A CROSS-SECTIONAL STUDY OF THE PRACTICE OF OBTAINING INFORMED CONSENT FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTER OF MEDICINE IN ANAESTHESIA, UNIVERSITY OF NAIROBI

DR. NTONJIRA J MUTHONI

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A CROSS-SECTIONAL STUDY OF THE PRACTICE OF OBTAINING INFORMED CONSENT FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

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DECLARATION

I declare that this dissertation is my original work and has not been submitted for a degree award in any university.

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DEDICATION

To my family and especially my mum, Beatrice Ntonjira, who supported me and continues to do so through all my endeavors. She is truly a blessing.

ACKNOWLEDGEMENTS

I wish to express my sincere appreciation to my supervisors, Dr. Muriithi J. Mugo and Dr. Caroline Mwangi for their guidance, patience and invaluable input during the formulation of my thesis.

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Finally I wish to thank the Kenyatta National Hospital and the University of Nairobi Ethics and Research committee for allowing me to carry out this study.

LIST OF FIGURES AND TABLES

LIST OF ABBREVIATIONS

AMA American Medical Association

ASA American Society of Anaesthesiologists

KNH Kenyatta National Hospital

SPSS Statistical Package for Social Sciences

USA United States of America

WHO World Health Organisation

LIST OF OPERATIONAL DEFINITIONS

Adult patient	A patient who has attained the age of 18 years and above
Paediatric patient	A patient below the age of 18 years
Reasonable patient standard	Information that should be disclosed by a doctor that any average patient can understand as defined in both criminal law and tort law.
Senior House Officer	A doctor undertaking post-graduate training in any medical specialty (Masters in Medicine)

ABSTRACT

Background

An average of eight thousand five hundred elective surgeries are carried out annually at the Kenyatta National Hospital. Before any invasive procedure, an informed consent is obtained from the patient or the next of kin after pre-operative counselling has been carried out. This study aimed at determining whether patients were adequately informed on the key components of informed consent and establishing whether patients were satisfied with the process of obtaining informed consent for elective surgery at the Kenyatta National Hospital.

Methodology

The study was structured as a cross-sectional survey in which a questionnaire was used to collect data from randomly selected adult patients scheduled to undergo elective surgery. The questionnaire was administered by the principal investigator. Data was then be analyzed using *SPSS Version 15*.

Results

Majority of the patients were informed on the nature of surgery (97.2%), the reason for surgery (98.2%) and the anaesthesia to be administered (76.7%). 89.4% of the patients were informed of the benefits of the surgical procedure while 53.7% of the patients were informed on the benefits of the anaesthesia to be administered. 78.8% of the patients were not informed on the possible complications of the scheduled elective procedure and 76.3% were not informed on any complications related to the anaesthesia. Only 8.8% of the patients interviewed were informed on alternatives to the proposed mode of treatment. Of these patients, 92.2% were not informed on any benefits and possible risks associated with the alternative modes of treatment. 83.4% of the patients were not informed on any alternative forms of anaesthesia. 59.4% of the patients understood the information provided during the pre-operative counselling and 78.4% of the patients interviewed felt satisfied with the current process of obtaining informed consent at the Kenyatta National Hospital.

Conciusions

The current practice of obtaining informed consent addressed certain aspects of informed consent such as nature and indication for surgery but patients were inadequately informed on complications related to surgery and anaesthesia, alternative forms of treatment and their risks and benefits. Despite the inadequacies, most patients felt satisfied with the current practice of informed consent at the Kenyatta National Hospital.

1.0 INTRODUCTION

Informed consent is the legal embodiment of the concept that each individual has the right to make decisions affecting his or her well-being. Informed consent means that the patient has not only consented to the procedure, but is also fully aware of all its benefits, possible risks and consequences[1].

The central notion of informed consent is that the patients have the proposed procedure explained to them in such a way that each can decide whether he or she can proceed with the treatment. It also requires that the consent comes from the patient's own free will without coercion[3]. In this respect, doctors should follow the principle of beneficience, that is, the duty of care[3].

In clinical practice, the signing of a consent form, presumably preceded by adequate exchange of information, are only undertaken in some circumstances, notably prior to major invasive procedures such as radiologic procedures and surgery[4].

Pre-operative counseling is an important part of the care given to patients undergoing surgery and may be received in one sitting, or over a period of time, either verbally or in writing or a combination of the two[4]. It ensures that the patient understands the disease that they have and the procedure that they are undergoing. A signed consent form is evidence that proper pre-operative counseling has been done and the patient has understood about the disease and the procedure and has opted willingly for the procedure. It ensures patient autonomy[3].

it is generally accepted that complete informed consent includes a discussion of the following elements; the nature of the procedure, reasonable alternatives to the proposed intervention, the relevant risks, benefits, and uncertainties related to each alternative, assessment of the patient's understanding and the acceptance of the intervention by the patient[4].

2.0 LITERATURE REVIEW

HISTORY OF SURGICAL INFORMED CONSENT

In the medieval times, doctors required patients to sign a *"pro corpora mortuoto"*, a document aimed at releasing them from any future responsibility to the patient or family in the event anything adverse happened following therapy. This is considered an early precursor of informed consent, although its purpose was to protect the doctor and not the patient[5-7].

In the 18th century, a patient sued his doctor for re-fracturing his leg and experimenting with a novel external fixating mechanism without informing the patient or obtaining approval. This 1767 *Slater vs. Baker and Stapleton* trial was the first example of an informed consent case[8]. The concept of informed consent was used in an 1845 novel by Edgar Allen Poe where a patient was asked for permission for an experimental therapy just before his death[9].

In *Mohr vs. Williams* in 1905, a woman agreed to an operation on her right ear. However, during the operation the surgeon also operated on her left ear. He was subsequently sued and convicted because he did not proceed according to the pre-operative agreement. The judge called this agreement a contract that authorizes the physician to operate only to the extent of the consent given[10].

In *Schoendorf vs. Society of New York Hospital* in 1914, Justice Benjamin Cardozo made a judgement in a case where a woman had consented to an abdominal examination under anaesthesia but not to an operation. Nevertheless, the surgeon removed a tumor that eventually led the patient to file a suit. Cardozo's opinion became one of the most basic elements in informed consent: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body"[11].

After the Second World War, there was a strong public reaction to the cruelties committed by the Nazi concentration camp doctors who performed tests on patients without prior information or approval. A code was written as a direct result of the Nuremberg trials and was

referred to as the Nuremberg Code. This Nuremberg code was an important step in the development of the informed consent process in trials [12].

In June 1964, The World Health Organisation set the Declaration of Helsinki with twenty-two preconditions for human research[13]. The Declaration of Helsinki is a set of ethical principles developed in Helsinki, Finland for the medical community by the World Medical Association (WMA). It is regarded as the cornerstone document of human research ethics. As a result, doctors were from then on required to obtain consent for research involving human subjects[13].

In 1972, *Canterbury vs. Spense* case determined that all risks and alternatives of a procedure have to be explained to a patient[14]. This trial demonstrated a shift from the doctors' point of view toward the patients' point of view as the standard of informed consent: "the reasonable patient standard."

PRESENT PRACTICE OF INFORMED CONSENT

Informed consent, under the bioethical principle of autonomy, has become a major issue with medico-legal and ethical implications in health care around the world. All institutions are required to take informed consent prior to any intervention or procedure done on the patient, but studies raise the question whether informed consent is being implemented in true spirit or it is being adhered to as a medico-legal formality[15].

There are five major components of informed consent i.e., voluntariness or autonomy, adequate disclosure of all the relevant information about the procedure, understanding of information by the patient, competence of the patient to grant consent and finally consent itself. The ultimate ethical objective should be the evolution of a process of informed consent which covers all aspects relevant to the patients' individual rights and preference and yet is not redundant in order to ensure better understanding on the patient's behalf[15].

The AMA Code of Medical Ethics establishes informed consent as an ethical obligation of physicians. In addition, legislation in all 50 states of the USA requires that patients be informed of all important aspects of a treatment and/or procedures, although the details of these laws and statutes differ greatly. Failure to obtain adequate informed consent renders a physician liable for negligence or battery and constitutes medical malpractice[16].

Informed consent is supported by three cornerstones: "preconditions," "information," and "consent"[17].

Preconditions include *competence* and *voluntariness*. A patient is a person who has a right of self-determination. He/she must be able to make decisions about his/her own body and must be able to decide freely without being influenced by others[17].

Information is the second cornerstone. According to the 1995 WHO declaration on the promotion of patients' rights, patients have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis and progress of treatment[17]. In addition, the physician should ensure that the patient understands the information provided before consenting to the medical procedure.

Consent is the third cornerstone which requires registration of the patient's decision and (written) consent[17]. It entails patients' voluntary decision and authorization to proceed with the consented procedure. Both require time, and on the part of the clinician, adequate knowledge of the material information, appropriate communication skills and the competence to bring the values and interests of the patient to bear on the decision making process[18].

Informed consent may be divided into two parts. These parts include; Express consent and Implied consent[19].

Express consent is what is normally thought of by consent when the patient consents by direct words, written or verbal[19]. Telephone consent is also acceptable, if necessary. In these cases, it is a good idea to have a second person listening on the conversation for the purpose of proof.

Implied consent is not expressly granted by a person but rather inferred by a patient's actions and the facts and circumstances of a particular situation[19]. For instance, co-operation during physical examination for pre-operative assessment, or for attachment of monitoring apparatus.

In most regions obtaining the patient's consent to medical care is a legal requirement and clinicians often struggle with the question of how to apply the ethical and legal concept of consent in their daily practice[20]. The ethical principle is based on the patient's right to make free decisions about his or her health (autonomy) and respect for persons where health care professionals are expected to refrain from carrying out unwanted interventions on the patient[21]. Under common law, treating a patient without his or her consent constitutes battery, whereas treating a patient on the basis of inadequately informed consent constitutes negligence[22]. Most consent-related litigation cases are based on allegations of negligence of the physician in disclosing sufficient information for the patient to make an informed decision regarding health care[23].

The World Health Organization's Constitution states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social condition[24]. Patient's rights largely confine themselves to regulating the relationship between the patient and the health care provider or institution. However, in the area of health, the individual is very much dependent on good advice because the expertise, skills and knowledge are in the hands of others, the medical staff[25].

The General Medical Council, United Kingdom states that *"Successful relationships between doctors and patients depend on trust. To establish that trust you must respect patients'*

autonomy[26]. It is therefore a requirement by the physician to disclose information regarding a procedure to enable a patient to give informed consent[27]. In history the deliberate withholding of any information thought by the physician to be detrimental to the patient's prognosis was encouraged and the patient had no meaningful role in the decision making process as it was considered the 'physician knows best'[27]. The patient had to trust and obey what the physician said. The beneficence model, based on the Hippocratic Oath that dates back to the early 19th century, was characterized by maximum physician discretion[28]. It was stressed that only physicians had the knowledge and skill necessary to know what would benefit their patients. The current informed consent doctrine, emphasizes disclosure to patients of information sufficient to permit them to make intelligent choices regarding treatment alternatives[29]. Disclosure promotes patients' informed and reflective participation in health care decision and ensures a continuing and trusting relationship between the patient and his or her physician[30].

The exception to the bioethics principle of disclosure is when the patient voluntarily requests to forego one or more elements of disclosure (waiver), or when the clinician withholds information during the consent process in the belief that disclosure of this information would lead to the harm or suffering of the patient (therapeutic privilege)[31]. Disclosure should take into account of the patient's cultural and religious beliefs. For example, in some cultures a family-centred model of decision making is favoured over one centred on the individual. The clinician can encourage patients in such a situation to involve family members in the consent process[32].

In the United States, the type and nature of information that must be disclosed to the patient during an informed consent discussion varies from state to state. Most states have adopted the "reasonable patient" standard, which requires a physician to disclose information that a reasonable patient under similar circumstances would want to know to make an informed decision[33]. Under this standard, the physician would only need to disclose those risks that are deemed "material." Material risks are those that "a reasonable person" would be likely to attach significance in deciding whether or not to forego the proposed therapy[33]. In common parlance, material risks are those that may not be severe but occur more commonly, for

instance bleeding, nausea, vomiting, oral and dental damage, sore throat as well as those that are rare but of major consequence such as death and paralysis.

In Kenya the law does not give a provision on how much information is 'adequate' for the patient. It is up to the physician to decide how much information to disclose to the patient during pre-operative counseling. Chapter Four of the Constitution of the Republic of Kenya, the Bill of Rights, on economic and social rights states that, *"Every person has the right to the highest attainable standard of health care service including reproductive health care"*[34], therefore patients should receive sufficient information regarding their health.

Bottrell et al examined the completeness of five hundred and forty consent forms from one hundred and fifty seven hospitals in the United States. Of these, 26.4% included all four of the basic elements (risks, benefits, alternatives, and other important aspects of the procedure). Eighty-seven percent noted the general possibility of risk, but less than half provided specific information. Alternatives of the proposed treatment were noted in 56.9% of the forms, and benefits appeared in 37%, though most of these were general references rather than specific information. Although 74% of consent forms were deemed incomplete, it is unknown whether physician-patient discussions that preceded the signing of the consent form included the missing information[35].

Effective communication is critical to the disclosure process. If the clinician fosters good communication the patient will be encouraged to provide personal information and express his or her values, goals and fears. A study by Mark et al found that 82.4% of the study participants reported that they understood everything that their physicians had described about a procedure and indicated that all of their questions had been answered. Eighteen patients had remaining unanswered questions. Half of this group requested more time to speak with their physicians, while the other nine felt that their questions were not important[36]. Wouter et al, in a review of surgical informed consent amongst patients undergoing elective surgery concluded that an optimally informed patient will have more realistic expectations regarding a surgical

procedure and its associated risks and benefits. During this study it was found that well informed patients were more satisfied and hence file fewer claims[37]. This is in contrast to a study carried out at Shifa International Hospital in Islamabad and Aga Khan University Hospital in Karachi to analyze the patients' perspective of the process of informed consent which revealed that sixty per cent of the patients did not understand the information provided. Fifty-six per cent of them reported that their decision to proceed with surgery was actually influenced by other people including the treating doctor. Twenty-nine percent of the patients signed their own consent form, the rest of them were signed by relatives. Forty-eight percent of the patient had been informed about possible complications of surgery[38].

A cross-sectional survey of surgeons in Nigeria was undertaken by University of Ibadan to find out surgeon's opinions and the practice of informed consent in Nigeria. Fifty-five percent of the surgeons agreed that sufficient information is not provided to patients while obtaining their consent for surgical procedures. Some of the reasons for this were language-barrier, lack of interaction between the patient and surgeon prior to surgery and fear of patients declining to surgery once the risks and complications of the procedure are disclosed. Medico-legal reasons (70.6%), informing patients about benefits, risks and alternatives (64.7%) and hospital policy (50.0%) were listed as some reasons for obtaining consent for surgical procedures. 84.3% percent of the surgeons felt that poor communication between surgeons and their patients may be one of the reasons why patients may decline to give consent for surgery[39]. This study found that most surgeons fell short in providing information to patients about their illnesses and when obtaining consents for surgical intervention[39].

D J Byrne, et al in a study to establish how informed is signed consent showed that 40% did not know which organ was operated on and 55% were unaware of the exact nature of the surgical procedure. The study concluded that several factors contributed to this[40], which included: the information given by the surgical staff of the unit was possibly inadequate because of insufficient time, the medical terminology was probably poorly understood by the patients and lack of basic communication skills on the part of the medical attendants[40].

Most patients expect the physician to assume the role of problem solver which involves identifying the patient's presenting problem and developing a list of treatment options[41]. Patients' desire for decision-making responsibility on which treatment option is best is variable[42]. It has been shown that patients who actively seek information do not necessarily wish to make the decision about which treatment option to follow. Some, particularly those who are elderly or acutely ill, are predisposed to follow the physician's recommendation[43]. This could be attributed to failure of the patient to understand about the disease, language barrier or lack of appropriate communication skill and lack of capacity of the patient to make an informed decision[36-40].

The law of informed consent remains ineffective at resolving patient comprehension issues primarily because differing interpretations exist regarding who is responsible for the duty to inform. Surgeons, nurses, and other health care providers must become aware of their responsibilities related to informed consent for treatment. A study carried out by Doughton et al found that despite the cadre of medical personnel carrying out the pre-op counseling, ninety-five per cent of the patients were satisfied with the information given to them prior to obtaining consent, though thirty-five per cent of the junior doctors admitted to obtaining consent for procedures of which they had little understanding despite being the primary clinicians who did the pre-operative counseling prior to signing of the informed consent[44].

For true autonomy to exist in informed consent for surgical procedures, consent forms should contain patients' primary languages whenever possible, or an adequate interpreter should be made available[45]. It is necessary for health care personnel to develop and use effective communication techniques and remember that although some patients are more visually attuned to new information, other patients may benefit more from listening or reading[45]. Patient information leaflets have been shown to be a useful tool for the surgeon to improve the recall of the information given to the patient, in order to facilitate informed consent[46]. In addition different methods of presenting information to patients such as use of audio-visual interventions, may improve the informed consent process[47]. In a study by Lavelle-Jones, 69% of

patients admitted that they did not read a consent form before signing it. In addition, approximately half of the patients awaiting treatment were unhappy with the amount of information they received, with twenty-one percent stating that most of the information they obtained about their surgical treatment was obtained outside of the hospital[48]. Braddock et al in a study to establish informed decision making in an outpatient practice focused on outpatient discussions, recognizing that some procedures may require more discussion than others. They created a three-tiered evaluation procedure, in which the completeness of patient-physician discussion differ according to the complexity of the decision being discussed[49]. Basic decisions, such as laboratory tests, required the least in-depth discussion, covering only the patient's role, the clinical nature of the decision, and exploration of patient preferences. Intermediate decisions, such as changes in medication, required a moderate depth of discussion, adding a discussion of alternative treatments, the risks and benefits of the alternatives, and an assessment of the patients understanding. Complex decisions such as surgery require a discussion of the uncertainties associated with the decision, in addition to all of the aforementioned steps[49].

The ethical principles of patient autonomy and respect for persons require that capable people be allowed to make their own informed decisions. However, the ethical principle of physician beneficence requires that incapable people be protected from making decisions that are harmful or that they would not make if they were capable. In law, capable patients are entitled to make their own informed decisions. If a patient is incapable, the physician must obtain consent from a designated substitute decision-maker[50].

When a clinician is unsure about a patient's capacity an assessment is needed. Clinicians may use three different measures of capacity: cognitive function testing, general impressions of capacity and specific capacity assessments. Although cognition and capacity are related, they are not identical. Most measures of cognitive status do not evaluate several cognitive functions, such as judgement and reasoning, that are relevant to capacity[51]. A person may have a perfect cognitive test score but still be incapable by virtue of delusions that directly affect the

treatment decision. A limitation of cognitive status tests is that cut-off scores for identifying incapacity have not been established[52]. Gaining a general impression of a patient's capacity is a simple and quick method of assessment but can be unreliable, inaccurate and easily biased. In a specific capacity assessment the clinician discloses information relevant to the treatment decision and then evaluates the person's ability to understand this information and to appreciate the consequences of his or her decision[53]. If the result of screening indicates that a patient may be incapable, further expert assessment is generally recommended, particularly if the clinician is unsure about the assessment or if the person challenges the finding of incapacity. Expert assessments can be conducted by individual practitioners such as psychiatrists and psychologists, hospital ethics committees or legal review boards[53].

The Practice of obtaining informed consent at the Kenyatta National Hospital was developed in the 1960s[54]. It was adopted from the Ministry of Health[54] and is still the same one currently in use (Appendix 3). It has neither been reviewed nor revised since its adoption.

As hospital policy, all patients undergoing any invasive procedure, surgical or radiological, are required to sign the informed consent form after pre-operative counseling has been carried out. Patients below the age of eighteen years or patients considered too ill to consent for any invasive procedure, the guardian or next of kin is required to sign the consent form on their behalf. In emergency cases where the next of kin is unavailable to sign the consent form, especially in cases where the patient has no identification, a consultant physician or surgeon may be authorized to sign the consent form on behalf of the patient.

As hospital policy, pre-operative counseling should be carried out prior to surgery and before administration of pre-medication. Currently there are no documented standards of practice available regarding the process of obtaining informed consent for surgery within the Surgical and the Anaesthesiology departments at the Kenyatta National Hospital[54]. Pre-operative counseling of the patient on the surgical procedure and taking of consent is carried out by the physician or health care provider in their respective outpatient clinic, ward or unit. The

Anaesthesiology department's standards of practice regarding patient management state that preoperative assessment of all patients undergoing surgery under anaesthesia should be done. This includes history taking; performing a physical examination; giving recommendations of investigations and consultations required; discussing with the patient the risks ,benefits of available techniques and patient's preferences; premedication and stratifying the patient's anaesthetic risk[55]. The anaesthesia related counseling sessions are usually done in the ward once the patient is admitted as there are no anaesthesia outpatient clinics at Kenyatta National Hospital. These sessions may be in one sitting or more and may include the patient's next of kin.

At the Kenyatta National Hospital, the consent form is valid for two weeks from the date it was signed, after which a new consent form should be obtained if the consented procedure is not carried out within the stipulated period.

3.0 JUSTIFICATION

Informed consent is part of the pre-operative routine prior to any surgical procedure as a matter of hospital policy, legal requirement and ethical obligation. A patient's decision to consent to a surgical procedure needs to be grounded on an adequate basis of relevant information. Without such a basis, a patient's decision to consent to surgery is not an effective informed consent.

Since the medico-legal requirement concerns the doctor's interest more than the information component, it is feared that doctors may secure documentation of informed consent without genuinely ensuring that the patient has received and understood the relevant information[56]. Doctors may think that telling patients about possible complications would discourage them from going ahead with surgery[56]. Keeping these factors in mind it is essential to formally explore the relationship of informed consent procedure with the patients' thought processes.

The effectiveness of the informed consent process in satisfying the patients' needs and rights and the patients' own perception of how the process should be, is an essential element in the process of obtaining informed consent[57].

There has been no study done at the KNH to assess the practice of obtaining informed consent and this survey will highlight any shortcomings and/or challenges faced in the process. It will not only strengthen efforts in improving the process of obtaining informed consent, but also provide a basis for further studies, and practical ways of improving the current process.

4.0 STUDY OBJECTIVES

Research question

Does informed consent as practiced at the Kenyatta National Hospital today effectively satisfy the patients' needs and rights?

Main Objective

To assess the patients' perspective on the process of obtaining informed consent for elective surgery at Kenyatta National Hospital.

Specific Objectives

1. To determine whether patients are informed about their diagnosis, the elective procedure they are to undergo and the type of anaesthesia to be administered.
2. To establish whether patients are informed on the benefits and complications associated with the elective procedure they are to undergo and the type of anaesthesia to be administered.
3. To determine whether patients are informed on the alternatives to the elective procedure they are to undergo and alternative forms of anaesthesia, their risks and benefits.
4. To establish whether patients are satisfied with the process of obtaining informed consent for elective surgery at the Kenyatta National Hospital.

5.0 METHODOLOGY

5.1 Study design

The study was designed as a cross-sectional study that involved the administration of interview-based questionnaires accompanied by a consent form to patients who were scheduled to undergo elective surgery at the Kenyatta National Hospital. The patients were selected via simple random sampling technique from elective theatre lists.

5.2 Study site

The study was carried out at the Kenyatta National Hospital.

5.3 Study period

The study was carried out between the months of March and May 2012.

5.4 Study participants

Participants were recruited from adult patients who were scheduled to undergo elective surgery at the Kenyatta National Hospital over the study period. They were identified from elective theatre lists submitted to the theatres from the surgical wards at Kenyatta National Hospital. The sampling method was simple random sampling technique. The elective theatre list was used as the sampling frame and the patients on the theatre list who fell on an odd number were selected as participants for the study. The study was explained to the participants and an informed consent obtained prior to participating in the study. The questionnaire was administered by the principal investigator before midnight of the scheduled day of surgery.

The following criteria were used to recruit participants for the study.

Inclusion criteria

- Adult patients who were scheduled to undergo elective surgery at the Kenyatta National Hospital gave consent to be included in the study.

Exclusion criteria

- Adult patients who were scheduled to undergo elective surgery at the Kenyatta National Hospital who declined to be included in the study.
- All paediatric patients who were scheduled to undergo elective and emergency surgeries at the Kenyatta National Hospital.
- All adult patients who were scheduled to undergo emergency surgeries at the Kenyatta National Hospital.
- Adult patients who were scheduled to undergo elective surgeries at the Kenyatta National Hospital and were considered too ill to consent for surgery, for instance, senile or comatose patients.

5.5 Sample size calculation

In this study the sample size was calculated using the formula:

$$n = \frac{z^2 pq}{d^2}$$

where

n was sample size (if the target population is more than 10,000)

z was the standard normal deviation at the required confidence level, in this case it was 1.96

p was the proportion in the target population estimated to have characteristics being measured.

Since there was no estimate available of the proportion in the target population assumed to have the characteristics of interest, 50% (0.5) was used as recommended by Fisher et al.

q was 1-p=0.5

d was the level of statistical significance set = 0.05.

Therefore;

$$n = \frac{(1.96)^2 \times (0.5) \times (0.5)}{(0.05)^2}$$

$$= 384$$

Since the study population in this study was less than 10000, the sample size was calculated as follows:

$$nf = \frac{n}{1+n/N}$$

Where

nf =the desired sample size (when the population is less than 10,000).

n = the desired sample size (when the population is more than 10,000) which was 384 (from above calculation)

N= the estimate of the population size, which in this case was the number of elective cases in Kenyatta National Hospital for the months of March, April and May 2011 were 1,080[35]. The total was 1080 which excluded paediatric elective cases.

Therefore;

$$nf = \frac{384}{1+(384/1080)}$$

$$= 283.18$$

Therefore the desired sample size for this study was 283.

5.6 Data collection and analysis

The data was collected using a questionnaire (Appendix 2). The principal investigator administered the questionnaires to the randomly selected participants in an interview-based manner after obtaining informed consent. Where there was a language barrier between the principal investigator and the participant, a translator was sought to ensure a clear understanding between the principal investigator and the participant.

Data quality was ensured by conducting continuous checks of the completeness questionnaires.

At the end of data collection period, data was entered and managed in Microsoft Access database. The safety of the data was ensured by using a password protected database and backup files were kept in an external hard drive. Data cleaning was done by testing consistency and range checks by the study statistician.

Data analysis was performed using SPSS version 17.0 and the study results were presented in form of tables, bar graphs and pie charts.

5.7 Data Dissemination

The results of this study will be disseminated to health care personnel involved in taking consent and the Kenyatta National Hospital/University of Nairobi, Ethics and Research Committee, with the intention of creating awareness on the process of obtaining informed consent. Finally, it is hoped that the study will be presented at scientific conferences and published in peer reviewed scientific journals.

5.8 Ethical considerations

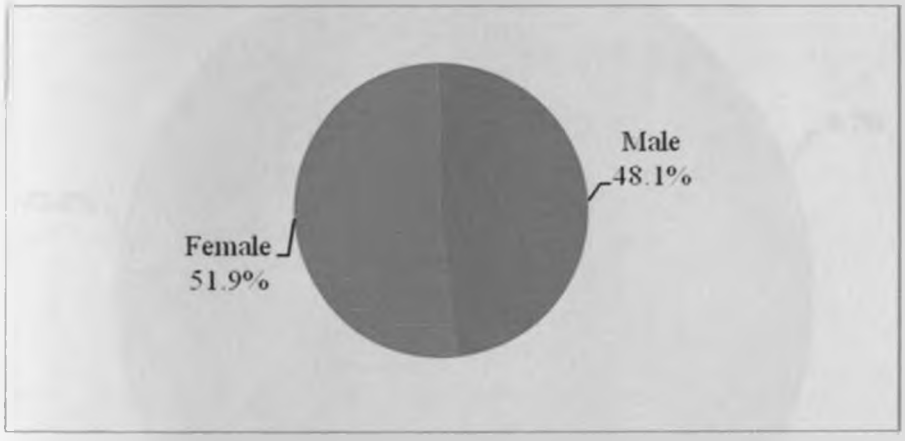
1. The nature and purpose of the study was explained to the participants in the study and consent obtained.
2. The study did not have any harmful effects on the patients or the hospital in general.
3. Confidentiality was maintained at all stages of the exercise.

4. Refusal to participate in the study did in no way influence the patients' care at the hospital.
5. Approval for the study was be sought from Kenyatta National Hospital-University of Nairobi, Ethics and Research Committee and obtained on 27th March 2012.
6. There were no cost implications to the participants at any point during the study.
7. Findings from the study were availed to the Ethics Committee of KNH and the University of Nairobi.

6.0 RESULTS

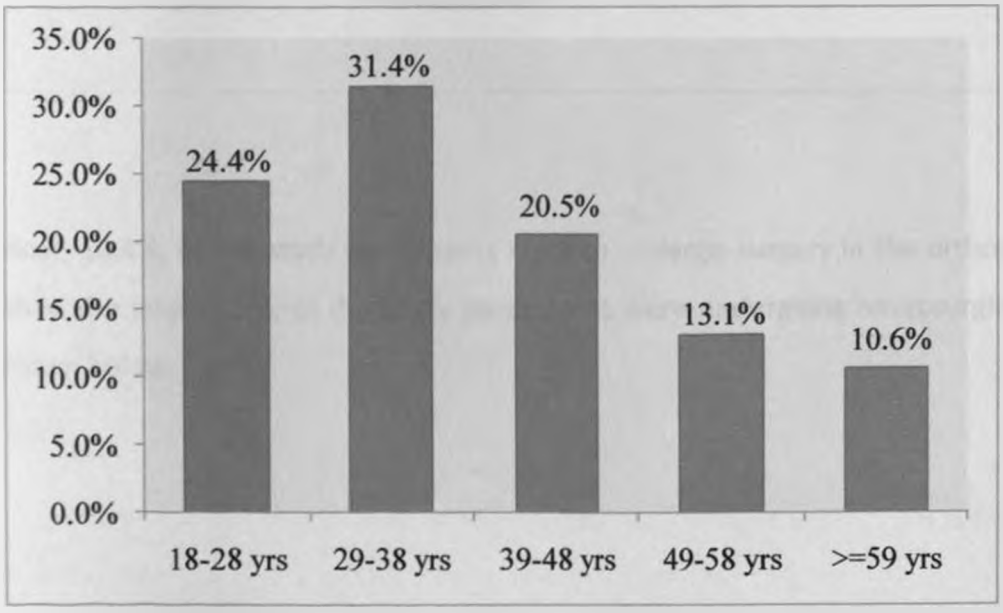
Respondents in this survey comprised of adult patients scheduled for elective surgery at the Kenyatta National Hospital. A total of 283 patients were interviewed between March and May 2012. The gender distribution was as shown in the pie chart below.

Figure 1: Pie chart showing the gender distribution of the patients



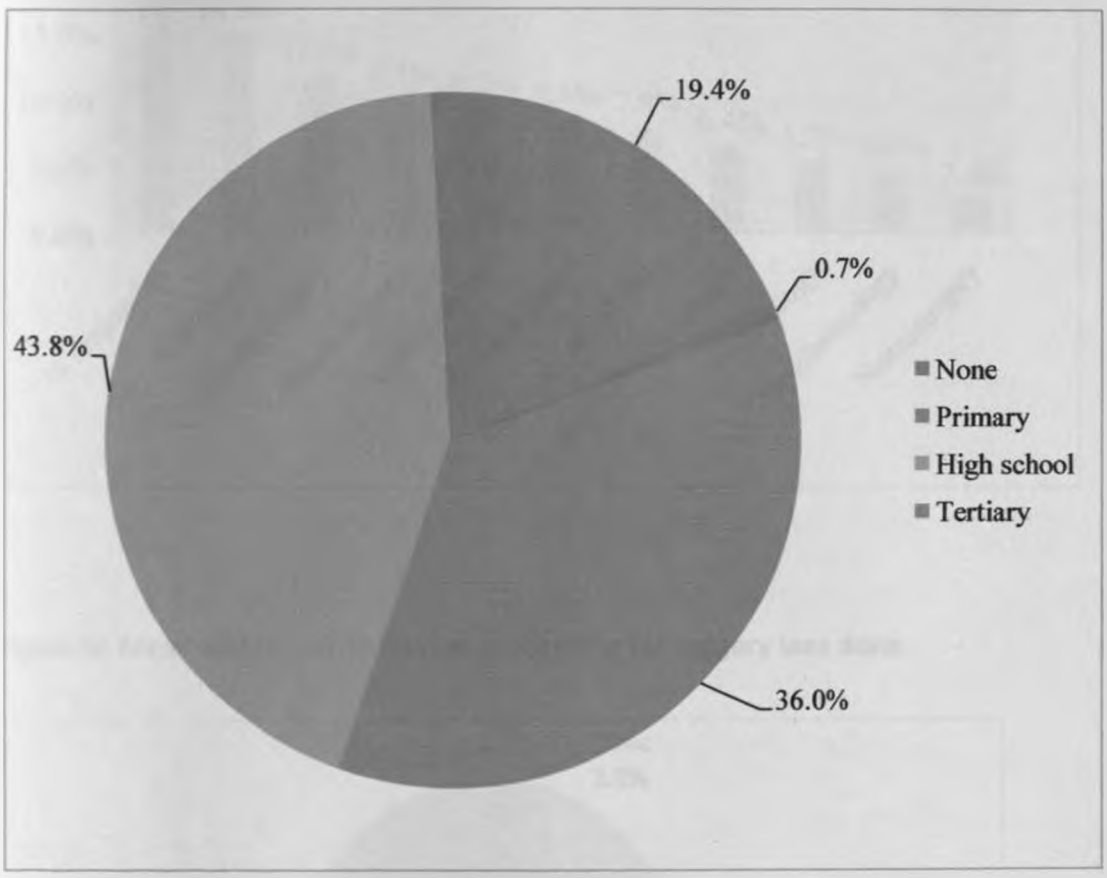
Most patients, 31.4%, were in the 29-38 year age group as shown below.

Figure 2: Bar graph showing the age distribution of the patients



Regarding the level of formal education of the respondents, 43.8% had high school education while 0.7% had no formal education as illustrated in Figure 3.

Figure 3: Pie chart illustrating the level of formal education of the patients



Most, 19.4%, of the study participants were to undergo surgery in the orthopaedics discipline while the least, 2.5%, of the study participants were undergoing neurosurgical procedures as shown below.

Figure 4: Bar graph showing the type of elective surgical procedure

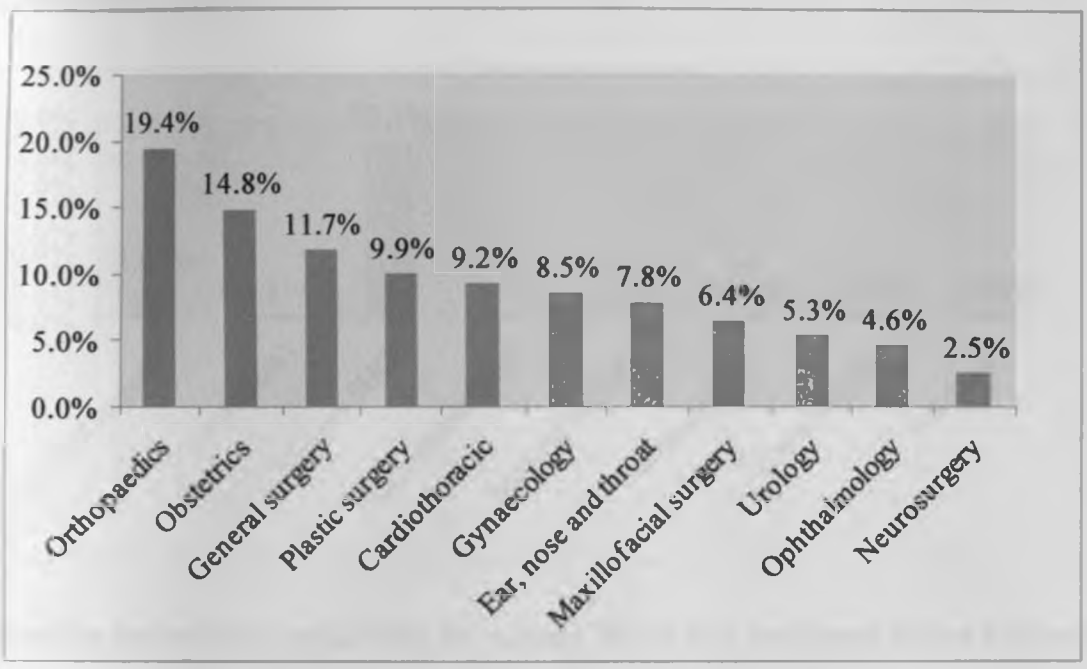
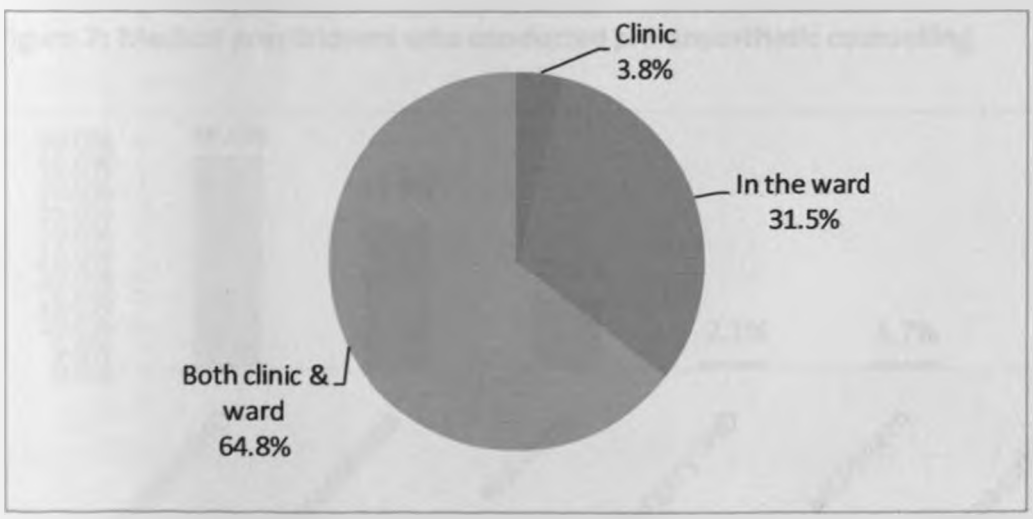
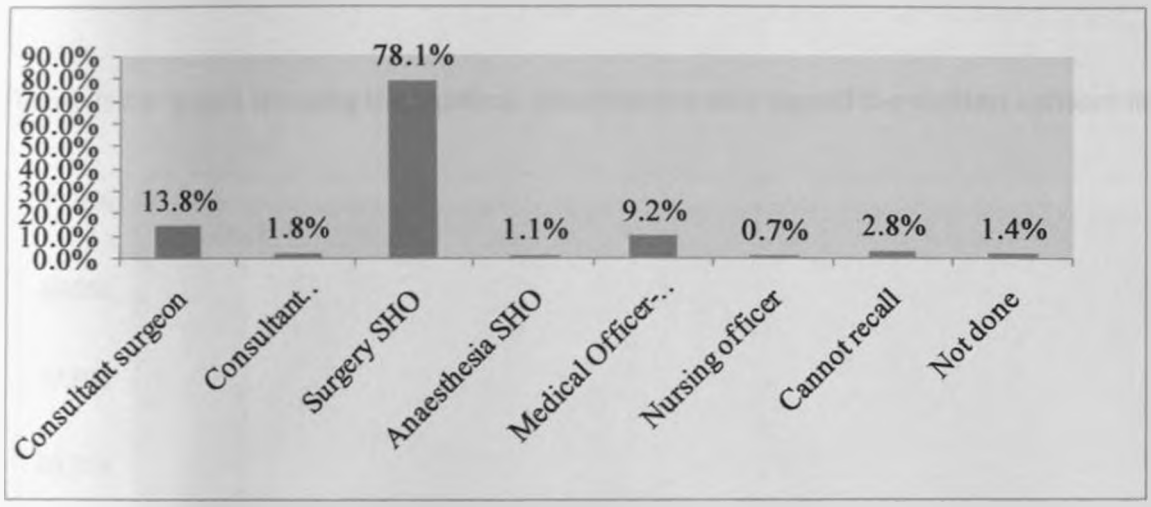


Figure 5: Areas where pre-operative counselling for surgery was done



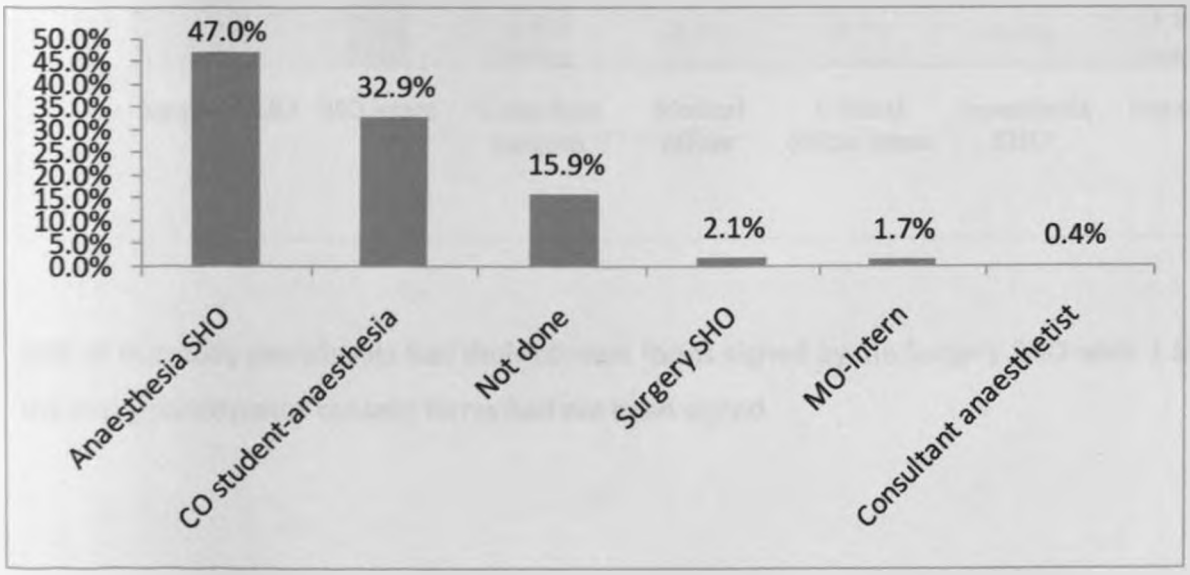
64.8% of the patients had their preoperative counselling done both in the clinic and the ward as shown above.

Figure 6: Bar graph showing the medical practitioners who conducted pre-operative counselling for surgery



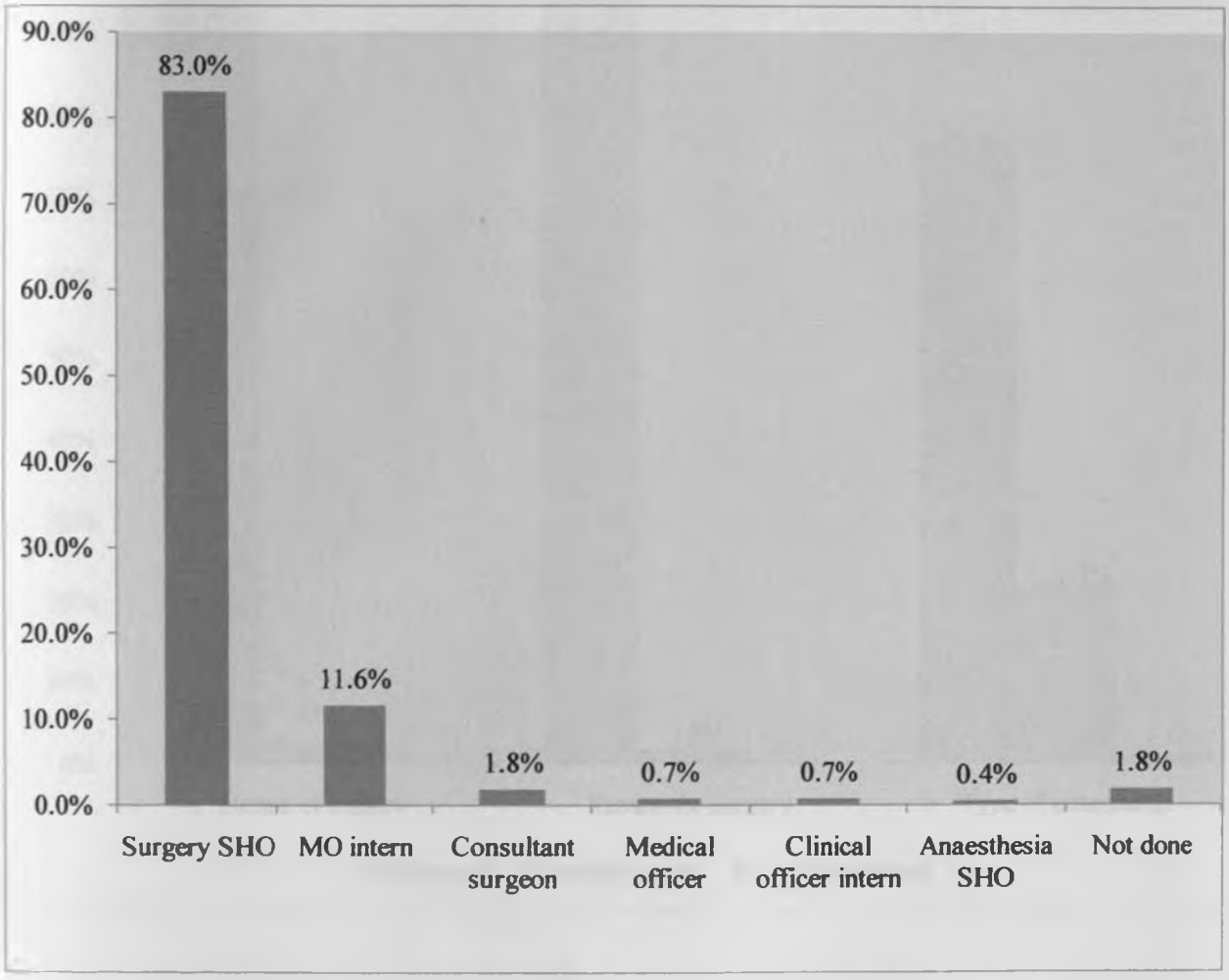
Regarding preoperative counselling for surgery, 78.1% was conducted by the Surgery SHO. 2.8% of the study participants could not recall who conducted the counseling and 1.4 % of the study participants had not received counselling.

Figure 7: Medical practitioners who conducted pre-anaesthetic counselling



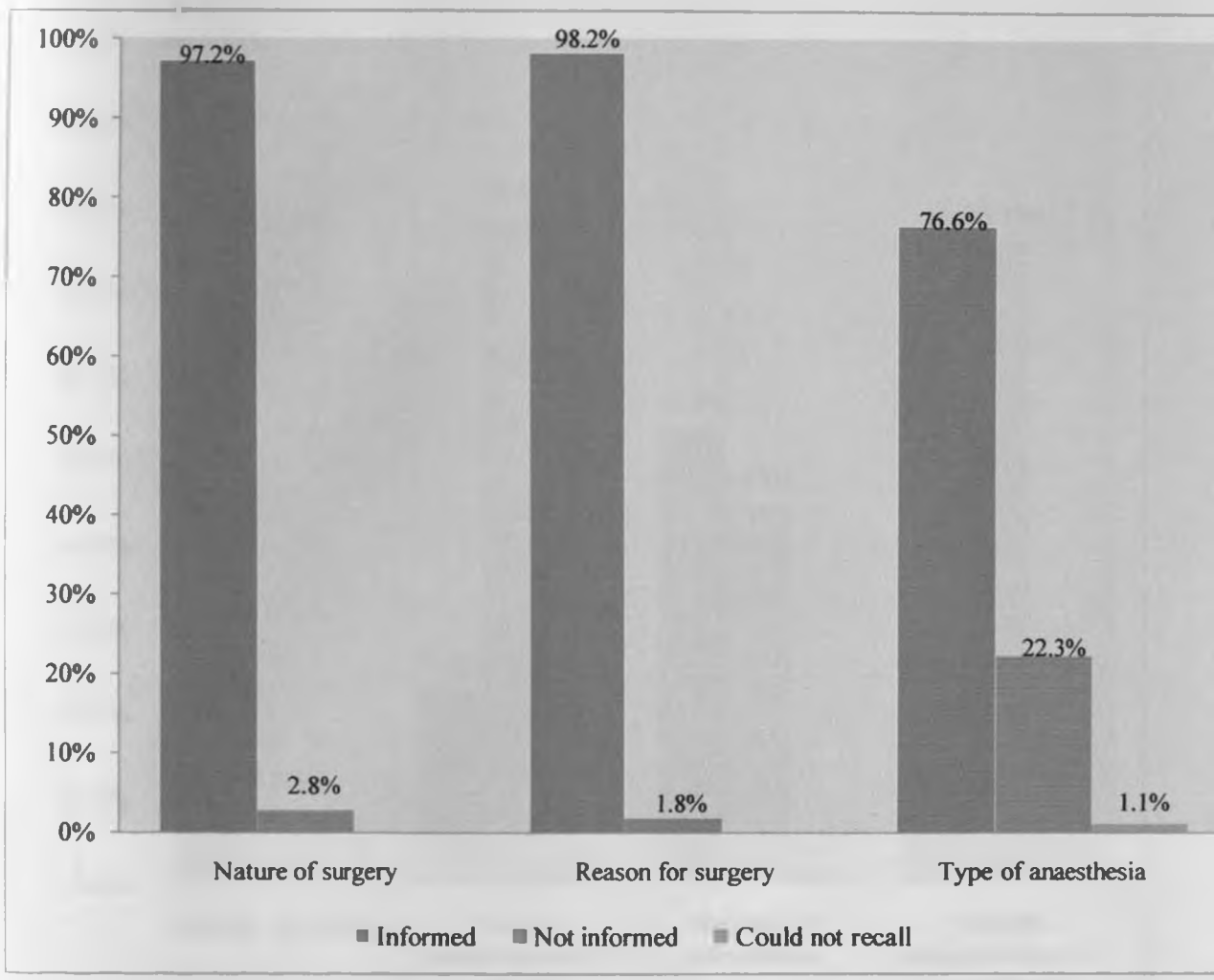
Regarding pre-anaesthetic counselling conducted amongst the study participants. 47% of it was conducted by anaesthesia SHO's and 15.9% of them had not received counselling.

Figure 8: Bar graph showing the medical practitioners who signed the written consent form



83% of the study participants had their consent forms signed by the Surgery SHO while 1.8% of the study participants' consent forms had not been signed.

Figure 9: Bar graph showing patients' knowledge regarding the nature of surgery, reason for surgery and anaesthesia to be administered



Amongst the study participants, 97.2 % had the nature of surgery, 98.2% had the reason for surgery and 76.6% had the type of anaesthesia explained to them. 1.1% of the patients could not recall the type of anaesthesia explained to them.

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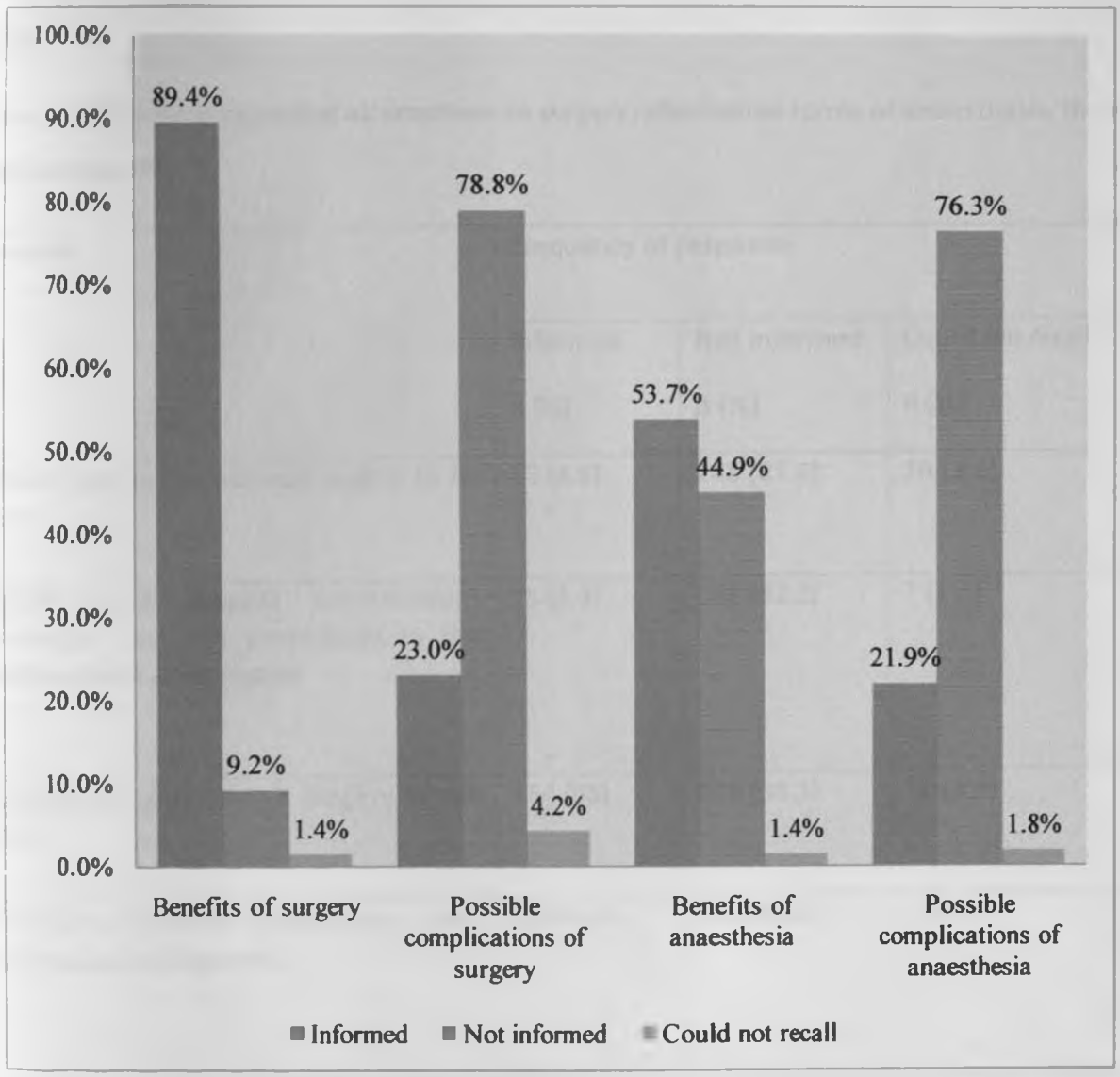
Figure 10: Bar graph illustrating information regarding benefits and complications associated with the elective procedure and anaesthesia



89.4% and 53.7% of the study participants had the benefits of surgery and benefits of anaesthesia explained to them. Only 23% and 21.9% of the patients had the possible complications of surgery and possible complications of anaesthesia explained to the respectively.

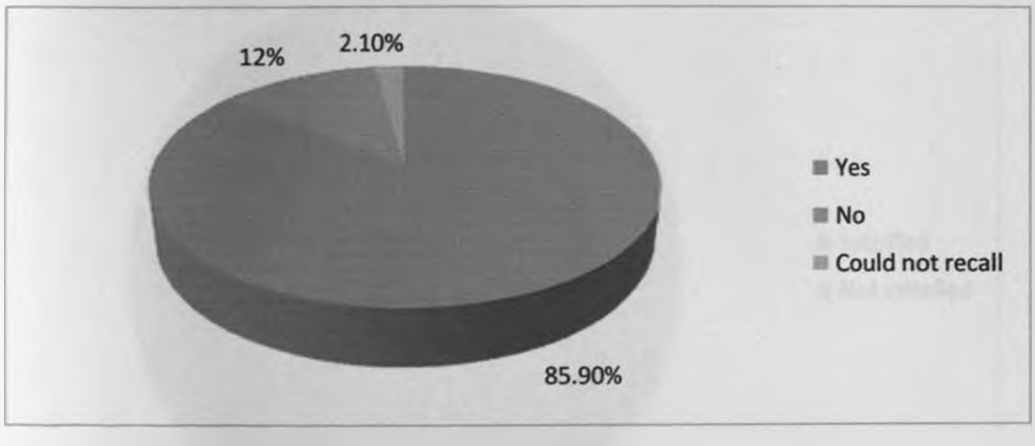
58 % of the study participants were informed on the possible complications if surgery was not done. 87.6 %, 92.2 % and 83.4 % of the participants were not informed on the alternatives to the elective surgery to be done, benefits and possible complications associated with the alternative surgical procedure and alternative forms of anaesthesia, their risk and benefits respectively.

Table 1: Information regarding alternatives to surgery, alternative forms of anaesthesia, their risks and benefits

Variable	Frequency of response		
	Informed n (%)	Not informed n (%)	Could not recall n (%)
Alternatives to the elective surgery to be done	25 (8.8)	248 (87.6)	10 (3.6)
Benefits and possible complications associated with the alternatives to the elective surgical procedure	15 (5.3)	261 (92.2)	7 (2.5)
Possible complications if surgery is not done	164 (58)	108 (38.1)	11 (3.9)
Alternative forms of anaesthesia, their benefits and possible risks	46 (16.3)	236 (83.4)	1 (0.4)

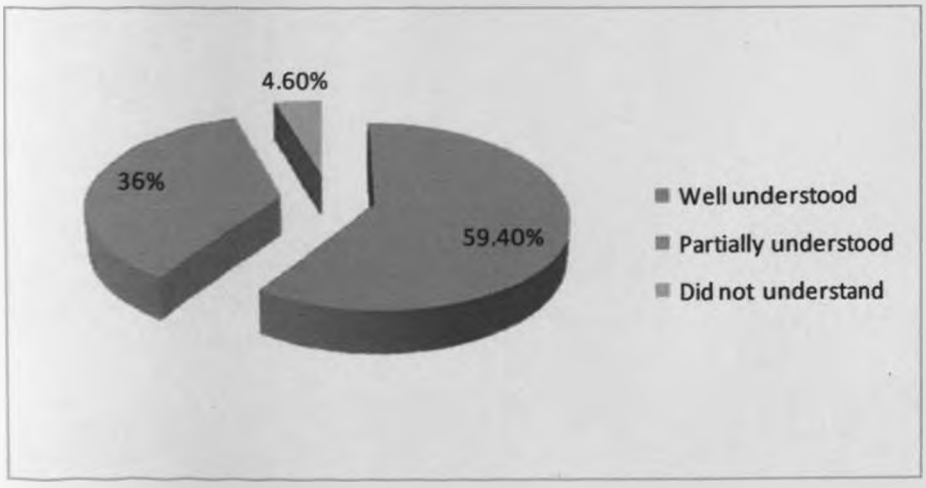
During pre-operative counselling, 85.9% of the patients were given an opportunity to ask questions prior to signing of the consent form as shown below.

Figure 11: Pie chart showing patients given an opportunity to have their questions answered during pre-operative counselling



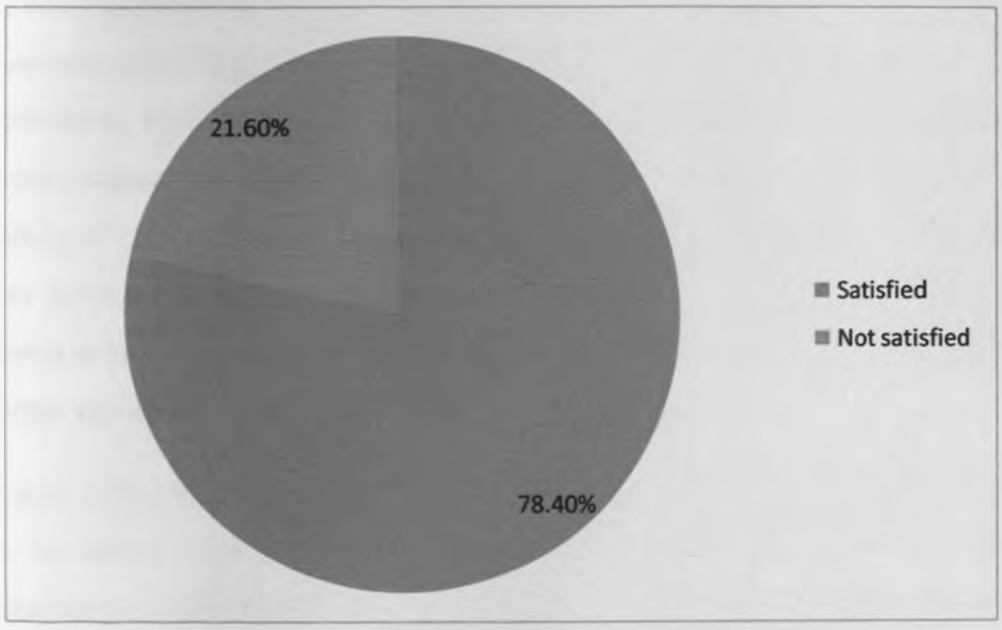
59.4 % of the study participants understood well the information provided to them prior to signing the consent form. Only 4.6% of them did not understand the information.

Figure 12: Pie chart showing the level of patients' understanding of the information given prior to signing the consent form



Following the pre-operative counselling sessions and signing of the consent form, 78.4% of the patients expressed satisfaction with the process of obtaining informed consent for elective surgery as shown in Figure 13.

Figure 13: Pie chart illustrating patients' satisfaction with the process of obtaining informed consent



7.0 DISCUSSION

During this survey, 283 randomly selected patients were interviewed, with the percentage of female patients being higher than male patients, which is consistent with the fact that there are more female surgical patients in the hospital than male patients [54].

The study participants were aged between 18yrs to over 59 years with the highest percentage of patients being between 29-38 years. This could be attributed to the fact that half of the respondents were undergoing surgery in four (orthopaedics, obstetrics, gynaecology and general surgery) out of the twelve disciplines in Kenyatta National Hospital. In these disciplines, majority of the patients are within the 29-38 age group[54]. A similar trend was observed in a study done by Mohammed Amir et al on surgical informed consent where majority of the patients were aged between 25-35 years[23] therefore majority of surgical patients are in the younger age group.

Majority of the patients had varying levels of formal education and only 0.7% of the patients had no formal education. Establishing the literacy level of patient during pre-operative counselling is important as patients may fail to understand the medical terminology often used by the physicians. If the patient has had little or no formal education, reading the written consent form may be difficult and this curtails on the patient's autonomy. In addition patients with less formal education are likely to be influenced by other people when deciding whether to proceed with the surgery or not, regardless of their knowledge on procedure. A study by Mohammed Amir et al found that 58% of patients did not read the consent form due to low literacy levels[23]. Gongal and Bhattarai established that the level of formal education is an important factor that affects the level of understanding of patients. This study concluded that more effort has to be made to make the uneducated patients understand about their diagnosis[58].

Marshall et al in a genetic study of breast cancer in Nigeria found that women with less education were more likely to ask their husbands for permission to participate in clinical

research and that education level significantly predicted the participant's ability to read the informed consent form[59].

The patient's level of education also makes it easier for information leaflets and audio-visual presentations to be used during pre-operative counselling. Patient information leaflets are a useful tool for the surgeon and anaesthetist to improve the recall of the information provided to the patient in order to facilitate informed consent[60]. A review on the use of audio-visual presentation of information in the informed consent process by Ryan et al showed that it improved the patients' understanding of the information provided and enhanced the quality of the information conveyed to the patients[47].

Regarding the type of surgical procedure, majority of the patients interviewed were scheduled to undergo orthopaedic procedures while the least number of patients were scheduled to undergo neurosurgical procedures. This is because most of the scheduled elective procedures are trauma-related due to the high incidence of trauma cases seen in the hospital[54]. The low number of elective neurosurgical procedures may perhaps be attributed to other factors such as complexity of the surgery, long duration of the procedure sometimes requiring post-operative admission in the Intensive Care Unit (ICU) therefore availability of beds in the ICU and availability of blood for peri-operative or post-operative transfusions become factors in planning for these elective procedures.

Patients receive information about their operation at the initial consultation when the surgery is proposed usually in the out-patient clinics and at the moment of signing a consent form. Even after a relatively short time, patients can have poor recall of information they have been given and in elective surgery there can be a considerable time gap between listing and admission. In this survey, it was established that the patients received the pre-operative counselling for surgery in the clinic and in the wards. It has been shown that more than one sitting for the pre-operative counselling helps improve the patients' understanding of the information provided[61].

Most patients (78.1%) had their pre-operative counselling for surgery conducted by senior house officers in surgery. This may be attributed to the fact that Kenyatta National Hospital is a

teaching hospital hence senior house officers have the most contact time with patients both in the wards and in the clinics as well as the number of senior house officers is the largest compared to other cadres of medical practitioners. 13.8% of the patients were counselled by consultant surgeons. This is consistent with a study done by Mohammed Amir et al that found that patients are informed on various aspects of the surgical procedure by the treating surgeon or members of his team and the consent signatures are taken by junior members of the team such as junior residents or medical officer-interns[23]. The cadre of the health care provider may influence the information provided to the patient. The task of signing the consent form may sometimes be left to the junior doctors who may have little understanding of the surgical procedure hence the patients may receive inadequate information[23].

A study by Houghton et al stated that *if the act of signing the consent form is to be more meaningful, it should be signed by the surgeon who is to perform the procedure as it would show that a discussion did take place between the surgeon and the patient prior to surgery*[62]. The Joint Consultants Committee, a representative forum of the Medical Royal Colleges and the British Medical Association designed a set of safeguards to protect the safety of patients when invasive procedures are carried out. These included that patients must be fully informed of the training and status of the person operating on them and give full consent[65].

In the Kenyatta National Hospital, there are different cadres of anaesthesia care givers. These include consultant anaesthetists, senior house officers, registered clinical officers and clinical - officer students undertaking a higher diploma in anaesthesia. All cadres of anaesthesia care givers may conduct pre-anaesthetic counselling. When senior house officers and clinical officer students conduct the pre-anaesthetic counselling, they are required to consult with the senior anaesthesia caregiver supervising them.

As per hospital policy, described in the standards of practice in anaesthesia, pre-anaesthetic counselling should be carried out prior to the elective surgery, which is usually the day before surgery. 79.9% of the patients had their pre-anaesthetic counselling conducted by the senior house officers and clinical officer students in anaesthesia (Figure 6). 0.4% of the patients had

their pre-operative counselling for anaesthesia carried out by consultant anaesthetists. These may be consultant anaesthetists who were not paired with senior house officers or clinical officer students in anaesthesia or they may have been keen on doing the pre-anaesthetic counselling themselves probably due to the complexity of the surgery or the condition of the patients.

15.9% of the patients had no pre-anaesthetic counselling done at the time of administration of the questionnaire. This could be that the pre-anaesthetic counselling was conducted later after the questionnaire had already been administered or the pre-anaesthetic counselling was not carried out prior to surgery. At the Kenyatta National Hospital there is no stipulated time for conducting pre-anaesthetic counselling and there are no pre-anaesthetic assessment clinics.

Following pre-operative counselling, patients are required to sign the consent form as an indication of consenting to the procedure. Patients who cannot sign, such as those who are illiterate or severely ill, are required to put a thumb print as a sign of consent or have their next of kin sign on their behalf respectively. The written consent form at the Kenyatta National Hospital (Appendix 3) is also signed by a medical practitioner, usually the one who conducted the pre-operative counselling for surgery. The consent form has no provision for the anaesthetist to sign following pre-anaesthetic counselling or for the patient to sign consenting to anaesthesia. It is assumed that once the patient has consented to surgery, consent for anaesthesia is implied. A review by Colleen E. O'Leary on the need for written consent for anaesthesia stated that surgeons are not trained to formulate an anaesthesia care plan or to discuss the risks and benefits of anaesthesia hence a separate written anaesthesia consent form is required that clearly outlines the anaesthesia plan, the common risks and benefits and is signed by the anaesthetist and the patient once consent is given[64].

A study that looked at the surgeons' and anaesthetists' attitude towards informed consent in the United Kingdom found that 97% of the surgeons agreed on informing the patient on the surgery, its risks and benefits and educating the patient on alternative treatment options[65]. 85% of the surgeons agreed that the consent process respects the patient's right to autonomy[65]. In

this survey, after pre-operative counselling, most patients (97.2%) knew the nature of surgery to be done and were aware of the reason for surgery (Figure 8).

89.4% of the patients interviewed were informed of the benefits of surgery but only 23% of the patients were informed of the possible complications that may arise following surgery. 76.3% of the patients were not informed of the possible complications associated with the type of anaesthesia to be administered as illustrated in Figure 9. This may be due to the fear that disclosure of complications related to the procedure and anaesthesia may increase the patients' anxiety levels and dissuade them from the surgery or the health care professional carrying out the counselling may be inadequately informed on what is required to be told to the patient.

A study on the surgeons' and anaesthetists' attitude towards informed consent conducted in the United Kingdom found that 50% of the surgeons and anaesthetists felt that major risks with an incidence of >1 in 1000 or more should be disclosed to patients as part of the consent process. Seventy percent of both surgeons and anaesthetists felt that minor risks with an incidence of >1 in 20 should be disclosed to the patient when obtaining consent[65].

During pre-operative counselling, patients should be informed on alternative forms of treatment, their risks and benefits in addition to the proposed surgical procedure or type of anaesthesia to be administered by the surgeon or anaesthetist respectively. In this study, 8.8% of the patients were informed on alternative forms of treatment to the elective surgery to be done. Of these patients, only 5.3% were informed on the benefits and possible complications to the alternative forms of treatment (Table 1). In the 1972 case, Canterbury Vs Spence[14] which formed one of the cornerstones of informed consent, the court stated that in consenting a patient, he or she should be given adequate information of the procedure, the diagnosis and differential diagnosis, required diagnostic procedures, detailed description of the surgical procedure with any post-operative treatment necessary, the risks of the surgical procedure, any alternative methods of treatment and expected results[14].

Most patients (85.9%) were given an opportunity to have their questions answered. 12% of the patients did not get their questions answered. Some reasons for this included the doctor conducting the pre-operative counselling said he was busy while some of the patients did not have any questions at the time the pre-operative counselling was being done. A study on the surgical informed consent in the Royal Sussex County Hospital in the United Kingdom by White and Walton et al showed that the factors that affect the amount of information conveyed to the patient during the consent process included patient's age, level of education, inquisitiveness and complexity of the procedure[65]. Once information regarding the proposed form of treatment has been relayed, patients should be accorded the opportunity to have their questions answered. This also helps in assessing the patient's level of understanding of the information provided and also assesses the patient's level of satisfaction with the consent process.

56.4% of the patients stated that they understood all the information provided and 78.4% of the patients stated that they were satisfied with the consent process at the Kenyatta National Hospital. This is despite inadequate information provided regarding the benefits and complications related to the planned surgical procedure and anaesthesia, alternative forms of treatment, their risks and benefits. A similar trend was observed in a study in Pakistan on informed consent for surgical consent where despite poor understanding of the information and other inadequacies, majority of the patients (93.5%) still felt satisfied with the process of informed consent[33]. In this study, the patients' perception of satisfaction appears to be dependent upon engagement in the discussion and decision-making rather than complete understanding of the information being provided.

8.0 CONCLUSIONS

1. The current practice of informed consent addresses certain aspects of informed consent such as nature and indication for surgery and the type of anaesthesia to be administered.

2. Patients are inadequately informed on the complications related to surgery, alternative forms of treatment, their risks and benefits.

3. Pre-anaesthetic assessment of patients does not address key aspects of anaesthesia such as benefits of the type of anaesthesia chosen, the possible complications related to anaesthesia and alternative forms of anaesthesia.

4. There is no written consent for anaesthesia therefore patients do not sign a written consent form for anaesthesia but consent is implied once they have consented to surgery.

5. Most patients at the Kenyatta National hospital are satisfied with the current practice of informed consent despite the shortcomings in addressing all the key components of informed consent.

9.0 RECOMMENDATIONS

A detailed informed consent form that addresses all the key aspects of informed consent which include the nature of the procedure, its benefits and possible risks, reasonable alternatives to the proposed intervention as well as relevant risks and benefits related to each alternative should be developed.

Similar studies targeting pre-operative counselling for specific disciplines such as cardiothoracic surgery, obstetrics and gynecology, otolaryngology, neurosurgery and orthopaedic surgery will assist in reviewing the current consent form.

A written consent form for anaesthesia that fully outlines the anaesthesia, its possible risks and benefits as well as alternatives to the proposed form of anaesthesia should be developed. The patient and anaesthesia care giver should sign the consent form once the patient has consented to the proposed anaesthesia.

The anaesthesia department should consider having pre-anaesthetic clinics where patients are assessed and counselled on anaesthesia prior to the elective procedure.

The surgery department should consider developing standards of practice for obtaining informed consent for surgery.

STUDY LIMITATIONS

A language barrier with some of the patients necessitated the use of a translator who may have altered the meaning of some of the responses.

Lack of a set time for pre-anaesthetic counselling made it difficult to determine whether pre-anaesthetic counselling for the patients was eventually done or not.

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APPENDIX 1

INFORMED CONSENT FORM

A CROSS-SECTIONAL STUDY OF THE PRACTICE OF OBTAINING INFORMED CONSENT FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

This informed consent form is for patients undergoing elective surgery at the Kenyatta National Hospital.

SECTION I: *Consent explanation*

I am Dr. Muthoni Ntonjira, a third year resident in the Mmed Anaesthesia program. I am carrying out a survey on the practice of obtaining informed consent for elective surgery at the Kenyatta National Hospital in part fulfillment of my post-graduate program requirements.

The objective of this study is to assess the practice of obtaining informed consent for elective surgery targeting on the patients' perspective of the practice. It will highlight key aspects of informed consent such as the information provided to the patient and the patient's level of understanding of the information provided. This survey further aims at establishing any challenges encountered in the process of obtaining informed consent.

You are hereby invited to participate in this study. Participation is entirely voluntary and you are free to withdraw from the study. Refusal to participate in the study will in no way influence your care at the hospital. You will also be accorded the opportunity to request for the results of the study once the study is complete.

All questionnaires will be anonymous and all information provided will be highly confidential.

For any queries arising before and during the course of the study, kindly contact;

1. Dr. Muthoni Ntonjira

Tel; 0722 389501

Dept. of Surgery/Anaesthesia

School of Medicine

University of Nairobi

2. KNH/UON-ERC

Email: uonknh_erc@uonbi.ac.ke

Website: www.uonbi.ac.ke

SECTION II: *Certificate of Consent*

I have read the foregoing information. I understand and agree to the following;

1. My participation in the study is entirely voluntary.
2. I am free to withdraw from the study at any point.
3. Refusal to participate in the study will in no way influence my care at the hospital.
4. I have been accorded the opportunity to ask questions and they have been answered to my satisfaction.
5. I hereby consent to participate in this research.

Name of Participant: .....

Signature: ..... Date: .....

Statement by the researcher

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher: .....

Signature: ..... Date: .....

FOMU YA KUTOA IDHINI

UDADISI KUHUSU SHUGHULI YA KUCHUKUA IDHINI YA UPASUAJI USIO WA DHARURA

SEHEMU YA KWANZA: *Ufafanuzi wa makubaliano*

Mimi ni Dkt Muthoni Ntonjira, mwanafunzi wa mwaka wa tatu wa masters katika kitengo cha anaesthesia. Nafanya utafiti kuhusu uchukuaji wa idhini ya upasuaji usio wa dharura katika hospitali kuu ya Kenyatta hii ikiwa mojawapo ya hitaji la masomo ya post-graduate.

Maudhui ya utafiti huu ni kudadisi uchukuaji wa idhini kwa upasuaji usio wa dharura haswa kujua maoni ya wagonjwa kuhusu uchukuaji wa idhini hii. Utafiti huu utamulika mambo muhimi ya uchukuaji idhini kama vile ujumbe apewayo Mgonjwa na kuelewa kwake kwa maelezo aliyopewa. Utafiti huu pia utabaini kama kuna changamoto zezote katika jitihada za kuchukua idhini ya upasuaji.

Mnaombwa kuhusika katika utafiti huu. Kuhusika katika utafiti huu ni wa hiari na una uhuru wa kujiondoa. Kukaidi kwako kuhusika katika utafiti huu hakutaadhiri huduma utakayopata kutoka kwa hospitali hii. Una uhuru pia kuomba kudurusu matokeo wakati yatakapotokea.

Fomu zote za maswali hazitakuwa na majina na ujumbe wote utawekwa siri.

Ukiwa na maswala yoyote kabla na wakati wa utafiti unaweza kujumuisha wafuatao;

1. Dr. Muthoni Ntonjira
   Simu; 0722 389501
   Dept. of Surgery/Anaesthesia
   School of Medicine - University of Nairobi

2. KNH/UON-ERC
   uonknh_erc@uonbi.ac.ke
   www.uonbi.ac.ke

Asante kwa kujumuika kwako.

Dkt. Muthoni Ntonjira

SEHEMU YA PILI: Idhini

Nimesoma habari ya hapo mbele. Nimeelewa na kukubali kuwa;

1. Kuhusika katika utafiti huu ni wa hiari .
2. Nina huru wa kujiondoa kutoka kwa utafiti huu wakati wowote.
3. Kutohusika katika utafiti huu hakutaadhiri huduma nitakayopata kutoka kwa hospitali hii.
4. Nimekuwa na fursa ya kuuliza maswali juu yake na maswali yote niliyokuwa nayo yamejibiwa barabara.
5. Natoa idhini ya kujumuika katika utafiti huu.

Jina la mhusika.....

Sahihi:..... Tarehe.....

Ujumbe kutoka mtafiti

Nakariri kwamba mhusika alipewa fursa ya kuuliza maswali kuhusu utafiti huu, na maswali yote aliyouliza mhusika yalijibiwa kwa mujibu wa uwezo wangu. Nakariri kwamba mhusika hajalazimishwa na idhini hii imepewa kwa huru.

Jina la mtafiti:.....

Sahihi:..... Tarehe:.....

APPENDIX 2

QUESTIONNAIRE

Serial Number: ..... Date: .....

A: BIODATA

1. Gender:

   Male ☐ Female ☐

2. Age:

   18-28 yrs ☐ 29-38 yrs ☐ 39-48 yrs ☐ 49-58 yrs ☐ ≥ 59 yrs ☐

3. Level of Formal Education:

   None ☐

   Primary school level ☐

   High school level ☐

   Tertiary level ☐

B: TYPE OF SURGICAL PROCEDURE

General surgery ☐ Gynaecology ☐

Orthopaedics ☐ Maxillofacial surgery ☐

Obstetrics ☐ Ear, Nose & Throat ☐

Ophthalmology ☐ Urology ☐

Cardiothoracic ☐ Neurosurgery ☐

Plastic surgery ☐

C: Below are questions with reference to the practice of obtaining informed consent.

1. Were you informed of the nature of surgery?
   Yes ☐ No ☐ Cannot recall ☐
2. Were you informed of the reason for surgery?
   Yes ☐ No ☐ Cannot recall ☐
3. Were you informed of the expected benefits of the surgery?
   Yes ☐ No ☐ Cannot recall ☐
4. Were you informed of the possible complications of the surgery?
   Yes ☐ No ☐ Cannot recall ☐
5. Were you informed of the alternatives to the surgery?
   Yes ☐ No ☐ Cannot recall ☐
6. Were you informed of expected benefits and possible complications of the alternatives to surgery?
   Yes ☐ No ☐ Cannot recall ☐
7. Were you informed of the possible complications if surgery is not done?
   Yes ☐ No ☐ Cannot recall ☐
8. Surgery pre-operative counseling done by;
   Consultant surgeon ☐ Medical officer ☐
   Consultant anaesthetist ☐ M.O intern ☐
   Surgery S.H.O ☐ Clinical officer intern ☐
   Anaesthesia S.H.O ☐ Nursing officer ☐
   Registered clinical officer ☐
   Clinical officer student-(Anaesthesia) ☐
   Cannot recall ☐
   Not done ☐
9. Preoperative counseling on surgery done
   In the clinic ☐
   On admission/in the ward ☐

10. Were you informed of the type of anaesthesia to be administered?

Yes ☐ No ☐ Cannot recall ☐

11. Were you informed of the benefits of the type of anaesthesia to be administered?

Yes ☐ No ☐ Cannot recall ☐

12. Were you informed of the possible complications associated with the type of anaesthesia to be administered?

Yes ☐ No ☐ Cannot recall ☐

13. Were you informed of the alternative forms of anesthesia that can be administered, their risks and benefits?

Yes ☐ No ☐ Cannot recall ☐

14. Anaesthesia pre-operative counseling done by;

Consultant surgeon ☐
Consultant anaesthetist ☐
Surgery S.H.O ☐
Anaesthesia S.H.O ☐
Registered clinical officer ☐
Medical officer ☐
M.O intern ☐
Clinical officer intern ☐
Nursing officer ☐
Clinical officer student-(Anaesthesia) ☐
Cannot recall ☐
Not done ☐

15. Were you given an opportunity to have your questions answered?

Yes ☐ No ☐ Cannot recall ☐

16. Did you understand the information given to you before signing the consent form?

Well understood ☐
Partially understood ☐
Did not understand ☐

17. Were you satisfied with the information provided?

Yes ☐ No ☐

18. Written Consent taken by;

Consultant surgeon	☐	Medical officer	☐
Consultant anaesthetist	☐	M.O intern	☐
Surgery S.H.O	☐	Clinical officer intern	☐
Anaesthesia S.H.O	☐	Nursing officer	☐
Registered clinical officer	☐		
Clinical officer student-(Anaesthesia)	☐		
Cannot recall	☐		
Not done	☐		

APPENDIX 3

KNH 325

KENYATTA NATIONAL HOSPITAL

CONSENT BY PATIENT/ NEXT OF KIN FOR AN OPERATION

I,..... of.....

hereby consent to undergo the operation(s) of .....

.....

the nature and effect of which have been explained to me by Dr. / Mr. .....

I also consent to such further or alternative operative measures as may be found to be neccesary during the course of the operation and to the administration of a local or other anaesthesia for any of these purposes.

* No assurance has been given to me that the operation will be perfomed by a particular surgeon.

Date..... (Signed) .....

I confirm that I have explained to the patient the nature and effect of this operation.

Date ..... (Signed) .....

* Delete if not required.

KNH 325

KENYATTA NATIONAL HOSPITAL

KUKUBALI KWA MGONNJWA / MCHUNGAJI KWA UPASUAJI

Mimi, ... kutoka .....

nimekubali kwenda kwa utibabu wa kupasuliwa kwa .....

.....

Ugonjwa ambao nimesha ambiwa na Daktari au Bwana .....

Mimi tena nimekubali kwa ugonjwa mwingine utakaopatikana wakati wa kupasuliwa na upeanaji wa dawa.

* Sina ukweli yakwamba upasuliwaji wangu utaendeshwa na Daktari yule au huyu.

Tarehe..... Sahihi .....

Nahakikisha yakwamba nimemweleza mgonjwa aina ya ugonjwa namna ya upasuaji.

Tarehe..... Sahihi .....

* Futa kama haitakiwi.

APPENDIX 4

WORK PLAN

ACTIVITY	2011 Aug	2011 Sept	2011 Oct	2011 Nov	2011 Dec	2012 Jan	2012 Feb	2012 Mar	2012 Apr	2012 May	2012 June
Proposal Writing	√	√	√	√							
Proposal Presentation					√						
Presentation to Ethical Review Committee						√	√	√			
Data Collection								√	√	√	
Data Processing										√	
Report Writing										√	
Study Presentation											√

APPENDIX 5

BUDGET

Item	Total cost (KShs)
Biostatistician Fee	25,000
Stationary & Related printing costs	15,000
Internet hours	1000
KNH/UoN Ethics & Research Committee fee	1000
Phone call costs	2000
Miscelleous	1000
SUBTOTAL	45,000
10% Contingency	*4,500*
GRAND TOTAL	49,500

APPENDIX 6

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke
Link:www.uonbi.ac.ke/activities/KNHUoN

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/68

27th March 2012

Dr Ntonjira J. Muthoni
Dept of Surgery
School of Medicine
University of Nairobi

Dear Dr. Ntonjira

RESEARCH PROPOSAL: "A CROSS-SECTIONAL STUDY OF THE PRACTICE OF OBTAINING INFORMED CONSENT FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL" (P10/01/2012)

This is to inform you that the KNH/UoN-Ethics & Research Committee (ERC) has reviewed and approved your above revised research proposal. The approval periods are 27th March 2012 to 26th March 2013.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN -ERC website www.uonbi.ac.ke/activities/KNHUoN

"Protect to Discover"

Yours sincerely

PROF A.N. GUANTAI
SECRETARY, KNH/UON-ERC

c.c. The Deputy Director CS, KNH
The Principle, College of Health Sciences, UON
The Dean, School of Medicine, UON
The Chairman, Dept of Surgery, UON
The HOD, Records, KNH
Supervisor: Dr. Munithi J. Mugo.Dept. of Surgery, UON
Dr. Caroline Mwangi Dept.of Surgery, UON

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