PATIENTS' PERCEPTIONS AND UNDERSTANDING OF INFORMED CONSENT FOR SURGICAL PROCEDURES.

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

Johannesburg, 2011

DECLARATION

I, **Tshimanga willy Kalala**, declare that this research report is my own work. It is being submitted for the degree of Master in Family Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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……day of ……2011

Student No: 0315457M.

In Memory of my father

Tshimanga Remy Nkunda

1930-1999

ABSTRACT

Background

Informed consent is required for any surgical procedure. It is a demonstration of a patient's agreement to have surgery performed. Many studies have considered the quality of informed consent in clinical trials. However, only few studies have assessed patients' understanding of the process of informed consent in clinical practice. This descriptive cross-sectional study has looked at patients' perceptions and understanding of informed consent process for surgical procedures.

Aim

To explore patients' perceptions on informed consent and ascertain if those who have signed for surgical procedures have adequate understanding of the informed consent process.

Objectives

1. To ascertain patients' perceptions of the process of informed consent;
2. To determine patients' recollection of elements of this process that were considered when they signed the consent.

3. To explore if patients understand the meaning and implications of the informed consent process;
4. To determine whether patients obtained information about procedures from sources other than the healthcare workers;

Methods

This was a descriptive cross-sectional study conducted among patients admitted at Leratong hospital for elective surgery. A sample of patients (n=98) selected from those booked for elective surgery at Leratong theatres between April 2008 and June 2008 were interviewed. Different aspects of information were analysed. Specifically: social and demographic profile, formal education, previous medical and surgical history, perceptions of informed consent, process of informed consent and knowledge of the procedure's indication, risks and alternatives. Equally considered were sources and value of external medical information.

Results

Patients interviewed represented 5.5% of the total of those booked for elective surgery. The median similar to the modal age was 38 years, 58.2% being females. Only 4.1% had tertiary education, 32% did not reach secondary school of which 11.2% had no formal education at all. Concerning their prior medical /surgical background, 26.5% were on chronic medical treatment and 48% had previous surgery. More than two third (91%) of them had stayed in the hospital for more than 12 hours prior to surgery.

Only 27% perceived the signing of consent form as a proof that they understood the procedure. It was demonstrated that the higher the education level the better the perceptions of informed consent process (P=0.0006). More than 2/3 of patients needed further explanation in their mother tongue to understand the information. Seventy-four per cent did not read the consent form. The understanding of information was more likely to be checked when the information was given by a doctor than by a nursing sister (P=0.014).

Only 8% admitted to know some alternatives to the proposed procedure, 13% of patients knew the risks. Formal education was not linked to better understanding of the informed consent process (P=0.245). Patients claiming to have received further information on the procedure from sources other than the healthcare system did not show an added advantage on understanding (P=0.152).

The study has demonstrated the low level of understanding of informed consent process in this provincial public hospital. It has shown the public perceptions of the consent form, and the advantage granted by the formal education in this regards.

Based on these results, it is therefore recommended that an approved translation of the consent form be made available to patients as an alternative to those who are not English speakers. A proper guideline should be established for physicians to ensure disclosure of information in language of choice of patients to obtain better informed consent.

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CHAPTER 1

1.0 INTRODUCTION

1.1 Background information

Informed consent is a cornerstone of modern medical practice. Informed consent is a process that flows from the interaction between the health care provider and the patient.

It serves to protect patient's autonomy that is one of four important principles of biomedical ethics presented by Beauchamp and Childress[1]. The autonomous action requires respectful dealing in disclosing information, searching for and encouraging autonomous decision-making**.** Informed consent is a doctrine that helps patients to protect themselves from unwanted interventions**.** It allows patients to take responsibility of their own lives[2].

Obtaining a valid informed consent is an ethical and legal requirement. The physician, in the process of obtaining informed consent, has the moral duty to respect patients' human dignity[3]. This is in line with the Bill of Rights of the South African Constitution that affirms in section 12 (2b):"Everyone has the right to bodily and psychological integrity, which includes the right to the security in and control over their body[4]". The National Health Act[5], then, states in its section 7(1) that "A health service may not be provided to a user without the user's informed consent".

A valid consent can be obtained only from an informed patient. The consent form serves to document the informed consent but it does not replace the process. The physician has to prove that he has made efforts to ensure that the patient understands the information provided. As an expert of his field, the physician must provide his patient with all the necessary information required to make a well-informed decision. Furthermore, it was proven that a well-informed patient is more proactive and compliant[6].

A patient can consent expressly to a treatment orally or in writing, or tacitly by conduct. However, where a patient enters a hospital or undergoes surgery written consent is required. In essence, there is no difference between a written and oral consent in law except that the former is easier to prove if there is subsequent dispute[7].

The quality of informed consent depends largely on the disclosure of information. It means information that a reasonable person in the patient's position needs to understand in order to make a liberal decision[7].

Studies on quality of informed consent in research trials have proven that a lack of formal education, advanced age, low socio-economic status or incurable illness are associated with poor quality consent[8,9,10.] However, studies to ascertain the quality of informed consent in clinical practice are in general scanty.

In western countries, studies on quality of informed consent have shown, in some cases, that physicians were not meeting the requirements for an adequate informed consent[11,12].

Apart from studies on consent for HIV testing, in South Africa, there have been limited studies on the quality of informed consent in clinical practice[13]. Voluntary counselling and HIV testing contributed to the fact that the mentioned study was truly informed.

The patient has the honour and privilege to afford a private and personalised conversation with a trained counsellor. The duty of such counsellor is to cover a given number of points about HIV and make the patient understand them before expressing choice.

HIV testing is less invasive than surgery. Even though getting a bad news is a life changing experience. Moreover, the patient still has the possibility of withdrawing the consent at any time during the process.

Consent for surgery does not benefit from services of such counsellors**.** In addition, the withdrawal of consent is not possible with a surgical patient once he/she is under anaesthesia.

Many studies had shown how the consent in surgical context were not as well informed as in this HIV testing study[6,14,15,16,17].

Aroori and Spence, in United Kingdom, have demonstrated that less than half of resident surgeons were able to answer all the questions posed by patients. Only few residents correctly listed all risks, benefits and alternatives for informed consent[17]**.**

Discussing about the procedure with patients is among responsibilities of surgeons**.** Yet, they expressed concerns that 'there were not enough time to spend talking about personal values and patients' preferences when there were lives to be saved and operations to be performed'[14]**.**

Keulers et al. in Netherlands discovered that surgeons underestimated their patients' desire to receive extensive information prior to a surgical procedure of any complexity. There was a mismatch between what surgical patients wanted to know of their conditions and treatment and what their surgeons thought they should be told. In more than 65%, surgeons routinely failed to meet their patients' appetite for information[6]. Furthermore, in Ghana, a study by Clegg-Lamptey and Hodasi showed that patients' information at Korle Bu teaching hospital was unsatisfactory. Eighty seven per cent of patients did not know about possible complications of surgery, 24% did not know the diagnosis[15]**.**

1.2 Statement on the problem

In South Africa, a study conducted among full-time consultants and registrars at the University of Cape Town and published in 1995 revealed that most doctors declared to meet most of legal requirements of informed consent. Almost two third of them said that they informed patients about the nature and purpose of the procedure. They mentioned the benefits and side effects that were most likely to be associated with the intervention[18].

In sharp contrast with these findings, observations made in local literature underline the inadequacy of consent obtained in everyday practice[19,20]. Studies worldwide support these

observations as reported earlier. However, most of these studies on quality of informed consent involved research trials[21,22].

An evaluation of patients' understanding of the process of informed consent in clinical practice would give an idea of what actually happens.

This focus on patients' understanding of the process of informed consent in clinical practice will definitely help to uncover the extent to which the consent obtained in daily practice requires improvement. This will obviously contribute to a better patient's satisfaction.

1.3 Motivation for the study

Studies on quality of informed consent were mostly conducted for clinical trials. Yet every day, patients give consent for medical treatment and surgical procedures in the public and private hospitals across the country. This begs the question about the adequacy of these consents.

An evaluation of the quality of the informed consent in clinical practice in public service amid shortage of staff and patients overload could be a revelation. It would help to uncover the state of patients' understanding of this important process. Hence, expose areas in need of improvement in order to get a better patients' satisfaction.

1.4 Definitions.

Consent: Permission or agreement[23].

Informed consent: Consent is informed if it is based on sufficient knowledge of the nature and effect of the act agreed to[7]. The concept of informed consent may also apply to refusal of treatment[6].

Informed consent process: The elements of informed consent that need to be satisfied are "threshold elements, information elements and consent elements. Competence to understand and decide and voluntariness in deciding without coercion are the threshold elements. Information elements are made up of disclosure (of information), recommendation (of a plan), and understanding of the information. Consent elements are decision (in favour or against the plan) and the authorization of the chosen plan"[1].

Valid informed consent: This applies when the patient:

- "has knowledge of the nature or extent of the harm or risk
- appreciates and understands the nature of the harm or risk
- has consented to the harm or has assumed the risk, and;
- The consent is comprehensive and extends to the entire transaction, inclusive of its consequences"[7].

CHAPTER 2

2.0 AIM AND OBJECTIVES

2.1 Aim

To explore patients' perceptions on informed consent and ascertain if those who have signed for surgical procedures have adequate understanding of the informed consent process.

2.2 Objectives

1. To ascertain patients' perceptions of the process of informed consent;
2. To determine patients' recollection of elements of this process that were considered when they signed the consent;
3. To explore if patients understand the meaning and implications of the informed consent process;
4. To determine whether patients obtained information about procedures from sources other than the healthcare worker.

CHAPTER 3

3.0 LITERATURE REVIEW

Studies on quality of informed consent have been conducted in South Africa and worldwide. It proves that determining the quality of informed consent is of paramount importance. Obtaining good quality consent is beneficial to both the patient and the doctor or the researcher. It allows patient participation in decision-making process, which is a matter of concern for ethics committees on research trials but also in clinical practice.

3.1 Informed consent in research trials

Oduro et al. conducted a study on understanding and retention of informed consent process among parents whose children participated in clinical trial, in rural northern Ghana. They found that understanding of informed consent was poor. Out of 270 respondents, in the study, 66% admitted that the study procedures were explained to them during the process. Yet only 20.4% recalled being told about the risks. While only 21% remembered, being told that, they could withdraw their consent …without giving reasons. About 30% understood that the information collected in the study would be used only for the purpose for which consent was obtained. Moreover, 7.8% knew that specimen would not be used for any other study without appropriate permission. This led this team of researchers to observe that in underdeveloped countries the understanding of informed consent process is low[8].

Similar findings were made in Mexico on the way medical research was conducted in poor countries. Verastegui analysed the understanding of research participants. He looked at the consenting of the vulnerable, in particular patients with advanced cancer. He asked 10 patients who participated in trials how they understood two sample consent forms. According to one of these individuals, the consent form was clear. The rest of the participants (9/10) thought: "the documents were lengthy, boring, and too complex to be understood. Most of the individuals needed to read the forms at least twice". Even when asked specific questions about the study there were only four out of ten participants who were able to describe correctly the purpose of the study[24].

Frimpong-Mansoh, in a paper on culture and voluntary informed consent in African health care systems, made some interesting remarks. She observed that "uninformed poor illiterates are easily exploited as 'guinea pigs', since their hopeless health conditions tend to dictate and compel their affirmative consent to requests for participation in vaccine trials, even when they do not adequately understand the potential risks involved"[9].

This lack of understanding is caused partly by the fact that potential participants in clinical trials are not acquainted with the ethical regulations related to research trials. Therefore, researchers were encouraged to ensure that potential participants understand clearly the research they were invited to participate in[8].

This is why Sugarman et al.[25] in United States of America (USA), conducted a study on evaluation of the quality of informed consent in clinical research. They concluded that there was a need for effective and efficient means of evaluating the quality of the consent process.

Joffe et al. also in the United States of America (USA), analysed the quality of informed consent of participants in cancer clinical trials. They found that patients with no college education and those who used languages other than English at home scored low in knowledge of the trials. Respondents who had discussions on consent with a nurse in attendance had a higher score in knowledge[10].

On a positive note, Barrett[26], still in USA, on his part analysed the quality of informed consent by measuring understanding among participants in oncology clinical trials.

All 207 participants responded that they understood that their treatment involved research. They were aware of what the researchers were trying to find, the risks to which the treatment exposed them, the limits on the confidentiality of their medical records. They knew whom to contact with additional questions. They understood the voluntary character of participation in the trial. All respondents declared that they understood the clinical trial when they signed the informed consent form. As much as 75% were able to say that they knew the experimental nature of the treatment and the procedures. An average of 63% knew that they had the option not to participate.

In South Africa, Minnies et al. made similar findings. They analysed the quality of patients understanding of the informed consent to participate in a vaccine trial, in Cape Town. The

majority of 192 subjects interviewed obtained scores more than 75% for recall and understanding of informed consent. They found that most participants were aware of the risks. More than half knew that they participated voluntarily[22].

Factors associated with better understanding were among others the experience of research nurse and the education level of the participant. Completion of Grade 7 or higher at school was linked to at least 75% in the recall test. If the consent was obtained by a nurse with more than two years- experience in research, the participant was three times more likely to score at least 75% than the participant consented by a nurse with less than two years of experience[22].

Moodley et al. reported similar factors associated to adequate understanding of the process of informed consent, even though they did not found in general a better understanding. In their study on informed consent and patients' perceptions of vaccine trials in South Africa, there was a positive correlation between high level of education and better understanding[21]

A review of studies on informed consent in USA by Flory and Emanuel corroborated the earlier findings. Furthermore, they noticed that: "extended discussion between study staff and research participants resulted in statistically significant increase in understanding in 3 of 5 trials"[27].

Yuval et al. in Israel further supported the findings that better understanding was related to more time and explanations from the research staff. An opportunity for discussion before giving consent yielded better understanding. Most patients remembered the oral explanation than the written material[28].

The majority of studies have shown that patients' understanding of informed consent for research trials was poor. Two studies in this review found acceptable level of understanding of informed consent. Yet, they still linked that to college education and positive intervention of consenting practitioners. Some researchers specifically concluded that illiterate and very ill patients did not comprehend what they engaged themselves into when signing complex and lengthy research consent forms[8,9,10,22,24].

3.2 Informed consent in clinical practice

An informed consent is required for any medical treatment or any surgical procedure. Obtaining consent proves that practitioners respect patients' autonomy and their human dignity.
There is a moral duty, which is fundamental to medical practice that a medical practitioner does not act against a patient's reasonable wishes[3].

There are universal guidelines on informed consent. These are intended to the protect patients and promote good ethical practice. Individuals should understand the purpose of the procedure, its process, risks, benefits, and alternatives prior to giving consent. They should make a free and voluntary decision about the intervention[29].

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In South Africa, studies on quality of informed consent have been mostly related to consent for clinical trials. However, the informed consent in clinical practice has not been less a subject of preoccupation.

In fact, in response to members' needs for ethical guidelines about the HIV testing, SAMA (South African Medical Association) replied with an interesting paper on informed consent. The article said: "The medical practitioner has the duty to obtain the consent as s/he is in a position to answer questions and provide further details. The following are elements of informed consent :(…) there should be sufficient information on the diagnosis, proposed treatment, expected benefit, risks, alternative treatment, probable results"[30].

These are universal requirements for a proper process of informed consent. In the introduction to medico-legal practice, Dada and Mcquoid, in South Africa, wrote that a patient's consent could be verbal or written. "Consent generally takes the form of a request made by a patient for a specific treatment or an operation". In some situations like a surgical procedure, it is better to have a written consent because it is easier to prove if a dispute arises[7]. In these cases it is necessary to have a written consent.

Informed consent should be viewed as a process and not a signature of a piece of paper[3,8 ,10,12,19]. To fulfil the informed consent process, the physician must explain to the patient in details: the diagnosis, the treatment and the prognostic, in a language understandable to the patient[31].

Similar to research trials, there is a list of elements of informed consent that have to be satisfied to obtain a valid informed consent. First, there are basic requirements covering the patient's competence and willingness to act freely. Then the information provided to the patient so that he or she has a clear understanding; therefore, facilitate a good decision-making. In summary, it encompasses disclosure of diagnosis, therapeutic, risks, alternatives. Then, the actual consent is

given as the patient chooses between the suggested plan and the alternative. At the end, he/she gives the authorization to proceed[1].

Besides, Ebbesen and Pedersen further emphasized the need for practitioners to respect patients' autonomy, avoid coercion and recognise their dignity and right to self-determination[32]. Ogunbanjo and Knapp van Bogaert added that all the above-mentioned steps in the process of the informed consent are indeed to be followed because it is an obligation for the doctor to do so when disclosing information related to the treatment or procedure[19].

In line with this practice, Upadhyay et al. in the United States of America (USA), asked 210 patients aged 63 years, in average, the level of care they would like to be asked permission for. In 85% or more patients wanted to participate in their health decision. Even in matters believed to be trivial and having minimal complications[11]. This demonstrates that patients appreciate to be involved in their health care activities.

In contrast, the level of awareness about the informed consent process, in some under-developed countries, is preoccupying. A study by Bhurgri and Qidwai in the community health centre at Aga Khan University hospital in Karachi, Pakistan, found a shocking result. Only 20% of respondents were aware of the process of informed consent. All of them were graduates[33]. This was actually in harmony with findings of studies on consent in clinical trials. The majority of those under consideration found a correlation between the level of education and understanding of informed consent[10,22,26].

This is why in the Pakistani context some patients even gave up their right to an informed consent altogether, leaving it to the doctor to decide about what was right for them. Because they thought, the doctor was "just like one of my brothers"[34].

Healthcare workers were found to be also part of the reasons why informed consent process was not properly implemented. Humayn et al. in Lahore, Pakistan; analysed the situation of adherence to the practice of informed consent, privacy and confidentiality in public and private hospitals. They found an inadequate observance of the practice of informed consent. Up to 90 % of patients in the public hospital had no informed consent taken from them[12].

In South Africa, Looking at the quality of the informed consent obtained in medical practice, Knapp van Bogaert and Ogunbanjo made an almost similar observation. They observed that in clinical practice, there is a tendency to give more importance to a paper, the informed consent form, in a number of South African public institutions than the actual explanations of the condition, risks and complications of the procedure[35].

This was further supported by this letter of complaint published in South African medical Journal of November 2005 under the title: "Legal, but is it right?" The letter talks about a case where a widowed woman underwent a reconstruction surgery for a breast cancer. She was not told that the procedure was not fully covered by the medical aid. Information about the fact that the reconstruction surgery would put her in need of radiotherapy apart from chemotherapy was lacking before signing the consent form for surgery. The letter further declared, "Surely, informed consent in private sector medicine includes telling the patient how much money they

are going to pay over and above the amount that their medical aid will contribute. There may not be a legal obligation in this regard, but doctors treat people, not isolated organs attached to unlimited bank accounts"[20].

This complaint correlates well with findings of a descriptive evaluation of audiotaped encounters of family physicians and internists by Braddock et al.[36] in USA, in 1999. The evaluation revealed that the six elements of informed decision-making were hardly met. In the majority of cases, decisions were made based on two or only one of these six elements: The clinical problem, alternatives, benefits and risks associated to the recommended plan, uncertainties about the procedure, patients' understanding and, expression of patients' preference. This clearly demonstrates a global trend on quality of informed consent in clinical practice.

However, this description seemed contrary to what Henley et al. have found in a study[18] conducted in Cape Town in 1995. This study referred to earlier, concluded that: "70% of doctors met many of the legal requirements for informed consent".

On the other hand, a United Kingdom study in 2002 by Worthington showed that: Physicians were concerned about not having enough time to spend talking about personal values and patients' preferences because they had to operate and save lives[14]. Many doctors still perceived their interactions with patients as limited. They gave scanty information and offered less decision-making authority[37]. It was still difficult to get rid of paternalistic attitudes.

Worthington further observed that obtaining the consent for surgical procedures was usually delegated to the junior surgeons or interns who did not perform such surgeries. Obviously, they

could not explain properly to patients what to expect in terms of risks and complications of operations[14]. This rendered these consents legally invalid because of lack of better understanding to meet, what Perry called" a requirement of adequate information for a patient to act voluntarily"[38].

Clegg-Lamptey and Hadossi, in Ghana, also emphasized that: "Doctors have sometimes been accused of arrogance. Because they dictate treatment even when there are other available options". Even though the lack of formal education is to blame for poor understanding, health care workers are too. They do not provide the necessary information or talk about alternatives that are available to patients[15].

Like Ghana, the underdeveloped world, including South Africa, experiences even greater problems due perhaps to lack of knowledge on the part of patients about the entire decision–making process. Dhai[39]noticed by the way that: "South Africa is home to a large number of vulnerable groups of poor populations who have limited or no access to education and health services and who accept authority without question".

In summary, universal guidelines on informed consent are widely acknowledged. They have been largely publicized. Yet, studies demonstrated a lack of patients' awareness about the need of informed consent. Others even reporting poor compliance on the part of practitioners to the guidelines. Consequently it has been demonstrated worldwide, in clinical practice a lack of information, insufficient consent or even lack of proper consent all together[7,14,15,19,30,32,39].

CHAPTER 4

4.0 MATERIAL AND METHODS

4.1 Study design

This is a descriptive cross-sectional study.

4.2 Site of the study

The study was conducted at Leratong hospital, a level 2 hospital with about 750 beds. The hospital has different departments each headed by a specialist helped by one or two other consultants. It is a referral hospital for two district hospitals, Dr Yusuf Dadoo hospital, and Carltonville hospital. Many clinics from Mogale City and Randfontein area are directly referring to it. The surgical disciplines represented are General surgery, Obstetrics & gynaecology and Orthopaedics. An ophthalmologist and one or two rotating registrars also do some surgeries. The ENT specialist has since left. The hospital is situated in the West Rand region of Johannesburg at the border of Kagiso Townships and Krugersdorp in Mogale City. An average of 287 000 inhabitants live in the area covered by the hospital.

4.3 Study population

The study population came from patients admitted at Leratong hospital for elective surgery in different disciplines, from April 2008 to June 2008(n=98). Namely: Obstetrics and gynaecology, orthopaedics and general surgery.

4.4 Sampling Method

A random sampling method was used. Every fourth patient on the elective theatre list was selected for interview during the period under review.

4.5 Sample size

In consultation with the MRC(medical research council) statistician, Dr Piet Becker, a sample size of 97 patients was considered enough to ensure that the 95 % confidence interval of this sample could extend no further than 0.1 (i.e. 10 %) from this estimated proportion.

4.6 Inclusion criteria

Patients aged 18 years or more, capable of giving consent and with acceptable knowledge of the chosen languages of interview (English, Setswana and IsiZulu) were eligible for the study. These patients had to have a signed consent form for surgery in their files.

4.7 Exclusion criteria

Were excluded from the study, any patient younger than 18 years of age, patients not competent to sign their own consent for surgery, patients not speaking the selected languages of interview, those too ill to participate in the study and, obviously patients without a signed consent form for surgery in their files.For practical reasons, patients from ophthalmology or ENT (Ear-Nose-throat) were not included because only one or two doctors were running these departments.

4.8 Measuring tool

A structured interview was used for data collection. A questionnaire in English and translated into IsiZulu and Setswana, served the basis for the standard interview. These were back-translated into English by a separate person to check for accuracy. No adjustments were necessary. Each questionnaire was administered by an interviewer fluent in the language of choice of the patient. Aspects covered were patients' demography, their personal medical and

surgical history. Equally considered were perceptions of the meaning of consent form, the actual process of informed consent, information on their condition received outside healthcare services, description of what actually took place concerning the informed consent process. At the end, patients' expression of feeling about the consent process was recorded. A copy of the questionnaire is in the annexure of this report.

4.9 Pilot study

A pilot study was conducted prior to the actual study. This helped identify logistic problems and determine the efficiency of the questionnaire.

4.10 Data collection

Daily a list of patients booked with the theatre for elective operation the next day was compiled. Some patients booked the same day for theatre the following day were also included. Procedures ranged from major surgical procedures to minor operations such as evacuation of the uterus, and incision and drainage of abscess. Any patient who spent more than 6 hours in the ward before the procedure was included.

Every fourth patient on the theatre list was contacted. In case where no signed consent form for surgery was found in the file, the interviewer proceeded to the next patient on the list. The ward

nurses kindly helped to find patients and checked if the patient had signed a consent form for surgery (countersigned or witnessed by a doctor and /or a sister).

The interviewer read the information letter and explained the research to the eligible patient. Each patient willing to participate in the study signed the consent to participate and kept a copy for him/herself. The interview was conducted in the language of choice of the participant.

Everyday completed questionnaires were collected by the researcher and filed. On occasions where efforts to contact patients with signed consent forms in files were unsuccessful, the interviewers kept the list and went back to review the patients in the morning before transfer to theatre for interview. Care was taken not to interfere with the preparation of the patients for theatre. Only patients still waiting to be prepared for theatre were interviewed in the morning.

Three counsellors working at the HIV/AIDS clinic were trained. They helped to administer the questionnaire in the languages of choice of the patients for a small fee. Two intern doctors were also trained to help with the interviews. They did that only for the patients in whose care they were not directly involved. Ward sisters contacted in advance by the researcher willingly helped to found patients and confirm one or two points from declarations made by the patients.

In case of some patients with unequivocal lack of understanding of consent, nurses in charge of wards were notified about the need to get the surgeons concerned to give further explanations before procedures. Despite a surgeon name on the theatre list, it was not always that of the operating surgeon.

4.11 Data analysis

The data coded were entered using Epi Info 2002 then, analysed. Prevalence was calculated. Furthermore, to assess factors that might have influenced the knowledge, use was made of two by two tables and logistic regression. Graphs and tables were generated using Microsoft office Excel.

4.12 Limitations of study

It is important at this stage to mention some of the limitations and challenges encountered during this study. Assessing understanding was a very difficult task to accomplish. Checking understanding of the consent process without having to observe the process itself was also a challenge. The study was conducted in a provincial hospital, which limits somehow the generalisation of the result to other settings.

The exact expression for “consent for operation” in the different languages used was difficult to comprehend by patients because it was not commonly used in daily life. Nevertheless, there was an advantage of showing the very form to patients.

The understanding of the study questionnaire by interviewers might have had some impact on the way some patients responded to the questionnaire.

4.13 Ethical issues

The research protocol was submitted for approval to the Human Research Ethics Committee (HREC Medical) of the University of the Witwatersrand. Corrections requested by the postgraduate committee prior to approval were also submitted and the clearance obtained (Protocol number: M060931). A copy of the clearance letter is attached in the annexure.

Permission was obtained from the Gauteng Health department, directorate of research. The superintendent of Leratong hospital subsequently authorised the study. The information about the research was spread through different heads of departments to doctors and sisters in the concerned departments.

Informed consent to participate was obtained from every patient prior to the interview (A copy here attached). All the wards involved received a letter and explanations from the researcher. The letter was found on the notice board of these wards during the duration of the study. Confidentiality and anonymity were assured to the extent described in the information letter (copy here attached).

No medico-legal issues suspected at the inception of the study occurred. It has not come to the attention of the research team that participants complained after being made aware of their rights related to the consent process. Cases of unequivocal lack of understanding were brought to the attention of doctors concerned with the help of sisters in charge of the wards.

No name appeared on the filled questionnaires. Copies of consent to participate were kept separately. The file number used to trace the patient in need of further explanations was cut- off with scissors by the researcher to preserve the anonymity of each questionnaire.

CHAPTER 5

5.0 RESULTS

5.1 Response rate

The total number of patients electively operated during the study period, covering from April 2008 to June 2008, at Leratong hospital theatre, is summarized in the table below (Table 1):

Table 1: Response rate per discipline

Department	Elective cases	Number interviewed	Percentage
General surgery	491	36	7.33%
Obstetrics & gynaecology	621	33	5.31%
Orthopaedics	656	29	4.42%
Total	1768	98	5.54%

Every one of 1768 patients was part of the study population. Each fourth patient on the list was approached for interview. The majority of patients had no signed consent forms, less than 24 hours prior to theatre time. Instead of 25% of the study population, only 5.54% of patients were interviewed, taking more time to reach the target sample.

Only 104 patients had a signed consent in the file at the time that they were approached to participate in the study. Three patients declined to participate. One more patient declared, after starting the interview, that he was fluent in Afrikaans. The interview was then, discontinued. Two questionnaires not completely filled in, were annihilated. At the end, 98 questionnaires were analyzed.

Of these 98 patients: 36 were from general surgery that had three consultants, 6 medical officers and, four rotating interns at the time of study. The next 33 patients were from the department of Obstetrics and gynaecology. This department had at the time, two full time consultants, two part-time consultants, seven medical officers, one community service doctor and four rotating interns. The remaining 29 patients came from orthopaedics. It had one consultant, six medical officers and two rotating interns.

Doctors in departments covered by the research project were aware of the research. It did not appear that they had made extra efforts by spending more time with patients in explaining further the consent process**.** This was evident because the team struggled to find patients booked for elective procedures with a completely signed consent form in the hospital record.

There were patients who demonstrated an unequivocal lack of understanding of informed consent process. Some said that they did not get explanations. Others declared for example:"I know nothing; I just hope to be healed". A 53 year- old man booked for a repeat debridement said:" I do not want this operation. They said that I will get better; but I am tired of these

operations". A 28year-old man who did not reach grade 5 said:" I was just told 'Sign here! Nothing else was explained to me".

5.2 Demographic profile of patients

The sample of patients was made of 58.2% of females and 41.8% of males, as illustrated in Figure 1.

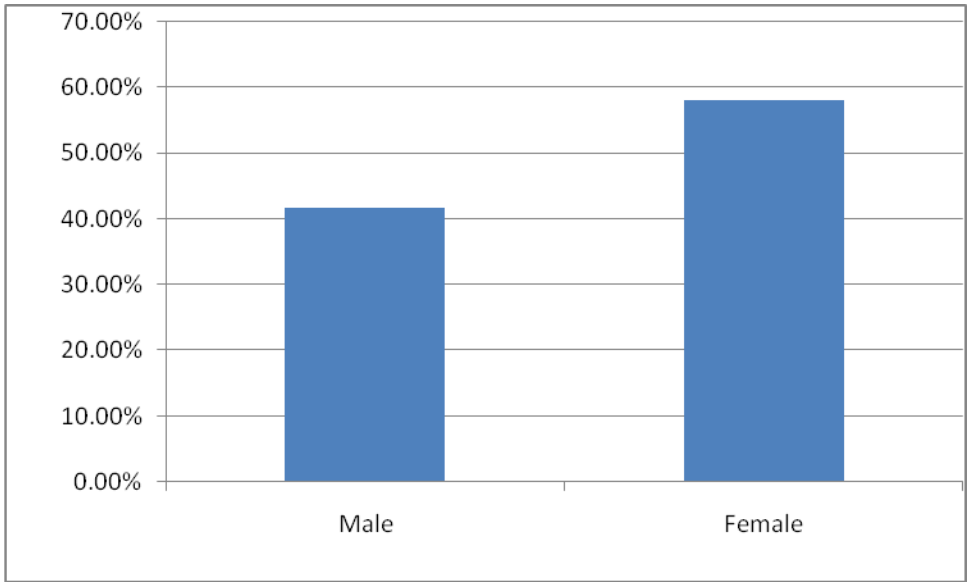

Figure 1: patients' distribution per gender

Patients were aged between 18 and 90 years of age. The mean age was 40.9 years. The median was equal to mode of 38 years. The majority of patients were aged between 31and 40 years (Figure 2).

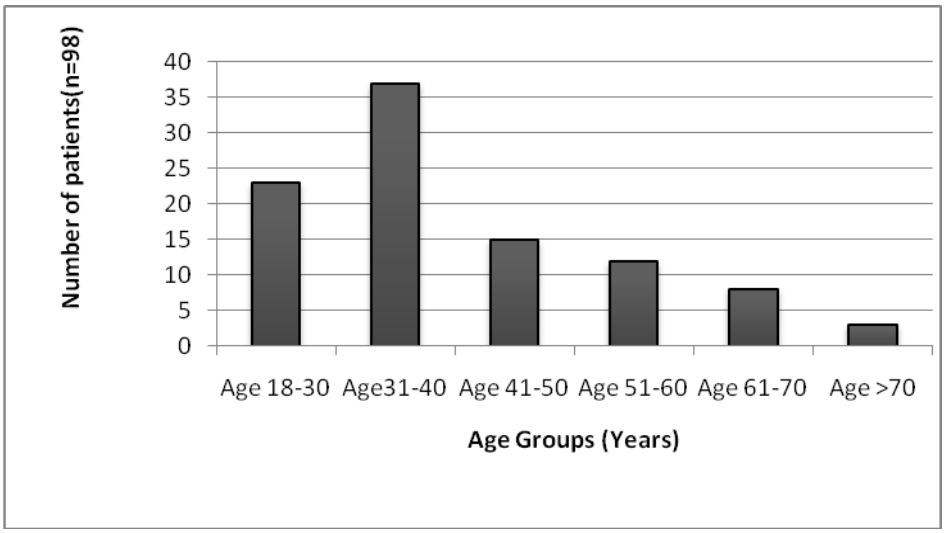

Figure 2: Patients' age categories

With regard to formal education, 32% of the patients did not reach secondary school. Out of them, 11.2% never had a formal education at all.

However, 63.2%of patients reached secondary school. Only 4.1% had a tertiary education, either a diploma or a degree (Figure 3).

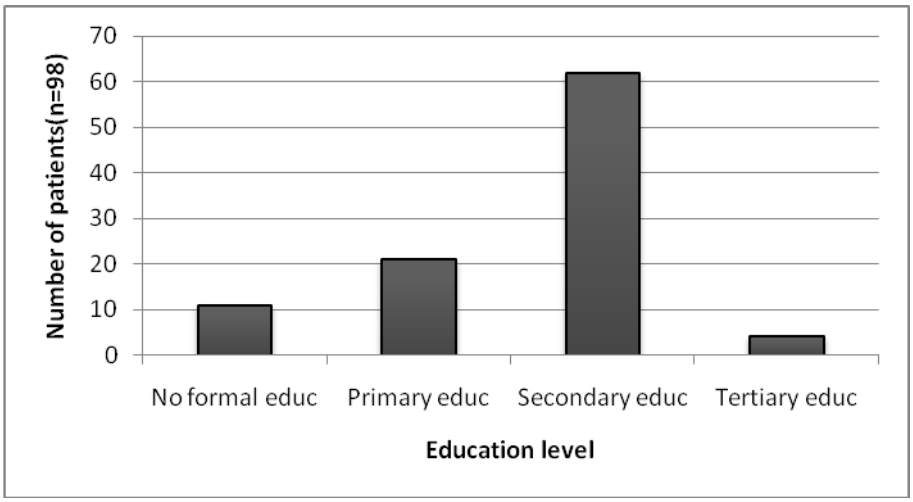

Figure 3: Formal education of patients

When it came to patients' medico-surgical background, 73.5% of patients were not on any chronic treatment, 52% had no history of surgical procedures (Table 2).

Table 2: Previous medical and surgical history

	Chronic treatment	Percent	Previous Surgery	percent
Yes	26	26.5%	47	48%
No	72	73.5%	51	52%
Total	98	100%	98	100%

The duration of hospital stay was sufficient for a good interaction between patients and healthcare workers. About 91% of patients spent more than 12 hours in the ward prior to the surgical procedure. Only 8% were booked for theatre within 12 hours of admission (Figure 4).

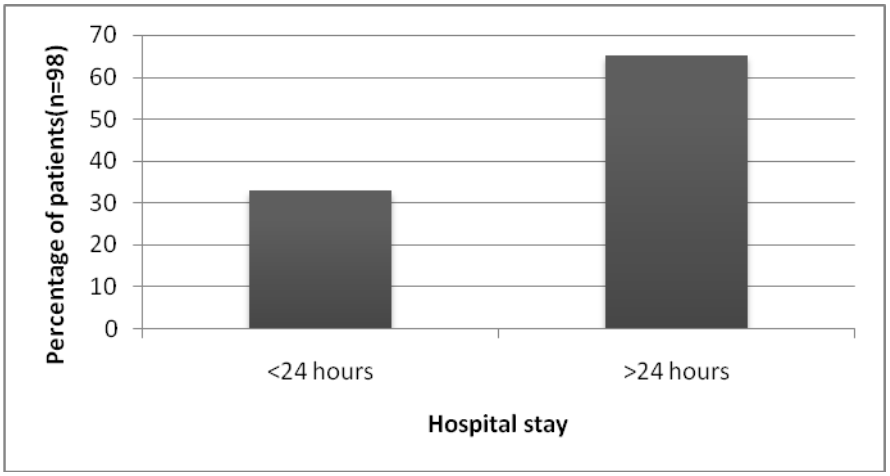

Figure 4: Patients' hospital stay

5.3 Patients' perceptions of informed consent

The perception that signing a consent form for surgical procedure gives power of decision to the patient was held by 87% of the sample. Moreover, the majority (89%) of patients believed that the signing of the consent form showed that they have agreed to the operation.

Only 27% thought that signing the form meant that they understood the procedure to which they agreed as illustrated in Figure 5. Yet, 69% agreed with the opinion that one cannot undergo surgery if he/she does not understand the operation.

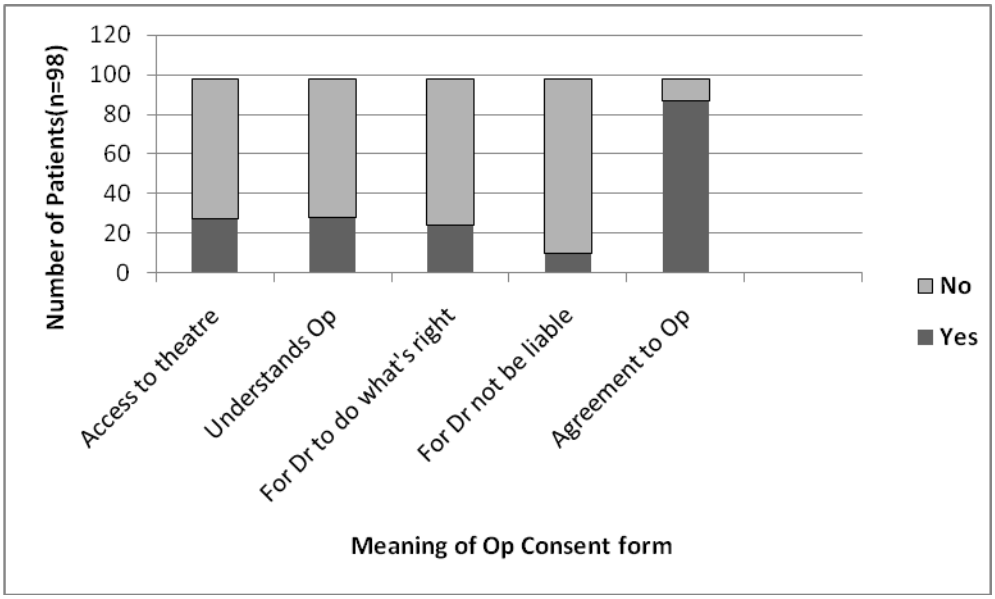

Figure 5: Patients' perceptions of meaning of consent form.

When asked to state their opinion on the suggestion that no patient could refuse an operation, if the procedure is to save one's life, only 44% disagreed and 66% either did not know or agreed with the statement (see Table 3).

Table 3: Opinion on declining suggested procedure.

	Frequency	Percent	Cumulative percent
Agree	33	37.5%	37.5%
Disagree	43	43.9%	77.6%
Do not know	22	22.4%	100%
Total	98	100%	100%

Particularly remarkable was that 24% of the sample declared that they do not know the importance of the consent form even though they signed it. While 21% admitted that despite the fact that they did not know its importance, they were not aware that they could ask questions. In addition, 27.6% of patients still perceived the signing of the consent form as just a mere administrative practice, to allow access to theatre.

5.4 Factors Associated with patients' perceptions on informed consent.

Of the many factors considered, only formal education had positive correlation with better perceptions of informed consent. Patients with a diploma or a degree were in their totality able to link informed consent (IC) to understanding of the procedure (p=0.0006). Other parameters could not directly be associated with appropriate perceptions of informed consent. Parameters such as previous surgery showed no added advantage over those without it (P=0.631). Chronic medical treatment, even though facilitating frequent contacts with healthcare workers, had no added benefit on perceptions of informed consent (P=0.638) as illustrated in Table 4.

Table 4: Factors determining patients' perceptions on informed consent (I.C.).

		I.C. means understanding of the procedure.		P value
		Yes	No	
Gender	**Female**	14	43	0.410
	Male	14	27	
Age group	**18-30 years**	7	16	0.555
	31-40 years	10	27	
	41-50 years	3	13	
	51-60 years	1	10	
	61-70 years	1	6	
	> 70 years	0	4	
Formal Education	**None**	2	9	0.0006
	Primary	1	19	
	Secondary	15	48	
	Tertiary	4	0	
Previous surgery	**Yes**	15	32	0.631
	No	13	38	
Chronic treatment	**Yes**	6	20	0.638
	No	22	50	

5.5 Elements of informed consent process covered with patients

Concerning the actual process of informed consent, 80% of patients did not read the consent form before signing it, 42% did not have the consent form read to them, but signed it anyway. Only 52% of patients reported that they had a chance to ask questions about the procedure or the actual consent form that they signed (see Figure 6

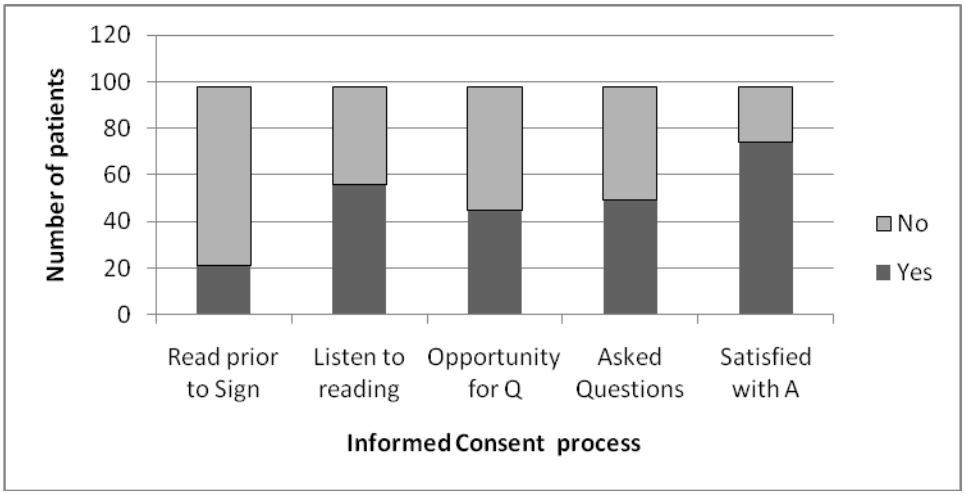

Figure 6: Informed consent process

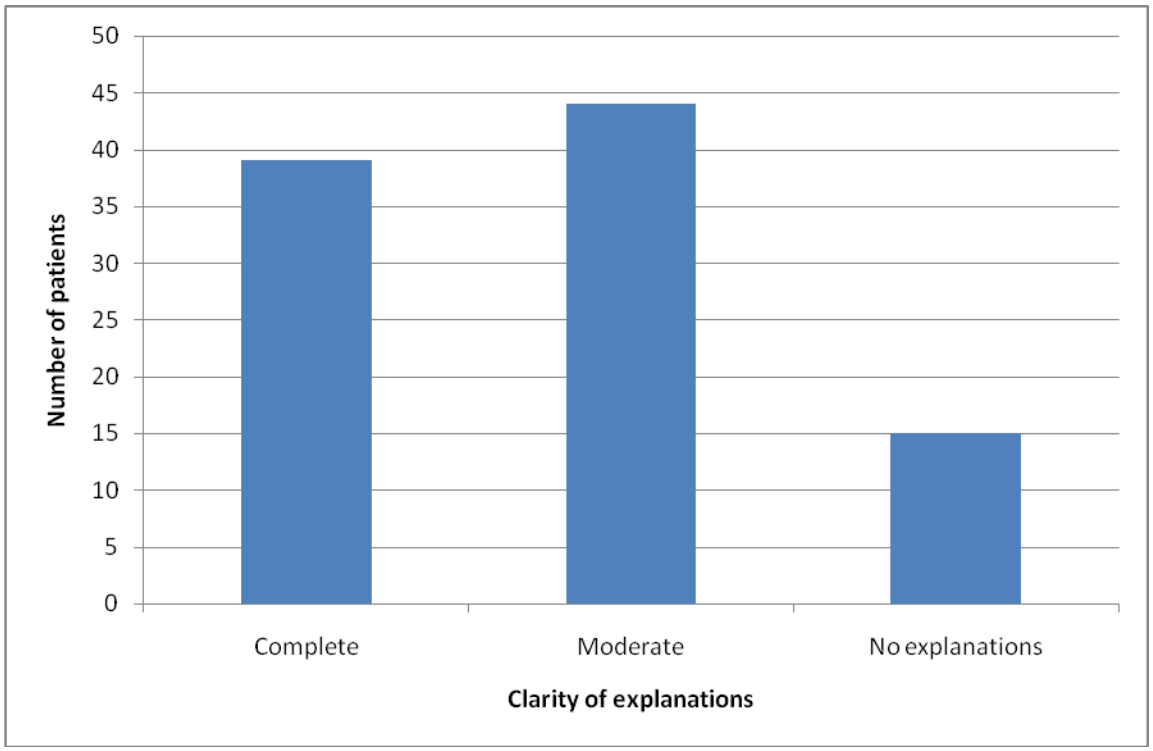

Figure 7: Clarity of explanations given to patients.

Eighty four percent of patients said that, the procedure was explained to them in a way that they could understand (39% stated that they understood completely well; 45% of them said that they understood moderately well). The rest claimed that they received no explanations.(see Figure 7).

More than half of patients got the explanation of the procedure from a doctor, the operating doctor or any other doctor, including the intern doctor. Patients were not in a position to say who will be the operating surgeon. Almost 30% got their explanations from the nursing sisters; while10 percent said that they got explanations from both the doctor and the sister. Worse, 15% of patients claimed that they received no explanations about the procedures**.**

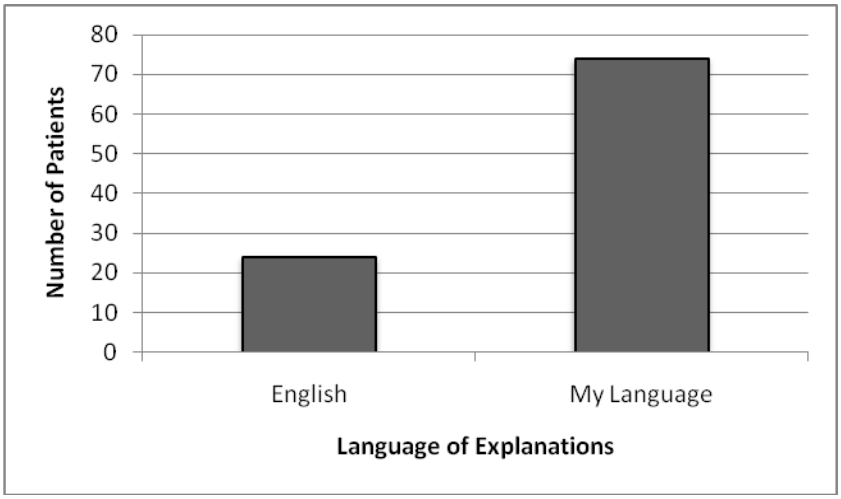

Figure 8: Language used for explanations

The majority of them (75%) had further explanations given in their mother tongue as illustrated in Figure 8.

Only 47% of patients recalled that the healthcare worker checked their understanding of the explanations. In half of the cases (50%), the understanding of explanations was checked by asking questions to the patient about the procedure.

Patients were more likely to have their understanding checked if the explanations were given by a doctor than by a nursing sister (P=0.014).

5.6 Actual understanding of the informed consent

To ascertain the actual understanding of the procedure, patients were asked to answer questions related to the procedure. Only 39% of patients were able to state the indication of the operation (in their own words). Most of them (60%) said that they were having the operation because they

were not well or they were sick. Alternatively, they simply did not know. At time, the procedure was for diagnostic purpose but some patients said that they would get better after the operation. Figure 9 summarizes patients' reply regarding different elements of a good quality informed consent .The study has found that 39% had knowledge of the indication for the procedure, 64% said that they knew the benefit of the procedure, 8% were told some alternatives to their procedure, and, 13% were aware of risks attached to the procedure. Patients' understanding check by the healthcare worker was acknowledged in 49%. Altogether 71% considered that they had freely expressed their choice.

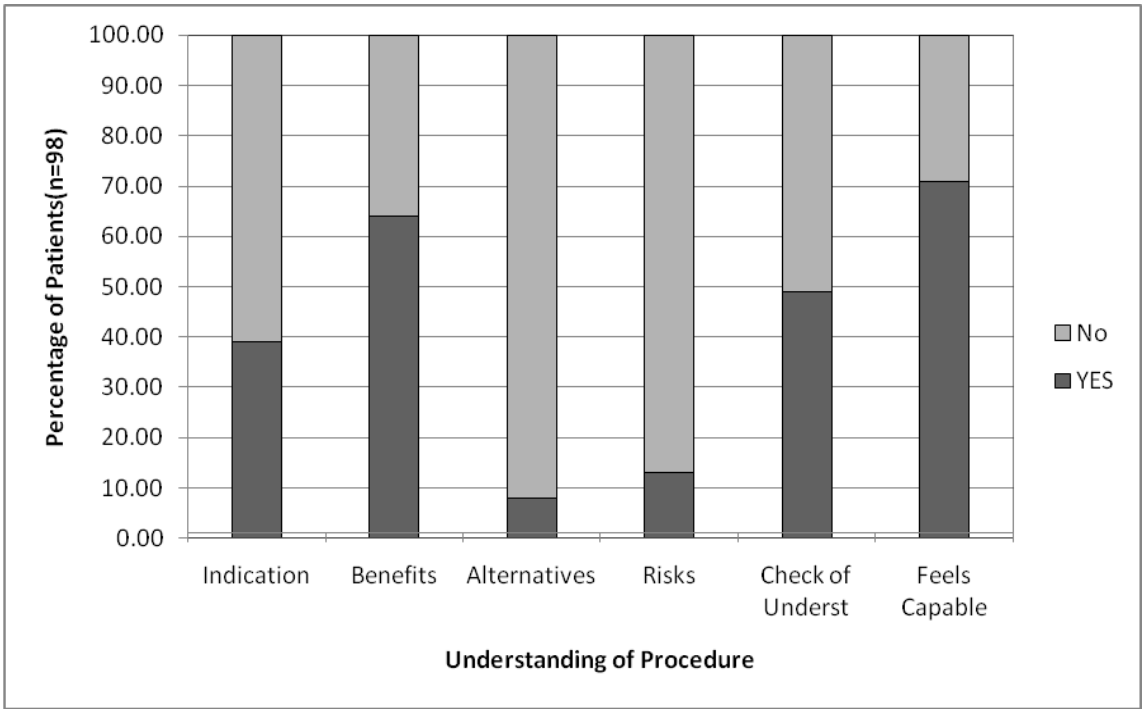

Figure 9: Patients' knowledge of information related to consent.

Based on the requirements of a valid informed consent for surgical procedure, the conclusion can be drawn that only 8% of patients had a complete understanding of all the components of a valid informed consent. Because it appears that, only these patients knew all the tested components:

the indication, the benefit, some risks, alternatives to the procedure and expressed freely their choice.

Yet, as many as 71% of patients said that they felt capable of freely making their own decision about the procedure (3% said that they felt under pressure to sign for the operation).

5.7 Factors determining patients' understanding of procedure

No single element among those under investigation could be correlated with the knowledge of risks of the procedure. Even patients who got the explanations from doctors did not show a better knowledge of the risks (P=0.778), indication or alternatives to the chosen procedure. Awareness of the right to ask questions was not associated with better knowledge of risks (P= 0.161). Even formal education level was not associated with better knowledge of the risks of the procedure (P=0.672) as shown in Table 5.

Table 5: Factors associated with knowledge of risks of the procedure

		Knowledge of Risks		P value
		Yes	No	
Aware of right to ask	**Yes**	10	44	0.161
	No	3	41	
Age Group	**18-30 years**	4	19	0.244
	31-40 years	3	34	
	41-50 years	4	12	
	51-60 years	0	11	
	61-70 years	0	7	
	>70 years	1	3	
Formal Education	**None**	2	9	0.672
	Primary	2	17	
	Secondary	6	52	
	Tertiary	1	3	
Procedure explained by:	**Nurse**	5	26	0.778
	Doctor	7	44	
	Nurse & Dr	1	11	
	None	0	4	

Despite the fact that more educated patients had higher chance of answering that they knew the importance of the informed consent (P=0.035), they did not have better knowledge of the elements used to assess adequate understanding of the procedure, such as knowledge of alternatives to the procedure (P=0.273) and knowledge of risks of the procedure (see Table 6).

Table 6: Factors associated with patients' knowledge of alternatives to procedure

		Knowledge of Alternatives		P Value
		Yes	No	
Aware of right to ask.	**Yes**	5	49	0.945
	No	3	41	
Age group	**18- 30 years**	4	19	0.739
	31-40 years	5	32	
	41-50 years	2	14	
	51-60 years	0	11	
	61-70 years	1	6	
	> 70 years	0	4	
Formal Education	**None**	0	11	0.273
	Primary	1	19	
	Secondary	10	53	
	Tertiary	1	3	
Procedure explained by:	**Nurse**	1	30	0.522
	Doctor	6	45	
	Nurse & Dr	1	11	
	None	0	4	

Table 7 shows that patients with high level of education were likely to have their understanding of the procedure checked by the healthcare worker (P=0.030). In addition, patients who got explanations from doctors were more likely to have their understanding checked than those who were helped by the sisters (P= 0.014).

Table 7: Factors associated with checking of understanding of the information

		Understanding Checking		P value
		Yes	No	
Aware of right to ask.	**Yes**	29	25	0.404
	No	19	25	
Age group	**18-30 years**	14	9	0.287
	31-40 years	17	20	
	41-50 years	7	9	
	51-60 years	4	7	
	61-70 years	4	3	
	> 70 years	0	4	
Formal Education	**None**	1	10	0.014
	Primary	7	13	
	Secondary	35	28	
	Tertiary	3	1	
Procedure Explained by:	**Nurse**	10	21	0.014
	Doctor	31	20	
	Nurse & Dr	7	5	
	None	0	4	

Patients who said that they were aware of their right to ask questions to clarify or otherwise were very likely to answer that they felt capable of making freely the decision on the procedure (P= 0.007)(see Table 8).

Table 8: Factors associated with free choice of the proposed procedure.

		Feeling capable of Deciding freely.		P Value
		Yes	No	
Aware of right to ask.	**Yes**	45	9	0.007
	No	25	19	
Age group	**18-30 years**	19	4	0.550
	31-40 years	25	12	
	41-50 years	13	3	
	51-60 years	10	1	
	61-70 years	6	1	
	> 70 years	3	1	
Formal Education	**None**	6	5	0.108
	Primary	14	6	
	Secondary	52	11	
	Tertiary	4	0	
Procedure Explained by:	**Nurse**	21	10	0.598
	Doctor	39	12	
	Nurse &Dr	8	4	
	None	2	2	

5.8 Sources of information besides healthcare workers

Fifty three percent (53%) of patients interviewed had not received information related to the operation from sources other than the healthcare workers. They made their decision based on the information given by the attending doctor or sister. Only 47% had information from the relatives and other acquaintances. None of the patients mentioned the internet as source of alternative information. Of those who had information from sources other than the healthcare workers, 61 % declared that this information actually helped them make the decision.

In comparison with the value of the information received from the healthcare workers (HCW), only 17.5% stated that it had more impact on their decision, 40% said that this information had the same value as that from healthcare workers. Whereas 38% viewed the outside input, less valuable than the information received from healthcare workers. Patients who said that the outside information was valuable, had no better understanding of informed consent than those who considered the outside information less helpful.

As illustrated in Table 9, patients with outside information had no added advantage when compared to their counterpart without outside information concerning knowledge of informed consent process. They had no advantage on knowledge of indication (P=0.578), knowledge of alternatives (P=0.850) or knowledge of risks (P=0.152).

Table 9: Correlation between quality of understanding and availability of external sources of information;

		Information external to HCW		**P Value**
		No	Yes	
Indication	**Yes**	22	16	0.578
	No	30	30	
Alternatives	**Yes**	5	3	0.850
	No	47	43	
Risks	**Yes**	4	9	0.152
	No	48	37	
Aware of right to ask.	**Yes**	21	28	0.068
	No	31	18	

CHAPTER 6

6.0 DISCUSSION

This study was conducted to determine the quality of informed consent for surgical procedures at Leratong hospital, a provincial hospital located in the vicinities of Kagiso townships in Krugersdorp. The study was done between April 2008 and June 2008.

6.1 Socio- demographic profile

About 5% of patients booked for elective procedures at theatres of Leratong hospital during this period were interviewed. They were aged between 18 and 90 years. The majority being between 31 and 40 years old, the median age was 38 years. When taking into consideration the fact that more than half of the sample had reached secondary school, the literacy level in this community is compatible with an acceptable appreciation of ethical and legal issues.

In clinical trials and clinical practice, specific guidelines and rules have to be adhered to in order to obtain a valid consent. For clinical trials in addition, a team of trained field workers have to fulfil certain requirements related to the consent. This situation usually brings up support and help to cover the gap of lack of adequate understanding in most cases[8,22]. On the contrary, in

clinical practice there are many challenges facing the surgeon in the process of obtaining a valid informed consent[19,17].

As in case of research trials, poor and illiterate people of African communities are vulnerable because of lack of knowledge of risks and inadequate understanding of medical concepts[9]. The lack of formal education coupled with a lack of health literacy - defined as "the ability to read, understand and use health information to make healthcare decisions" renders understanding of consent process even more difficult[40].

However, this is the profile of the majority of communities in sub-Saharan Africa.

In this study, most patients were not fluent in English, 75% of them having the consent explained further in their mother tongue. Yet, the hospital consent form is only in English and not quite easy to understand for a layman.

The age and gender did not have much bearing on the process of appreciation of information related to informed consent. The hospital stay of more than 12 hours for 91% of patients showed no particular advantage. Instead, it constituted a considerable missed opportunity not exploited by healthcare workers to educate patients awaiting surgery on informed consent process.

6.2 Perceptions of informed consent

The broad perception of informed consent among the study population is acceptable. A considerable 87% of patients perceiving the consent form as giving power of decision to patients. On the top of that, 89% considered that informed consent is a proof that they agreed to undergo

the procedure. This is in line with the objectives of informed consent which is to help patients to participate in the decision-making process. The majority of patients are aware of it.

On the other hand, only 27% were able to say that the signing of the consent form for operation meant that they understood what would happen to them. Bhurgri and Qidwai got similar findings in a survey of 80 patients, 45% of them graduates, at Aga Khan University hospital, in Karachi, Pakistan. Only 20% of the respondents, all graduates, were aware of the process of informed consent[33].

As many as 24% admitted, even after signing the consent form, that they did not know the importance of the consent form. Understandably, when patients were asked to say the meaning of informed consent, some patients still held ideas like: informed consent is to allow access to theatre (27.6%), or informed consent form serves to allow the doctor to do what he thinks is the right thing for the patient.

Quite similar to the observation made by Knapp van Bogaert and Ogunbanjo. They stated that there is a persistent risk to give more importance to a mere completion of a piece of paper called consent form than a better understanding of what actually happens[35].

This inappropriate perception of informed consent process is in part a reflection of the background of patients, particularly the level of health education. The assumption was that the degree at which the principle of informed consent for medical care has been publicized through mass education by the related government institutions has probably contributed to this situation.

Many underdeveloped countries still struggle with the fact that patients don't know their rights with regards to consenting or not for any medical treatment or surgical procedure[8,9,13]. In Pakistani communities, this duty is sometimes left to the family to decide. Others even leaving it up to the doctor to do what, he/she thinks, could be the right thing for the patient[34].

6.3 Elements of informed consent covered and understanding of the process

Studies done to evaluate patients' understanding of the process of informed consent have generally come to the conclusion that it is very difficult to evaluate patients understanding[8,10]. Minnies et al. acknowledged that there were difficulties in measuring understanding of informed consent process[22]. These difficulties were encountered also in this study when trying to determine ways of assessing appropriate understanding. The notion of understanding of informed consent is not one that is easy to evaluate.

Considering elements of information and decision-making on the informed consent process, it was requested that patients tell their experiences of informed consent process. The respondents told what actually happened when they were approached to give consent for surgical procedures. Only 20% said that they read the informed consent form before signing it, others got it read to them. This demonstrates clearly the poor level of patients' involvement in the decision making process.

For one to be considered having adequate understanding, he or she should be able to state at least what the indication of the procedure is, how will it benefit him or her, what risks he or she will encounter, what are the alternatives to the procedure[7,30]. Tested through interviews, the majority of this sample faired very badly. For instance, 87% were not aware of risks associated to the procedure, 61% did not know the indication, 92% were unable to recall an alternative to the procedure.

Similar trend was observed in the study by Clegg-Lamptey and Hodasi, where 87% of patients operated at Korle-Bu teaching hospital did not know the complications of the surgery[15]. It is not clear why surgeons seemed not to talk much about the risks of the procedures. It was however noticed in the study by Aoori and Spence that only few resident surgeons could list correctly all risks, benefits and alternatives[17]. It is not obvious whether avoiding talking about risks was to allay patients' anxieties or their own.

Oduro et al. working on understanding and retention of informed consent process among parents in rural northern Ghana, confirmed the fact that understanding of informed consent in underdeveloped countries was low[8].

This is in line with a prior study by Krosin et al. in Mali. They found that participants had difficulty understanding many concepts relevant to informed consent like withdrawal criteria, side effects, investigation or therapy[41].

When correlating the level of understanding of the process with patients characteristics one finding stood out, despite the general poor understanding of the process of informed consent. In most clinical trials, patients with higher formal education happened to do better than others[10,22,26]. This study also found similar result on the meaning attached to signing of consent form for operation. The more educated a patient, the more likely he/she was to link informed consent to the understanding of the procedure (P=0.0006). In fact, all patients having a diploma or a degree made the said connection.

In the same vein, a review of studies on informed consent by Sugarman and McCrory supported these findings. After analysis of 99 articles, covering a wide range of aspects of informed consent, they concluded that there was lower understanding of information on informed consent among older persons and those with fewer years of education[42]. Verastegui also made the same observation[24]. In contrast, this study did not found a correlation between understanding of informed consent process and age (P=0.287).

Moreover, contrary to findings in this study, Minnies et al. in Cape Town, had a higher percentage of patients with adequate understanding. Seventy five percent of the sample had a high level of understanding of informed consent process in a vaccine trial[22]. Despite the fact that the context of the study was different, these findings are likely explained by the observation made earlier. The fact that researchers spent a lot of money in the training of field workers whose job is to explain the trial to patients until they understand it well enough to participate.

This is why their suggestion that patients with a minimum of grade 7 be considered for research studies in order to reach an adequate level of understanding of the process of informed consent is not applicable in clinical practice. It is not feasible in clinical environment where every patient has to give consent for whatever procedure he/she has to undergo to have a required minimum education level.

Ideally, the patient-physician relationship should be like research subject-investigator because patients need as much information and understanding as the research subjects do before signing the consent form. Informed consent should not be different in clinical practice and research trials[43].

This study has found that contrary to other studies, the education level did not determine the ability for patients to recall the risks associated with the procedures (P= 0.672) or the indication of the procedure. The most likely assumption for this situation is that healthcare workers did not systematically mention the risks of the operation and other elements of a valid consent to patients.

Clegg-Lamptey and Hodasi support this assumption. They observed that a possible explanation for poor patients understanding could be that consenting medical staff had less communication skills, did not have the proper knowledge or experience or did not make time to speak properly to patients[15].

Berman et al. made similar findings. They stated that few guidelines existed describing what surgeons should discuss. Younger and private surgeons discussed complications more often than older surgeons and those in academic practice[16].

This is in line with findings of this study where only 13% of patients could recall risks related to the procedure.

Shenker et al. noticed in USA that they were no guidelines for practitioners determining pre-operative requirements of a valid truly informed consent. Hence, the emphasis on the statement that informed consent is ethically required of healthcare practitioners in their relationship with all patients, and should not be viewed as a luxury[44].This is why Straus et al. stressed that informed consent is a process requiring a dialogue. Through this communication, physicians have a responsibility to ensure that their patients know even the regulations related to the consent process[45].

Concerning the quality of information given to patients, this study found that patients who had the consent process explained by the doctor had a higher chance of having the information checked (P=0.014).Which shows that the consenting healthcare worker had an important role to play. Minnies et al. as mentioned earlier, made similar findings. Experienced nurses obtained higher percentage of understanding among research subjects than those with less experience[22].

Worsening the situation of lack of understanding was the fact that consent forms were only in English in a hospital where 75% of patients got their procedure further explained in their mother tongue. This constituted a huge handicap to the process of informed consent. Besides, the form is not clearly understandable from a nonprofessional standpoint.

Hill et al. went even further on mentioning difficulties in translating medical terminologies into lay and local languages. They wondered how someone would understand an ethical concept that he or she hardly uses in everyday life to communicate[46]. It is obvious that concepts like "risks" "benefits", "random" were not easily understood[22].

Understandably, the majority of patients did not read the actual form. An analysis of consent forms used in public or private hospitals in South Africa and patients' interpretation could be a subject of another research study.

Discussing the impact of language barriers on informed consent, Hersnt et al. in USA, found that even in a hospital with onsite interpreters' service, vulnerable patients, those with limited English proficiency, had in their file poor documentation to prove that informed consent was properly obtained prior to procedures. Yet, this was why this service has been made available in the first place[47].

Furthermore, it is important to consider the workload in public hospital as one of the contributing factors to lack of interaction between surgeons and patients. This is exactly what Humayn et al. have found: "Poor adherence to the principle of informed consent on the part of doctors in public hospitals in Pakistan"[12].

Yet, similar findings came out of the comparison of ethical considerations by molecular biologists at University research unit and molecular biologists at private biopharmaceutical

company in Denmark. Molecular biologists at university research unit did not talk about ethical issues regularly when on duty whereas molecular biologists at private biopharmaceutical company considered ethical evaluation as one of the priority of what they did for fear of consumers and mainly the investors[48]. This shows that even with an acceptable workload the difference between private and public sector persists.

Lupton wrote of a case where the English courts stated that:" failure to give the patient adequate information about a procedure is negligent per se". Hence, if a doctor did not give adequate information at the time of obtaining consent, it would be difficult to escape negligence charges[49].

With this background, it is assumed that poor understanding of informed consent process is a reflexion of less efforts exerted by surgeons in providing the needed information to patients.

This study did not assess patients' satisfaction with the treatment for which the consent was given. However, looking at the benefit of making consent more informed, Rounsaville et al. observed that understanding of a study had an impact on the response to related treatment. A study assessing understanding of the process of consent by people referred by the court had found that court- referred individuals who were "going through the motions" because of perceived pressure were less likely to invest energy in understanding the study. This minimised the efficacy of treatment and the benefit for these patients[50].

It most clearly underlines the impact of proper understanding of the informed consent process on patient satisfaction.

6.4 Sources of information besides healthcare workers

This study did not found a correlation between obtaining information outside healthcare workers and better understanding of informed consent process. This could be because of the level of education of people in the study sample and their health education in particular. The majority of patients in this set-up relied on hospital doctors and nurses for their health information.

This is in line with findings by Muller et al. on sources of information on haemophilia. They found that a higher number of participants in the study considered the healthcare workers as the most reliable source of information related to haemophilia A[51].

Even though we did not ask participants to state their available access to a computer or a library, it appeared that patients, in this sample, did less or no research at all on the topic despite the fact that the procedures were elective.

Even though there is a lot of information on the internet, most patients trust their healthcare workers. Having even to verify any health information with them. It fits well with findings made by Dutta-Bergman concerning health information found on the internet. It says that sources without expertise turn to mislead the patients without health education causing misdiagnosis and wrong treatment[52].

Health literacy is not only a problem in underdeveloped countries, because of large majority of illiterates. Even North Americans have it. A recent study in Canada by Burkell and Campbell

mention an International Adult Literacy Survey that has found that almost half of North Americans are lacking the minimum quantitative literacy skills. They require explanations to understand information necessary to participate in a screening test[53].

Having received information from sources outside the healthcare systems did not have an impact on patients' understanding of informed consent process (P=0.152).

CHAPTER 7

7.0 CONCLUSION AND RECOMMENDATIONS

Patient satisfaction is very important for any medical practitioner. Informed consent, which is a medico-legal requirement, is an important contributing factor to patient satisfaction. Overcrowded hospitals, increased burden of diseases, scarce resources and ever-diminishing number of medical personnel constitute some of many challenges facing public health systems. Yet, the cost-effectiveness of patient satisfaction cannot be overemphasized.

This study conducted at Leratong hospital on patients waiting for elective surgical procedures between April 2008 and June 2008 has demonstrated that patients' understanding of informed consent process is very poor. Their lack of adequate perceptions of informed consent was associated with the lower level of formal education. However, it was also clear that even patients with proper education did not prove to have an adequate understanding of informed consent process. This was considered to be related to the fact that surgeons did less or no efforts at all to educate their patients in this regards.

Surgeons did not make time to tell patients the diagnosis, treatments available, risks and benefits of proposed procedures and alternatives available. Above all, the consent form, a legal

document, was hardly read by patients. Reason being partly that the form is available only in English, with no authorised translation in patients' languages.

Therefore, these are some recommendations:

- Guidelines should be compiled for physicians about elements of informed consent process that have to be covered with each patient booked for surgical procedure. Documentation of such should specify time spent and the presence of interpreter, if applicable.
- The health department should obtain and make available an official translation of the consent form in local languages. This simplified and clear version of consent form should be read by or to the patient prior to signature.
- Regular feedback on patients' satisfaction with the process of informed consent should form part of quality assurance for public hospitals.
- Interpreters' services should form part of different hospitals staffing or incorporate notion of language interpreting in the training of nurses in view of high number of physicians not speaking patients' languages.

CHAPTER 8

8.0 References

1 Beauchamp TL, Childress JF, editors. Principles of biomedical Ethics. New York: Oxford University Press; 1994.

2 Enoch S, Shaaban H, Dunn KW. Informed consent should be obtained from patients to use products (skin substitutes) and dressings containing biological material. J Med Ethics 2005; 31(2):2-6.

3 Andanda P. Informed consent. Dev World Bioeth. 2005 Mar; 5(1):14-29.

4 South African Parliament (1996):Constitution of South Africa. Bill of Rights. Act No 108 of 1996. Government gazette of South Africa (Cape Town), 378 (17678).18 December 1996.

5 South Africa (2003): National Health Act No 61 of 2003.Government gazette of South Africa No 26595,23 July 2004.

6 Keulers BJ, SCheltinga MRM, Houterman S, Van der Wilt GJ, Spauwen PHM. Surgeons underestimate their patients' desire for preoperative information. World J Surg 2008 June;32(6):964-70.

7 Dada MA, Mcquoid–Mason DJ, editors. Introduction to medico-legal practice. Durban: Butterworths; 2001.

8 Oduro AR, Aborigo RA, Amugsi D, Anto F, Anyorigiya T, Atuguba F et al. Understanding and retention of informed consent process among parents in rural northern Ghana. BMC Med Ethics 2008;9:5.

9 Frimpong-Mansoh A. Culture and voluntary informed consent in African health care systems. Dev W Bioethics 2008;8(2):104-114.

10 Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. Lancet 2001;358:1772-77.

11 Upadhayay S, Beck A, Rishi A, Amoateng-Adjepong Y, Manthous CA. Patients' predilections regarding informed consent for hospital treatments. J Hosp Med. 2008:3(1):1-3.

12 Humayn A, Fatima N, Naqqash S, Hussain S, Rasheed A, Imtaz H et al. Patients' perception and actual practice of informed consent, privacy and confidentiality in general medical outpatient departments of the tertiary care hospitals of Lahore. BMC Med Ethics 2008;9:14.

13 Karim QA, Karim SSA, Coovadia HM, Susser M. Informed consent for HIV testing in a South African hospital: is it truly informed and truly voluntary? Am J Public Health 1998 Apr;88(4):637-640.

14 Worthington R. Clinical issues on consent: some philosophical concerns. J Med Ethics 2002:28:377-80.

15 Clegg-lamptey J, hodasi W. An audit of aspects of informed consent and pain relief in general surgery units of Korle Bu teaching hospital. Ghana Med J 2005 Jun; 39(2):63-67.

16 Berman L, Dardick A, Bradley EH, Gusberg RJ, Fraenkel L: informed consent for abdominal aortic aneurysm repair: assessing variations in surgeons' opinion through a national survey. J vasc Surg2008 Feb;47(2):287-295.

17 Aroori S, Spence RAJ. Chronic pain after hernia surgery-An informed consent Issue. Ulster Med J 2007;76(3):136-140.

18 Henley L, Benatar SR, Robertson BA, Ensink K. Informed consent –a Survey of doctors' practices in South Africa. S Afr Med J 1995; 85(12): 1273-8.

19 Ogunbanjo GA, Knap van Bogaert D. Ethical issues in family practice: informed consent – Disclosure of information in clinical practice. Sa Fam Pract 2004;46(3):35-37.

20 Kirby HJ. Legal, but is it right? S Afr Med J , 2005 Nov; 95(11):816-818.

21 Moodley K, Parker M, Myer L. Informed consent and participants' perceptions of influenza vaccine trials in South Africa. J Med Ethics 2005;31:727-732.

22 Minnies D, Hawkridge T, Hanekom W, Ehrlich R, London L, Hussey G. Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting. BMC Med Ethics 2008(Sept);9:15.

23 Hawkins M, Delahunty A, McDonald F, editors. Oxford Mini School Dictionary. New York, Oxford university press 2002.

24 Verastegui EL. Consenting of the vulnerable: The informed consent procedure in advanced cancer patients in Mexico. BMC. Med Ethics.2006:7:13.

25 Sugarman J, Lavori PW, Boeger M, Cain C, Edsond R, Morrison V et al. Evaluating the quality of informed consent. Clin trials 2005; 2(1): 34-41.

26 Barett R. Quality of informed consent: Measuring understanding among participants in Oncology clinical trials. Oncol Nurs Forum 2005 Jul;32(4):751-5.

27 Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research. A systematic review. JAMA 2004;292:1593-1601.

28 Yuval R, Halon DA, Merdler A, Khader N, Karkabi B, Uziel K et al. Patients comprehension and reaction to participating in a double blind randomized clinical trial (ISIS-4) in acute myocardial infarction. Arch Intern Med 2000 Apr; 160(8):1142-6.

29 Jefford M, Moore R. Improvement of informed consent and quality of consent documents. BMC Med Ethics 2008; 9:12.

30 Ethical human rights and guidelines on HIV II [Editorial]. S Afr Med J 2002 Feb;92(2):117-119.

31 Humayn A, Fatima N, Naqqash S, Hussain S, Rasheed A, Imtaz H et al. Patients' perception and actual practice of informed consent, privacy and confidentiality in general medical outpatient departments of the tertiary care hospitals of Lahore. BMC Med ethics 2008;9:14.

32 Ebbesen M, Pedersen B. the principle of respect for autonomy- concordant with the experience of Oncology physicians and molecular biologists in their daily work? BMC Med Ethics 2008;9:5.

33 Bhurgri H, Qidwai W. Awareness of the process of informed consent among family practice patients in Karachi. J Pak Med Assoc. 2004 Jul; 54(7):398-401.

34 Jafarey AM, Farooqui A. Informed consent in the Pakistani milieu: the physician's perspective. J Med Ethics 2005;31(2):93-6.

35 Knapp van Bogaert D, Ogunbanjo GA. Informed consent: over-and-under interpretation. SA Fam Pract 2006;48(3):62-63.

36 Braddock CH, Fihn SD, Levinson WJ, Albert A, Pearlman RA. How doctors and patients discuss routine clinical decisions. Informed decision-making in outpatient setting. J Gen Inter Med 1997; 12(6):339-45.

37 Whitney SN, McGuire AL, McCullough LB. A typology of shared decision making, informed consent and simple consent. Ann Intern Med2004 ;140(1):54-9.

38 Perry C. Negligence in securing informed consent and medical malpractice. J Med Humanit Bioeth 1988; 9(2): 111-20.

39 Dhai A. Research ethics review- protecting participants in research. S Afr Med J 2005 Aug; 95(8):595-7.

40 Lehna C, McNeil J. Mixed-methods exploration of parents' health information understanding. Clin Nurs Res 2008 May; 17(2):133-144.

41 Krosin MT, Kletzman R, Levin B, Chemp J, Ranney ML. Problems in comprehension of informed consent in rural and peri-urban Mali, West Africa. Clin trials 2006;3(3):306-13.

42 Sugarman J, McCrory DC, Hubal RC. Getting meaningful informed consent from older adults: a structured literature review of empirical research. J Am Geriatr Soc 1998 Apr; 46(4): 517-24.

43 Santallin-Doherty P, Cabral-castarneda A, Soto-Ramirez L. Informed consent in clinical practice and medical research. Rev Invest Clin 2003May-Jun; 55(3):322-33.

44 Shenker Y, Wang F, Selig SJ, Rita NG, Fernandez A. The impact of language barriers on documentation of informed consent at a hospital with on site interpreter services.
J Gen Intern Med 2007 Nov; 22(Suppl 2):294-299.

45 Straus S, Stelfox T. Whose life is it anyway? Capacity and consent in Canada. CMAJ 2007 Nov; 177(11):1329.

46 Hill Z, Tawiah-Agyemang C, Oeda-Danto S, Kirwood B. Informed consent in Ghana: what do participants really understand? J Med Ethics 2008 Jan;34(1):48-53.

47 Hersnt M, Massicotte EM, Bernstein M. patient satisfaction with outpatient lumbar microsurgical discectomy: A qualitative study. Can J Surg 2007 Dec;50(6):445-449.

48 Ebessen M, Pedersen BD. Empirical investigation of ethical reasoning of physicians and molecular biologists: the importance of the four principles of biomedical ethics. Philos Ethics Humanit Med 2007;2:23.

49 Lupton M. Informed consent: can a patient ever be fully informed? Curr Opin Obst Gynecol 2005 Dec; 17(6):601-4.

50 Rounsaville DB, Hunkele K, Easton CJ, Chich C, Caroll KM. Making consent more informed: preliminary results from a multiple-choice test among probation-referred marijuana users entering a randomised clinical trial. J Am Acad Psychiatry Law 2008;36(3): 354-359.

51 Muller KL, Guelcher C, Taylor A. Haemophilia A: patients' knowledge level of treatment and sources of treatment-related information. Haemophilia 2009Jan;15(1):73-77.

52 Dutta-Bergman M. Trusted online sources of health information: differences in demographics, health beliefs, and health-information. J Med Internet Res2003 Jul-Sep;5(3):e21.Epub 2003 Sept 25. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1550562/?tool=Pubmed(accessed on 11/07/2009).

53 Burkell J, Campbell DG. "What does this mean?" How Web-based consumer health information fails to support information seeking in the pursuit of informed consent for screening test-decisions. J Med Libr Assoc2005 Jul; 93(3):363-373.