of autonomy and self-determination, in which the voluntary informed consent principle is rooted, seems to be **incommensurable with communitarian values** (Frimpong-Mansoh, 2008:

107; Constantino & Jackson, 2005: 21-22; Glass & Cluxton, 2004: 232; Sullivan, 2000: 274).

What is important to remember is that the principle of voluntary informed consent **is neutral to culture**. The principle, by its nature, is about respect for humanity and its values. Cultural boundaries and practices are transcended by the value of humanity. Therefore, cultural beliefs and practices that do not respect the value of humanity are morally questionable. The unconditional value of a person demands the ethical obligation of intrinsic respect for personal autonomy and consent. This is a fact that no matter the cultural space anyone inhabits, this relates to all human beings. Furthermore, an individual's contingent membership of a community or culture does not (and need not) deny the individual **personal autonomy** and the intrinsic respect required for it. Every person, by virtue of being human has a moral right, no matter where they live, to have their right to voluntary consent respected (Sarkar, Grandin, Gladstone, Muliyil & Kang, 2009: 40; Frimpong-Mansoh, 2008: 109; Zalon, Constantino & Andrews, 2008: 98; Robichaux, Dittmar & Clark, 2005: 11-14).

Voluntary informed consent does **not necessarily have to be an isolated** decision made by an individual away from relatives, community members or other people. A person may sometimes **have a better option** of making a decision as a result of the communal discussions and debates. Given the widespread problems of poverty and illiteracy that create vulnerable and fertile grounds for exploitations of medical patients, this model of collective decision-making is essential in Africa. A formal act exhibited to demonstrate a person's wishes is the individually expressed consent, but the process of arriving at this decision could be informed and fostered by communal discussions (Frimpong-Mansoh, 2008: 112; Marshall, Adebamowo, Adeyemo, Ogundiran, Vekich, Strenski, Zhou, Prewitt, Cooper & Rotimi, 2006: 1993; Bhutta, 2004: 771).

The African communitarian customary requirement of **communal leaders' approval**, before an important healthcare decision can be taken, may generate a perception that it is impossible to truly fulfil the voluntary component of the principle of informed consent in African communitarian

culture. Sugarman, Popkin, Fortney and Rivera (in National Bioethics Advisory Commission, 2001: Online) and other ethical consultants state that, because important decisions are often made in conjunction with families or even left to communities, the notion of individual informed consent can seem inappropriate in some settings. It also seems that based on community leaders' influence and authority, that if a decision is made in favour of the proposed medical treatment, patients may be extremely reluctant to refuse or withdraw from the treatment process because of the collective nature of community activities in communitarian cultures (National Bioethics Advisory Commission, 2001: Online).

Frimpong-Mansoh (2008: 110) believes that, *"the fact that we act on, and exercise our rights of, autonomy and self-determination in legal, social and cultural contexts indicates that human beings possess restricted rights but not absolute rights."* Although acting within the contexts of cultural norms and institutions does not by itself imply lost, diminished or compromised rights of autonomy and self-determination. In particular, consulting community leaders on issues of healthcare before consenting to the medical treatment is not, in itself, a violation of their rights of autonomy and self-determination.

Community leaders' legitimacy and authority derive from the **responsibility** the community entrusts in them to **secure and safeguard** their wellbeing. This responsibility is rather not different from the responsibilities leaders e.g. mayors, councillors, school principals or nursing home directors have to their members in Western countries. For that reason, researchers in Western countries **cannot directly contract** patients in nursing homes, students, etc. to conduct a project without first consulting and obtaining permission from the leaders or directors of such institutions (National Bioethics Advisory Commission, 2001: Online).

What needs to be remembered is that community leaders in Africa are required to take **decisions based on the opinion and wishes** of the people they represent. It is custom that the legitimacy and authority of community leaders in Africa are rooted in the democratic will of the people. Among injunctions recited to the chief at his installation before he undertakes his oath

are, that *"we do not wish that he should be disobedient (or refuse to take advice), and that we do not wish that he should act on his initiative (literally out of his own head, that is acting without reference to the viewers or wishes of the people)"* (Gyekye in Wiredu & Gyekye, 1992: 243).

What needs also to be remembered is that communal approval is only **one** of the processes of informed decision-making in Africa. This means that community leaders' approval does not constitute an authorization to the individual to be submitted to medical treatment. Ultimately, the consent of the individual and/or their proxies (such as family members) is required for medical treatment (Irabor & Omonzejele, 2009: 39-40).

Kegley (in Boylan, 2004: 95) states that it is inadequate to restrict medical decisions to individual patients and their egoistic choices, given the **complex social nature** of a person's identity and the social context of his or her existence and wellbeing: individual rights have limits. In general, diseases do not have a solitary causal mechanism. Apart from the effects of diseases, it has psychological, economic, religious and cultural ramifications for the individual patient and close relatives and therefore medical decision-making is a family issue. The recognition of the personal values of the individual is equally important as the recognition of the impact of illness and medical decisions on the community. Therefore, medical decision-making should be understood *"as involving more than an isolated individual right-bearer and autonomy and responsibility, individual and community need to be more carefully balanced"* (Kegley in Boylan, 2004: 91).

2.8 INFORMED CONSENT AND THE PATIENT

Various medical or nursing policy documents stipulate the **requirement** to obtain informed consent prior to any medical or nursing care procedures (World Medical Association. Declaration of Helsinki, 2001: Online). These documents require that all procedures to be carried out within a framework of informed consent. So, for the principles of informed consent to be applied appropriately and consistently prior to any medical or nursing care procedure,

medical care practitioners and nurses need to understand the **ethical and legal** rationale behind this requirement.

The requirement for consent according to the Nuremburg Code (1947: Online) was made with specific reference to the human participant entering medical research. However, clinical procedures including nursing care procedures made use of the concept of consent ever since. The concept of informed consent stem from the general concept of consent, with the expectation that patients should give their informed consent prior to clinical procedures in addition to those associated with research (Beauchamp & Childress, 1994: 67).

Beauchamp and Faden (1986: 274) **define informed consent** as the patient's autonomous authorization and emphasize that it is more than just a simple expressed agreement to the proposal by the patient. They argue that it is possible to submit to or comply with a plan of another without any actual agreement but that merely assenting to a procedure is not indicating one's consent. In fact, they describe how, in giving consent, a patient actively authorizes the proposal in the act of consent (Beauchamp & Faden, 1986: 278). To give such autonomous authorization a patient should be informed, be able to comprehend the information and voluntarily consent to the procedure. They also argue that these components of informed consent are largely undisputed in the ethical and philosophical literature (Beauchamp & Faden, 1986: 275).

The principles of informed consent are argued by those advocating it, that its **purpose** is to **protect patient autonomy** or self-determination. Kirby (1983: 70) states that the: *"The fundamental principle underlying consent is said to be the right to self-determination: the principle or value choice of autonomy of the person."* Autonomy is more than freedom from unwanted interference but incorporates the positive concept of meaningful choice in decision-making. Therefore, the promotion of autonomy entails promotion of the patient's meaningful decision-making (Beauchamp & Childress, 1994: 67).

Hansson (1998: 186) argues that the quality of consent should vary according to the values at stake in a particular procedure. Because the integrity, health

and wellbeing of a patient are vulnerable both in clinical and research procedures and that the quality of informed consent should reflect these values at stake. That is, greater attention needs to be given to facilitating a patient's autonomous authorization of a procedure when there is a greater threat to the individual autonomy. The quality of the informed consent obtained should reflect the significance of the threat to individual autonomy.

Meaningful decision-making (autonomous authorization) is likely to be facilitated if information is directed to a **specific patient's individual needs** rather than professionally perceived need of an imagined 'reasonable' patient (Engelhardt, 1986: 274). Therefore relevant information needs to be given to patients in order to give autonomous authorization to a procedure.

Factors that contribute to a patient's **ability to make** a meaningful decision are, that they should not be under undue pressure to accept a procedure (including from health care professionals) and should be competent to do so (Appelbaum, Lidz & Klitzman, 2009: 32; Wilkinson, 2001: 343).

Informed consent is required **prior** to any procedure and would threaten the patient's autonomy if undertaken without the patient's authorization. O'Neil (1989: 109) is of the opinion that the requirement for informed consent is associated with respect for personhood and identifies the significant attributes of informed consent if personhood is to be respected. The researcher further states that it is important to explain which aspects of actions must be consented to if nobody is to be treated as less than a person. That process must then show how these morally significant aspects of plans, proposals and intentions are picked out as candidates for consent.

O'Neil (1989: 109) also argues that the actions that are identified as 'morally significant' aspects of care, require a patient's consent and that these 'morally significant' actions are those which threaten patient autonomy.

It is not easy to identify procedures, which might constitute a **threat** to a patient's autonomy, if carried out without consent. It is sometimes suggested that patients have given **implied** consent to all nursing care procedures when entering a hospital, which implies that nursing care procedures cannot

threaten patient autonomy, but it is argued that this is not the case. In contrast Fleming (1998: 112) defines implied consent as: "*a consent that must be informed and the patient has to be capable of resisting the intended procedure."* So, given the potential **threat of nursing** care procedures to patient autonomy, informed consent is relevant prior to all nursing care procedures. It is important to note when the principles of informed consent are discussed in the literature, the assumption is often made that consent is required only prior to major clinical interventions or where an intervention presents significant risk to the individual. For example, Kirby (1983: 69) made the association between the requirement for informed consent and the degree of risk a procedure entails and argues that consent should be obtained: *"before any diagnostic or therapeutic procedure… which may have any reasonable possibility of harm to the patient."* The common association of informed consent with major therapeutic interventions and research fails to identify the importance of informed consent. Therefore, if the purpose of informed consent is to protect and promote patient autonomy, it is required whenever patient autonomy is at risk and not merely prior to certain, predefined procedures.

Initial information can be offered to a patient in order to facilitate meaningful decision-making prior to nursing care procedures. It is reasonable to assume if the patient declines this initial information, that the procedure is not meaningful to them and that further discussion is not necessary. If they accept the initial information, more information can be given until they request no further information. In this way, it is ensured that the amount of information that is given is patient- rather than provider-led. Therefore, the informed consent **process** should not be regarded as a rigid process, requiring the disclosure of a strict amount of information. Instead it should be regarded as a **flexible** process in which the amount of information required will facilitate a meaningful decision-making process by the patient (Aveyard, 2000: 352-353).

Many nurse practitioners believe that informed consent is **not essential** or that it should prohibit the delivery of care, thus they regarded informed consent as desirable but not essential (Aveyard, 2005: 26). If healthcare practitioners do not demonstrate a commitment to informed consent, the

principles of informed consent will not infiltrate their practice, as a consequence. The undeveloped concept of informed consent prior to nursing care procedures, may lead to the unwanted and inappropriate delivery of care by nurses, and the risk of acting unlawfully in addition to failing in professional standards (Aveyard, 2005: 27). Some ethicists rather prefer that patients should be **persuaded** by health care professionals, who are morally bound to do so, to accept the best course of action and not unwanted care imposed on them.

However, it is important that the boundaries of **persuasion** are not exceeded (Culver & Gurt, 1982: 174). Beauchamp and Faden (1986: 374) defines persuasion as: *"the intentional and successful attempt to induce a person, through appeals to reason, to freely accept – as his or her own – the beliefs, attitudes values, intentions or actions advocated by the persuader"*. Thus persuasion entails that the patient *'freely accepts'* the persuader's *'beliefs, attitudes, intentions or actions'* and that after persuasion the patient still acts voluntarily.

A culture of **delivering care within the framework of informed consent** needs to be developed by nurses. Every nursing care procedure should be influenced by the principles of informed consent and that nurses should offer initial information in all aspects of nursing care (Aveyard, 2000: 357).

Nurses should deliver appropriate care when patients are unable to consent and be sensitive to patients who refuse care. Nurses must also move towards a culture that respects patients' rights to be informed, to be given a choice, and to refuse care should they wish to do so, away from the attitude that nursing care must be delivered. Education plays an important role in achieving this, therefore the principles of informed consent should be taught in basic nurse education courses in consultation with the legal profession. That would bring nursing practice in line with current health care policy that emphasizes patient choice and provider accountability (Schopp, Välimäki, Leino-Kilpi, Dassen, Gasull, Lemonidou, Scott, Arndt & Kaljonen, 2003: 49).

2.9 THE ROLE OF THE NURSE

Although nursing is no longer a predominantly religious profession, the role of the nurse always had its roots in moral values, which has often been considered a vocation (Hewison, 2001: 253). It is not surprising to find that the term 'nursing' is synonymous with caring for the sick and 'lame,' because the role of the nurse includes having to deal with situations and events such as: caring for people with long term illnesses and conditions, for those who are at the end of their life, comforting and assisting patients and their relatives, fundamental care such as bathing, and health promotion (Fealy, 2004: 649).

Henderson (1996: 15) defined the unique function of the nurse as *"… to assist the individual, sick or well, in the performance of those activities contributing to the health or its recovery (or peaceful death) that he would perform unaided if he had the necessary strength, will or knowledge. And to do this in such a way as to help him gain independence as rapidly as possible."* But this role seems to have changed a little, as illustrated by the UK Royal College of Nursing (2003: 5), which defines nursing as *"… the use of clinical judgment in the provision of care to enable people to improve, maintain, or recover health, to cope with health problems, and to achieve the best possible quality of life, whatever their disease or disability, until death."* Allan and Barber (2005: 393) argue that despite these definitions of nursing, the physical, emotional closeness and intimacy which are values promoted by the *'new nursing'*, and relationships of *'emotional intensity'* with their patients have not always been facilitated by nurses.

Recently the **brand** of nursing appears to be less strong, more complex, with multiple images prevailing. This is in contradiction to the past where the brand of nursing was strong. Nursing was seen to have a clear identity with people knowing what a nurse was and what a nurse did (Harmer, 2010: 297). Maben and Griffiths (2008: 8) further identify the five core aspects of what is **valued** most about the nursing role:

- Making a difference to patients' lives;
- Working in a team and being a role model;
- Delivering excellent care;

- Keeping in close contact with patients; and
- Being able to continuously develop, allowing learning which, in turn, improves care.

A trend seems to have developed for nurses in recent years, to adapt as their roles have **expanded** which seems to have been inevitable. So, with the modification and development of the nurse's role it is important to always remember the core values and roles of nursing, with the focus on nursing's original professional identity while trying to advance the profession (Pennery in Harmer, 2003: 338). Nelson and Gordon (2004: 255) suggest that the nurse's professional identity and the search for social legitimacy are in jeopardy, when continuingly altering of the nurses' role and boundaries of role activity takes place. Therefore, as we continually reinvent ourselves through extending our roles, we face the danger of losing the traditional professional identity of nursing (Barber, 2002: 14).

In nursing practice, protection of patient's rights forms the central importance of informed consent. However nurses have been conspicuously silent on this issue *"… despite the obvious and serious professional as well as moral implications of current consent to treatment practices"* and the fact that nursing has not done all that it could to support reform in these areas (Johnstone, 1994: 223). Mental health nurses walk an ever-increasing fine line as caregiver and **patient advocate** for mentally ill persons to maintain their dignity as autonomous persons (Weiss, 1990: 25). However, the researcher is of the opinion that there should be no differentiation among patients, and that all categories of patients should be treated the same.

According to Usher and Arthur (1998: 693), the notion of **process** consent is focus on the mental health treatment, where opinions and ideas of others are often imposed upon patients, where the patient needs to be regularly informed about any changes in the process just as any professional would in their application of intervention. In this way, the important question to be asked at regular intervals in the therapeutic process, *"Is the client informed at this stage of the process?"* The patient should be informed of any changes in the treatment process when new decisions are made and the appropriate consent

obtained. Ideally, the patient will be involved in the decision-making surrounding their treatment. In this way, the consent process is followed by the therapy process, which should **result in increased empowerment** of the patient. The notion of process consent frameworks emphasize the relationship and communication, and recognize the importance of the evolving nurse-patient relationship and the various assumed nursing roles (Forchuk & Brown, 1989: 30).

Viewing informed consent as an ongoing consensual process not only **engages** the patient in decisions about their care but places added **responsibility** on the nurse practitioner to ensure that consent is indeed current (Usher & Arthur, 1998: 696). When a nurse witnesses a patient's signature on a consent form for surgery or a medical procedure, they testify in black and white that the patient signed the form in their presence. But their **role** is actually more complicated than watching the patient signing that form. What is not evident is whether the patient has given informed consent, an area, which is unclear for many nurses. Some authors believe that in strict terms, a patient gives informed consent only after he/she receives full disclosure of pertinent information and fully understands a procedure's benefits and risks (Quallich, 2005: 51; South Africa. Department of Health, 2004: 4-5; Council for International Organizations of Medical Sciences, 2002: Online; American Nurses Association, 2001: Online; Dunn, 1999: 41).

Nowadays, the law obligates that a discussion for informed consent should take place between whoever is **going to perform a procedure and the patient**. Generally, it is a physician's responsibility, however, if a nurse practitioner or a physician assistant will perform the procedure, it is their responsibility to collaborate with the patient and obtain informed consent. A person can be charged with negligence when a patient is not adequately informed about the treatment, and assault when the patient is treated without consent, therefore it is very important in today's legal and ethical climate to ensure patient involvement. The health care practitioner must invite and answer the patient's questions when explaining treatments and alternatives in terms the patient understands and specifying who is performing the procedure. Consent is invalid when a patient is coerced into consenting to a

procedure and the health care practitioner could be held liable if he performs the procedure (Paterick, Carson, Allen & Paterick, 2008: 313; Quallich, 2005: 49; South Africa. National Health act 2003: 20; Cady, 2000: 106; Dunn, 1999: 42).

The nurse practitioner **is not responsible** for explaining the procedure to the patient, although they may be asked to obtain a signed consent form from the patient. The nurse practitioner's role in obtaining informed consent is to advocate for the patient by protecting their rights, preserving their dignity, identifying fears, and determining their level of understanding and approval of their care to be given. Consideration needs to be given to individual because each patient's response is unique and based on their personality, education level, emotional make-up, and intellectual capacity (Aveyard, 2005: 27-28; Quallich, 2005: 51; American Nurses Association, 2001: Online; Dunn, 1999: 42-43).

The patients must be able to **state in their own words** what they have been told in order to verify that they had received enough necessary information to give consent. Therefore, the nurse obtaining the signature should ask the patient to explain to them what the patient thinks is going to happen for which they are consenting to. The nurse practitioner should notify the physician or health care provider if they have any doubts about the patient's understanding or decision-making capacity. Furthermore the physician, health care provider or the facility's risk manager should be informed if they believe that the patient's consent is **not voluntary** (South Africa. Department of Health, 2004: 4-5; Dunn, 1999: 42-43; Beauchamp & Faden, 1986: 278). In South Africa, health care practitioners should be particularly aware of the laws that govern health care involving children.

According to the South African Children's act (2005: 90), a child is a person under the age of 18 years, and that, (1) A child may consent to their own medical treatment or to the medical treatment of their child if - (a) the child is older than 12 years; and (b) the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment. (2) A child may consent to the performance of a surgical

operation on themselves or their child if - (a) the child is older than 12 years; and (b) 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 (c) the child is duly assisted by their parent or guardian, but these prescriptions are subjected to the Act Regulations. Therefore, the nurse practitioner should check with their risk manager if they are unsure whether a minor is permitted to give consent.

The patient must be capable of understanding the nature and consequences of his/her decision and communicating the decision to be considered competent. Someone else must give consent in the following situations: In the case of a child, (1) the parent or guardian; (2) in emergencies, the superintendent of a hospital (or the person in charge of the hospital in the absence of superintendent); (3) if the parent or guardian unreasonably refuses to give consent or assist, is incapable of doing so, cannot be readily traced or is deceased, the Minister of Social Development; and (4) in all instances where another person who may give consent refuses or is unable to give such consent, a High Court or a children's court (South Africa. Children's act 2005: 90). In the case of an adult, (1) if the patient is unable to give informed consent, but instructs someone in writing to give such consent on his/her behalf or permission to give such consent in terms of any law or court order; (2) if the patient is unable to give consent and no one is instructed or permission to give such consent, the following people may give consent in the specific order listed, the spouse or partner of the patient or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or sister of the patient (South Africa. National Health act 2003: 11).

Someone can only be declared legally incompetent by a court, but **the nurse practitioner can gauge** the patient's capacity to know and understand the meaning of a decision. The nurse practitioner can engage in logical conversation if the patient is alert and oriented, and if the patient comprehends information, assume the patient is capable of decision-making. If the nurse practitioner believes that the capacity is limited, they should consider whether the problem is temporary. For example, decisions should be postponed if the patient is sedated, until the effects of the medication wear off.

The nurse practitioner should also notify the physician or health care provider and document their concerns in the chart, if they doubt the patient's capacity to give informed consent (Jaynes, 2005: 106; Quallich, 2005: 50-51; American Nurses Association, 2001: Online; Dunn, 1999: 43; Usher & Arthur, 1998: 696).

The nurse practitioner should **ensure** that the form is properly prepared once they are comfortable that the patient is capable of giving informed consent. They must check the following details:

- *"Completeness."* Does the form include all the necessary information?
- *"Authorized signature."* The patient or a responsible adult must sign. If the patient cannot, marking an 'X' as the signature is acceptable, as long as someone has read the entire form to the patient and the nurse practitioner document on the form why an 'X' appears instead of the patient's signature.
- *"Signature of witness."* The patient's signature or mark must be witnessed by someone who is not related to the patient and not involved in giving care during the procedure. Generally, operating room staff members should avoid signing; they might unexpectedly be asked to assist even if they are not scheduled to participate in the procedure. The patient should also be reminded that she has the right to cancel the procedure at any time, even after she has signed the consent form. The patient should also be encouraged to ask questions or express any concerns about the procedure and if any, notify the physician or health care provider. The nurse practitioner should rather not take the responsibility of answering the questions themselves because they could be held responsible for giving incorrect or incomplete information or interfering with the patient/provider relationship. Finally, the nurse practitioner should make sure that the signed document conforms to the facility's policy (Wegmann, 2009: 23; Kluge, 2007: 410; Moskop, 2007: 47; South Africa. Department of Health, 2004: 4; Bhutta, 2004: 775; World Medical Association. Declaration of Helsinki, 2001: Online; Searle, 2000: 250; Dunn, 1999: 43).

When a patient **refuses** a procedure, the nurse practitioner should use the same principles to determine if the patient is making an informed decision, then notify the physician or health care provider. The refusal should also be documented in the patient's chart, if the patient is competent and has refused the procedure after reviewing the advantages and disadvantages. To help protect the provider and the hospital from liability, the facility may ask the patient to sign a refusal form. The nurse practitioner should document in their notes what the patient said, the physician or health care provider's response, the patient's mental status, who was notified (such as the nurse-manager or social services department), and when (Quallich, 2005: 49-50; Dunn, 1999: 43; Fromer, 1981: 385). Generally, a minor cannot refuse treatment without their parent or guardian's consent. However, a parent or guardian can refuse treatment of a child if they can show that there is a medically accepted alternative choice to the medical treatment or surgical operation concerned, otherwise a parent or guardian lacks authority to refuse treatment of that child by reason only of religious or other beliefs (South Africa. Children's act 2005: 92), for example the Jehovah's Witness who refuses a blood transfusion because of their religious beliefs, lacks authority to refuse such treatment (Du Toit & Van Staden, 2005: 46).

It sometimes happens that the physician or health care provider will have to contact the patient's family or guardian and seek **telephonic consent** for treatment. Generally, the physician will place the call and the nurse practitioner listens in as a witness. If the physician already spoke with the person giving consent but a signed form is not in the chart, the nurse practitioner may obtain **telephonic consent** if someone else who understands medical terms listens in as a witness. If the nurse practitioner witnesses a **telephonic consent**, they should follow these guidelines:

- *"In the chart,"* carefully document what was said and by whom.
- *"On the consent form,"* document that consent was given by phone. Include the name of the person giving consent, his relationship to the patient, the reason the patient could not sign, and the date and time. Witnesses to the conversation should sign the form as well. If possible, the person providing consent should sign the consent form within a

reasonable time after the telephone conversation (Kimberley Hospital Complex, 2008: 75; Young, Mogthlane & Geyser, 2003: 78; Dunn, 1999: 43-44).

Different to the principle of telephonic consent, the nurse practitioner's role in obtaining informed consent is more complex than just witnessing a signature on a form. The nurse practitioner protects the patient, the person performing the procedure, and the facility from legal pitfalls only by assessing whether the patient is properly prepared to make a major health care decision (Shaw & Degazon, 2008: 49; Jormsri *et al.,* 2005: 583; Quallich, 2005: 51; Hewitt, 2002: 444; American Nurses Association, 2001: Online; Dunn, 1999: 44; Weiss, 1990: 26). Thus the nurse acts as an advocate for the patients and their families.

2.9.1 Nurse Advocate

The word advocacy has appeared in nursing literature over the past decades with increasing frequency (Malik, 1997: 130). Snowball (1996: 67) argued that the term ***'advocacy'*** has become a convenient ***'buzzword'*** that has been linked with concepts of morality, ethics, autonomy and patient empowerment. Little practical guidance is offered on how the role of advocacy should be interpreted by the nurse in clinical practice because most of the literature on the topic of advocacy appears to be philosophical in nature (Hewitt, 2002: 439).

According to Snowball (1996: 67), nursing began to develop its professional identity in the 1960's. During that time Virginia Henderson (cited in Styles, 2006: 113) made an inference that nursing was becoming a separate entity in its own right and describe nursing as patient- rather than institution-led. During the late 1970's, the role of patient advocate was claimed by nurses as part of their expertise (Gadow in Spicker & Gadow, 1980: 84).

An increased confidence in the professionalism and skill of nursing appears to be linked with the emergence of advocacy in the literature. Advocacy then became intertwined in the ***'art of nursing,'*** which was based upon ethical constructs, as opposed to task-orientated behaviour.

Copp (1986: 259) argued that it has been recognized that patients are extremely vulnerable to the powerful institutional processes in the health care system. The self-determination of the patient is still restricted by the generous paternalism exercise of the health care professionals, despite its intents to free itself.

Morrison (in Millar & Burnard, 1994: 273) argued that, because of the usual doctor-patient relationship, which does not allow the patient a sense of control, patients normally surrender their independence to the institutional care system. The patients' inability to speak on behalf of themselves, is a result of the doctor that knows everything but who is uninformative to the patient. Too much emphasis have been placed on waiting times, meals and service allowing the right of patients to information being sacrificed (Mallik, 1998: 1001).

Dubler (1992: 82) describes advocacy in caring as, providing for the patient's interests and needs as they define them by acting to the limit of professional ability. Theorists, educators and clinicians in a wealth of nursing literature, has promoted the nurse as an ***'ideal patients'*** advocate and advocacy, has become a central component in the teaching of nursing ethics (Jameton, 1984: 140). One of the roles that separate nursing from medical ethics is, patient advocacy. Holden (1991: 394) argues that moral and ethical reasoning, autonomy and patient empowerment have become synonymous with the triad of nurse, patient and advocacy. However, the question must be asked if nurses possess the authority to challenge either the medical profession or the bureaucratic health care system when it comes to issues of power and inequality, which are fundamental to the discussion of advocacy (Hewitt, 2002: 441).

Nurse advocacy has attracted medical hostility, causing doctors to feel threatened by the affect it had on the nurses' traditional role as information givers. Therefore, nurses have been fearful to speak out for patients, even when patients were suffering, due to the effects this might have on their careers. Due to accountability to their employers, nurses may be restricted from independent action as an advocate. When the nurse attempts to enter

the domain of advocacy, it may lead to conflict of interest when an employer may claim a moral right to loyalty from their employees (Mallik & McHale, 1995: 28-29). Mardell (1996: 34) warns that nursing has been littered with the casualties of advocacy conflicts over the years. Whilst Carpenter (1992: 26-27) states that when the nurse is required to undertake advocacy in the majority of situations, no conflict will be involved. In order for a patient to make informed decisions about treatment, many have seen the great potential of advocacy as a source of information that will assist them in making the decision. Therefore, accepting risks unconditionally creates the ideal ethical basis for professional practice (Winslow, 1984: 32).

2.10 THE ROLE OF THE PHYSICIAN

In the past, a physician would single-handedly decide on an appropriate treatment for a patient with little or no input from the patient. Patient autonomy and self-determination were undermined by this paternalistic approach, yet it was unchallenged before the 20th century. Between the 1900 and 1940, physicians began obtaining *'simple consent,'* an oral agreement to a procedure, whilst the patient did not understand much about it (Zucker *et al.,* 2010: 24; Quallich, 2005: 49; Whitney *et al.,* 2004: 55; Dunn, 1999: 41; Meisel & Kuczewski, 1996: 2521).

In 1957, the term *'informed consent,'* which includes legal and ethical principles, was first used in a lawsuit. Then in 1972, the patient's right to involvement in the Patient's Bill of Rights was affirmed by the American Hospital Association, which provides the basis for patient care to this day. The Patient's Bill of Rights ensures the right to:

- Obtain complete, current information about diagnosis, proposed treatment, and prognosis; risks and benefits of treatment; and alternative treatments.
- Receive information in terms the patient can understand in order to give informed consent before the start of the procedure or treatment.
- An interpreter, if necessary (Zucker *et al.,* 2010: 24; Kluge, 2007: 410; South Africa. Department of Health, 2004: 4-5; South Africa. National

Health act 2003: 20; Council for International Organizations of Medical Sciences, 2002: Online; National Bioethics Advisory Commission, 2001: Online; World Medical Association. Declaration of Helsinki, 2001: Online; Dunn, 1999: 41-42).

In our society, respect for patient autonomy is of great **moral importance** in clinical practice. The sharing of appropriate information with patients forms the foundation of the medical informed **consent moral and legal** responsibility, which generally is not disputed (Appelbaum *et al.,* 2009: 33; Paterick *et al.,* 2008: 317; Kluge, 2007: 411).

"The legal foundation for adopting the doctrine of medical informed consent is: (1) To establish and promote patient autonomy and; (2) to promote informed, rational decisions." Therefore, *"the courts hold that it is reasonable to require physicians to inform, educate, and partner with patients because patients are generally unable to dissect the details of medical science needed to make an educated decision about treatment"* (Castell v De Greeff, 1994; Cobbs v Grant, 1972). An informed decision might be the product of this **educational process**, should the patient receive enough information. Even if there is not an ideal patient-physician partnership as a result of the disclosure of information, there should at least be progress of patient autonomy in the decision-making process and achieving a foundation for an ethical and trusting relationship between a physician and patient (Castell v De Greeff, 1994; Cobbs v Grant, 1972).

Medical informed consent is ethically, morally and legally mandated by the responsibilities deriving from the relationship between the physician and patient. Ethically, physicians engaged in relationships with patients involving medical informed consent have a moral responsibility to identify the best treatments for each patient on the basis of available medical evidence and to discuss with patients the prospects of success, benefits and the potential risks (Paterick *et al.,* 2008: 313; Quallich, 2005: 49; Kapp, 2002: 1199-1200; World Medical Association. Declaration of Helsinki, 2001: Online). Patients must be allowed to **ask questions** regarding the proposed treatment, benefits and risks and the physician must answer those questions from the available

medical literature and their professional experience. Informed decision-making in the most complex medical situations is promoted by the exchange of information and ideas that is founded in the patient-physician partnership (Paterick *et al.,* 2008: 313; Rado, 2008: 505; Kapp, 2002: 1199-1200).

2.10.1 Assault and Negligence

Due to the ethical and legal implications of the medical informed consent process, all physicians have a **mandatory obligation** to understand this **process**, which will allows sharing of information and exchange of ideas in medical practice that will produce informed decisions (Paterick *et al.,* 2008: 313; Rado, 2008: 503). It is a process and not a once off, because the patient's capacity to consent may change.

Medical informed consent laws in South Africa has stated that: (1**) assault** is defined as the unlawful, intentional, application of force, against the body of another (or the threat thereof); (2) false or negligent representation by a health care practitioner may result in a claim of assault; and (3) in the case of no 'informed consent,' and thus services rendered, constituted assault against the bodily integrity of the patient, therefore the doctor/hospital may incur liability for (a) breach of contract; (b) civil or criminal assault (a violation of bodily integrity); (c) civil or criminal iniuria (a violation of dignity/privacy), or (d) negligence, as the case may be (Oldwage v Louwrens, 2000; Castell v De Greeff, 1994).

A physician can only be held **liable for negligence** if the following four elements cannot be established for his defence:

- A duty of the physician to meet a particular standard of care,
- The physician's failure to perform that duty,
- A casual connection (proximate cause) between the physician's failure and the patient's injury, and
- An injury for which monetary compensation is adequate relief (Keeton, Dobbs, Keeton & Owen, 1984: 164-165).

The physician's duty is measured by two dominant approaches, the ***'physician-based'*** standard and the ***'patient-based'*** standard, which defines

the standard of disclosure of information to the patient. The *'physician-based'* standard requires the physician to disclose information what another reasonable physician would disclose, for example, that other physicians possessing the same skills and practising in the same or a similar community disclose in a similar situation. The *'patient-based'* approach decides whether a reasonable patient in making a decision would consider other information important and therefore required disclosure (Beauchamp & Childress, 1994: 120; Veatch, 1989: 175).

Disclosure of information **might not be required** if a patient is incompetent to make a reasoned decision. If disclosure of information would interfere with treatment or would adversely affect the condition or recovery of the patient, the physician can also withhold information under the therapeutic privilege. And in situations where attempts to secure consent would delay necessary and proper treatment, the emergency exception to disclosure applies (South Africa. National Health act 2003: 20-22; Carnerie, 1987: 55). Lastly, risks that the patient is already aware of, or risks that are commonly known to patients, physicians do not need to disclose (Cady, 2000: 106).

2.10.2 Choice

The doctrine of informed consent is more appropriately applied to situations in which the patient has a **choice** to make, since most informed consent cases deal with elective surgery. Emergency procedures are an exception to the informed consent doctrine to avoid potentially life-threatening delays (Fiesta, 1999: 6; South Africa. National Health act 2003: 11).

The patient's **capacity** to understand the physician's explanation of the proposed treatment is the common issue that affects the consent **validity**. Therefore, the assessment of the patient's **capacity** during the informed consent discussion is the physician's **legal duty**. The physician may request a second opinion regarding the patient's **capacity**, if he has any doubt about the patient's ability to understand the nature of the explanation and the decision's complications. Physicians may also ask the patient's permission to involve family members in the informed consent conversations, to lower any legal risks towards them. If the patient refuses to give such permission, the

nurse or caregiver must document these comments in the patient's medical record (Fiesta, 1999: 6-7). Or the patient may also ask the doctor's permission to involve the family in the decision-making process. As in the case of a black patient, who is family and community oriented, and who requires support from the family during this crisis period to make the decision-making process easier (Du Toit & Van Staden, 2005: 40).

In situations where the **patient does not remember** the discussion or denies receiving an explanation, the signature on the consent form creates a presumption that the patient had been advised of the appropriate risk. Hospitals can use consistent language in a printed consent document to deal with universal issues that may have legal significance regardless of the type of surgery involved. For example, teaching hospitals should clarify that students or residents may participate in the procedure and that the hospital may use information such as slides or video of the procedure for educational purpose. Important statements that physicians sometimes forget to mention or discuss such as, *"there is no guarantee that this surgery will be a success,"* should be included by hospitals (Fiesta, 1999: 7).

The patient must be able to give consent **freely** and also be able to **withdraw** consent freely at any time. The patient's ability to change or withdraw consent is not affected by whether consent was given orally or in writing. A period of 24 to 48 hours might be allowed by the physician for the patient to reflect after consenting to a treatment strategy. During this period the patient can carefully look at the benefits, risks and alternative treatment strategies and come to an independent decision either to proceed with or to withdraw from the proposed treatment. Further, if the patient orally decides to withdraw from the proposed treatment, the physician can either have the patient signed a withdrawal of consent document, or the physician can document the information in the medical records of the patient with specific reference to the date and time (Paterick *et al.,* 2008: 317; South Africa. National Health act 2003: 28).

A competent patient may decline any and all treatment. Even patients who are mentally ill are generally considered competent to decline treatment. But a

responsible physician will ask a psychiatrist to evaluate mentally ill patients, who refuse treatment that is beneficial to them (Roberts, 1998: 100).

Patient's decisions must not be **coerced or manipulated** by members of the health care team or by any other person, such as family, friends, or financial contributors, otherwise the consent will be invalid. The duty of the health care practitioner is to give the patient all the relevant information regarding the proposed operation or procedure, and to make sure that the patient is competent to understand, remember and consider the information regarding the proposed treatment. An exception to medical informed consent would only be considered in an instance if there is enough evidence and motivation that the medical informed consent causes more harm than good (Baeroe, 2010: 91; South Africa. National Health act 2003: 20)

Dealing with the **responsibility** for medical care is not an easy task for patients, because they have the choice of telling physicians what to do in relation to health care decisions. The tone of medical practice has shifted from paternalistic to consultative, in which the physician has to give all information regarding the proposed treatment strategy including the benefits, risks and alternative treatment strategies, and the patient makes a choice. This attitude has been well described by Gawande (2002: 1) who stated that only a decade ago, doctors regarded patients as children, too fragile and simple minded to handle the truth about the diagnosis, let alone make decisions regarding their treatment options. Therefore, they made all the decisions and did not consult patients about their desires and priorities, and patients did what they were told. He is also of the opinion that this change in the decision-making paradigm has improved the quality of medical care generally, although it may not fit all patients. Gawande (2002: 130) also suggests that the shift in responsibility has gone too far: The awkward truth about patient autonomy is that patients are glad to have their autonomy respected, but very often they do not want the freedom autonomy provides, therefore choose sometimes to give it up. The latter is further strengthened by the causes and consequences of poverty such as illiteracy, where patients do not feel confident enough to ask questions and make decisions for themselves, therefore leaving the doctor to make the decision for them (Du Toit & Van Staden, 2005: 212).

When patients have to make decisions regarding medical treatment, they see choice as both a **burden and a blessing**. Therefore, it is important that the physician evaluates each patient-physician relationship individually to clarify each party's responsibilities in the decision-making process. The physician must document this process in detail in the medical record with the assumed responsibilities of each partner in the patient-physician relationship. This process requires empathy, time, mutual understanding, and courage (Paterick *et al.,* 2008: 318).

2.10.3 Valid Consent

To give valid informed consent, the patient's action must be **voluntary** and the patient must be competent. Voluntary can be described as, not a result of force, manipulation or coercion, and the absence of undue external interference. The patient's cognitive level must not be influenced by medication, and the patient should be free from personal emotional stress, or external stress by family members or physicians (Appelbaum *et al.,* 2009: 32; Paterick *et al.,* 2008: 316; Wilkinson, 2001: 343).

A patient or person can only be determined competent or incompetent by a court of law, and not by an ordinary person. The patient's capacity should be the focus with medical informed consent. Capacity means *"the ability to process information received and to communicate a meaningful response."* One of the elements of capacity is that the decision-making person is an adult with no judgment of incompetence or otherwise prohibited by law from exercising that decision-making capacity. Decision-making capacity means *"the ability to understand the significant benefits, risks, and alternative to proposed health care and to make and communicate a health care decision"* (Minnesota Office of the Revisor of Statutes: 2007: Online).

Medical informed consent is **necessary in emergency medical** situations. Although it is a medical emergency, there is evidence that some patients do not fully comprehend all the information given to them to make a fully informed decision, but some patients do comprehend all the information and are capable of given an informed medical consent. A dialogue between the physician and patient is essential. During an emergency medical situation, it is

the unique opportunity to involve family members of health care surrogates in the decision-making process. The patient does not need to stand alone in the patient-physician partnership (Paterick *et al.,* 2008: 317-318; Moskop, 2007: 47; Quallich, 2005: 49; Fish, 2004: 449-450).

2.10.4 Disclosure of information

Even if the probability of occurrence is insignificant, all **severe risks** such as death, paralysis, loss of cognition, loss of a limb, should always be disclosed. Even **less severe** risks that take place frequently should always be disclosed. Risks that are insignificant with low probability of occurrence need not be disclosed. Frequency should be recognized as an important component of a risk and not solely the consequence of a risk, emphasized by courts (Stansfield, 1979: 869). The professional standard requires the doctor, to disclose any information to the patient, what any reasonable and prudent physician with the same background, training, and experience would have disclosed to the patient in the same or similar circumstances (Zucker *et al.,* 2010: 24; Paterick *et al.,* 2008: 315). Explicit guidelines regarding the disclosure of risks are not given by the professional standard.

Courts declare that full disclosure is not required. Full disclosure for physicians involved in medical informed consent, is a course of action that is difficult to stop once it has begun, and can lead to serious problems or disaster. One reason why full disclosure as a standard of practice should not be expected are, the large number of possible and potential risks from routine procedures can span a range of consequence (Lieberman, 1974: 945).

The doctrine of medical informed consent states that there must be a balanced discussion of the treatment strategy before a patient chooses to proceed with a treatment that has risks, including the potential risks and hoped-for benefits. Special attention should be given to the magnitude and frequency of the risks (Hanson, 2001: 71).

What also should be considered are **alternative treatments** and their benefits, risks, and measured usefulness; the possible results of no treatment; and the probability that the proposed strategy will offer a good outcome.

Further, a good outcome and the major expected problems during recovery are described as well as the estimated time to resume normal life activities. Based on the foundation of understanding, the physician should not proceed with treatment until he believes the patient understands the risks and benefits that were presented in a language the patient understands (Hanson, 2001: 71).

2.10.5 The medical informed consent document

The purpose of the medical consent form **and documentation** of the informed consent discussion in the exact terms of the medical consent is, to protect the physician or the institution in case the patient alleges lack of informed consent. The physician would then be able to present the documentation in the court of law as evidence that medical consent was in fact secure. If the medical consent was voluntarily and given by a competent person, and if the information in the medical consent form and documentation of discussion is comprehensive, the probability of a successful lawsuit is low (Van Oosten, 1996: 71; Castell v De Greeff, 1994). However, it is important to remember that a medical consent form does not equate to medical consent, but it only represents evidence that the medical consent process occurred. Despite a signed form, a patient could still present evidence that medical informed consent did not occur, for example when a nurse presented the benefits, risks and alternative treatment to the patient and the physician signed the form as if consent had been obtained (Health Care Professions Council of South Africa, 2007: 10-11).

If a hospital or a health care institution chooses to honour a medical informed consent form, it should contain **all the information** needed to comply with the elements of medical informed consent. The form should contain an accurate description of the proposed procedure, its risks and benefits, the potential advantages and disadvantages of no treatment is to be used, alternative treatment strategies and their risks and benefits, the potential for a successful outcome, the estimated recuperation time, and the estimated time required to return to normal activity. The consent form should contain the name of the physician involved as well as clauses dealing with photography, disposition,

and use of removed tissues, organs, and body parts. Patients should be made aware that they are allowed to cancel or strike out areas on the medical consent document with which they do not agree or to which they do not consent (Montana State Hospital Policy and Procedures, 2009: Online; Kimberley Hospital Complex, 2008: 72-76; Paterick *et al.,* 2008: 316; Minnesota Alliance for Patient Safety, 2007: Online; Waikato District Health Board, 2005: Online).

Further, if the physician is of the opinion that the limits described by the patient on the medical consent document prohibits standard medical practice, he or she should document all the patient-imposed restrictions in the record, with an explanation of how these limits prohibits standard medical practice, and that the limits were discussed and described to the patient. Alternatively, the physician might advise the patient to seek care with another physician if he or she believes that the patient's restrictions seriously inhibit good medical practice and might lead to an undesirable clinical outcome (Paterick *et al.,* 2008: 316-317; Quallich, 2005: 50).

2.11 CONCLUSION

The literature review presented that clear guidelines and legislation exist for the process of informed consent regarding an operation or procedure in health care both locally and internationally. The conclusion however is that the problem of informed consent is either not unique to South Africa, but exist internationally too. However, not much research has been done locally regarding this phenomenon, while a lot have been done internationally. A few prominent studies that were done involve cases for example, Oldwage v Louwrens (2000) and Castell v De Greeff (1994), therefore one of this study's objectives are to contribute to the development of knowledge in this defined field of research. Not many studies describe the total process of informed consent for an operation or procedure, but rather focus on informed consent for biomedical research. However, the studies that do focus on informed consent for an operation or procedure will either focus on one element of informed consent only, whereas a lot of these studies were done by law

practitioners and not by health care practitioners themselves. Therefore it is recommended that more studies involving informed consent for an operation or procedure needs to be done by health care practitioners in the future. This study however will only describe the process of informed consent for an operation or procedure in a public hospital in the Northern Cape, but also has the potential of identifying the gaps in the that specific process on which the recommendations will be based. The next chapter will give a concise presentation of the plan and structure of the study.

CHAPTER 3
Methodology

3.1 INTRODUCTION

In the previous chapter, literature on informed consent was discussed. This chapter however focuses on the methodology of the study concerned. The methodology refers to the research design, data-gathering technique, study population and sampling, pre-test, data collection, validity and reliability, data analysis, and ethical issues taken into account during this study. Then a discussion of the research findings with specific recommendations regarding those findings will follow in the next two chapters, as well as possible limitations of the study (Botma, Greeff, Mulaudzi & Wright, 2010: 296).

3.2 RESEARCH DESIGN

A research design is regarded as a blueprint for conducting a study that enhances control over external factors that could possibly interfere with the validity of the study results. The probability that the study results are accurate reflections of reality, are increased by the control provided by the design (Polit & Beck, 2008: 509; Burns & Grove, 2005: 211). Some researchers consider a research design to be the entire strategy for a study, from the point of problem identification to final plans of data collections. Other researchers limit the design within clearly defined structures within which the study is implemented (Burns & Grove, 2005: 211; Uys & Basson, 2005: 37-38).

The researcher is guided by the research design during the process of planning and implementation of the study in order to gather evidence about the knowledge desired. The design must be efficient, in other words, it must actually achieve the intended goal in the simplest and cheapest way, while being acceptable to both the researcher and participant. Therefore the

researcher needs to specify in the research design the number of groups that will be used during the study, whether these groups will be drawn randomly from the populations involved and whether they will be assigned randomly to groups, and what exactly will be done with the groups in the case of experimental research (Welman, Kruger & Mitchell, 2011: 52; Burns & Grove, 2005: 211; De Vos *et al.,* 2005: 389). The researcher used a descriptive design to yield the knowledge sought.

3.2.1 Descriptive design

A descriptive design was used in an attempt to understand informed consent in relation to surgery in the hospital setting the way things are. This design is also used in studies where more information is required in a particular field about a specific phenomenon as it occurs naturally. Descriptive studies may indicate how variables are related to each other and in what manner they affect each other, but there is no intention of establishing a cause-effect relationship. Although the descriptive design is also used to explain and predict human behaviour it was not the aim of this research (Welman *et al.,* 2011: 23; Brink, 2006: 102).

According to Brink and Wood (1998: 148), descriptive designs are based on the following assumptions:

- In the study population a single variable exists that is easy to describe. Informed consent was described in this study.
- The literature that is describing the population or the variable is sufficient. Sufficient literature regarding informed consent exists in a variety of sources.
- The study may commence without a theoretical framework but a thorough literature review must be done as rationale for the study. No theoretical framework was developed but a thorough literature review was conducted.
- In the case of a known concept, the rationale and theoretical framework for the planned study may be provided by existing studies. The study was based on the four elements of informed consent namely, disclosure of essential information, comprehension of consent information, competency to give consent and decision-making capacity, and voluntary consent.

- Findings cannot be generalized in a study where the criteria for external validity cannot be met because of unknown population parameters. This assumption was taken into consideration during the interpretation of data and contribution to the limitations of this study.

Advantages of descriptive designs are that the descriptions obtained from the study can lead to generation of hypotheses. Descriptive designs could be used to: develop theory; determine what others in similar circumstances are doing; identify problems with current practice; and justify current practice. Problems with current practice will most likely be identified in this study. It was an appropriate design because it is relatively inexpensive and takes less time to conduct. The disadvantages of the study are that the level of the information obtained, is superficial and the design cannot be used to establish a cause-effect relationship between variables (Botma *et al.,* 2010: 110).

A descriptive design focuses on gathering of information from a representative sample of a population. In descriptive studies, the emphasis in the collection of data is on structured observation, questionnaires and interviews or survey studies (Brink, 2006: 103). Data were gathered over a period of three months through structured interviews.

3.3 RESEARCH TECHNIQUE

According to Uys and Basson (2005: 55), a research technique is used as a method by which the researcher can obtain primary information. A structured interview, based on a questionnaire, was used as a research method to gather information regarding informed consent in relation to surgery in the hospital setting.

Questions asked by the researcher were designed beforehand and arranged in a specified order. In some instances, the researcher is allowed to explain the meaning of the question or modify the way in which the question was posed so that the participant can better understand it. However, participants

are given limited opportunities in making additions to previous statements to make the meaning less strong or less general; or to explain the underlying meaning of their responses. This strategy increased the control the researcher exerted over the interview (Botma *et al.,* 2010: 140; Griffiths, 2009: 85-86; Polit & Beck, 2008: 371; Burns & Grove, 2005: 396).

Advantages of structured interviews are that due to the flexibility of this technique, the researcher can get more detailed information than can be obtained with other techniques. Structured interviews gather data that are relatively easy to analyze and ensures that all or most questions are answered. Researchers can use their interpersonal skills to enhance the participant's cooperation and to get more information. Data can be collected from participants who are unable or unlikely to complete questionnaires, such as the very ill or those whose reading, writing, and ability to express themselves, are limited (Griffiths, 2009: 86; Finck, 2008: 163; Polit & Beck, 2008: 371; Burns & Grove, 2005: 397).

Disadvantages are that these methods often take considerable effort and time to develop and refine. They are seldom appropriate for an in-depth examination of a phenomenon (Finck, 2008: 163; Polit & Beck, 2008: 371). Researchers must assume that the information provided by the participant is accurate, because an interview is regarded as a form of self-report. If accurate data needs to be gathered in a timely manner, interviewers would require extensive training and monitoring. Special skills would also be required from these interviewers to interpret responses that are not included in the questionnaire. Interviews are costly because it requires much more time than needed for self-complete questionnaires and scales. Sample size is usually limited because of time and cost. Inconsistency in data collection from one participant to another and subject bias always possesses a threat to validity of the study (Finck, 2008: 163; Burns & Grove, 2005: 397). In spite of the disadvantages cited in the literature the researcher did not feel that it really impacted on the study because he conducted all the interviews and budgeted time and money for the data gathering process.

Furthermore the researcher did not experience difficulty in constructing items for the questionnaire because they were based on the information gathered in the literature review. The researcher had several contact sessions and discussions with his supervisor, other content experts, and the biostatistician when developing the questionnaire for the structured interview. Open questions, closed questions, dichotomous questions, multiple-choice questions, completion questions, scaled questions, statements, and follow-up questions were included in the questionnaire (De Vos *et al.,* 2005: 174). The researcher also tested the usability of the questionnaire.

Figure 3.1 illustrates the steps followed in the development of the questionnaire for the structured interview.

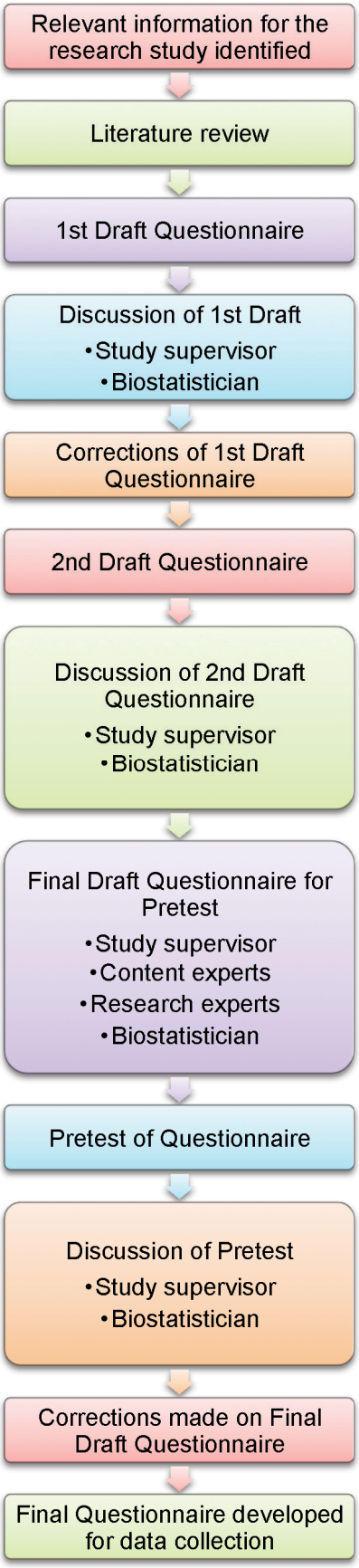

Figure 3.1: Steps followed in the development of the questionnaire

Furthermore, Table 3.1 indicates the relationship between the literature review and the items used in the questionnaire during the structured interview.

Table 3.1: The relationship between the literature review and the items used in the questionnaire.

Nr	Literature content	Question number
1	Demographic information of participant	1.1; 1.2; 1.3; 1.4
2	Disclosure of essential information	4; 4.1; 4.2; 4.3; 4.4; 5; 6; 7; 8; 15; 23
3	Comprehension of consent information	1.4; 6; 10; 12
4	Competency or capacity to give consent	1.1; 6; 7; 9; 9.1; 9.2; 10; 12, 18
5	Voluntary consent	9; 9.1; 9.2; 16; 18; 20; 27
6	Informed consent and the patient	12; 13; 18
7	The role of the physician or nurse	2; 4.1; 5; 7; 8.1; 9; 11; 12; 17; 19; 20; 21; 22; 23; 24; 25; 26; 27
8	Respect	29

3.4 POPULATION

A **population** is referred to as a well-defined set that has certain specified properties. It includes all the **elements** that forms part of the researcher's unit of analysis. A population is the larger pool from which the researcher's sampling elements are drawn, and to which the researcher wants to generalize his findings. It can be composed of people, animals, objects or events with some common characteristics (LoBiondo-Wood & Harber, 2010: 221; Terre Blanche, Durrheim & Painter, 2007: 133).

The definition illustrates that, the population may be broadly defined and potentially involve millions of people or narrowly specified only to include a small number of people. Therefore, when the researcher decides on the population criteria, that is, the entire set of cases about which the researcher would like to make generalizations, a **target population** is established. However, it is often not feasible to pursue a research study using a target population, because of time, money, and personnel. An **accessible population** can be used instead; one that meets the target population criteria

and that is available (LoBiondo-Wood & Harber, 2010: 222; Bordens & Abbott, 2008: 158).

The researcher has to identify the population descriptors that form the basis for the **inclusion (eligibility)** or **exclusion (delimitations) criteria** that are used to select a sample. Proper description of the exact criteria used to decide whether an individual would be classified as a member of a given population, has to be demonstrated by the researcher. The characteristics of the population and the sample should be congruent, in other words, the population descriptors that provide the basis for inclusion (eligibility) criteria should be evident in the sample (LoBiondo-Wood & Harber, 2010: 222; Polit & Beck, 2008: 338; Saks & Allsop, 2008: 157).

The target populations were those patients who underwent a general surgical procedure at a public hospital in the Northern Cape. The accessible population, however, was the portion of the general surgical patients (target population) who had general surgery to whom the researcher had reasonable access. The average size of the accessible population was 53 patients per month, which was based on the institutions general surgical statistics of 2009. The findings of the study will be generalized to the accessible population rather than to the target population. Another important aspect of the unit analysis process is sampling which will be discussed hereafter.

3.5 SAMPLING

A **sample** is defined as a subset of individuals selected from a larger population (Bordens & Abbott, 2008: 159), and **sampling** is the process of selecting those individuals from a larger population to represent the entire population in a research study. Although sampling is regarded as a complex process, it is familiar to us. On a daily basis we gather knowledge, make decisions, and formulate predictions based on sampling procedures. Researchers can obtain knowledge from samples, draw inference and make generalization about the population without examining each element in the population. When a specific criterion for selection is included in the sampling

procedure, all the characteristics of the phenomena of interest will be, or are likely to be, present in all the participants being studied. The evidence generated by the sample composition, is strengthened by the researcher's efforts to ensure that the sample is representative of the target population (LoBiondo-Wood & Harber, 2010: 221-224; Finck, 2008: 291; Saks & Allsop, 2008: 156-157).

Representativeness is foremost the main concern in sampling. A sample is representative when it possesses the key characteristics closely related to those of the study population. Representative samples are an important factor in descriptive studies whose aim is to estimate accurately the properties of populations. A researcher cannot guarantee that a sample is representative of a population without a database of the entire population as evidence. If the researcher uses a sampling strategy that minimizes or controls **sample bias**, the data obtained from a sample is almost always a reasonable accurate presentation of the phenomena under investigation (LoBiondo-Wood & Harber, 2010: 224; Saks & Allsop, 2008: 157; Terre Blanche *et al.,* 2007: 49). The sample was representative in the sense that all the participants were patients who had undergone a general surgical operation or procedure in a public hospital in the Northern Cape, therefore could be included in the study in an attempt to understand the research phenomena.

Another concern in sampling is the **size of the sample**; a large nonrandom sample may be quite unrepresentative of the study population, and the same with a very small **random sample**. The sample must be large enough to allow the researcher to make inferences about the study population. The size of the sample depends on the type of study conducted and on numerous measurement and statistical criteria. Often sample size is partially determined by practical constraints, for example, the researcher's accessibility to study participants, how much money and time is available for study, etc. The determination of a sample size, also known as **power analysis**, takes place when the number of participants in the study determines (to some degree) the power the researcher has to detect an affect or true difference in experimental and control groups (Finck, 2008: 250-251; Terre Blanche *et al.,* 2007: 49). Power analysis could not be determined because there were no experimental

or control groups. After due consideration of all the factors the researcher decided on nonprobability convenient sampling because of time and fiscal constraints.

3.5.1 Nonprobability Sampling

Elements are chosen by nonrandom methods when nonprobability sampling techniques are used. A disadvantage of this strategy is that the researcher is unable to estimate each element's probability of being included in the sample. Essentially, the chance of every element's inclusion in the nonprobability sample cannot be ensured. As a result, this type of strategy is less likely to produce accurate and representative samples than probability sampling (LoBiondo-Wood & Harber, 2010: 225; Polit & Beck, 2008: 341). Despite this fact, convenience sampling was used as the primary sampling method because it was feasible and affordable.

3.5.1.1 Convenience Sampling

In **convenience sampling**, the most convenient available people are used as study participants, in other words, participants that happened to be in the right place at the right time. Available participants are simply included in the study until the desired sample size is reached. Usually not all individuals included in a convenience sample are known to the researcher (Polit & Beck, 2008: 341; Burns & Grove, 2005: 350).

The advantages of convenience sampling are that generally it is inexpensive, accessible and the researcher requires less time to obtain study participants than other types of samples. The only concern that the researcher has is to obtain a sufficient number of participants who meet the same criteria. Even though convenience sampling is not the strongest approach, it sometimes is the most appropriate sampling strategy to use in conducting studies on topics that could not be examined through the use of probability sampling. Thus information can be acquired from unexplored areas through the means of this sampling strategy. Convenient sampling can be useful when it is used with knowledge and care in implementing descriptive and correlational studies. However, this type of sampling strategy is not recommended for examining

the impact of treatment in a study (LoBiondo-Wood & Harber, 2010: 226; Saks & Allsop, 2008: 158; Burns & Grove, 2005: 351; Babbie, 2004: 82).

The disadvantage of convenience sampling is that accessible participants might be atypical of the study population with regard to critical variables. Convenience sampling, also known as **'accidental sampling,'** is considered a weak approach to sampling because it provides limited control for biases (Polit & Beck, 2008: 341). The risk of bias is greater than in any other type of sample and range from minimal to serious. The probability that researchers may use individuals, who feel strongly about the issue being studied, is increased by the use of voluntary participation, which may favour certain outcomes in the study. Therefore, researchers need to think carefully, identify and describe known biases in their sample criteria used to determine the target population in order to improve the representativeness of the sample (LoBiondo-Wood & Harber, 2010: 226; Burns & Grove, 2005: 350).

Convenience sampling was used to select post-operative surgical patients in the general surgical unit, which were the most convenient accessible people as study participants (Polit & Beck, 2008: 341; Saks & Allsop, 2008: 158). Based on the population statistics of 2009, the researcher would be able to select approximately 53 participants per month. Therefore, the researcher aimed to obtain 150 participants over a period of three months for the study as the sample for the structured interview, using the convenience sampling method.

Participants that were included in the study were post-operative general surgical patients older than 18 years, who had undergone an operation or procedure at a public hospital in the Northern Cape. The convenience factor was that all participants who were discharged on a daily basis were included in the study sample. Participants that were excluded were the ones that suffered from pain; those under sedation; and those who had a decreased level of consciousness or a psychiatric co-morbidity (American Association of Critical-Care Nurses, 2006: Online).

3.6 PRETEST

A **pretest** is defined as, (1) the selection of data prior to the main data collection process; also known as baseline data; (2) the trial administration of a newly developed instrument to identify flaws, such as the usability of the measuring tool and recording forms or to assess time requirements (Botma *et al.,* 2010: 275; Polit & Beck, 2008: 762).

Researchers who develop a new instrument for the purpose of methodological studies almost always subject it to a thorough pretesting process in order to evaluate and refine the measuring tool. However, it is recommended to conduct a small pretest even when the data collection plan involves existing instruments. The pretest usually involves a few participants that meet the criteria of inclusion, however the data collected during this process are not included in the main study (Botma *et al.,* 2010: 275; Polit & Beck, 2008: 380).

The purpose of the pretest includes determining the time it will take to administer the entire instrument package and whether participants find it burdensome. Because in some instances researchers use multiple instruments, which makes it difficult to estimate how long it will take to administer the complete set. These estimates might be important for the purpose of the participant's informed consent or for the development of the study or project budget. If the pretest instruments require more time than is acceptable, the researcher would be obligated to eliminate certain variables or instruments guided by the study's priority. Other purposes of the pretest includes the following: (1) identifying parts of the instrument package that are difficult to read, understand or interpret by the pretest participant, that is, if the instructions on the measuring instrument are clear or if there is any ambiguity in the questions or assessment; (2) identifying any instruments or questions that is embarrassing or cultural insensitive, leading to participants finding it objectionable or offensive; (3) determining whether the sequence of instruments or questions is sensible; (4) determining the need for training of field workers; and (5) determining whether the measuring instruments yield data that will answer the research question (Botma *et al.,* 2010: 275; Polit & Beck, 2008: 380; De Vos *et al.,* 2005: 206-213).

The researcher conducted the pretest at the selected hospital, as this is the only level three public hospital in the Northern Cape; secondly, it was cost effective for the researcher as there were no traveling expenses. A structured interview was used as research technique to obtain the primary information from 10 post-operative general surgical patients who met the inclusion criteria of the study. The pretest results were excluded from the main study.

The researcher ensured that the participants that were included in the pretest met the inclusion criteria as indicated previously in this chapter (See paragraph 3.4). A week before the pretesting took place, the researcher went to the hospital's Chief Executive Officer (CEO), Assistant Director of General Surgery, and all the Unit Managers of the general surgery units to inform them that the pretest will commence within a week. With the application for the research study approval, the researcher requested the CEO not to discuss the content of the application with any health care professional as it may undermine the validity and reliability of the information obtained during the pretest and the main study. Copies of the research study's approval from the UFS Ethics Committee and the hospital were handed to all Unit Managers to ensure that all staff members were informed of the activity that would take place. Study participants, however were all verbally informed by the researcher who read and explained the information document to all of them (See Addendum F). Once the participant was satisfied with all the information given to them, and all questions were answered in a satisfactory manner, the researcher asked their consent to participate in the research study and to sign the applicable document (See Addendum G) as proof of consent. Participants gave their signature on the consent form and those who could not write marked 'X' whereby the researcher wrote their full name and surname next to it. Only then data was collected by means of a structured interview. After the structured interview, the participant received a copy of the Information Document and the signed Consent Document. The researcher then thanked the participant for his/her participation, greeted and left.

No study limitations were noted by the researcher during data collection in the pretest. All participants responded to questions in a satisfactory manner. The pretest took five days to complete due to the availability of participants. The

time frame of each interview differed from each participant to the other, from 20-30 minutes. The results of the pretest were discussed with the study supervisor and the biostatistician in order to benefit from their expertise and to refine the questionnaire. Both of them were in agreement that some questions had to change, omitted or be adapted to answer the research question.

The following changes, omissions and adaptations were made to the questionnaire.

Question 1.4 initially read:

Highest level of education:……

Options were added to the question to make it easier for the participants to choose. Thereafter, the question read as follows.

Highest level of education

1: Uneducated	2: Primary	3: Secondary	4: Tertiary

Question 2.1 initially read:

If yes, have you read the Patient's Bill of Rights?

The question however was omitted from the final questionnaire, because with the pretest the researcher found that most of the participants were aware of the Patient's Bill of Rights, they also understood these rights under the 'different levels of understanding' as categorized in the pretest questionnaire, but might not necessarily have read the bill.

Question 4.1 initially read:

If yes, name all the people that gave you information

☐ Physician

☐ General Practitioner (GP)

☐ Nurse

☐ Other, specify……

The term ‘Doctor’ replaced both the terms ‘Physician’ and ‘General Practitioner,’ because the participants did not know the difference between the latter. Therefore, the question read as follows.

If yes, name all the people that gave you information

☐ Doctor

☐ Nurse

☐ Other, specify……..

Question 4.2 initially read: In how many sessions was the procedure explained to you?.....

Different options were provided to the participant to make it easier for the participant to give at least an estimate number of visits because most of them during the pretest could not remember the specific number of visits they had from the medical practitioner. The question was changed as follows:

In how many sessions was the procedure explained to you?

Less than 5 ☐ 5 – 10 ☐ More than 10 ☐

Question 4.3 initially read:

Would you have preferred, More ☐ or Fewer ☐ sessions?

The question was difficult for the participant to answer, because they could not say whether they would have preferred more or less visits, but they could explain that they were satisfied or not satisfied with the number of sessions. Therefore the question was changed as follows:

Are you satisfied ☐ or not satisfied ☐ with the number of visits?

Question 5 initially read:

On which of the following aspects did you receive information		
	Yes	No
Procedure		
Risks		
Benefits		
Alternative treatment		
Good outcome		
Worst outcome		
Expected problems during recovery		
Estimated time to resume normal life activities		
Self-care after the procedure or operation		
The use of medication/drugs		

The options however were adapted because the participants could not make the distinction between certain options, therefore caused confusion. The following changes were made – the term 'Risk' replaces 'Worst outcome' and 'Expected problems during recovery,' and the term 'Advantages' replaces 'Good outcome.'

Question 11 was placed right after Question 4.1 to enhance a better flow of questions.

Question 13. 2 initially read:

Motivate your answer…….

The question seemed unnecessary because most of the participants had no explanation to give, whether Question 13. 1 was positive or negative (yes/no), therefore needed to be omitted.

Question 16 initially had only two options:

Did the doctor who explained to you carry out the procedure?

Yes ☐ No ☐

The option 'Not sure' was added to 'Yes' and 'No,' because not all participants were certain who performed the operation or procedure.

Question 20 initially had three options:

When the doctor explained the procedure to you, did you feel

drowsy ☐ excited ☐ or anxious ☐

The option 'Normal' was added to 'Drowsy, Excited, or Anxious' because there was participants who felt normal, because they had no medication or anything that made them felt different.

Question 20.1 as a result had to change due to the change made in the previous question. Before change it read:

If yes, what made you drowsy/excited or anxious?

Now it read as follows:

If you felt drowsy, excited or anxious, what caused it?

Question 25 initially read:

Did you know that you may change your mind within a day regarding the procedure or operation? Yes ☐ No ☐

The question however was changed because primarily it remains the responsibility of the medical practitioner to give the patient all the relevant

information to make an informed decision regarding the proposed treatment strategy.

Therefore the question was changed and read as follows:

Were you informed that you may change your mind within a day regarding the procedure or operation? Yes ☐ No ☐

3.7 DATA COLLECTION

Data collection is defined as the process of selecting participants and gathering data from these participants. The steps of data collection are specific to each study and also depend on the research design and measuring method. The methods of collecting data from participants may include the following: observing, testing, measuring, questioning, recording, or any combination of these methods. The researcher has an active role in this process of data collection either by collecting data or by supervising data collectors. The researcher must have the skills to: manage people and solve problems effectively as data collection tasks are implemented; resolve kinks in the research plan and use support systems effectively (Burns & Grove, 2005: 430). The researcher collected all the data and was on the spot to solve any problems.

During the process of data collection, researchers perform four tasks in both quantitative and qualitative research. These tasks interrelate and occur concurrently rather than in a sequence. The tasks involve selecting participants, collecting data in a consistent manner, maintaining research controls as indicated in the research design, and solve problems that pose a threat to the research study (Burns & Grove, 2005: 430).

Ethics approval had to be sought before data collection could commence. After several contact sessions with the study supervisor, content experts and biostatistician the application was submitted for approval at the UFS Ethics Committee. See addendum D for a copy of the approval letter.

For the purpose of getting permission for collecting data at the selected hospital, the researcher made an appointment with the CEO of the institution. On appointment, the CEO and the researcher discussed the content of the application and the importance of the study. The researcher requested the CEO not to discuss the application or study with any health care practitioner as it might influence the validity and reliability of the data collected. Thereafter, an official application was submitted in the form of a letter and was approved by the CEO of the hospital (See Addendum E).

In a quantitative study, both the data collection plan and the implementation thereof affect the quality of the data collected. The researcher himself collected the data, because the study was small enough to be handled by one person. Although the researcher collected the data him-self, he strongly considered various elements that may have influenced the data collecting process namely previous interviewing experience, congruency with sample population, appearance and availability of the researcher (Polit and Beck, 2008: 382).

The researcher worked for five years in a Trauma and Emergency Unit, dealt with recording of patient information through the process of interviewing patients, relatives, emergency response personnel, etc. using the Triage system. He assisted patients on a daily basis to complete customer satisfaction questionnaires. In general, the researcher has good verbal and social skills, which allow effective communication with study participants.

The researcher was dressed in uniform and wore his nametag when collecting data from participants. The researcher avoided wearing anything that conveyed his political, social, or religious views, for example, clothing with political or religious statements, jewelry with peace symbols, political buttons, etc.

3.7.1 Process of data collection

A week prior to the actual data collection procedure, the researcher informed the hospital staff when the study will commence. The researcher informed them what time he would arrive and how long he would stay in the ward. This

confirmation was done to remind the nursing staff in a polite manner of the study that would take place. Copies were made of the Information Document, Consent to participate in the research, and Questionnaire in both English and Afrikaans (See Addendum F, G and H). A register was developed to assist the researcher with recordkeeping.

Data collection took place from June to August 2011, on the day of the participant's discharge from the hospital to ensure consistency in the data collection process and to avoid conflict between the participants and the health care practitioners prior to the procedure or an operation. A total of 150 questionnaires were completed through structured interviews. Maintaining this consistency and control during participant selection and data collection; helped to protect the integrity or validity of the study (Burns & Grove, 2005: 430).

When the researcher entered the ward he went to the RN in charge of the ward and obtained a list of patients who were to be discharged after their general surgery. Nursing staff sometimes accompanied the researcher to the identified participant's bedside to inform them about the study. The researcher introduced himself and greeted all potential participants with a friendly professional demeanor. He conversed in a natural tone to build and establish rapport (Polit & Beck, 2008: 365; Uys & Basson, 2005: 63). After having checked that the patient met the inclusion criteria the researcher ensured privacy of interview by taking the participant into a private room or drew the curtains around the participant's bed when no room were available, where after the information was read and explained as recorded on the Information Document (See Addendum F) to the study participant. Potential participants were informed of the nature of the questions and the type of response to be expected of them. They were also informed that they were not expected to provide information when they are disinclined to do so, or to act in any way contrary to their beliefs or principles (Uys & Basson, 2005: 62-63). Once the participant was satisfied with all the information they received, and all questions were answered in a satisfactory manner, the researcher asked their consent to participate in the research study and to sign the applicable document (See Addendum G) as proof of consent. Those who could not sign

the document marked ‘X’ whereby the researcher wrote their full name and surname next to it.

The hospital consent document was reviewed to determine whether the participant had consented to the procedure or operation and if that was recorded. The detail information that was recorded in the participant’s record and the category of staff that gave the information to the participant was noted.

After having obtained informed consent and establishing that the patient met the inclusion criteria the researcher used the questionnaire to obtain data from the participant in a respectful and dignified manner. Each question was read out to the participant by the researcher and the participant was given time to respond. The researcher focused on the answers given by the participant and tried to eliminate any form of interruption or leading the participant in answering (Uys & Basson, 2005: 63). Whenever a participant did not understand a question, the researcher repeated the same question, or explained the meaning of the question, or modified the way in which the question was posed so that the participant could understand it (Burns & Grove, 2005: 396). The researcher recorded all the information as expressed by the participant immediately to ensure that information was precise and correct, and also to avoid important aspects of the interview process from getting lost (Uys & Basson, 2005: 64). Participants were allowed to express their feelings, although the researcher kept the interview within the study aims and objectives. After the structured interview, the researcher provided the participant with a copy of the Informed Document and signed Consent Document. He then thanked the participant for their participation, greeted and left.

3.7.2 Managing data

Each questionnaire was numbered and logged in the register kept by the researcher and stored in a safe place. At the end of the data collection period, the researcher coded every question on each questionnaire. The researcher also developed a list of codes for open-ended items. After that, all the questionnaires were handed to a biostatistician at the UFS for data capturing

and analysis. The software they used to analyze the data is known as Statistical Analyses Software (SAS). When the researcher received the questionnaires from the biostatistician, he stored it in safe place for a period of three years as prescribed by international research guidelines, thereafter it will be destroyed. The complete data analysis process however will be discussed in Chapter 4.

3.7.3 Challenges in data collection

The following were identified as challenges the researcher experienced in this study:

- The researcher planned to see at least five participants per day based on the general surgical statistical information of the selected hospital, but unfortunately was not the case.
- There were days that the researcher conducted five interviews per day and some days none.
- Medical practitioners responsible for the discharge of patients in the general surgical wards did not have a fixed routine of doctors rounds, causing the researcher to run around between general surgical wards.
- Patients stood for long periods in hospital before discharge, causing cancellations of booked operations or procedures.
- Sometimes nursing staff would identify patients that did not qualify to be included in the research study, but due to the researcher's experience as a RN, he was able to identify that.

3.8 VALIDITY OF STUDY

Study validity is referred to as a measure of the truth or accuracy of a claim, which is an important concern throughout the research process. Validity is considered a complex idea that is important to both the researcher and those reading the study report and consider using the research findings in their practice. In order for the researcher to make a critical analysis of the research, he should be able to think through threats that occurred to the validity and make judgments about the affects of these threats to the integrity of the

research findings. Validity provides a basis in the process of adding new information to the evidence base for patient care (Burns & Grove, 2005: 214).

Validity was safeguarded through three sources namely: the literature, content experts, and representativeness of the relevant population. The researcher did an extensive literature review through the use of electronic resources, books and journals for the following reasons: (1) to gather all the relevant information to compile a questionnaire for the purpose of the structured interview; (2) address the study objectives as indicated in Chapter One; and (3) avoid obtaining data which is not related to the study objectives.

Several consultations took place with the study supervisor from the idea from which the study was developed to the end where the approximate truth or falsity of the idea was addressed. The biostatistician became involved from the time the research proposal was drafted until the end of the research study. Regular consultations were held with the supervisor and a biostatistician to review the data collection tool and to ensure that the information was accurate and interpretable. Corrections were made according to comments and suggestions from these experts. The researcher used follow up appointments as control measure to prevent factors that could influence the study negatively and to verify that changes were made according the expert's comments. Several content experts were consulted on regular basis for their input and assistance (See Figure 3.1: Steps followed in the development of a questionnaire).

With the assistance of the biostatistician the researcher sampled a representative portion of the accessible population. The study focused on the process of informed consent prior to an invasive operation or procedure and the researcher chose post-operative general surgical patients as the study population. In this case, the data obtained from the study sample gave a reasonable accurate presentation of the phenomena under investigation (LoBiondo-Wood & Harber, 2010: 224; Saks & Allsop, 2008: 157; Terre Blanche *et al.,* 2007: 49).

3.9 RELIABILITY OF THE STUDY

Reliability is defined as the degree of consistency or accuracy with which an instrument measures an attribute (Polit & Beck, 2008: 764), in other words, the event to which an instrument gives the same results when repeated. Reliability is concerned with consistency, accuracy, precision, stability, equivalence, and homogeneity (LoBiondo-Wood & Harber, 2010: 295).

In this study the reliability factor was mostly enhanced by the use of a questionnaire in a structured interview to obtain data from the study participant. A pretest was done prior to the actual data collection period to improve the quality of the questionnaire by editing items on the data-collecting tool. After corrections were made, the questionnaire was approved by the study supervisor, content experts and a biostatistician and regarded as the final questionnaire. The final questionnaire, available in English and Afrikaans was used with every participant to ensure that everyone was asked the same questions, which ultimately enhanced the consistency in the research study. Interviews were conducted during the day after doctor's rounds were finished and patients were discharged. Questionnaires were completed by the researcher instead of fieldworkers, which gives more reliability to the measurement method. The researcher designed the questionnaire, therefore was familiar with the content and construct of the questions allowing the researcher to have a more fluent interview with the participants as would be expected with fieldworkers. The researcher is also conversant with the terminology used in the questionnaire, allowing the researcher to explain or modify questions in an easier manner whenever a participant did not understand a research question. Consistency of the study was enhanced by the use of one person who conducted the structured interviews. Only patients who had an operation or procedure categorized under general surgery were interviewed on the day of discharge from hospital.

3.10 ETHICAL CONSIDERATIONS

According to Polit and Beck (2008: 753), **research ethics** is defined as "… a system of moral values that is concerned with the degree to which research procedures adhere to professional, legal, and social obligations to the study participants." When human beings are used as study participants; which is usually the case in nursing research, the researcher must ensure that the rights of those human beings are protected. Ethical consideration in research applied to both the participants involved in the research and the researcher who carried out the research (Uys & Basson, 2005: 96). Various codes of ethics have been developed in response to the violation of human rights and moral principles in research (Polit & Beck, 2008: 168).

The **Nuremberg Code of 1947** became the first internationally recognized set of guidelines established to protect the rights of research participants. This Code mandated that study participants must be able to give voluntary consent to participate in a study for the good of society with balanced risk and benefit, adequate protection of participants from risks or harm, the participant's right to withdraw at anytime from the study, and qualifications for researchers (Brink, 2006: 30; Burns & Grove, 2005: 177). Although the Code omitted two major classes of research subjects, namely children and the mentally incompetent persons, the **World Health Organization (WHO), and Declaration of Helsinki** corrected this by including children, only if permission from the parent(s) is obtained, and mentally incompetent persons, if proxy consent is obtained, that is consent from the closest family member. The Declaration further distinguishes between research that benefits the research participant (therapeutic research) and research which has indirect benefits for the participant (non-therapeutic research), and sets clear restrictions on researchers undertaking the latter (Berg, 2007: 55; Brink, 2006: 30; Burns & Grove, 2005: 177; Uys & Basson, 2005: 97).

In South Africa, the South African Medical Research Council (MRC), the Human Science Research Council (HSRC), the Democratic Nursing Organization of South Africa (Denosa), and recently the Department of Health

(DoH) have developed guidelines for research conducted in the country (Brink, 2006: 31).

Another important code of ethics; is the **Belmont Report** which further describes ethical research practice that involves human participants. The Belmont Report articulated three primary principles of ethical treatment of human participants underlying all medical and behavioral research: **beneficence, respect for human dignity, and justice**. These principles are discussed briefly hereafter followed by the procedures the researcher adopted to comply with these principles (Bordens & Abbott, 2008: 193; Polit & Beck, 2008: 170; Burns & Grove, 2005: 735).

3.10.1 Beneficence

Beneficence is one of the most fundamental ethical principles in research. It obligates the researcher to minimize harm and to maximize possible benefits. Participants should be treated in an ethical manner and their decisions respected, they should be protected from harm, and efforts should be made to secure their wellbeing. Research that involves humans should be intended to produce benefits for the participants themselves, for a common situation, or for the good of society (LoBiondo-Wood & Harber, 2010: 250; Polit & Beck, 2008: 170).

The study is relevant to three groups namely: the health care practitioners who include the general surgeons and nurses, the policy-makers who are the hospital management, and the study population who are the patients.

Thus the study might demonstrate usefulness in three broad respects such as:

- Contribution to existing knowledge.
- The hospital management (policy-maker), health care practitioners and health care practices might find usefulness and meaning in the study.
- The results of the study might be generalized to relevant groups in other settings who stand to benefit from it.

The results might also contribute to theoretical knowledge of the profession and also the research methodology. Furthermore, the results will be disseminated orally in community meetings and conferences for public scrutiny and critique. It will also be published in nursing journals for nurse practitioners to use as theoretical information and research methodology (De Vos *et al.,* 2005: 115-116).

Beneficence includes the participant's right to freedom from harm and discomfort, and the right to protection from exploitation.

3.10.1.1 The right to freedom from harm and discomfort

The researcher has the responsibility to secure the wellbeing of the participant, who has a **right to protection from discomfort and harm**. This right may involve physical, emotional, spiritual, economical, social or legal wellbeing (Brink, 2006: 32). When a research study involves humans, the researcher has an obligation to avoid, prevent, or minimize harm (nonmaleficence) of the research participant. Research participant's involvement in a study should only be directed towards achieving scientifically and societally important aims that could not otherwise be realized, therefore participants should not be subjected to unnecessary risks for harm or discomfort (Polit & Beck, 2008: 170).

In this study, no physical or physiological harm was inflicted on participants because the study did not involve any innovation therapy or treatment. The risk of the participant developing fatigue or a headache due to the structured interview was minimal because the interview took approximately 30 minutes and the questions were formulated at the level of an eighth grade. No psychological or emotional harm was inflicted because the study was not more intrusive than it needed to be. The researcher was very sensitive towards the responses and reactions of the participants. No social or economic harm or discomfort was caused that includes the expenses involved in traveling to and from the data-collection site.

3.10.1.2 The right to protection from exploitation

The researcher should further ascertain that research participants not be placed at a disadvantage or exposed to situations for which they have not been prepared. Assurance that their participation in the research study, or the information that they might provide will not be used against them in any way; needs to be given by the researcher (Polit & Beck, 2008; 171).

All information was kept confidential and no names or identifying information were recorded on the questionnaires. Aggregated results would be disseminated through conference proceedings and/or publications in academic journals. Additional to beneficence is respect for human dignity which is the second ethical principle presented in the Belmont Report.

3.10.2 Respect for human dignity

Respect for human dignity refers to the participant's right to self-determination and to act as autonomous agents who are capable of making their own decisions. Thus, the research participant has the freedom to enter into participation voluntarily and be fully informed. Participants with diminished autonomy or capacity are entitled to protection (LoBiondo-Wood & Harber, 2010: 250; Bordens & Abbott, 2008: 193).

3.10.2.1 The right to self-determination

The right to self-determination involves the individuals' right to be treated as autonomous agents, capable of controlling their own activities. It is the prospective participant's right to decide voluntarily whether to participate in a study, without risking any penalty or prejudicial treatment. It also includes the individual's right to ask questions, to refuse to give information, or to withdraw from the study at any time (Polit & Beck, 2008: 172; Brink, 2006: 32; Burns & Grove, 2005: 181).

A person's right to self-determination further includes freedom from **coercion** of any type. Coercion occurs when the researcher explicitly or implicitly threatens the participant with a penalty when they refuse to participate in a study, or offering the participant excessive rewards for agreeing to participate.

Careful thought should be taken especially if the researcher is in a position of authority, control, or influence over the potential participant, not to risk coercion (Polit & Beck, 2008: 172).

The risk of the participant's care being adversely affected was eliminated, because the participant was interviewed on the day of discharge, leaving no time to affect their relationships with the health care practitioners. The process of informed consent was followed to protect the right to self-determination:

- The researcher designed a consent document that was used to obtain consent from the prospective participant to participate in the study.
- The participant's role in the study was clearly defined by the researcher, to ensure that they understood their status in the study.
- Participants were informed of the study goals and the type of questions that were asked.
- The structured interview method was described to them and the estimated time commitment from them. Information on who was funding the study and its academic requirements were shared with participants.
- The researcher explained the convenient sampling method and how many participants took part in the study.
- The participants were informed of any possibility of harm or discomfort.
- The benefits of the study to patient care and the health care institution were mentioned. They were also informed that no stipend would be given to any participant for taking part in the study.
- Assurance was given that participant's privacy and confidentiality were protected at all times.
- The researcher indicated that participation was strictly voluntary and failure to do so would not influence their treatment process in the hospital.
- The participants were informed that even after consent has been given to participate they still had the right to withdraw from the study or withheld information from the researcher.
- Information on whom they can contact if they had further questions, comments or complaints, were also given to them (Polit & Beck, 2008: 176-177).

- No participant was forced, coerced or manipulated to participate in the research study. In the interview process, participants were allowed to ask questions and gave their opinion.

3.10.2.2 The right to full disclosure

The principle of respect for human dignity further includes the individual's **right to full disclosure of information** in order to make an informed and voluntary decision about study participation. Full disclosure involves a full description of the nature of the study given by the researcher, the individual's right to refuse participation, the researcher's responsibilities, and the potential risks and benefits of the study. The right to self-determination and the right to full disclosure are two major elements on which informed consent are based (Polit & Beck, 2008: 172).

The third principle included in the Belmont Report concerns justice which will be discussed hereafter.

3.10.3 Justice

Justice means that every study participant should be treated fairly. When a benefit to which a participant is entitled is denied without good reason or when a burden is imposed unduly, an injustice occurs (LoBiondo-Wood & Harber, 2010: 250). The burden of research is equally divided between the researcher and the participant by the principle of justice. Costs and potential benefits of research should be shared among them. The principle of justice guards against the use of participants simply because they are readily available, are convenient, and may have difficulty in refusing participation in research (Bordens & Abbott, 2008: 194). The principle of justice includes participants' right to fair treatment and their right to privacy.

3.10.3.1 The right to fair treatment

The right to fair treatment entails that participants should be treated fairly and should receive what they are due or owed. Fair treatment means equitable selection of study participants and their treatment during the research study. Participants should therefore be selected only for reasons

directly related to the problem studied, and not because of the convenience of study population, their compromised position or vulnerability. Fair treatment also includes the fair distribution of risks and potential benefits regardless of age, race, or socioeconomic status (LoBiondo-Wood & Harber, 2010: 252; Bordens & Abbott, 2008: 194; Brink, 2006: 33).

Convenient sampling was done for reasons directly related to the study phenomenon and to ensure that participants would be treated fairly in the selection process. All participants were treated with equal respect regardless of their beliefs, habits and lifestyles, as they were from different backgrounds and cultures. They were treated in a non-prejudicial manner, whether they declined or withdraw after agreeing to participate in the study (Polit & Beck, 2008: 173-174). The researcher used two languages, namely English and Afrikaans, because the majority of the population in that region of the country is competent in these languages.

3.10.3.2 The right to privacy

The right to privacy entails the freedom of the participant to determine the time, extent, and circumstances under which private information is shared or withheld from the researcher (LoBiondo-Wood & Harber, 2010: 252; Brink, 2006: 33). Although participants were encouraged to answer all questions honestly, they were informed that if they felt uncomfortable, they did not need to answer the question. All the participants answered all the questions during the structured interviews.

3.11 CONCLUSION

In this chapter a detailed description of the research methodology was given, in other words, a description of how the study was conducted. It was concise, yet it provided sufficient detail to allow the reader to critique or replicate the study procedures. The study's design, technique, population, sampling, data collection, validity, reliability, and ethical considerations were discussed in this chapter. The study included a pretest, therefore a detailed description of all its processes including the planning, implementation and results obtained were

presented. The changes that were made in the study were based on the pretest and further described (Burns & Grove, 2005: 587-588). In the next chapter, a detailed discussion on the process of data analysis, results and findings will follow.

CHAPTER 4
Data analysis, results and findings

4.1 INTRODUCTION

Polit and Beck (2008: 751) defines data analysis as "… the systematic organization and synthesis of research data." Researchers are enabled by the use of statistical procedures to organize, interpret, and communicate numeric information – because without statistics, quantitative data would be a choice mass of numbers.

In order to perform statistical analysis of data from a quantitative study, the researcher must be able to (1) prepare the data for analysis; (2) describe the sample; (3) test the reliability of the measures used in the study; (4) perform exploratory analyses of the data; (5) perform analyses guided by the study objectives, questions, or hypotheses; and (6) interpret the results of statistical procedures (Burns & Grove, 2005: 441). To obtain a proper understanding of the process of analysis, the researcher will describe the statistical theory hereafter.

Statistics are described as either descriptive or inferential. The purpose of descriptive statistics is to describe and synthesize data. Examples of descriptive statistics are averages and percentages. When descriptive index is calculated from a population data, it is called a parameter; and from a sample, it is called a statistic. Generally research questions are about parameters, therefore the researcher uses inferential statistics – which is a result of statistics that has been calculated and estimated to make inferences about the population (Polit & Beck, 2008: 556). This study made use of descriptive statistics, however, the researcher will discuss the levels of measurement next because the analyses depended on how variables were measured.

Before the researcher can analyse the data, he had to ascertain the measurement level of the data that was collected. There are variables which denote categories, while other variables give measurements or counts resulting in two broad classes namely: categorical (or qualitative) data and quantitative (or numerical) data (De Vos *et al.,* 2005: 219). The variables in this study gave measurements or counts therefore it were categorized as quantitative (or numerical) data.

4.2 LEVELS OF MEASUREMENT

The process of assigning numbers to variables or events according to rules is called measurement. When a specific number is assigned to a variable in the research study, every other variable similar to that variable must be assigned with that number. The nature of the object or the event being measured, determine the measurement level. An important first step in evaluating the statistical analyses used in a study is to understand the different levels of measurement. The researcher's flexibility in choosing a statistical procedure depends on the height of the level of measurement (LoBiondo-Wood & Haber, 2010: 310-311). There are four levels of measurement: nominal, ordinal, interval, or ratio on which, a discussion will follow.

4.2.1 Nominal Measurement

Nominal measurement is the lowest level of measurement, which involves the classification of characteristics into mutually exclusive categories by the use of numbers. The number used in the nominal measurement have no quantitative meaning, they are merely symbols representing different values of an attribute. The researcher coded for example, males as 1 and females as 2, but the number 2 does not represent a greater value than the number 1. No information about an attribute is provided by this measurement, except equivalence and non-equivalence. This type of measurement must have categories that are mutually exclusive and collectively exhaustive. For example, when the researcher was measuring racial classification, he used the following codes: 1 = Black, 2 = White, 3 = Coloured, 4 = Asian, 5 = Indian.

Each participant was classified into one and only one category. The numbers in this measurement has no mathematical meaning, but it can be used to state frequency of occurrence within the categories (LoBiondo-Wood & Harber, 2010: 312; Polit & Beck, 2008: 557; De Vos *et al.,* 2005: 219-220).

4.2.2 Ordinal Measurement

Ordinal measurement is next in the measurement hierarchy and is used to show relative ranking of variables or events. A specific criterion is used to order variables or events indicating that this level of measurement goes beyond mere categorization. The numbers assigned to each category can be compared, and a variable or event in a higher category can be distinguished to have more of an attribute than those in the lower category. Ordinal measurement captures information about both equivalence and relative ranking among objectives; however, it does not indicate how much greater one level is than another. The same as with nominal measurement, ordinal-level data are restricted in the event of mathematical manipulation. Frequency counts, percentages, and several other statistical procedures are appropriate for analyzing ordinal-level data (LoBiondo-Wood & Harber, 2010: 312; Polit & Beck, 2008: 557; De Vos *et al.,* 2005: 219-220). The researcher used an ordinal measurement when the participant's highest level of education was measured in the study. For example: 1 = Uneducated, 2 = Primary, 3 = Secondary, 4 = Tertiary. The numbers in this case signified the different levels of education. All participants assigned the value of four were equivalent to each other with regard to educational level and were higher ranked compared to those in other categories.

4.2.3 Interval Measurement

Interval measurement occurs when the researcher can specify the rankings of events or variables on a scale with equal intervals between the numbers. Although more information is obtained from an interval measurement than an ordinal measurement, no information about absolute magnitude is given. In interval scales, the zero point remains arbitrary and not absolute. Interval scales expand analytical possibilities because interval-level data allow more manipulation of data, including the addition and subtraction of numbers and

the calculation of means (LoBiondo-Wood & Harber, 2010: 313; Polit & Beck, 2008: 557-558; De Vos *et al.,* 2005: 219-220). The number of sessions the doctor explained the procedure to the patient was an example: a number of five to 10 sessions is five times more than less than five sessions. The same difference separates more than 10 sessions and five to 10 sessions, and the two differences in the number of sessions are equivalent.

4.2.4 Ratio Measurement

Ratio measurement is the highest level of measurements and it provides information concerning the rankings of events or variables on scales with equal intervals and absolute zeros. Many physical measures provide ratio-level data because the number presents the actual amount of the property the object possesses. All arithmetic operations are permissible, because ratio scales have an absolute zero. All statistical procedure is possible as long as it is appropriate to the design of the study (LoBiondo-Wood & Harber, 2010: 313; Polit & Beck, 2008: 558; De Vos *et al.,* 2005: 219-220). The same example used to determine interval-level data are also suitable for ratio-level data.

In the previous chapter, a detailed description of the research methodology was given. That description included everything from the research design to the ethical consideration of the research study. This chapter however focuses on the analysis of the data obtained during the structured interviews of post-operative general surgical patients at a public hospital in the Northern Cape.

4.3 DESCRIPTIVE STATISTICS

Descriptive statistics are the beginning of data analysis in any study in which the data are numerical, including some qualitative studies. Descriptive statistics allow the researcher to organize the data in meaningful ways to facilitate insight and to examine a study phenomenon from a variety of angles. Descriptive analysis can give rise to theory development and generation of hypotheses (Burns & Grove, 2005: 461). The only descriptive statistics that

will be described next is frequency distribution, because it is most suitable for the study.

4.3.1 Frequency distribution

Frequency distribution is one way of organizing descriptive or numeric data and is usually the first strategy used to organize data for examination. In a frequency distribution, the values are systematically arranged from low to high (or vice versa), together with a count of the number of times each value was obtained. The data can also be grouped into two types of frequency distributions, which are ungrouped and grouped (LoBiondo-Wood & Harber, 2010: 313; Polit & Beck, 2008: 560; Burns & Grove, 2005: 461).

In most studies some categorical data is presented as an ungrouped frequency distribution. When an ungrouped frequency distribution is developed, all the categories of the variable on which data is available are listed and each datum on the list is counted. This type of frequency distribution is generally used on discrete rather than continuous data. However, when a grouped frequency distribution is developed, it is necessary to establish a method of classifying the data. The size of the group or the interval width is defined and must be exhaustive so that no datum will fall into two groups and each group will be mutually exclusive. The grouping of the data should prevent an overlap, each datum falls into only one of the established groups. Any method of grouping, results in loss of information, however this approach should allow for a precise presentation of the data to provide the greatest possible meaning in terms of the purpose of the study, without serious loss of information. If data of one study is to be compared with data in another study in the same field of research, the groupings should be similar between the two studies (LoBiondo-Wood & Harber, 2010: 314; Burns & Grove, 2005: 462).

The researcher in this study however made used of the percent distribution to present the study data. Percent distribution indicates the percentages of the sample variables that fall in a specific group, as well as the number of variables in that group. Percent distributions are particularly useful when present data is compared with findings from other studies that have varying

sample sizes. A cumulative distribution is a type of percent distribution in which the percentages and frequencies of ages are summed as one move from the top of the table to the bottom (or the reverse). Thus, the bottom category would have a cumulative frequency equivalent to the sample size, that is 150 in this study and a cumulative percentage of 100 (See Table 4.1 as an example). Information about frequency distribution can be displayed as tables, diagrams, or graphs. The four types of illustrations that are commonly used are: pie diagrams, bar graphs, histograms, and frequency polygons (LoBiondo-Wood & Harber, 2010: 314; Polit & Beck, 2008: 560-561; Burns & Grove, 2005: 462).

Table 4.1: An example of a Cumulative Frequency Table

Age	Frequency	Percentage	Cumulative Frequency	Cumulative Percentage
18	3	2.00	3	2.00
19	2	1.33	5	3.33
20	2	1.33	7	4.67
21	5	3.33	12	8.00
22	2	1.33	14	9.33
23	2	1.33	16	10.67

4.4 DISCUSSION OF RESULTS

The results will be presented under the following headings identified in the questionnaire, namely:

- Demographic information of participant
- Disclosure of essential information;
- Comprehension of consent information;
- Competency or capacity to give consent;
- Voluntary consent;
- Informed consent and the patient;
- The role of the physician or nurse; and
- Respect.

Questions in the questionnaire that addressed the abovementioned headings are indicated in Chapter 3, Table 3.1.

4.4.1 Demographic information of participant

Demographically, the sample consisted of 150 post-operative general surgical participants of which 56% (n=84) were male and 44% (n=66) female. Table 4.2 shows that the median age of all participants was 42 years with 18 years as the youngest and 80 years the eldest.

Table 4.2: Demographic information of participants (n-150)

Characteristics	No. (%) of participants
Age	
Median	42
Min	18
Max	80
Gender	
Male	84 (56%)
Female	66 (44%)
Race	
Black	75 (50%)
White	8 (5.33%)
Coloured	65 (43.33%)
Asian	1 (0.67%)
Indian	1 (0.67%)
Highest level of education	
Uneducated	21 (14%)
Primary	38 (25.33%)
Secondary	78 (52%)
Tertiary	13 (8.67%)

The majority of the participants, 50% (n=75), were black, with the coloured group the second highest of 43,33% (n=65), and the rest of the racial groups lower than 10% respectively. The participant's level of qualification is as

follows (starting with the level with the highest percentage): secondary, 52% (n=78); primary, 25.33% (n=38); uneducated, 14% (n=21); and tertiary, 8.67% (n=13). Only 13 (8.67%) had a tertiary qualification while 78 (52%) completed secondary school education. The rest were educated at primary school level or were uneducated. Although most respondents were educated their level of understanding may be limited.

With specific focus on low literacy, which is an important barrier to informed participation in a procedure or operation, these findings suggest that patients with limited literacy skills should be considered a vulnerable population and that special consideration should be given to their protection during procedures or operations. Therefore, additional steps should be taken to ensure comprehension of consent information among those patients with limited literacy skills (Denny & Grady, 2007: 384). More than a third (39.33%) of the sample constituted a vulnerable group due to their level of education.

4.4.2 Disclosure of essential information

Everybody (100%) received information about the procedure they were scheduled for.

Table 4.3: Information given to the participant

Variables	No. (%) of participants
Persons who gave information	
Doctor	150 (100%)
Nurse	32 (21.33%)
Other: CANSA Representative	5 (3.33%)
Place where information was given	
Consultation room	
Doctor	3 (2%)
Doctor + Nurse	1 (0.67%)
Ward	
Doctor	95 (63.33%)
Doctor + Nurse	24 (16%)
Doctor + Other	1 (0.67%)

Variables	No. (%) of participants
Doctor + Nurse + Other	4 (2.67%)
Pre-operative room	
Doctor	1 (0.67%)
Other	
Emergency Centre	53 (35.33%)
Specialist Clinics	21 (14%)

The doctor informed all participants while the nurse informed 21.33% (n=32) and only five (3.33%) received information from other people. The results show that the person primarily responsible for performing the operation or procedure gave the information to all the participants. However it does not show whether the doctor had explained the nature of the procedure, benefits, alternatives, the risks and complications, but will be discussed later in the chapter (Fiesta, 1999: 6). Since the doctor explained the operation or procedure to all the participants, the nurse's position could have been either to identify the participants' fears, assist the doctor in obtaining a signed consent form from the participants, determining their level of understanding and approval of their care to be given, because the nurse is not responsible for explaining the operation or procedure to the participants (Aveyard, 2005: 27-28; Quallich, 2005: 51; American Nurses Association, 2001: Online; Dunn, 1999: 42-43).

The majority of the participants (73.33%, n=110) received information regarding the proposed treatment in less than five sessions, followed by 20% (n=30) of participants having five to 10 sessions and 6.67% (n=10) of participants having more than 10 sessions (See Figure 4.1). Most of the information was given to them in the general surgical ward with 63,33% (n=95) by doctors, 16% (n=24) by doctors and nurses. Other participants however received information in areas such as the Emergency Centre (35.33%, n=53) and the Specialist Clinics (14%, n=21) respectively. The majority of the participants (96.67%, n=145) indicated that they were satisfied

with the number of sessions and the rest of the participants (3.33%, n=5) were not satisfied.

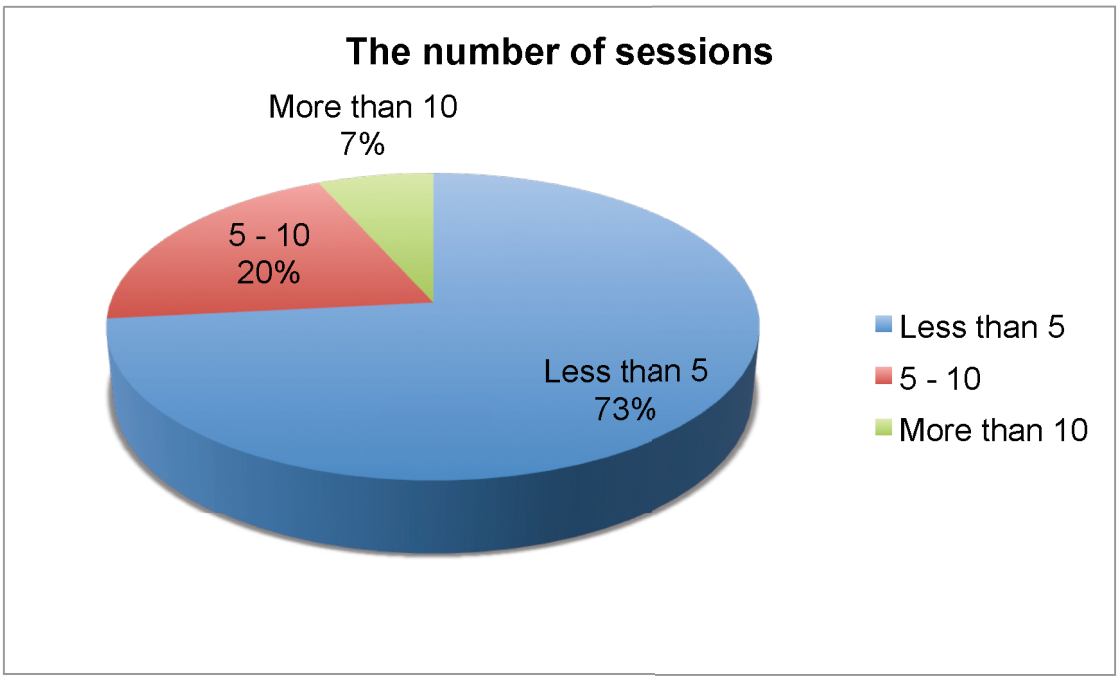

Figure 4.1: The number of sessions in which the procedure was explained to participants.

More than two-thirds of participants (73.33%) received information regarding the proposed operation or procedure in less than five sessions, although it is well documented that much of the information given to a participant during a consultation is often forgotten and/or misunderstood (Ley, 1972: 23). It has also been shown that the patient has forgotten the information that was discussed with the doctor, within five minutes of departing from the consultation room (Kitching, 1990: 298). Of all the information given, the participant only remembers approximately 20%. However, if there is additional visual or written information, this may be increased to 50% (Gauld, 1981: 556). Therefore it is recommended that doctors have more sessions with participants to improve their chances of memorizing the information.

When treatment is recommended for a patient, the health care practitioner should obtain informed consent from the patient, especially if the treatment is invasive. According to Fish (2004: 449) and Rado (2008: 504), five distinct

components that should be addressed when in consultation with a patient before medical or surgical treatment are:

- *"The diagnosis or nature of the specific condition that requires treatment.*
- *The purpose and distinct nature of the treatment.*
- *Risks and potential complications associated with the proposed treatment(s).*
- *All reasonable alternative treatments or procedures, and a discussion of their relative risks and benefits, including the option of taking no action.*
- *The probability of success of the proposed treatment(s)."*

Even if the probability of occurrence is insignificant, all severe risks such as death, paralysis, loss of cognition, loss of a limb, should always be disclosed. Even less severe risks that take place frequently should also be disclosed. Risks that are insignificant with low probability of occurrence need not be disclosed. Frequency should be recognized as an important component of a risk and not solely the consequence of a risk, emphasized by courts (Stansfield, 1979: 869). The professional standard requires the doctor, to disclose any information to the patient, what any reasonable and prudent physician with the same background, training, and experience would have disclosed to the patient in the same or similar circumstances (Zucker *et al.,* 2010: 24; Paterick *et al.,* 2008: 315). Explicit guidelines regarding the disclosure of risks are not given by the professional standard.

According to Figure 4.2 participants received information regarding the: procedure (100%, n=150); risks (64%, n=96); benefits (78%, n=117); alternative treatment (17.33%, n=26); estimated time to resume normal life activities (18.67%, n=28); self-care after the procedure or operation (22%, n=33); and the use of medication or drugs (35.33%, n=53).

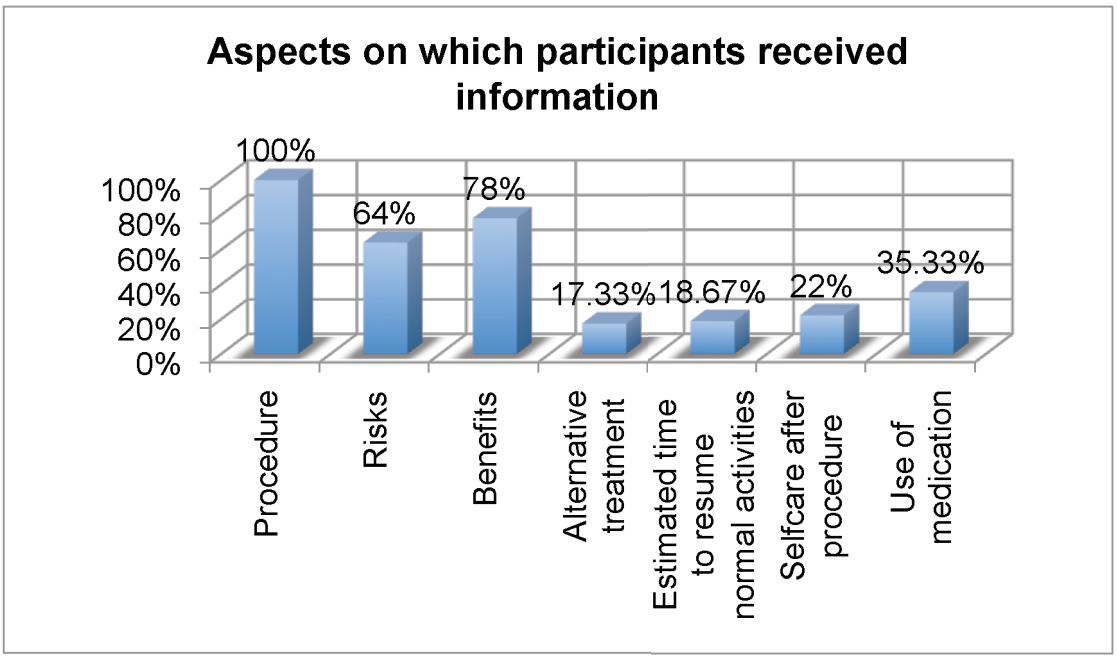

Figure 4.2: Aspects on which participants received information

The results indicated that participants had undergone surgery, but were not properly informed regarding all the aspects deemed necessary for full disclosure before surgery. The doctor has the responsibility to provide the participant with information of the nature, risks, consequences and alternatives associated with the proposed therapy, and if anyone fails to disclose to the requisite standard, it may result in a claim of assault. It is unlawful when surgery is performed without the informed consent of the patient, and that consent for any medical procedure is required from a competent, adequately informed adult patient (South Africa. National Health act 2003: 20-22).

Further, a good outcome and the major expected problems during recovery should been described, as well as the estimated time to resume normal life activities. Based on the foundation of understanding, the physician should not proceed with treatment until he believes the patient understands the risks and benefits that were presented in a language the patient understands (Hanson, 2001: 71).

4.4.3 Comprehension of consent information

Only 61 (40.67%) participants were aware of the Patient's Bill of Rights. According to Table 4.4. 40 (65.57%) of those 61 participants understood these rights to some degree. In addition to the low literacy level of the participants the fact that the majority (59%) were unaware of the Patient's Bill of Rights further contributed to the vulnerability of the group.

Table 4.4: Participants' awareness and understanding of The Patient's Bill of Rights

Variables	No. (%) of participants
Are you aware of the Patient's Bill of Rights	
Yes	61 (40.67%)
No	89 (59.33%)
If yes, indicate to which degree you understand these rights	
Completely	3 (4.92%)
Most	13 (21.31%)
Some	40 (65.57%)
Nothing	5 (8.20%)

The South African Constitution act 1996 (Act No. 108 of 1996), in particular, section 12 (2) of the Bill of Rights maintains that *"Everyone has the right to bodily and psychological integrity, which includes the right (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiment without their informed consent."* This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.

All 150 participants (100%) stated that they understood what procedure they had with Appendectomy or removal of appendix (16%, n=24) and abdominal operation or laparotomy or laparoscopy (15.33, n=23) as the highest, followed by amputation of a leg (8%, n=12) and gastroscopy (camera swallowed) (6.67%, n=10) respectively.

Table 4.5 will further demonstrate the participants' understanding of the given information.

Table 4.5: Participants' understanding of the given information

Variables	No. (%) of participants
How would you described the information that was given	
Clear	142 (94.67)
Confusing	8 (5.33%)
Irrelevant	0
Did you understand the terminology used?	
Yes	131 (87.33%)
No	7 (4.67%)
Partially	12 (8%)
Did the conversation take place in a language you understand	
Yes	145 (96.67%)
No	5 (3.33%)
If not, was an interpreter present?	
Yes	5 (100%)
No	0
Were you asked to explain the procedure in your own words?	
Yes	18 (12%)
No	132 (88%)

A predominant majority of the participants (94.67%, n=142) felt that the information given to them before the procedure was clear, while the rest of the participants (5.33%, n=8) felt that the information was confusing.

There are several reasons why the majority of participants felt that the information given to them was clear, and these include the following: The results showed that the doctors focused on areas, which they thought were important for the participants to know as indicated in Figure 4.2. The results depicted that the procedure and benefits were mentioned the most, the risks to a lesser extent followed by the other aspects respectively. Furthermore, the

participant's attitudes and perceptions might have also influenced this result. If the participant did not ask questions, it did not mean full comprehension or utter confusion, but signified that the participant was unaware of what they did not know. In some cases participants might be intimidated by the situation, they sometimes do not want to risk embarrassment by asking for clarification or might simply consent to satisfy the doctor (Brady, 2003: 36; Hochhauser, 2003: 10). In addition, factors that could have adversely influenced the rest of the participants' decisions are old age, cognitive impairment, low educational attainment, and poor literacy skills (Joffe *et al.,* 2001a: 1772).

The largest part of the participants (87.33%, n=131) indicated that they understood the terminology used during the information session, while the rest of the participants did not (4.67, n=7) or partially (8%, n=12) understand the terminology. In order for the majority of participants to feel that the information given to them was clear, they had to understand the terminology used by the doctor. It was however the doctor who was primarily responsible for their care's responsibility to ensure that the procedure or operation was explained in terms and a language they understood (Little *et al.,* 2008: 627).

An absolute majority of participants (96.97%, n=145) indicated that the conversation took place in a language they understood. However the rest of the participants (3.33%, n=5) who did not understand the language, indicated that an interpreter was present to assist them in understanding the information. Another reason why the majority felt that the information given to them was clear, was because the conversation between them and the doctor took place in a language they understood, and if not, an interpreter was present. It is however expected of the doctor to provide all the relevant information regarding the proposed treatment in a language they understand and in a manner that considers their level of literacy (South Africa. National Health act 2003: 20).

Twelve percent (n=8) of participants were asked to explain the procedures in their own words, while the rest of the participants (88%, n=132) were not asked. Although the majority of participants felt that the information given to them was clear, that they understood the terminology used during the

information session, and that the conversation took place in a language they understood, the doctor still had to confirm understanding of the consent information. Since more than a third (39.33%) of the sample constituted a vulnerable group due to their level of education, it is therefore important that the doctor should take whatever measures necessary to ensure that the informed consent form represents true understanding and not just a signed form.

Several methods exist that can be used to foster understanding of complex information in a way that may be more easily understood by the participant. For example, a brief interview can be used to identify any misunderstandings. In the interview, the participant may be asked to describe the procedure or operation, or answer simple open-ended questions, which may reveal their comprehension of the consent information. Further, documentation of the answers will provide verification that a truly informed consent was obtained. Alternatively, the nurse practitioner can also be used to question the participant to further assess understanding, and this interview should also be documented (Jaynes, 2005: 106). There are either several other methods that could be used by the doctor, for example the *'teach-back method'* and the *'teach-to-goal strategy'* (Kripalani *et al.,* 2008: 17; Schillinger *et al.,* 2003: 83; Raich *et al.,* 2001: 437).

Kripalani *et al.* (2008: 17) suggest that the teach-back method is preferred to confirm understanding of consent information, and its use is advocated by the National Quality Forum in Washington, DC, the Agency for Healthcare Research and Quality, and other groups. They further suggest that this specific method is a feasible and generalized approach that could be adopted in most healthcare institutions to help assess the patients' comprehension of the consent information. Healthcare practitioners should ask patients to describe their understanding of the purpose, risks, and benefits of the procedure or operation. Moreover, by asking the patient to teach-back the procedure or operation information, allows the doctor to find out in real time how well the patient understood the material or information. Misconceptions can be clarified immediately, and patients can be asked again to teach-back the information to ensure their comprehension (Schillinger *et al.,* 2003: 83).

This approach is called the *'teach-to-goal strategy,'* a method used to ensure that understanding of information is achieved (Raich *et al.,* 2001: 437-445).

4.4.4 Competency or capacity to give consent

Of all the information sessions that took place, 29 (19.33%) participants indicated that their families were involved, while 121 (80.67%) families were not involved. All 29 participants indicated that they consented to their families' involvement in the information session. Of the 121 whose families were not involved, 31 (25.62%) indicated that they would have preferred them to be involved, while the other 74.38% (n=90) indicated that they would not have preferred them to be involved. See Table 4.6 for a description of the families' involvement in the informed consent discussion.

Table 4.6: Families involvement in the informed consent discussion

Variables	No. (%) of participants
Were family involve in discussion?	
Yes	29 (19.33%)
No	121 (80.67%)
If yes, did participants give consent?	
Yes	29 (100%)
No	0
If not, would participant have preferred them to be involved?	
Yes	31 (25.62%)
No	90 (74.38%)

On the one hand, South Africa is characterized by communitarian customary requirements of communal leaders' approval before an important healthcare decision can be taken in conjunction with families' and/or even communities' input. As in the case of a black participant, who is family and community oriented, and who requires support from the family during a crisis period to make the decision-making process easier (Du Toit & Van Staden, 2005: 40). However the results indicated that coloureds (33.33%) have a higher percentage than blacks (20%) in wanting their families involved during the

process of informed consent. This means that doctors should now have the same consideration for families of the coloured racial group as for blacks in the process of informed consent for an operation or procedure. Furthermore, consideration for families' involvement should not be limited to these two groups only, but should be extended to other racial groups too especially if the families' involvement would be in the best interest of the participant (Kegley in Boylan, 2004: 91; Fiesta, 1999: 6-7).

On the other hand, some studies have shown that doctors are prohibited by privacy laws to discuss specifics of a participant's condition with family members even when that discussion would seem to be in the participant's best interest. For that reason, doctors should be encouraged when they believe it to be necessary, to talk with their competent participants about including a family member in discussions, and to lower any legal risks towards them. The doctor should even make a note of this discussion in the participant's chart, and if the participant consents to that or refuses to give such permission, the doctor should have the participant complete and sign any forms required (Zucker *et al.,* 2010: 26; Fiesta, 1999: 6-7).

Doctors need to remember that it is inadequate to restrict medical decisions to individual participants and their egoistic choices, given the complex social nature of a person's identity and the social context of his or her existence and flourishing: individual rights have limits. Generally, diseases do not have a solitary causal mechanism. Apart from medical effects from diseases, it has psychological, economic, religious and cultural ramifications for the individual participant and close relatives and therefore medical decision-making is a family issue. The recognition of the personal values of the individual is equally important as the recognition of the impact of illness and medical decisions on the community (Kegley in Boylan, 2004: 95).

According to the literature, in order for a participant to give valid informed consent, their actions must be voluntary and they must be competent. In other words, the participant's cognitive level must not be influenced by medication, and the participant should be free from personal emotional stress, or external stress by family members or physicians (Appelbaum *et al.,* 2009: 32; Paterick

et al., 2008: 316; Wilkinson, 2001: 343). Although none of the participants were medicated whilst giving consent, there was one of them who experienced severe stress whilst giving consent, which made the informed consent process questionable.

The majority of participants (68%, n=102) indicated that they felt normal when the doctor explained the procedure to them, while the rest of the participants felt drowsy (3.33%, n=5) and anxious (28.67%, n=43) respectively. From the participants that felt drowsy and anxious, two outstanding factors responsible for participants' reaction were pain (22.92%, n=11) and first operation or procedure (31.25%, n=15). The participants' anxiety was further classified into three levels and the results were as follows: mild (67.44%, n=29); moderate (20.93%, n=9); and severe (11.63%, n=3).

Table 4.7: Participants' cognitive level when procedure was explained to them

Variables	No. (%) of participants
When procedure was explained, how did you feel?	
Normal	102 (68%)
Drowsy	5 (3.33%)
Excited	0
Anxious	43 (28.67%)
If drowsy/excited or anxious, what cause it? (Outstanding factors)	
Pain	11 (22.92%)
First operation or procedure	15 (31.25%)
If anxious, what was the level of it?	
Mild	29 (67.44%)
Moderate	9 (20.93%)
Severe	5 (11.63%)

Each participant (100%, n=150) who took part in the research study indicated that the law did not prohibit them from signing a contract. However a person can only be determined competent or incompetent by a court of law, and not by an ordinary person. The participant's capacity should be the focus with

medical informed consent (Minnesota Office of the Revisor of Statutes: 2007: Online).

4.4.5 Voluntary consent

A small number of participants (2%, n=3) thought that information regarding the proposed treatment was withheld from them, and the other 98% (n=147) of participants did not think so. The participants who thought that information was withheld from them, gave the following reasons for their argument: (1) the post-operative condition of the participant did not confirm the pre-operative information they received; and (2) the size of the wounds are bigger compared to the information received prior to the operation or procedure.

The researcher argued that it is a positive development in healthcare to find that the majority of participants thought that no information was withheld from them. As for the other 2%, according to the literature, a person can be charged with negligence when the participant is not adequately informed about the treatment (Paterick *et al.,* 2008: 314; South Africa. National Health act 2003: 20).

A small number of participants (1.33%, n=2) indicated that they were under pressure to consent to the operation or procedure, while the predominant majority of participants (98.67%, n=148) were not under pressure. Although it was just a small percentage of the study sample that was under pressure, it led to the action of those participants not being voluntarily, resulting in the consent to be invalid.

Voluntary can be described as, not a result of force, manipulation or coercion, and the absence of undue external interference (Appelbaum *et al.,* 2009: 32; Paterick *et al.,* 2008: 316; Wilkinson, 2001: 343). The key to ensure voluntary and informed consent is to ensure a context that allows the optimal absorption of information and weighing of choices. Recognizing the importance of context also requires that informed consent should be viewed as a continuous process as priorities and vulnerabilities change over time (Berry *et al.,* 1996: 508-509).

Factors that contribute to a participant's ability to make a meaningful decision are, that they should not be under undue pressure to accept a procedure (including from health care professionals) and should be competent to do so (Appelbaum *et al.,* 2009: 32; Wilkinson, 2001: 343).

Table 4.8 describes the influences made by others on the participant's decision. A small number of participants (2.67%, n=4) indicated that their decision regarding the operation or procedure, were influenced by other people while the other 97.33% (n=146) were not influenced. The group that influenced the participants' decision the most was the nursing staff (40%, n=2), followed by the parents (20%, n=1), husband (20%, n=1) and children (20%, n=1) respectively.

Table 4.8: Influences made by others on the participant's decision

Variables	**No. (%) of participants**
Did others influence your decision regarding the procedure?	
Yes	4 (2.67%)
No	146 (97.33%)
If yes, who	
Parent(s)	1 (20%)
Husband	1 (20%)
Children	1 (20%)
Nursing staff	2 (40%)

Voluntary informed consent does not necessarily have to be an isolated decision made by an individual away from relatives, community members or other people. A person may sometimes have a better option of making a decision as a result of the communal discussions and debates. Given the widespread problems of poverty and illiteracy that create vulnerable and fertile grounds for exploitations of medical patients, this model of collective decision-making is essential in Africa. A formal act exhibited to demonstrate a person's wishes is the individually expressed consent, but the process of arriving at this decision could be informed and fostered by communal discussions (Frimpong-Mansoh, 2008: 112; Marshall *et al.,* 2006: 1993; Bhutta, 2004: 774).

However, the participant's decisions must not be coerced or manipulated by members of the health care team or by any other person, such as family, friends, or financial contributors, otherwise the consent will be invalid. The duty of the health care practitioner is to give the participant all the relevant information regarding the proposed operation or procedure, and to make sure that the participant is competent to understand, remember and consider the information regarding the proposed treatment. An exception to medical informed consent would only be considered in an instance if there is enough evidence and motivation that the medical informed consent causes more harm than good (Baeroe, 2010: 91; South Africa. National Health act 2003: 20)

4.4.6 Informed consent and the patient

The majority of the participants (75,33%, n=113) were given the opportunity to ask questions regarding the proposed treatment, while 22.67% (n=34) of participants were not allowed and 2% (n=3) partially allowed. All 113 participants that were allowed to ask questions indicated that their questions were answered in a satisfactory manner.

The number of participants that were not allowed or partially allowed constituted almost a third (24.67%) of the sample, which is not acceptable since everyone should have been allowed to ask questions regarding the proposed treatment, benefits and risks and the doctor must answer those questions from the available medical literature and their professional experience. Informed decision-making in the most complex medical situations is promoted by the exchange of information and ideas that are founded in the participant-physician partnership (Paterick *et al.,* 2008: 313; Rado, 2008: 505; Kapp, 2002: 1199-1200).

Nowadays, the law obligates that a discussion for informed consent should take place between whoever is going to perform a procedure and the patient. Generally, it is a physician's responsibility, however, if a nurse practitioner or a physician assistant will perform the procedure, it is their responsibility to collaborate with the patient and obtain informed consent. A person can be charged with negligence when a patient is not adequately informed about the

treatment, and assault when the patient is treated without consent, therefore it is very important in today's legal and ethical climate to ensure patient involvement. The health care practitioner must invite and answer the patient's questions when explaining treatments and alternatives in terms the patient understands and specifying who is performing the procedure. Consent is invalid when a patient is coerced into consenting to a procedure and the health care practitioner could be held liable if he performs the procedure (Paterick *et al.,* 2008: 314; Quallich, 2005: 49; South Africa. National Health act 2003: 20; Cady, 2000: 106; Dunn, 1999: 42). Figure 4.3 depicts the consent given by participants for the proposed treatment.

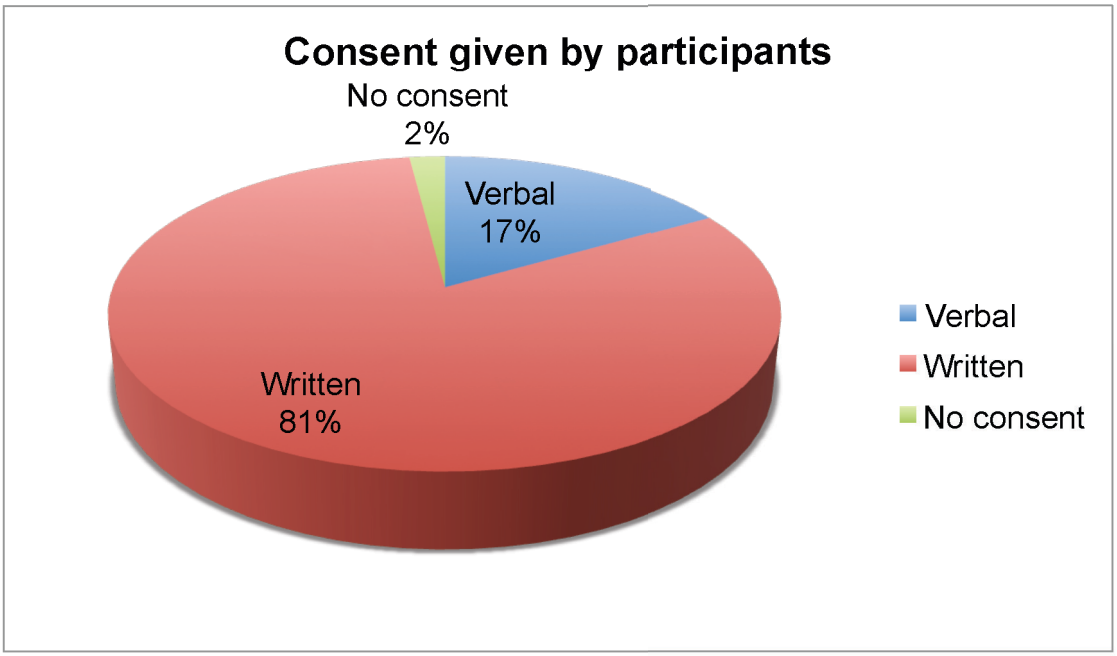

Figure 4.3: Consent given by participants for the proposed treatment

Of all the participants that received information regarding the proposed treatment, 16.67% (n=25) of them gave verbal consent-, 81.33% (n=122) gave written consent-, and 2% (n=3) gave no consent to the proposed treatment. Both verbal and written consent are acceptable methods of consent and are largely used in consent procedures, therefore their results are acceptable. However the other 2% that did not give consent is unacceptable. The researcher confirmed this information because there was no proof of consent in these participants' records. The only exceptions to the rule of disclosure where the doctor does not need to disclose information to

the participant includes the following four situations: (1) in a life- or limb-threatening emergency; (2) when disclosing information could threaten the participant or cause them harm or suffering; (3) when the participant chooses not to hear all the information; and (4) when the participant had prior knowledge of the treatment procedure (Zucker *et al.,* 2010: 25; Wegmann, 2009: 25; Rado, 2008: 504-505; Fish, 2004: 449-450; South Africa. National Health act 2003: 20; Dunn, 1999: 42). However these situations were not part of the inclusion criteria. Participants that formed part of the inclusion criteria were those older than 18 years who underwent a surgical procedure at the identified public hospital in the Northern Cape, and who had stayed at least one night after the procedure or operation. The ones that were excluded were those who suffered from pain; or those who were under sedation; or those who had a decreased level of consciousness or a psychiatric co-morbidity (American Association of Critical-Care Nurses, 2006: Online). Therefore the conclusion is that treatment of the 2% of participants can constitute as assault because it took place without their consent (South Africa. National Health act 2003: 20).

Informed consent is defined as the patient's autonomous authorization and emphasizes that it is more than just a simple expressed agreement to the proposal by the participant. It is possible to submit to or comply with a plan of another without any actual agreement but that merely assenting to a procedure is not indicating one's consent. In fact, by giving consent, a participant actively authorizes the proposal in the act of consent (Beauchamp & Faden, 1986: 278). To give such autonomous authorization a participant should be informed, be able to comprehend the information and voluntarily consent to the procedure. These components of informed consent are largely undisputed in the ethical and philosophical literature (Beauchamp & Faden, 1986: 275).

4.4.7 The role of the physician or nurse

The overall number of participants (100%, n=150) indicated that they were not informed that the hospital might use information such as slides or videos of the procedure for educational purposes. Important information such as this,

which every doctor neglected to mention, played an important part in the decision-making process. Participants could either have consented to the proposed treatment or refused to give such permission, which ultimately might have influenced the results of this study.

However, in situations like these where the participant does not remember the discussion or denies receiving an explanation, the signature on the consent form created a presumption that the participant had been advised of the appropriate aspect. Therefore, it is recommended that hospitals should use consistent language in a printed consent document to deal with universal issues that may have legal significance regardless of the type of surgery involved. For example, teaching hospitals, like in this case, should clarify that students or residents may participate in the procedure and that the hospital may use information such as slides or video of the procedure for educational purpose. These are important statements that doctors sometimes forget to mention or discuss with the participant (Fiesta, 1999: 7).

Most of the participants (61.33%, n=92) indicated that the doctor did explain afterwards how the procedure went, while the other 38.67% (n=58) indicated that the doctor did not explain. The informed consent process should not be regarded as a rigid process that requires the disclosure of a strict amount of information. Instead it should be regarded as a flexible process in which the amount of information required will facilitates a meaningful decision-making process by the participant which does not stop with the surgical procedure but continues until the participant is discharged (Aveyard, 2000: 352-353). Therefore it is important for the doctor to continue with care of the participant as it forms part of the informed consent process. The doctor could either be charged with negligence when a participant is not adequately informed about the treatment until discharged (Paterick *et al.,* 2008: 314; Oldwage v Lourens, 2000; Castell v De Greeff, 1994; Keeton *et al.,* 1984: 164-165).

Of all the participants who had an operation or procedure done, 33.33% (n=50) indicated that the same doctor who explained the procedure to them, carried out the procedure, while the other 31.33% (n=47) of participants indicated that it was not the same doctor who carried out the procedure and

35.33% (n=53) of participants were not sure who carried out the procedure. See Figure 4.4 for an illustration of the participant's indication whether the same doctor who explained to them carried out the procedure.

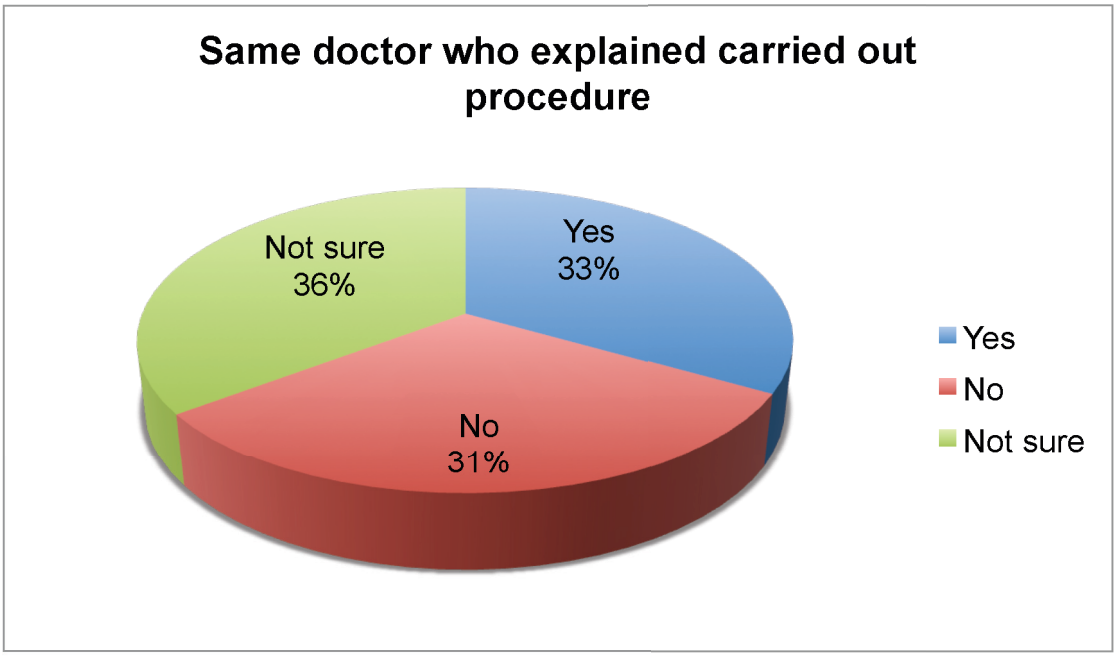

Figure 4.4: Participants indicating whether the same doctor who explained to them carried out the procedure.

Only a third of the study sample (33.33%) indicated that the same doctor who explained the procedure to them carried out the procedure, that is worrisome, because the law obligates that a discussion for informed consent should take place between whoever is going to perform the procedure and the participant (Paterick *et al.,* 2008: 313; Quallich, 2005: 49; South Africa. National Health act 2003: 20; Cady, 2000: 106; Dunn, 1999: 42).

However the other third of the study sample (31.33%) who indicated that it was not the same doctor who carried out the procedure can charge the doctor with assault, deriving from false or negligent representation by the doctor unless they have been informed prior to the operation or procedure that another doctor was going to perform the procedure and the participant had consented to it. If the participant however was not informed, therefore no 'informed consent' took place, the services rendered constituted assault against the bodily integrity of the participant and the doctor/hospital may incur

liability for (a) breach of contract; (b) civil or criminal assault (a violation of bodily integrity); (c) civil or criminal iniuria (a violation of dignity/privacy), or (d) negligence, as the case may be (Oldwage v Louwrens, 2000; Castell v De Greeff, 1994).

In the case of the other 35.33% of participants who were not sure who carried out the procedure, these were some of their explanations: when they entered the theatre, they were anxious and therefore did not pay much attention to who were present. Staff was dressed in the same theatre outfit, which made it difficult for them to identify or distinguish between the different health professionals or recognize familiar faces. There were incidents where doctors did not even introduce themselves prior to the operation or procedure therefore they do not know their names. Sometimes in theatre, they would only see or not see the doctor who obtained consent from them after the operation or procedure had taken place, therefore could not confirm their presence, etc.

However it is the right of the participant to be informed who will be doing the procedure or operation, whether it will be a consultant, trainee (under supervision), etc. They also need to be informed on the years of experience and technical skills of the doctor, including the doctor's personal success and complications rate (Ladas, 2006: 187). In spite of these findings all participants indicated that a good understanding between them and the doctor existed.

Even if there was not an ideal participant-physician partnership as a result of the disclosure of information, at least there has been progress of participant autonomy in the decision-making process and achievement of a foundation for an ethical and trusting relationship between a physician and participant (Castell v De Greeff, 1994; Cobbs v Grant, 1972). Table 4. 9 further describe the additional information the doctor should provide to the participant even if there was not an ideal patient-physician relationship.

Table 4.9: Additional information the doctor should provide to the participant during the informed consent process

Variables	Yes (Participants %)	No (Participants %)
About a second opinion	4 (2.67%)	146 (97.33%)
May withdraw consent at any time	21 (14%)	129 (86%)
May change your mind about procedure	17 (11.33%)	133 (88.67%)
They have to sign a form if they change their minds	23 (15.33%)	127 (84.67%)
Might refuse all treatment	24 (16%)	126 (84%)

Table 4.9 depicts that the doctor disclosed the information on refusal and withdrawal only to a small number of participants. However this is information that is required from a doctor to disclose what another reasonable doctor would disclose. Disclosure of such information would allow the participant to consider its importance in their decision-making process. Nevertheless it should be given in clear understandable terms, which is easy for the participant to understand (Ladas, 2006: 187). The information that was not given to the majority of participants influenced their right to practise self-determination, which is protected by legislation. The participant's decision on whether to consent or refuse a procedure was based on their right to receive sufficient information in order to make an informed choice (South Africa. National Health act 2003: 20).

Four percent (n=6) of participants experienced problems after the operation or procedure that was not explained to them when they gave consent, while the other 96% (n=144) did not experience any problems. From the problems participants experienced post-operatively or post procedurally, pain and discomfort (40%, n=2) were the most, followed by swollen abdomen and pain (20%, n=1), constipation and urinary retention (20%, n=1), and possible infections post operative (20%, n=1). Although it is a small percentage of

participants that experienced problems post-operatively or post-procedurally, the doctor should always disclose all the relevant information to the participant concerned.

4.4.8 Respect

According to the literature, respect is viewed as the central moral attitude from which all other moral principles are explained, therefore considered to be the primary ethical principle (Downie & Telfer, 1970: 33-34). Rokeach (1979: 69) views respect as a human value that addresses justice, honor and human dignity. Respect is considered a humanity principle that acknowledges human beings as autonomous agents who naturally have inherent intrinsic value (Milner, 1986: 86). Levine (1977: 846-847) considers respect to be the core value of human rights that honours other's freedom of choice, worthiness as humans and opportunity for equality. Values of human dignity, intrinsic worthiness, autonomy, individual uniqueness and self-determination reflect in these definitions of respect.

From a caregiver's perspective, respect is demonstrated through the interaction with patients by acknowledging their presence, uniqueness and individuality by means of empathy, support and acceptance of a person's unique cultural heritage and the capacity to show regard and consideration to their cultural orientation (Forrest, 1989: 815). Leininger (1989: 251) believes that respect for a person's cultural rights suggests respect for their basic human rights. Table 4.10 however will demonstrate if participants received respect from hospital staff as demonstrated by the literature.

Table 4.10: The respect participants received from hospital staff

	Respected	**Not Respected**
Medical	148 (98.67%)	2 (1.33%)
Nursing	145 (96.67%)	5 (3.33%)
Administrative staff	150 (100%)	0
Supportive staff	149 (99.33%)	1 (0.67%)

The overall respect for participants was categorized as follows: medical staff (98.67%, n=148); nursing staff (96.67%, n=145); administration staff (100%, n=150); and the supportive staff (99.33%, n=149). However, the problems that participants experienced were categorized as follows: (1) medical staff – the physical treatment of participant (50%, n=1), and not enough information received (50%, n=1); (2) nursing staff – patients not allowed enough time to wash (20%, n= 1), patient overnight in hospital on a wooden bench (20%, n=1), bad behaviour towards patient (40%, n=2), and long waiting periods for treatment (20%, n=1); and (3) supportive staff – accused patients of disrupting the ward (100%, n=1).

Unfortunately the results depict that not all participants were treated with respect. From all categories of staff, nurses were the majority in not showing respect to participants. It is important that nurses acknowledge that dehumanization of participants often occurs when nursing care takes place without respect (McGee, 1994: 681). One way of redeeming themselves is through the act of caring, because caring is regarded as a commitment that entails respect for all persons and that participants should be respected as individuals because they matter as persons (Bandman & Bandman, 2002: 13).

Fry (1988: 48) argues that caring: (1) is vitally important in directing the behaviour of nurses and other health professionals; (2) is a *'universal attitude'* that is acceptable across many generations and cultures; (3) identifies certain behaviours that is associated with perfectness in human behaviour; and (4) has a high regard for others. Further, caring does not only involve carrying out nursing procedures, but is based on an *"attitude of nurturing, and helping one another grow"* (Lindberg *et al.,* 1990: 5).

4.5 CONCLUSION

In this chapter an in depth analysis of the study results was presented. The researcher organized the study results by the research questions to give meaning to the data and make it easy to understand. Furthermore, figures

and tables were used to present the large amount of detailed information concisely and clearly. Sophisticated computerized colour figures were used to draw the readers' attention and provide a picture of the results, whilst black-and-white tables will make it easy for the reader to do a review of the results (Burns & Grove, 2005: 589-590).

The study results however identified many of the health care practitioners' failures regarding informed consent for an operation or procedure in the identified hospital in the Northern Cape. That means, if health care practitioners continue to practice health care in that manner, they can be charged with negligence if the participant is not properly informed regarding all aspects deemed necessary for informed consent before surgery. If anyone continues to treat participants without informed consent, it may result in a claim of assault. The results also indicated that more than a third (39.33%) of the sample constituted a vulnerable group due to their level of education. In addition, the fact that the majority (59%) was unaware of the Patient's Bill of Rights further contributed to the vulnerability of the group. Furthermore, the results also indicate that participants experienced some form of disrespect in different ways from the different categories of the hospital staff.

This concludes that the current practice regarding informed for an operation or procedure at the identified hospital needs urgent attention. The next chapter however will discuss the study's recommendations, limitations and conclusions.

CHAPTER 5

Recommendations, limitations and conclusions

5.1 INTRODUCTION

The previous chapter discussed data analysis and results on the process of informed consent in a public hospital in the Northern Cape. An outline of the research recommendations, limitations and conclusions will be presented in this chapter.

The study is relevant to three groups namely: the health care practitioners that includes the general surgeons and nurses; the policy makers who are the hospital management; and the study population who are the patients.

Thus the study might demonstrate usefulness in three broad respects such as: (1) contribution to existing knowledge; (2) the hospital management (policy maker), health care practitioners and health care practices might find usefulness and meaning in the study; and (3) the results of the study might be generalized to the relevant groups in other settings who stand to benefit from it.

The results might also contribute to theoretical knowledge of the profession. Furthermore, the results will be disseminated orally in community meetings and conferences for public scrutiny and critique. It will also be published in peer-reviewed journals for health care professionals to use as theoretical information and research methodology (De Vos *et al.,* 2005: 115-116).

5.2 RECOMMENDATIONS

It was previously mentioned in the study that the results will be most valuable to three groups namely: the hospital management (policy maker), the health

care practitioners (general surgeons and nurses), and the patients (study population), and therefore recommendations will be directed to them. Because the researcher made use of a descriptive design, the results obtained from the study can lead to generation of hypotheses. Descriptive designs could also be used to: develop theory; determine what others in similar circumstances are doing; identify problems with current practice; and justify current practice. These designs are relatively inexpensive and take less time to conduct (Botma *et al.,* 2010: 110). The recommendations are directed mainly to the hospital management and the health care practitioners and not the patients, however behavioural change of the hospital management and health care practitioners might be to the advantage of the patients.

5.2.1 The hospital management (policy maker)

The recommendations to the hospital management will be discussed under the following headings: (1) Patient's Bill of Rights; (2) the informed consent document; (3) training of health care practitioners; (4) monitoring and evaluation process; and (5) research.

5.2.1.1 Patient's Bill of Rights

The hospital management can increase patients' awareness of the Patient's Bill of Rights through posters, leaflets and information sessions in clinics and wards.

5.2.1.2 The informed consent document

It is recommended that the hospital should use consistent language in a printed consent document to deal with universal issues that may have legal significance regardless of the type of surgery involved. For example, teaching hospitals, as in this case should clarify that students or residents may participate in the procedure and that the hospital may use information such as slides or video of the procedure for educational purpose. These are important statements that doctors sometimes forget to mention or discuss with the participant (Fiesta, 1999: 7).

5.2.1.3 Training of health care practitioners

It is recommended that the hospital management should use the training of health care practitioners to:

- Facilitate the implementation and integration of the policy for informed consent for a surgical procedure in the institution's health care system through different programmes, for example, through orientation and induction of newly appointed personnel, training and development programmes, etc.
- Establish a unit within the institution that would be responsible for the continuous development of health care professionals, which will coordinate and ensure effective implementation and promotion of the policy throughout the whole institution.
- Attend relevant meetings and training sessions that are directed at the improvement of health care services in the institution.
- Provide relevant health information to health care users to assist in achieving optimal understanding of the informed consent and health care related rights.
- Maintain constructive working relationships between members of the relevant health care team through meetings, workshops, training sessions, etc.

5.2.1.4 Monitor and evaluation process

It is also recommended that the hospital management should use the monitor and evaluation process to:

- Coordinate and monitor the implementation of the informed consent policy and the evaluation thereof in order to provide a quality health care service, contributing towards the institutional targets and objectives, which are aimed at the delivering of quality health care to all people in the Northern Cape.
- Develop and maintain a database on various aspects related to informed consent as well as a compliance- and reporting system for health care practitioners with regard to informed consent for treatment or operations.

- Manage the collection, collation, analysis and dissemination of data related to matters of informed consent from various sources by using tools that are used to measure comprehension such as: The Deaconess Informed Consent Comprehension Test (Miller, O'Donnell, Searight & Babarash, 1996: 872-878); The Informed Decision Making Checklist (Verheggen, Jonkers & Kok, 1996: 137-153); The Quality of Informed Consent (Joffe *et al.,* 2001b: 139-147); The Post-Decision Questionnaire (Wendler, 2004: 2001-2004); The Informed Consent Questionnaire-4 (Guarino, Elbourne, Carpenter & Peduzzi, 2006: 19-30); and The Brief Informed Consent Evaluation Protocol (BICEP) (Sugarman, Lavori, Boeger, Cain, Edson, Morrison *et al.,* 2005: 34-41).

5.2.1.5 Research

The institution has the responsibility to contribute to the body of knowledge regarding informed consent for treatment or operation through continuous research in order to develop this area of interest. The researcher recommended that further research be conducted on the same recommendations made to the hospital management, heath care practitioners and patients.

5.2.2 The health care practitioners (general surgeons and nurses)

The recommendations to health care practitioners include the following: (1) strategies to improve participants' understanding of the consent information; (2) cultural influences; and (3) respect.

5.2.2.1 Strategies to improve participants' understanding of the consent information

These strategies include the following:

- Special consideration should be given to participants with low literacy for their protection during procedures or operations, and additional steps should be taken to ensure comprehension among those participants with limited literacy skills (Denny & Grady, 2007: 384).

- Several methods that can be used to foster understanding of complex information in a way that may be more easily understood by the participant. For example, a brief interview, the *'teach-back method'* and the *'teach-to-goal strategy'* (Kripalani *et al.,* 2008: 17; Jaynes, 2005: 106; Schillinger *et al.,* 2003: 83; Raich *et al.,* 2001: 437); by providing face-to-face interactions (Flory & Emanuel, 2004: 1593-1601); written information in a short and readable form (Sreenivasan, 2003: 2016-2018; Coyne, Xu, Raich, Plomer, Dignan, Wenzel, Fairclough, Habermann, Schnell, Quella & Cella, 2003: 836-842; Paasche-Orlow, Taylor & Brancati, 2003: 721-726; Franck & Winter, 2004: 13-18; Shalowitz & Wendler, 2006: 685-688); calling participants after they have signed the consent form, allowing them to ask questions or express concerns (Turner in Fitzpatrick & Wallace, 2005: 297-299); or a videotape of the treatment or operation have all been recommended as ways to enhance the informed consent process for clinical treatment (Koren, Kearns, Reed & Pons, 2003: 147-152; McLaughlin, Brindley & Crowther, 2002: CD003717).
- It is recommended that doctors have more sessions with participants to improve their chances of memorizing the information because participants forget and/or misunderstood much of the information given to them during the consultation (Ley, 1972: 23), however if there is additional visual or written information, the participant's memory might increased to 50% (Gauld, 1981: 556).
- Further, a good outcome and the major expected problems during recovery, should been described, as well as the estimated time to resume normal life activities. Based on the foundation of understanding, the doctors should not proceed with treatment until they believe the participant understands the risks and benefits that were presented in a language the participant understands (Hanson, 2001: 71).

5.2.2.2 Cultural influences

Doctors should do more to involve participants' families in the informed consent discussion because South Africa is characterized by communitarian customary requirements of communal leaders' approval before an important healthcare decision can be taken in conjunction with families' and/or even

communities' input. As in the case of a black participant, who is family and community oriented, and who requires support from the family during a crisis period to make the decision-making process easier (Du Toit & Van Staden, 2005: 40). Doctors should also be encouraged when they believe it to be necessary, to talk with their competent participants about including a family member in discussions, and to lower any legal risks towards them. They should even make a note of this discussion in the participant's chart, and if the participant consents to that or refuses to give such permission, the doctor should have the participant complete and sign any forms required (Zucker *et al.,* 2010: 26; Fiesta, 1999: 6-7). Special attention should be paid to the coloured population because contrary to current knowledge the coloured participants in this study were more eager than the black population to involve family members in the consenting process.

5.2.2.3 Respect

In order for patients to feel respected, health care practitioners and supportive staff must do the following:

- Medical practitioners must handle patients gentler and provide enough information regarding a proposed treatment.
- Nurse practitioners must allow patients enough time to bath, give them a comfortable place when they overnight at hospital, be more friendly and open, and handout medication more efficiently.
- Supportive staff must also be more friendly and supportive to patients.

The recommendations do not exclude the rest of the information that is important in the process of informed consent for treatment or operation. Sufficient information was given about that in Chapter 2, The Literature Review, however it still remains the health care practitioners responsibility to acquaint themselves with the relevant legislation in South Africa that guides their practices regarding informed consent for treatment and/or operations.

5.2.3 The patients (study population)

The recommendations to the patients include the following:

- Patients have health care related rights which are included in the following documents: (1) The Constitution of the Republic of South Africa, Bill of Rights (1996: 6-15); (2) The rights and duties of users and health care personnel included in the South African National Health act (2003: 20-28); and the Patient Rights Charter (2007: Online). They must learn to practise these rights and responsibilities.
- Patients have the right to be informed by the doctor who will carry out the operation or procedure of all the information deemed necessary for full disclosure before surgery (South Africa. National Health act 2003: 20-22). Informed consent is a process and therefore it is important that the patients must be informed about their self-care responsibilities and what they can expect during the recuperation phase of their illness.
- In a training hospital, patients have the right to know who will be doing the procedure or operation, whether it will be a consultant, trainee (under supervision), etc. They must also know the years of experience and technical skills of the doctor, including the doctor's personal success and complications rate (Ladas, 2006: 187).

5.3 RECOMMENDATIONS FOR FURTHER RESEARCH

Clearly, there is a need for further study in this area of interest to gather knowledge regarding the vulnerability of participants with low literacy in the process of informed consent. Also the tendency of coloureds, who show a greater need of collective decision-making than blacks in the process of informed consent.

However the influences of possible limitations the study was subjected to has also to be taken in consideration.

5.4 LIMITATIONS OF STUDY

Participants were chosen by a nonrandom method because a nonprobability sampling technique was used. A disadvantage of this strategy is that the

researcher was unable to estimate each participant's probability of being included in the sample, essentially, the chance of every participant's inclusion in the nonprobability sample cannot be ensured. As a result, this type of strategy is less likely to produce accurate and representative samples than probability sampling. (LoBiondo-Wood & Harber, 2010: 225; Polit & Beck, 2008: 341). Despite this fact, convenience sampling was used as the primary sampling method because it was feasible and affordable.

The disadvantages of the study are that the level of the information obtained, is superficial and the design cannot be used to establish a cause-effect relationship between variables (Botma *et al.,* 2010: 110). In other words, it will be difficult for the researcher to say that certain situations in the informed consent process were a direct result of another, etc. Findings are restricted to the study population and cannot be generalized to other health care institutions (Brink & Wood, 1998: 148).

Only literature that was written in English was included in the study, therefore some literature might have been missed. The researcher made used of a data collection tool to assess informed consent of general post-operative and post-procedural participants in an identified hospital in the Northern Cape developed himself, which has not been tested by other researchers in its existing form. Additionally, because the researcher's aim was to describe informed consent of general post-operative and post-procedural participants, he excluded participants from other disciplines. Participants from other disciplines might have differed significantly in their response to the questions therefore ultimately influenced the results of the study.

5.5 CONCLUSIONS

The aim of the study was to describe the process of informed consent of post-operative and post-procedural participants in an identified hospital in the Northern Cape. However the study found that all the stakeholders involved in the practicing of informed consent for treatment or operation had some failures and shortcomings. It is therefore recommended that stakeholders

should use these recommendations to build the capacity of health care practitioners with regard to informed consent in order to provide quality health care services to the participant. Two findings that were prominent in the study were that a large portion of the study participants had been vulnerable due to low literacy, and coloureds showed a greater need of collective decision-making than blacks in the process of informed consent. Furthermore, regardless of the study's limitations, the study yields concerning results of current practices regarding the informed consent process in the institution's general surgical department.

REFERENCES

Akkad, A., Jackson, C., Kenyon, S., Dixon-Woods, M., Taub, N. & Habiba, M. 2004. Informed consent for elective and emergency surgery: questionnaire study. *BJOG: An International Journal Of Obstetrics And Gynaecology,* 111(10), pp. 1133-1138.

Allan, H. & Barber, D. 2005. Emotional boundary work in advanced fertility nursing roles. *Nursing Ethics,* 12(4), pp. 391-400.

Amelung, K. 2000. Competency to Consent – A German Approach. *European Journal of Crime, Criminal Law & Criminal Justice,* 8(1), pp. 1-12.

American Association of Colleges of Nursing. 1998. *The essentials of baccalaureate education for professional nursing practice*. Washington, DC: Author.

American Association of Critical – Care Nurses. 2006. *Ethics in Critical Care Nursing Research* [online]. Available from: http://www.aacn.org/AACN/research.nsf/ [Accessed 04 May 2009].

American Nurses Association. 2001. *Code of ethics for nurses with interpretive statements* [online]. Available from: http://www.nursingworld.org/codeofethics [Accessed 04 May 2009].

Andrus, M. & Roth, M. 2002. Health literacy: a review. *Pharmacotherapy,* 22(3), pp. 282-302.

Appelbaum, P. & Grisso, T. 1988. Assessing patients' capacities to consent to treatment. *The New England Journal Of Medicine,* 319(25), pp. 1635-1638.

Appelbaum, P., Lidz, C. & Klitzman, R. 2009. Voluntariness of consent to research: a conceptual model. *Hastings Center Report,* 39(1), pp. 30-39.

Ashraff, S., Malawa, G., Dolan, T. & Khanduja, V. 2006. Prospective randomised controlled trial on the role of patient information leaflets in obtaining informed consent. *ANZ Journal Of Surgery,* 76(3), pp. 139-141.

Aveyard, H. 2000. Is there a concept of autonomy that can usefully inform nursing practice? *Journal of Advanced Nursing,* 32(2), pp. 352-358.

Aveyard, H. 2005. Informed consent prior to nursing care procedures. *Nursing Ethics,* 12(1), pp. 19-29.

Azoulay, E., Pochard, F., Kentish-Barnes, N., Chevret, S., Aboab, J., Adrie, C., Annane, D., Bleichner, G., Bollaert, P., Darmon, M., Fassier, T., Galliot, R., Garrouste-Orgeas, M., Goulenok, C., Goldgran-Toledano, D., Hayon, J., Jourdain, M., Kaidomar, M., Laplace, C., Larche, J., Liotier, J., Papazian, L., Poisson, C., Reignier, J., Saidi, F. & Schlemmer, B. 2005. Risk of post-traumatic stress symptoms in family members of intensive care unit patients. *American Journal of Respiratory & Critical Care Medicine,* 171(9), pp. 987-994.

Babbie, E. 2004. *The Practice of Social Research.* 10th ed. Belmont, CA: Wadsworth/Thomson Learning.

Baeroe, K. 2010. Patient autonomy, assessment of competence and surrogate decision-making: a call for reasonableness in deciding for others. *Bioethics,* 24(2), pp. 87-95.

Bamford, C., Lamont, S., Eccles, M., Robinson, L., May, C. & Bond, J. 2004. Disclosing a diagnosis of dementia: a systematic review. *International Journal of Geriatric Psychiatry,* 19(2), pp. 151-169.

Bandman, E. & Bandman, B. 2002. *Nursing ethics through the life span.* Upper Saddle River, New Jersey: Prentice Hall Pearson Education, Inc.

Barber, B. 1980. *Informed Consent in Medical Therapy and Research.* New Jersey: Rutgers University Press.

Barber, D. 2002. The extended role of the nurse: practical realities. *Human Fertility,* 5(1), pp. 13-16.

Beauchamp, T. & Childress, J. 1989. *Principles of Biomedical Ethics.* New York: Oxford University Press.

Beauchamp, T. & Childress, J. 1994. *Principles of Biomedical Ethics.* New York: Oxford University Press.

Beauchamp, T. & Childress, J. 2001. *Principles of biomedical ethics.* New York: Oxford University Press.

Beauchamp, T. & Faden, R. 1986. *A History and Theory of Informed Consent.* New York: Oxford University Press.

Berg, B. 2007. *Qualitative research methods for the social sciences.* Boston: Pearson.

Berg, J., Appelbaum, P., Lidz, C. & Parker, L. 2001. *Informed Consent: Legal Theory and Clinical Practice.* 2nd ed. New York: Oxford University Press.

Berlin, R. & Canaan, A. 1991. A family systems approach to competency evaluations in the elderly. *Psychosomatics: Journal of Consultation Liaison Psychiatry,* 32(3), pp. 349-354.

Berry, D., Dodd, M., Hinds, P. & Ferrell, B. 1996. Ethical issues. Informed consent: process and clinical issues. *Oncology Nursing Forum,* 23(3), pp. 507-512.

Bevis, E. 1981. Caring: A life force. In: Leininger, M. (Ed.). *Caring: An essential human need.* Thorofare: Charles B Slack, pp. 49-60.

Bhutta, Z. 2004. Beyond informed consent. *Bulletin of the World Health Organization,* 82(10), pp. 771-A.

Blackwell's Dictionary of Nursing. 1997. South Africa. Juta & Co. (Pty) Ltd.

Blancett, S. & Sullivan, P. 1993. Ethics survey results. *Journal of Nursing Administration,* 23(3), pp. 9-13.

Blustein, J. 1993. The family in medical decision-making. *Hastings Center Report,* 23(3), pp. 6-13.

Borawski, D. 1994. Resources used by nurse administrators in ethical decision-making. *Journal of Nursing Administration,* 24(3), pp. 17-22.

Bordens, K. & Abbott, B. 2008. *Research Design and Methods. A process approach.* 7th ed. New York: McGraw-Hill Companies, Inc.

Botma, Y., Greeff, M., Mulaudzi, F. & Wright, S. 2010. *Research in Health Sciences.* Cape Town: Pearson Education South Africa (Pty) Ltd.

Brady, J. 2003. Multimedia Delivery Can Enhance the Consent Process. *Applied Clinical Trials,* 12(1), p. 36.

Breese, P., Burman, W., Rietmeijer, C. & Lezotte, D. 2004. The Health Insurance Portability and Accountability Act and the informed consent process. *Annals of Internal Medicine,* 141(11), pp. 897-898.

Brink, H. 2006. *Fundamentals of Research Methodology for Health Care Professionals.* 2nd ed. Cape Town: Juta & Co. (Pty) Ltd.

Brink, P. & Wood, M. 1998. *Advanced Design in Nursing Research.* 2nd ed. London: Sage.

Brock, D. & Buchanan, A. 1990. *Deciding for Others: The Ethics of Surrogate Decision Making.* New York: Cambridge University Press.

Browne, A. 1993. A conceptual clarification of respect. *Journal of Advanced Nursing,* 18(2), pp. 211-217.

Bunkers, S. 1992. A strategy for staff development: self-care and self-esteem as necessary partners. Clinical Nurse Specialist: *The Journal for Advanced Nursing Practice,* 6(3), pp. 154-159.

Burns, N. & Grove, S. 2005. *The Practice of Nursing Research. Conduct, Critique and Utilization.* 5th ed. USA: Elsevier Saunders.

Business live. 2011. *Death of 29 babies probed* [online]. Available from: www.businesslive.co.za/deaths-of-29-babies-probed [Accessed 03 August 2011].

Cady, R. 2000. Informed consent for adult patients – a review of basic principles. *MCN. The American Journal Of Maternal Child Nursing,* 25(2), p. 106.

Campbell, F., Goldman, B., Boccia, M. & Skinner, M. 2004. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: a comparison of print, video, and computer-based presentations. *Patient Education And Counseling,* 53(2), pp. 205-216.

Carnerie, F. 1986. Crisis and Informed Consent: Analysis of a Law-Medicine Malocclusion. *American Journal of Law & Medicine,* 12(1), p. 55.

Carpenter, D. 1992. Professional development module. P9: Advocacy. Part (ii): The 'how' of advocacy. *Nursing Times,* 88(27), pp. 26-27.

Carper, B. 1978. Fundamental patterns of knowing in nursing*. ANS. Advances In Nursing Science,* 1(1), pp. 13-23.

Castell v De Greeff [1994] (4) SA 408 (C).

Chester v Afshar [2005] 1 AC 134, HL, para 14 per Lord Steyn.

Cobbs v Grant [1972] 8 Cal 3d 229 502 P2d 1.

Constantino, R. & Jackson, N. 2005. Psychiatric nursing: the cross-roads of ELSI. *LNC Resource,* 2(2), pp. 21-22.

Copp, L. 1986. The nurse as advocate for vulnerable persons. *Journal of Advanced Nursing,* 11(3), pp. 255-263.

Côté, A. 2000. Telling the truth? Disclosure, therapeutic privilege and intersexuality in children. *Health Law Journal,* 8, pp. 199-216.

Coulson, K., Glasser, B. & Liang, B. 2002. Informed consent: issues for providers. *Hematology/Oncology Clinics Of North America,* 16(6), pp. 1365-1380.

Council for International Organizations of Medical Sciences. 2002. International ethical guidelines for biomedical research involving human

subjects [online]. Available from: www.cioms.ch/publications/layout_guide2002.pdf [Accessed 20 august 2011].

Coyne, C., Xu, R., Raich, P., Plomer, K., Dignan, M., Wenzel, L., Fairclough, D., Habermann, T., Schnell, L., Quella, S. & Cella, D. 2003. Randomized controlled trial on an easy-to-read informed consent statement for clinical trial participation: a study of the Eastern Cooperative Oncology Group. *Journal of Clinical Oncology,* 21(5), pp. 836-842.

Cresia, J. & Parker, B. 1991. *Conceptual Foundations of Professional Nursing Practice.* St Louis: Mosby.

Culver, C. & Gurt, B. 1982. *Philosophy in medicine.* New York: Open University Press.

Denny, C. & Grady, C. 2007. Clinical research with economically disadvantaged populations. *Journal of Medical Ethics,* 33(7), pp. 382-385.

De Vos, A., Strydom, H., Fouché, C. & Delport, C. 2005. *Research at Grass roots. For the Social Sciences and Human Service Professions.* 3rd ed. Pretoria: Van Schaik Publishers.

Dierckx de Casterlé, B., Janssen, P. & Grypdonck, M. 1996. The relationship between education and ethical behavior of nursing students. *Western Journal Of Nursing Research,* 18(3), pp. 330-350.

Dimond, B. 1991. Legal aspects of nursing. *Nursing The Elderly: In Hospital, Homes And The Community,* 3(2), pp. 26-29.

Downie, R. & Telfer, E. 1970. *Respect for Persons.* New York: Schocken Books.

Drew, N. 1986. Exclusion and confirmation: A phenomenology of patients' experiences with caregivers. *IMAGE: Journal of Nursing Scholarship,* 18(2), pp. 39-43.

Dubler, N. 1992. Individual advocacy as a governing principle. *Journal of Case Management,* 1(3), pp. 82-86.

Dunn, D. 1999. Exploring the gray areas of informed consent. *Nursing,* 29(7), pp. 41-45.

Du Toit, D. & Van Staden, S. 2005. *Nursing Sociology.* 3rd ed. Pretoria: Van Schaik Publishers.

Dyer, A. & Bloch, S. 1987. Informed consent and the psychiatric patient. *Journal Of Medical Ethics,* 13(1), pp. 12-16.

Easton, R., Graber, M., Monnahan, J. & Hughes, J. 2007. Defining the scope of implied consent in the emergency department. *American Journal of Bioethics,* 7(12), pp. 35-38.

Engelhardt, H, Jr. 1986. *Foundations of Bioethics.* 1st ed. Oxford: Oxford University Press.

Ericksen, J. 1989. Steps to ethical reasoning. *The Canadian Nurse,* 85(7), pp. 23-24.

Etchells, E., Sharpe, G., Burgess, M. & Singer, P. 1996. Bioethics for clinicians: 2. Disclosure. *CMAJ: Canadian Medical Association Journal = Journal De L'association Medicale Canadienne,* 155(4), pp. 387-391.

Eyler, L. & Jeste, D. 2006. Enhancing the informed consent process: a conceptual overview. *Behavioral Sciences & the Law,* 24(4), pp. 553-568.

Faden, R., Beauchamp, T. & King, N. 1986. *A history and theory of informed consent.* New York: Oxford University Press.

Fagermoen, M. 1997. Professional identity: values embedded in meaningful nursing practice. *Journal of Advanced Nursing,* 25(3), pp. 434-441.

Fahrenwald, N., Bassett, S., Tschetter, L., Carson, P., White, L. & Winterboer, V. 2005. Teaching core nursing values. *Journal of Professional Nursing,* 21(1), pp. 46-51.

Fealy, G. 2004. 'The good nurse': visions and values in images of the nurse. *Journal of Advanced Nursing,* 46(6), pp. 649-656.

Fiesta, J. 1999. Informed consent: what health care professionals need to know, Part 2. *Nursing Management,* 30(7), pp. 6-7.

Finck, A. 2008. *Practicing research. Discovering evidence that matters.* California: Sage Publications, Inc.

Fish, S. 2004. Informed consent: time for a national dialogue? *Annals of Emergency Medicine,* 43(4), pp. 449-451.

Fleming, J. 1998. *The law of torts.* 9th ed. North Ryde, NSW: Law Book Company.

Flory, J. & Emanuel, E. 2004. Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review. *JAMA: Journal of the American Medical Association,* 292(13), pp. 1593-1601.

Forchuk, C. & Brown, B. 1989. Establishing a nurse-client relationship. *Journal of Psychosocial Nursing & Mental Health Services,* 27(2), pp. 30-34.

Forrest, D. 1989. The experience of caring. *Journal Of Advanced Nursing,* 14(10), pp. 815-823.

Fowler, M. 1989. Ethical decision-making in clinical practice. *Nursing Clinics of North America,* 24(4), pp. 955-965.

Fowler, M. & Levine-Ariff, J. 1987. *Ethics at the bedside.* Philadelphia: J.B. Lippincott.

Franck, L. & Winter, I. 2004. Research participant information sheets are difficult to read. *Bulletin of Medical Ethics,* 195, pp. 13-18.

Frimpong-Mansoh, A. 2008. Culture and voluntary informed consent in African Health care systems. *Developing World Bioethics,* 8(2), pp. 104-114.

Fromer, M. 1981. *Ethical issues in health care.* St Louis: C.V. Mosby.

Fry, S. 1994. *Ethics in nursing practice: a guide to ethical decision-making.* Geneva: International Council of Nurses.

Fullbrook, S. 2007. Best interests. An holistic approach: part 2(b). *British Journal of Nursing (BJN),* 16(12), pp. 746-747.

Gadow, S. 1980. Existential advocacy: philosophical foundation of nursing. In: Spicker, S. & Gadow, S. (Ed.). *Nursing: Images and Ideals.* New York: Springer Publications Co, pp. 79-101.

Gallagher, A. 2004. Dignity and respect for dignity – two key health professional values: implications for nursing practice. *Nursing Ethics,* 11(6), pp. 587-599.

Gardner, D. 1985. *Presence.* Philadelphia: W.B. Saunders.

Gauld, V. 1981. Written advice: compliance and recall. *The Journal Of The Royal College Of General Practitioners,* 31(230), pp. 553-556.

Gaut, D. 1979. *An application of the Kerr-soltis model to the concept of caring in nursing.* London: University Microfilms International.

Gawande, A. 2002. *Complications: A surgeon's notes on an imperfect science.* New York: Metropolitan Books.

Gendron, D. 1990. Learning caring behavior in an integrated manner. In: Leininger, M. & Watson, J. (Ed.). *The caring imperative in education.* New York: National League for Nursing, pp. 277-286.

Glass, E. & Cluxton, D. 2004. Truth-telling: ethical issues in clinical practice. *Journal of Hospice & Palliative Nursing,* 6(4), pp. 232-243.

Golec, L. 2004. Are you truly informed about informed consent? The Monitor, 18(3), pp. 15-23.

Goode, E. 1997. *Deviant behavior.* New Jersey: Prentice Hall.

Green, S. 1996. Editorial. *Journal of Medical Defence Union,* 12, p.49.

Griffin, A. 1980. Philosophy and nursing. *Journal Of Advanced Nursing,* 5(3), pp. 261-272.

Griffiths, F. 2009. *Research methods for health care practice.* London: Sage Publications Ltd.

Grisso, T., Appelbaum, P. & Hill-Fotouhi, C. 1997. The MacCAT-T: a clinical tool to assess patients' capacities to make treatment decisions. *Psychiatric Services (Washington, D.C.),* 48(11), pp. 1415-1419.

Guarino, P., Elbourne, D., Carpenter, J. & Peduzzi, P. 2006. Consumer involvement in consent document development: A multicenter cluster randomized trial to assess study participants' understanding. *Clinical Trial,* 3, pp. 19-30.

Gyekye, K. 1992. Traditional political ideas and their relevance to development in contemporary Africa. In: Wiredu, K. & Gyekye, K. (Ed.). *Persons and Community: Ghanaian Philosophical Studies.* Washington: The Council for Research in Values and Philosophy, pp. 241-255.

Habiba, M., Jackson, C., Akkad, A., Kenyon, S. & Dixon-Woods, M. 2004. Women's accounts of consenting to surgery: is consent a quality problem? *Quality & Safety in Health Care,* 13(6), pp. 422-427.

Haddock, J. 1996. Towards further clarification of the concept "dignity". *Journal of Advanced Nursing,* 24(5), pp. 924-931.

Hamric, A. 2000. Moral distress in everyday ethics. *Nursing Outlook,* 48(5), pp. 199-201.

Hanna, N. 1998. Challenging medical decision-making: Professional dominance, patient rights or collaborative autonomy? Oxford Journal of Legal Studies, 18(1), 143-152.

Hanson, L. 2001. Informed consent and the scope of a physician's duty to disclose. *North Dakota Law Review,* 77, p. 71.

Hansson, M. 1998. Balancing the quality of consent. *Journal Of Medical Ethics,* 24(3), pp. 182-187.

Harmer, V. 2010. Are nurses blurring their identity by extending or delegating roles? *British Journal of Nursing,* 19(5), pp. 295-299.

Health Care Professions Council of South Africa. 2007. *Seeking patients' informed consent: The ethical considerations.* 2nd ed. Pretoria: HPCSA.

Helgeson, V., Cohen, S., Schulz, R. & Yasko, J. 1999. Education and peer discussion group interventions and adjustment to breast cancer. *Archives Of General Psychiatry,* 56(4), pp. 340-347.

Henderson, V. 1966. *The nature of nursing: a definition and its implications for practice, research, and education.* New York: McMillan.

Hewison, A. 2001. Values in the National Health Service: implications for nurse managers. *Journal of Nursing Management,* 9(5), pp. 253-258.

Hewitt, J. 2002. A critical review of the arguments debating the role of the nurse advocate. *Journal of Advanced Nursing,* 37(5), pp. 439-445.

Hochhauser, M. 2003. Subject Recruitment and Informed Consent. *Applied Clinical Trials,* 12, p. 10.

Holden, R. 1991. Responsibility and autonomous nursing practice. *Journal of Advanced Nursing,* 16(4), pp. 398-403.

Howard, J., Davis, F., Pope, C. & Ruzek, S. 1977. Humanizing health care: the implications of technology, centralization, and self-care. *Medical Care,* 15(5), pp. 11-26.

Iltis, A. 2006. Lay concepts in informed consent to biomedical research: the capacity to understand and appreciate risk. *Bioethics,* 20(4), pp. 180-190.

Integrated Health Service Plan. 2009. Part IV: Nursing Values and Resistance. *Registered Nurse: Journal of Patient Advocacy,* 105(7), pp. 19-20.

Irabor, D. & Omonzejele, P. 2009. Local attitudes, moral obligation, customary obedience and other cultural practices: their influence on the process of gaining informed consent for surgery in a tertiary institution in a developing country. *Developing World Bioethics,* 9(1), pp.34-42.

Jacobs, B. 2001. Respect for human dignity: a central phenomenon to philosophically unite nursing theory and practice through consilience of knowledge. *ANS. Advances In Nursing Science,* 24(1), pp. 17-35.

Jameton, A. 1984. *Nursing practice: the ethical issues.* New Jersey: Prentice Hall.

Jaynes, T. 2005. Informed Consent: Imparting Knowledge or Signing a Form? *Applied Clinical Trials,* 14(6), pp. 104-106.

Joffe, S., Cook, E., Cleary, P., Clark, J. & Weeks, J. 2001a. Quality of informed consent in cancer clinical trials: a cross-sectional survey. *Lancet,* 358(9295), p. 1772.

Joffe, S., Cook, E., Cleary, P., Clark, J. & Weeks, J. 2001b. Quality of informed consent, a new measure among research subjects. *Journal of the National Cancer Institute,* 93(2), pp. 139-147.

Johnston, C. & Holt, G. 2006. The legal and ethical implications of therapeutic privilege – is it ever justified to withhold treatment information from a competent patient? *Clinical Ethics,* 1(3), pp. 146-151.

Johnstone, M. 1994. *Bioethics: a nursing perspective.* 2nd ed. Sydney: W.B. Saunders.

Jones, M. 1999. Informed consent and other fairy stories. *Medical Law Review,* 7(2), p. 103.

Jormsri, P., Kunaviktikul, W., Ketefian, S. & Chaowalit, A. 2005. Moral competence in nursing practice. *Nursing Ethics,* 12(6), pp. 582-594.

Kapp, M. 2002. Evidence-based medicine and informed consent. *Academic Medicine: Journal Of The Association Of American Medical Colleges,* 77(12), pp. 1199-1200.

Katims, I. 1993. Nursing as aesthetic experience and the notion of practice. *Scholarly Inquiry For Nursing Practice,* 7(4), pp. 269-278.

Keeton, W., Dobbs, D., Keeton, R. & Owen, D. 1984. *Prosser and Keeton on Torts.* 5th ed. St Paul, MN: West Publishing Company.

Kegley, J. 2004. A new bioethics framework for facilitating better decision-making about genetic information. In: Boylan, M. (Ed.). *Public Health Policy and Ethics*. Dordrecht: Kluwer Academic Publishers, pp. 91-101.

Kelly, B. 1990. Respect and caring: ethics and essence of nursing. In: Leininger, M. (Ed.). *Ethical and moral dimensions of care.* Detroit, Michigan: Wayne State University Press, pp. 67-80.

Kilkus, S. 1993. Assertiveness among professional nurses. *Journal of Advanced Nursing,* 18(8), pp. 1324-1330.

Kim, S., Caine, E., Currier, G., Leibovici, A. & Ryan, J. 2001. Assessing the competence of persons with Alzheimer's disease in providing informed consent for participation in research. *The American Journal Of Psychiatry,* 158(5), pp. 712-717.

Kimberley Hospital Complex. 2008. *Policy on informed consent for treatment/operation.* KHC: Quality Assurance Department.

Kinney, C. 1985. A reexamination of nursing role conceptions. *Nursing Research,* 34(3), pp. 170-176.

Kirby, M. 1983. Informed consent: what does it mean? *Journal Of Medical Ethics,* 9(2), pp. 69-75.

Kitamura, F., Tomoda, A., Tsukada, K., Tanaka, M., Kawakami, I., Mishima, S. & Kitamura, T. 1998. Method for assessment of competency to consent in the mentally ill. Rationale, development, and comparison with the medically ill. *International Journal Of Law And Psychiatry,* 21(3), pp. 223-244.

Kitamura, T. 2005. Stress-reductive effects of information disclosure to medical and psychiatric patients. *Psychiatry & Clinical Neurosciences,* 59(6), pp. 627-633.

Kitamura, T. & Kitamura, F. 2000. Reliability of clinical judgment of patients' competency to give informed consent: A case vignette study. *Psychiatry & Clinical Neurosciences,* 54(2), pp. 245-247.

Kitching, J. 1990. Patient information leaflets – the state of the art. *Journal Of The Royal Society Of Medicine,* 83(5), pp. 298-300.

Klaich, K. 1990. Transitions in professional identity of nurses enrolled in graduate educational programs. *Holistic Nursing Practice,* 4(3), pp. 17-24.

Klimeck, M. 1990. Virtue, ethics and care: developing the personal dimension of caring in nursing education. In: Leininger, M. & Watson, J. (Ed.). *The caring imperative in education.* New York: National League for Nursing, pp. 177-187.

Kluge, E. 2007. Informed Consent in Health Research. *International Journal of Pharmaceutical Medicine,* 21(6), pp. 405-414.

Koren, G., Kearns, G., Reed, M. & Pons, G. 2003. Use of healthy children as volunteers in drug studies: the ethical debate. *Clinical Pharmacology Therapy,* 73(3), pp. 147-152.

Kripalani, S., Bengtzen, R., Henderson, L. & Jacobson, T. 2008. Clinical research in low-literacy populations: using teach-back to assess comprehension of informed consent and privacy information. *IRB: Ethics & Human Research,* 30(2), pp. 13-19.

Kuczewski, M. 1996. Reconceiving the family. The process of consent in medical decisionmaking. *The Hastings Center Report,* 26(2), pp. 30-37.

Ladas, S. 2006. Informed consent: still far from ideal? *Digestion,* 73(2), pp. 187-188.

LaDuke, S. 2002. Ethical issues in pain management. *Critical Care Nursing Clinics of North America,* 14(2), pp. 165-170.

Lakomy, J. 1993. The interdisciplinary meanings of human caring. In: Gaut, D. (Ed.). *A global agenda for caring*. New York: National League for Nursing, pp. 181-199.

Leddy, S. & Perry, J. 1993. *Conceptual bases of professional nursing.* 3rd ed. Philadelphia: Lippincott.

Leininger, M. 1989. The transcultural nurse specialist: imperative in today's world. *Nursing & Healthcare,* 10(5), pp. 250-256.

Lenburg, C. 2000. Promoting competence through critical self-reflection and portfolio development: the inside evaluator and the outside context. *Tennessee Nurse,* 63(3), p. 11.

Levine, M. 1977. Nursing ethics and the ethnical nurse. *The American Journal Of Nursing,* 77(5), pp. 845-849.

Levine, R. 1986. *Ethics and regulation of clinical research.* 2nd ed. Baltimore-Munich: Urban & Schwarzenberg.

Lewis, S. 2003. Caring as being in nursing: unique or ubiquitous. *Nursing Science Quarterly,* 16(1), pp. 37-43.

Ley, P. 1972. Comprehension, memory and success of communications with the patient. *Journal for Institutional Health Education,* 10, pp. 23-29.

Lidz, C. 2006. The therapeutic misconception and our models of competency and informed consent. *Behavioral Sciences & the Law,* 24(4), pp. 535-546.

Lieberman, M. 1974. The physician's duty to disclose risks of treatment. *Bulletin Of The New York Academy Of Medicine,* 50(8), pp. 943-948.

Lindberg, J., Hunter, M. & Kruszewski, A. 1990. *Introduction to nursing. Concepts, issues and opportunities.* Philadelphia: Lippincott Company.

Lindemann, N. 1992. Taking families seriously. *Hastings Center Report,* 22(4), pp. 6-12.

Little, M., Jordens, C., McGrath, C., Montgomery, K., Lipworth, W. & Kerridge, I. 2008. Informed consent and medical ordeal: a qualitative study. *Internal Medicine Journal,* 38(8), pp. 624-628.

LoBiondo-Wood, G. & Harber, J. 2010. *Nursing research. Methods and critical appraisal for evidence-based practice.* 7th ed. St Louis, Missouri: Mosby, Inc.

Maben, J. & Griffiths, P. 2008. *Nurses in society: Starting the debate.* Kings College, London: National Nursing Research Unit.

Macklin, R. 2004. *Double standards in medical research in developing countries.* Cambridge: Cambridge University Press.

Mairis, E. 1994. Concept clarification in professional practice – dignity. *Journal of Advanced Nursing,* 19(5), pp. 947-953.

Mallik, M. 1997. Advocacy in nursing – a review of the literature. *Journal of Advanced Nursing,* 25(1), pp. 130-138.

Mallik, M. 1998. Advocacy in nursing: perceptions and attitudes of the nursing elite in the United Kingdom. *Journal of Advanced Nursing,* 28(5), pp. 1001-1011.

Mallik, M. & McHale, J. 1995. Support for advocacy. *Nursing Times,* 91(4), pp. 28-29.

Mannahan, C. 1989. Professional maturity: the stages of developing self-esteem. *AORN Journal,* 49(2), p. 593.

Mardell, A. 1996. Advocacy: exploring the concept. *British Journal of Theatre Nursing,* 6(7), pp. 34-36.

Marshall, P., Adebamowo, C., Adeyemo, A., Ogundiran, T., Vekich, M., Strenski, T., Zhou, J., Prewitt, T., Cooper, R. & Rotimi, C. 2006. Research and practice. Voluntary participation and informed consent to international genetic research. *American Journal of Public Health,* 96(11), pp. 1989-1995.

Mayberry, J. & Mayberry, M. 1996. Effective instructions for patients. *Journal Of The Royal College Of Physicians Of London,* 30(3), pp. 205-208.

McGee, P. 1994. The concept of respect in nursing. *British Journal of Nursing (BJN),* 3(13), p. 681.

McLaughlin, K., Brindley, A. & Crowther, C. 2002. Informational video for potential participants of clinical studies used in the process of seeking informed consent. *Cochrane Database Systems Review,* 3, CD003717.

Meade, C. 1999. Improving understanding of the informed consent process and document. *Seminars in Oncology Nursing,* 15(2), pp. 124-137.

Meisel, A. 1973. Emotional stresses of patient-physician encounters. *JAMA: The Journal Of The American Medical Association,* 223(9), pp. 1037-1038.

Meisel, A. 1979. The "exceptions" to the informed consent doctrine: striking a balance between competing values in medical decision-making. *Wisconsin Law Review,* 1979(2), pp. 413-488.

Meisel, A. & Kuczewski, M. 1996. Legal and ethical myths about informed consent. *Archives of Internal Medicine,* 156(22), pp. 2521-2526.

Miller, C., O'Donnell, D., Searight, H. & Babarash, R. 1996. The deaconess informed consent comprehension test. *Pharmacotherapy,* 16(5), pp. 872-878.

Miller, F. 2005. Does Research Ethics Rest on a Mistake? *American Journal of Bioethics,* 5(1), pp. 34-36.

Miller, S. & Mangan, C. 1983. Interacting Effects of Information and Coping Style in Adapting to Gynecologic Stress: Should the Doctor Tell All? *Journal of Personality & Social Psychology,* 45(1), pp. 223-236.

Milner, A. 1986. *Human rights and human diversity: An essay in the philosophy of human rights.* New York: State University Press.

Minnesota Alliance for Patient Safety. 2007. *Minnesota informed consent* [online]. Available from: http://www.mnpatientsafety.org. [Accessed 20 August 2011].

Minnesota Office of the Revisor of Statutes. 2007. *Decision-making capacity* [online]. Available from: http://www.revisor.leg.state.mn.us/stats/ [Accessed 20 August 2011].

Molyneux, C., Peshu, K. & Marsh, K. 2004. *Understanding of informed consent in a low-income setting: three case studies from the Kenyan coast.* USA: Elsevier Saunders.

Montana State Hospital Policy and Procedure. 2009. *Procedure for obtaining informed consent for medical and surgical procedure* [online]. Available from: http://www.procedureobtaininginformedconsent.pdf [Accessed 20 August 2011].

Morrison, P. 1994. Psychological aspects of care. In: Millar, B. & Burnard, P. (Ed.). *Critical care nursing.* London: Ballière-Tindall, pp. 273-289.

Moskop, J. 2007. Information disclosure and consent: patient preferences and provider responsibilities. *The American Journal Of Bioethics: AJOB,* 7(12), p. 47.

Moye, J., Gurrera, R., Karel, M., Edelstein, B. & O'Connell, C. 2006. Empirical advances in the assessment of the capacity to consent to medical treatment: clinical implications and research needs. *Clinical Psychology Review,* 26(8), pp. 1054-1077.

National Bioethics Advisory Commission. 2001. *Ethical and policy issues in international research. Clinical Trials in Developing Countries* [online]. Available from: http://bioethics.georgetown.edu/nbac/clinical/Vol1.pdf [Accessed 20 August 2011].

National Quality Forum, editor. 2003. *Safe practice for better healthcare* [online]. Available from: http://ahrq.gov/qual/nqfpract.pdf [Accessed 20 August 2011].

Nelson, S. & Gordon, S. 2004. The rhetoric of rupture: nursing as a practice with a history. *Nursing Outlook,* 52(5), pp. 255-261.

Northouse, L. & Northouse, P. 1998. *Health Communication. Strategies for Health Professionals.* 3rd ed. Stamford: Appleton & Lange.

Nuremberg Code. 1947. *Permissible Medical Experiments* [online]. Available from: http://www.cirp.org/library/ethics/nuremberg/ [Accessed 04 May 2009].

Ohlen, J. & Segesten, K. 1998. The professional identity of the nurse: concept analysis and development. *Journal of Advanced Nursing,* 28(4), pp. 720-727.

Oldwage v Louwrens [2000] 1 All SA 532 (c).

O'Neill, O. 1989. *Constructions of reason: explorations of Kant's practical philosophy.* Cambridge: Cambridge University Press.

O'Neill, O. 2003. Some limits of informed consent. *Journal of Medical Ethics,* 29(1), p. 4.

Oxford Advanced Learner's Dictionary. International Student's Edition. 2010. 7th ed. Oxford: Oxford University Press.

Paasche-Orlow, M., Taylor, H. & Brancati, F. 2003. Readibility standards for informed-consent forms as compared with actual readability. *The New England Journal of Medicine,* 348(8), pp.721-726.

Parsons, R. 2000. *The ethics of professional practice.* Boston, MA: Allyn and Basson.

Paterick, T., Carson, G., Allen, M. & Paterick, T. 2008. Medical Informed Consent: General Considerations for Physicians. *Mayo Clinic Proceedings,* 83(3), pp. 313-319.

Pearce, F. 2009. ML02P Adult surgical patients: the question of competency to consent. *ANZ Journal of Surgery,* 79, p. 48.

Pedroni, J. & Pimple, K. 2001. *A Brief Introduction to Informed Consent in Research with Human subjects.* 2nd ed. New Haven and London: Yale University Press.

Penman, D., Holland, J., Bahna, G., Morrow, G., Schmale, A., Derogatis, L., Carnrike, C. & Cherry, R. 1984. Informed consent for investigational chemotherapy: patients' and physicians' perceptions. *Journal Of Clinical Oncology: Official Journal Of The American Society Of Clinical Oncology,* 2(7), pp. 849-855.

Pennery, E. 2003. Specialist nursing roles: What are the challenges. In: Harmer, V. (Ed.). *Breast Cancer: Nursing Care and Management.* London: Whurr Publishers, pp. 334-351.

Pera, S. & Van Tonder, S. 2005. *Ethics in health care.* 2nd ed. Landsdowne: Juta Academic.

Polit, D. & Beck, C. 2008. *Nursing Research. Generating and Assessing Evidence for Nursing Practice.* 8th ed. New York: Lippincott Williams & Wilkins, a Wolters Kluwer business.

Polit. D., Beck, C. & Hungler, B. 2001. *Essentials of Nursing Research: Methods Appraisals and Utilizations.* 5th ed. Philadelphia: Lippincott.

Porter, R. & Porter, M. 1991. Career development: our professional responsibility. *Journal of Professional Nursing,* 7(4), pp. 208-212.

Quallich, S. 2005. The Practice of Informed Consent. *Dermatology Nursing,* 17(1), pp. 49-51.

Rado, S. 2008. A patient's right to know: a case for mandating disclosure of physician success rate as an element of informed consent. *Health Matrix: Journal of Law-Medicine,* 18(2), pp. 501-530.

Raich, P., Plomer, K. & Coyne, C. 2001. Literacy, Comprehension, and Informed Consent in Clinical Research. *Cancer Investigation,* 19(4), p. 437.

Rhodes, R. 2005. Rethinking research ethics. *The American Journal Of Bioethics: AJOB,* 5(1), pp. 7-28.

Roach, M. 1997. *Caring from the heart. The convergence of caring and spirituality.* New Jersey: Paulist Press.

Roberts, L. 1998. The ethical basis of psychiatric research: conceptual issues and empirical findings. *Comprehensive Psychiatry,* 39(3), pp. 99-110.

Robichaux, C., Dittmar, V. & Clark, A. 2005. Are we providing culturally competent care? *Clinical Nurse Specialist: The Journal for Advanced Nursing Practice,* 19(1), pp. 11-14.

Rodney, P. & Starzomski, R. 1993. Constraints on the moral agency of nurses. *Canadian Nurse,* 89(9), pp. 23-26.

Rokeach, M. 1979. *Understanding human values.* New York: The Free Press.

Rozovsky, F. 1984. *Consent to treatment: A practical guide.* Boston, MA: Little, Brown and Company.

Saks, M. & Allsop, J. 2008. *Researching health. Qualitative, quantitative and mixed methods.* London: Sage Publications Ltd.

Sarkar, R., Grandin, E., Gladstone, B., Muliyil, J. & Kang, G. 2009. Comprehension and Recall of Informed Consent among Participating Families in a Birth Cohort Study on Diarrhoeal Disease. *Public Health Ethics,* 2(1), pp. 37-44.

Scanlon, C. & Fleming, C. 1989. Ethical issues in caring for the patient with advanced cancer. *Nursing Clinics of North America,* 24(4), pp. 977-986.

Scanlon, C. & Glover, J. 1995. A professional code of ethics: providing a moral compass for turbulent times. *Oncology Nursing Forum,* 22(10), pp. 1515-1521.

Schaeffer, M., Krantz, D., Wichman, A., Masur, H., Reed, E. & Vinicky, J. 1996. The impact of disease severity on the informed consent process in clinical research. *The American Journal Of Medicine,* 100(3), pp. 261-268.

Schillinger, D., Piette, J., Grumbach, K., Wang, F., Wilson, C., Daher, C., Leong-Grotz, K., Castro, C. & Bindman, A. 2003. Closing the Loop: Physician Communication With Diabetic Patients Who Have Low Health Literacy. *Archives of Internal Medicine,* 163(1), p. 83.

Schmand, B., Gouwenberg, B., Smit, J. & Jonker, C. 1999. Assessment of mental competency in community-dwelling elderly. *Alzheimer Disease And Associated Disorders,* 13(2), pp. 80-87.

Schopp, A., Välimäki, M., Leino-Kilpi, H., Dassen, T., Gasull, M., Lemonidou, C., Scott, P., Arndt, M. & Kaljonen, A. 2003. Perceptions of informed consent in the care of elderly people in five European countries. *Nursing Ethics,* 10(1), pp. 48-57.

Searle, C. 2000. *Professional practice: A South African nursing perspective.* 4th ed. Heinemann.

Sears, J. 2005. Context is key for voluntary and informed consent. *The American Journal Of Bioethics: AJOB,* 5(1), p. 47.

Seria, N. & Cohen, M. 2010. *Teachers, nurses in South Africa start indefinite strike over pay dispute* [online]. Available from: http://www.bloomberg.com/news/2010-08-18/teachers-nurses-in-south-africa-start-indefinite-strike-over-pay-dispute [Accessed on 03 August 2011].

Shalowitz, D. & Wendler, D. 2006. Informed consent for research and authorization under the Health Insurance Portability and Accountability Act Privacy Rule: an integrated approach. *Annals Of Internal Medicine,* 144(9), pp. 685-688.

Shaw, H. & Degazon, C. 2008. Integrating the core professional values of nursing: A profession, not just a career. *Journal of Cultural Diversity,* 15(1), pp. 44-50.

Smith, M. 1999. Caring and the science of unitary human beings. *Advances in Nursing Science,* 21(4), pp. 14-28.

Snowball, J. 1996. Asking nurses about advocating for patients: “reactive” and “proactive” accounts. *Journal of Advanced Nursing,* 24(1), pp. 67-75.

Solomon, M. 2011. *Manto: villain. Sunday Times: hero? MA assignment* [online]. Available from: http://mishsolomon.com/2011/07/13/manto-villain-sunday-times-hero-ma-assignment/ [Accessed 20 August 2011].

South Africa. 1996. *The Constitution of the Republic of South Africa.* 9th ed. Claremont: Juta Law.

South Africa. 2000. *Promotion of Access to Information Act, act 2 of 2000.* Pretoria: Government Printer.

South Africa. 2003. *National Health Act, act 61 of 2003.* Pretoria: Government Printer.

South Africa. 2005. *Children's Act, act 38 0f 2005.* Pretoria: Government Printer.

South Africa. Department of Health. 2004. *Ethics in Health Research: Principles, Structures and Processes.* Pretoria: Government Printer.

South Africa. Department of Health. 2006. *Guidelines for Good Practice in the Conduct of Clinical Trails with Human Participants in South Africa.* Pretoria: Government Printer.

South Africa. Department of Health. 2007. Patient Rights Charter [online]. Available from: http://www.doh.gov.za/docs/legislation/patientsright/chartere.html [Accessed 31 October 2011].

South Africa. Department of Justice. 1996. *Bill of Rights.* Pretoria: Government Printer.

South African Medical Research Council. 2002. *Guidelines on Ethics for Medical Research: General Principles including research on children, vulnerable groups, international collaboration and epidemiology.* Parowvalley: South African Medical Research Council.

South African Nursing Council. 2004. *Draft Charter of Nursing Practice. Code of Conduct and Ethics of Nursing* [online]. Available from:

http://www.sanc.co.za/pdf/Charter%20Draft.pdf [Accessed on 25 July 2011].

Sreenivasan, G. 2003. Does informed consent to research require comprehension? *Lancet,* 362, pp. 2016-2018.

Stansfield, M. 1979. Malpractice: toward a viable disclosure standard for informed consent. *Oklahoma Law Review,* 32(4), pp. 868-890.

Steele, S. & Harmon, V. 1983. *Value clarification in nursing.* Norwalk, Connecticut: Appleton Century Crofts.

Streiner, D. & Norman, G. 2003. *Health measurement scales: A practical guide to their development and use.* 3rd ed. Oxford (UK): Oxford University Press.

Styles, G. 2006. 30th anniversary commentary on Henderson V. (1978) The concept of nursing. *Journal of Advanced Nursing,* 3, pp. 113-130.

Sugarman, J., Lavori, P., Boeger, M., Cain, C., Edsond, R., Morrison, V. & Yeh, S. 2005. Evaluating the quality of informed consent. *Clinical Trials (London, England),* 2(1), pp. 34-41.

Sugarman, J., Popkin, B., Fortney, J. & Rivera, R. 2001. International perspectives on protecting human research subjects. In: National Bioethics Advisory Commission (NBAC). *Ethical and Policy Issues in International Research. Clinical Trials in Developing Countries* [online]. Available from: http://bioethics.georgetown.edu/nbac/clinical/Vol1.pdf [Accessed 20 August 2011].

Sullivan, M. 2000. Ethical Principles in Pain Management. *Pain Medicine,* 1(3), pp. 274-279.

Taylor, C. 1995. Rethinking nursing's basic competencies. *Journal of Nursing Care Quality,* 9(4), pp. 1-13.

Terre Blanche, M., Durrheim, K. & Painter, D. 2007. *Research in practice. Applied methods for the social sciences.* 2nd ed. Cape Town: University of Cape Town Press (Pty) Ltd.

Thompson, J., Melia, K. & Boyd, K. 1988. *Nursing ethics.* 2nd ed. New York: Churchill Livingstone.

Thompson, J. & Thompson, H. 1990. *Professional ethics in nursing.* Malabar, Florida: Krieger Publishing Company.

Thompson, J. & Thompson, H. 1992. *Bioethical decision-making for nurses.* Lanham, Maryland: University Press of America.

Tschudin, V. 1993. *Ethics. Nurses and patients.* London: Scutari Press.

Turner, B. 2005. Informed consent. In: Fitzpatrick, J. & Wallace, M. (Ed.). *Encyclopedia of Nursing Research.* 2nd ed. New York: Springer Publishing Company Inc. pp. 297-299.

UK Royal College of Nursing. 2003. *Defining nursing.* London: RCN.

United Nations. 1948. *Universal Declaration of Human Rights* [online]. Available from: http://www.un.org/events/humanrights/2007/hrphotos/declarations%20_eng.pdf [Accessed 20 August 2011].

University of Washington. School of Medicine. 2008. *Ethics in Medicine* [online]. Available from: http://depts.washington.edu/bioethx/topics/consent.html [Accessed 04 May 2009].

Usher, K. & Arthur, D. 1998. Process consent: a model for enhancing informed consent in mental health nursing. *Journal of Advanced Nursing,* 27(4), pp. 692-697.

Usher, K. & Holmes, C. 1997. Ethical aspects of phenomenological research with mentally ill people. *Nursing Ethics,* 4(1), pp. 49-56.

Uys, H. & Basson, A. 2005. *Research methodology in nursing.* 2nd ed. Cape Town: Kagiso Tertiary.

Van der Wal, D. 2005. The caring ethic in nursing. In: Pera, S. & Van Tonder, S. (Eds). *Ethics in health care.* 2nd ed. Landsdowne: Juta Academic, pp. 11-23.

Van Kleffens, T., van Baarsen, B. & van Leeuwen, E. 2004. The medical practice of patient autonomy and cancer treatment refusals: a patients' and physicians' perspective. *Social Science & Medicine,* 58(11), pp. 2325-2336.

Van Oosten, F. 1996. *International encyclopedia of laws.* Kluwer Law International.

Veatch, R. 1989. *Death, dying, and the biological revolution.* 2nd ed. New Haven, CT: Yale University Press.

Vellinga, A., Smit, J., van Leeuwen, E., van Tilburg, W. & Jonker, C. 2004. Competence to consent to treatment of geriatric patients: judgements of physicians, family members and the vignette method. *International Journal of Geriatric Psychiatry,* 19(7), pp. 645-654.

Verheggen, F., Jonkers, R. & Kok, G. 1996. Patients' perception on informed consent and the quality of information disclosure in clinical trials. *Patient Education and Counselling,* 29, pp. 137-153.

Waikato District Health Board. 2005. *Policy: Informed consent* [online]. Available from: http://www.waikatodhb.govt.nz/policies/informedconsent.pdf [Accessed 20 August 2011].

Watson, J. 1985. *Nursing: Human science and human care. A theory of Nursing.* New York: National League for Nursing.

Wegmann, H. 2009. Informed Consent – Essential Contents and Consequences of Violation. *Journal of International Biotechnology Law,* 6(1), pp. 20-28.

Weinman, J. 1990. Providing written information for patients: psychological considerations. *Journal Of The Royal Society Of Medicine,* 83(5), pp. 303-305.

Weis, D. & Schank, M. 1991. Professional values and empowerment: a role for continuing education. *Journal of Continuing Education in Nursing,* 22(2), pp. 50-53.

Weis, D. & Schank, M. 2000. An instrument to measure professional nursing values. *Journal of Nursing Scholarship,* 32(2), pp. 201-204.

Weiss, F. 1990. The right to refuse: informed consent and the psychosocial nurse. *Journal of Psychosocial Nursing & Mental Health Services,* 28(8), pp. 25-32.

Welman, C., Kruger, F. & Mitchell, B. 2011. *Research methodology.* 3rd ed. Cape Town: Oxford University Press Southern Africa (Pty) Ltd.

Wendler, D. 2004. Can we ensure that all research subjects give valid consent? *Archives of Internal Medicine,* 164, pp. 2001-2004.

Whitney, S., McGuire, A. & McCullough, L. 2004. A typology of shared decision making, informed consent, and simple consent. *Annals Of Internal Medicine,* 140(1), pp. 54-59.

Wikipedia. 2011. *Jacob Zuma* [online]. Available from: http://en.wikipedia.org/wiki/Jacob_Zuma [Accessed 20 August 2011].

Wilkinson, T. 2001. Research, informed consent, and the limits of disclosure. *Bioethics,* 15(4), pp. 341-363.

Will, C. 2001. Knowledge in nursing: contemplating life experience. *Canadian Journal of Nursing Research,* 33(3), pp. 107-116.

Winslow, G. 1984. From loyalty to advocacy: a new metaphor for nursing. *Hastings Center Report,* 14(3), pp. 32-40.

World Medical Association. Declaration of Helsinki. 2001. *Ethical principles for medical research involving human subjects.* Bulletin of the World Health

Organization [online]. Available from: http://www.wma.net/e/policy/pdf/17c.pdf [Accessed 09 September 2011].

Wright, R. 1987. *The practice of ethics. Human values in health care.* New York: McGraw-Hill.

Young, A., Mogotlane, M. & Geyser, N. 2003. *Juta's manual of nursing.* Volume 1. Juta Academic.

Zalon, M., Constantino, R. & Andrews, K. 2008. The Right to Pain Treatment: A Reminder for Nurses. *Dimensions of Critical Care Nursing,* 27(3), pp. 93-101.

Zhang, Z., Luk, W., Arthur, D. & Wong, T. 2001. Nursing competencies: personal characteristics contributing to effective nursing performance. *Journal of Advanced Nursing,* 33(4), pp. 467-474.

Zucker, K., Boyle, M., Jefferson, T. & Ratliff, D. 2010. Consent to Medical Treatment. *U.S. Army Medical Department Journal,* pp. 24-27.

ADDENDUM A

General Surgical Admission Statistics of the Kimberley Hospital Complex for 2009

KIMBERLEY HOSPITAL COMPLEX

Health Informatics Unit

Surgery theatre cases Jan – Dec 2009

	JAN	FEB	MAR	APR	MAY	JUN	JULY	AUG	SEP	OCT	NOV	DEC
Booked Cases	43	41	44	60	51	46	66	57	65	60	84	27
Emergency Cases	72	74	75	114	51	89	101	79	105	105	82	102
Total	115	115	119	174	102	135	167	136	170	165	166	129

ADDENDUM B

Time schedule for the study

TIME SCHEDULE (2009-2011)

ACTIVITY	2009	2010	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
1. Proposal	*													
2. Expert Committee		*												
3. Evaluation Committee				*										
4. Ethics Committee					*									
Planning														
5. Literature Review		*	*	*	*									
6. Compile Questionnaire			*	*	*		*							
7. Pretest						*								
Data Gathering														
8. Implementation								*	*	*				
9. Coding								*	*	*				
10. Computer								*	*	*				
11. Methodology Chapter										*				
12. Data Analysis and Final Report										*	*			
13. Interpretation and Presentation											*	*		
14. Language Editing												*	*	
15. Technical Layout													*	
16. Duplication													*	
17. Binding of Copies													*	
18. Submit for Final Assessment													*	

ADDENDUM C

Budget for the study

BUDGET (2009-2011)

Registration and Class Fees: 2009-2011		R14,520
Proposal		
Resources acquired	Laptop	R13,000
	Printer	R3,000
	Paper	R1,500
	Cartridges	R2,500
	Internet Modem	R1,600
	Handbooks	R3,000
Expert Committee: Postage of copies of research proposal		R200
Evaluation Committee: Postage of copies of research proposal		R200
Ethics Committee: Postage of copies of research proposal		R200
Transport to Bloemfontein for 60 visits @ R300 per visit		R18,000
Planning		
Literature Review (Internet Sources, Handbooks, Journals)	Internet	R4,500
Compiling Questionnaires	Handbooks	R4,500
Recommendations	Journals	R4,500
Bibliography		
Data analysis		
Biostatistician		
Report		
Language Editing @ R40 for 300 words (200 pages)		R6,000
Technical Layout		R170
Duplication and Binding of copies for Final Submission		R3,500
TOTAL		**R80,890**

ADDENDUM D

Permission to conduct study granted by the Ethics Committee,

University of the Free State

UNIVERSITEIT VAN DIE VRYSTAAT
UNIVERSITY OF THE FREE STATE
YUNIVESITHI YA FREISTATA

Direkteur: Fakulteitsadministrasie / Director: Faculty Administration
Fakulteit Gesondheidswetenskappe / Faculty of Health Sciences

Research Division
Internal Post Box G40
☎(051) 4052812
Fax (051) 4444359

E-mail address: StraussHS@ufs.ac.za

Ms H Strauss

2011-03-11

MR RM KRUGER
SCHOOL OF NURSING
UFS

REC Reference number: REC-230408-011

Dear Mr Kruger

ECUFS NR 32/2011
PROJECT TITLE: INFORMED CONSENT: A POST-OPERATIVE ASSESSMENT.

- You are hereby kindly informed that the Ethics Committee approved the above study at the meeting held on 08 March 2011.

  [Prof Y Botma, did not take part in the discussion of this study]

- Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

- Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

- The Committee must be informed of any serious adverse event and/or termination of the study.

- A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

- Kindly refer to the ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

.....

CHAIR: ETHICS COMMITTEE
Cc. Prof Y Botma

ADDENDUM E

Permission to conduct research granted by the Chief Executive Officer (CEO) of Kimberley Hospital Complex

DEPARTMENT OF HEALTH
LEFAPHA LA BOITEKANELO
ISEBE LEZEMPILO
DEPARTEMENT VAN GESONDHEID

Kimberley Hospital Complex
Du Toitspan Road
Private Bag X5021
KIMBERLEY
8300

Kimberley Kakaretso Teemaneng
Du Toitspan Road
Kgetsanaposo X5021
KIMBERLEY
8300

Isibedlela sasa Kimberley
Du Toitspan Road
Private Bag X5021
KIMBERLEY
8300

kimberley Hospitaal Kompleks
Du Toitspanweg
Privaatsak X5021
KIMBERLEY
8300

Tel. (053) 802 9111

Fax. (053) 802 2432 / 802 2436

Enquiries :
Dipatlisiso :
Imibuzo :
Navrae :

Mr. G Moncho
Tel: (053) 802 2124
Fax: (053) 831 4587

Reference :
Tshupelo :
Isalathiso :
Verwysings :

Date :
Leshupelo :
Umhla :
Datum :

28 March 2011

Mr. R M Kruger

KIMBERLEY
8301

Dear Mr. Kruger

RE: REQUEST TO DO RESEARCH AT KIMBERLEY HOSPITAL

This letter serves to confirm that approval has been granted for you to do research at Kimberley Hospital Complex as discussed in our meeting held on Monday 28 March 2011.

Kind Regards

.....
MR. G MONCHO
CHIEF EXECUTIVE OFFICER

ADDENDUM F

Information Document used during structured interviews

INFORMATION DOCUMENT

Dear Sir or Madam

I, Roger Kruger, am a postgraduate student at the University of the Free State studying Masters in Social Science (Nursing). I am doing research on the process of obtaining informed consent, because I have found that many patients are subjected to medical or scientific procedures without their consent, or that patients who gave consent, have no understanding or comprehension of the procedure or operation for which they consented.

I am asking/inviting you to participate in this research study.

The aim of the study is to describe the process of obtaining informed consent prior to a surgical procedure or an operation.

In this instance, I will interview you on the day of discharge from hospital, and record the information on a form. It will take approximately 30 minutes of your time. You have been selected to participate in the study because you have been hospitalised during a period that is convenient for the researcher to gather the required information.

You will have the choice to answer the questions in English or Afrikaans.

You will not directly benefit from participating, but the results may benefit future patients. No risks, physical or social harm are foreseen. You may decide not to participate without any retribution. Participation is voluntary and you may withdraw at any stage during the research.

All information will be confidential and no names or identifying information will be recorded. Results of the study will be disseminated by means of conference proceedings and/or publications in academic journals. You are welcome to contact the researcher, Mr Kruger if you have any questions. His

contact details are given below. Thank you for your willingness to participate in the research.

MR R.M. KRUGER
12 FERARRA COURT
140 DU TOITSPAN ROAD
CITY CENTRE
PO BOX 3729
DIAMOND
KIMBERLEY
8305

TEL: (082) 6805853
FAX: (086) 6979523
E-MAIL: krugerroger@gmail.com

Contact details of REC Secretariat and Chair – for reporting of complaints/problems.

THE CHAIRPERSON: ETHICS COMMITTEE
FOR ATTENTION: MS H. STRAUSS
BLOCK D, ROOM 108,
FRANCOIS RETIEF BUILDING
PO BOX 339 (G40)
NELSON MANDELA DRIVE
FACULTY OF HEALTH SCIENCES
UNIVERSITY OF THE FREE STATE
BLOEMFONTEIN
9300

TEL: (051) 4052812
FAX: (051) 4444359
E-MAIL: StraussHS@ufs.ac.za

ADDENDUM G

Consent to participate in research document

CONSENT TO PARTICIPATE IN RESEARCH

You have been asked to participate in a research study.

You have been informed about the study by the researcher, Roger Kruger.

You have been informed that participants will not receive compensation from the researcher, because participation will not involve any financial strain.

You may contact Roger Kruger at (082) 6805853 any time if you have questions about the research.

You may contact the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS at telephone number (051) 4052812 if you have questions about your rights as a research participant.

Please note that participation is voluntary, and you will not be penalized if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the participation information sheet, which is a written summary of the research.

The research study, including the above information, has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

…… ……..

Signature of Participant Date

ADDENDUM H

Questionnaire for participants undergoing general surgery on informed consenting

QUESTIONNAIRE

Questionnaire for patients undergoing general surgery on informed consenting

You have been asked to participate in a research study. Please note that by answering these questions you are voluntarily agreeing to participate in this research study. You will remain anonymous and your data will be treated confidentially at all times. You may withdraw from this study at any given moment during the completion of the questionnaire. The results of the study may be published.

	Case number						1-3
1	Demographic information of participant						
1.1	Age……. Years						4-5
1.2	Gender: Male ☐ Female ☐						6
1.3	Race						
	1: Black	2: White	3: Coloured	4: Asian	5: Indian		7
1.4	Highest level of education						
	1: Uneducated	2: Primary	3: Secondary	4: Tertiary			8
2	Are you aware that there is a Patient's Bill of Rights? Yes ☐ No ☐						9
2.1	If yes, indicate to which degree you understand these rights						
	1: Completely	2: Most	3: Some	4: Nothing			10
3	Did you understand what procedure was done on you? Yes ☐ No ☐						11
3.1	If yes, please explain?..... ……						12-13
3.2	If no, please explain?..... ……						14-15

4	Did you receive information about the procedure? Yes ☐ No ☐					16
4.1	If yes, name all the people that gave you information					
	☐ Doctor					17
	☐ Nurse					18
	☐ Other, specify ……..…….					19-20
4.2.	Where did any of these persons explain the procedure to you?					
		Doctor	Nurse	Other		
	Consultation room					21
	Ward					22
	Pre-operative room					23
	Theatre					24
	Other, specify……					25-26
4.3	In how many sessions was the procedure explained to you? Less than 5 ☐ 5 – 10 ☐ More than 10 ☐					27
4.4	Are you **satisfied** ☐ or **not satisfied** ☐ with the number of visits?					28
5	On which of the following aspects did you receive information					
				Yes	No	
	Procedure			☐	☐	29
	Risks			☐	☐	30
	Benefits			☐	☐	31
	Alternative treatment			☐	☐	32
	Estimated time to resume normal life activities			☐	☐	33
	Self-care after the procedure or operation			☐	☐	34
	The use of medication/drugs			☐	☐	35

6	Did you feel that the information given to you before the procedure was 1: Clear ☐ 2: Confusing ☐ 3: Irrelevant ☐	36
7	Did you understand the terminology used during the information session? Yes ☐ No ☐ Partially ☐	37
8	Did the conversation take place in a language you understand? Yes ☐ No ☐	38
8.1	If no, was an interpreter available? Yes ☐ No ☐	39
9	Were any family members involved in the informed consent discussion? Yes ☐ No ☐	40
9.1	If yes, did you consent to the involvement of family members? Yes ☐ No ☐	41
9.2	If the family members were not involved, would you have preferred them to be involved? Yes ☐ No ☐	42
10	Were you asked to explain the procedure in your own words? Yes ☐ No ☐	43
11	Were you informed that the hospital might use information such as slides/video of the procedure for educational purpose? Yes ☐ No ☐	44
12	Were you allowed to asked questions regarding the proposed treatment? Yes ☐ No ☐ Partially ☐	45
12.1	If yes, were your questions answered in a satisfying manner? Yes ☐ No ☐	46
13	Did you give, Verbal ☐ Written ☐ or No ☐ consent	47
14	Did the doctor explain afterwards on how the procedure went? Yes ☐ No ☐	48
15	Did the doctor who explained to you carried out the procedure? Yes ☐ No ☐ Not sure ☐	49

16	Do you think information regarding the proposed treatment was withheld? Yes ☐ No ☐		50
16.1	If yes, explain……...		51-52
	……		53-54
	……		55-56
	……		57-58
	……		59-60
17	Is there a good understanding between you and the physician? Yes ☐ No ☐ Indifferent ☐		61
18	Were you under pressure to consent to the procedure? Yes ☐ No ☐		62
19	When the doctor explained the procedure to you, did you feel **normal** ☐ **drowsy** ☐ **excited** ☐ or **anxious** ☐		63
19.1	If you felt drowsy/excited or anxious, what caused it?		64-65
	……		66-67
	……		68-69
	……		70-71
	……		72-73
19.2	If you were anxious, what was the level of it? 1: Mild ☐ 2: Moderate ☐ 3: Severe ☐		74
20	Did you experience severe stress when you consented to the procedure? Yes ☐ No ☐		75

21	Are you prohibited by law to sign a contract? Yes ☐ No ☐		1
21.1	If yes, why?..... ……. ……. ……. …….		2-3 4-5 6-7 8-9 10-11
22	Were you informed that you might obtain a second opinion? Yes ☐ No ☐		12
23	Were you informed that you might withdraw consent at any time? Yes ☐ No ☐		13
24	Were you informed that you might change your mind within a day regarding the procedure or operation? Yes ☐ No ☐		14
25	Were you informed that if you change your mind, you have to sign a form? Yes ☐ No ☐		15
26	Were you informed that you might refuse all treatment? Yes ☐ No ☐		16
27	Did other people influence your decision regarding the procedure? Yes ☐ No ☐		17
27.1	If yes, who…….. …….. …….. ……. …….		18 19 20 21 22

28	Did you experience any problems after the procedure that was not explained to you when you gave consent? Yes ☐ No ☐			23
28.1	If yes, what?..... ……			24-25
29	To which degree do you feel the staff respected you?			
		Respected	Not respected	
	Medical			26-27
	Nursing			28-29
	Administration			30-31
	Supportive staff			32-33
29.1	Please explain the disrespect if any was shown by the,			
	Medical staff…….. ……			34-35
	Nursing staff……... ……..			36-37
	Administration staff…… ……..			38-39
	Supportive staff…….. ……..			40-41

Thank you for your time.