AN INVESTIGATION OF INFORMED CONSENT IN CLINICAL PRACTICE IN KENYA

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JULY, 2008

Sheshia-Odwori,
An investigation of informed consent in
DECLARATION

"THIS THESIS IS MY ORIGINAL WORK AND HAS NOT BEEN PRESENTED FOR A DEGREE IN ANY OTHER UNIVERSITY."

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DEDICATION

This work is dedicated to my husband Brian for his never ending support and my children Nadine and Neville - my sources of inspiration and happiness.
ACKNOWLEDGEMENTS

I would like to express my heartfelt gratitude to the Almighty God for granting me good health throughout the period of study.

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<td>Acquired Immunodeficiency Syndrome</td>
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<td>AKH</td>
<td>Aga Khan University Hospital</td>
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<tr>
<td>CIOMS</td>
<td>Council for International Organization of Medical Sciences</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>KEMRI</td>
<td>Kenya Medical Research Institute</td>
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<td>KNH</td>
<td>Kenyatta National Hospital</td>
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<td>Universal Declaration of Human Rights</td>
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<td>USA</td>
<td>United States of America</td>
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<td>Vs.</td>
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<td>WHO</td>
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CASES


Corn Vs. French, 71 Nev. 280 (289 P. 2d 173) (1955)

Derner Vs. Gerety, 515 P 2d 645 (N. M 1973)

Halushka Vs. University of Saskatchewan, 53 D.L.R. (2d) 436 (1965) 479 (Cal. 1990)

Mohr Vs. Williams, 194 N. W. 12(Minn. 1905)

Natanson Vs. Kline, 350 P 2d 1093(Kan. 1960)

Salgo Vs. Leland Stanford Board of Trustees, 317 P 2d 170 (Cal. 1957).

Schloendorff Vs. Society of New York Hospital, 105 N. E. 92 (NY 1914).

White Vs. Turner 120 DLR (3d) 269 at 283 per Linden J. (1981).

STATUTES

The Anatomy Act, Cap 249 (Rev 1968)

The HIV and AIDS Prevention and Control Act, 2006

The Human Tissue Act, Cap 252 (Rev 1967)
ABSTRACT

Consent to medical treatment is considered essential in a doctor-patient relationship. However, cases of breaches abound. Informed consent involves the elements of information, comprehension and volition. The information provided must be sufficient, understandable and there must be no coercion or undue influence in its procurement. The purpose of this study was to investigate the extent to which informed consent is applied in clinical practice in Kenya. Aga Khan University Hospital (private) and Kenyatta National Hospital (public) were purposively selected for the study. The study sample consisted of 401 inpatients and 46 doctors drawn from the Surgical, Paediatric and Obstetrics and Gynaecology departments. Data was collected using a pre-tested interview schedule for patients and a semi-structured questionnaire for doctors. The independent variables in the study were age, sex, marital status, occupation, income, languages spoken and education level. The dependent variables were information, comprehension and volition. The Statistical Package for Social Sciences (SPSS) was used to treat data. Data was presented using graphs, pie charts, frequency tables and percentages. The Pearson Chi Square test was used to test for relationships between variables. The findings of the study showed that the information provided to patients was not sufficient to procure informed consent since it focused mainly on diagnosis (82.7%). There was a disparity in the responses of information provided on risks (patients 23.1%, doctors, 76.1%) and benefits (patients 31.1%, doctors 91.3%). The Pearson chi square test showed a significant association between marital status and whether any information was provided or not ($\chi^2 = 8.569$, df =1, $p=0.003$). The oral method (words) was predominantly (80%) used to provide information to patients. Although a majority (84.2%) of patients said they understood the information provided only 58.7% of the doctors’ concurred. The use of technical language was identified as a major barrier (patients 21%, doctors 33%) to comprehension. The Pearson chi square test showed a significant association between marital status and whether one asked questions on medical treatment or not ($\chi^2 = 14.633$, df = 1, $p=0.0001$). Although most (92%) patients provided consent voluntarily, 55.4% of the patients did not know they had an option to accept or decline treatment. The Pearson Chi-square test showed a significant association between volition and marital status ($\chi^2 = 7.702$, df =1, $p=0.006$). The Pearson Chi square test also showed a significant association between department and type of consent given ($\chi^2 = 81.9$, df =2, $p=0.000$). Written consent was more likely to be provided in the surgical department where invasive procedures are carried out. The study concludes that information provided to patients prior to obtaining consent is insufficient, findings on comprehension are inconclusive and patients provide consent without coercion or undue influence. The results of this study lead to the inexorable conclusion that although consent is obtained in clinical practice in the two hospitals under study, it is not informed and comprehensible. The study recommends training of medical doctors on the art of communication in order to enhance the doctor-patient relationship. It also recommends that the Ministry of Health enhance public education and awareness on medical rights and develop National guidelines for the process of obtaining informed consent.
CHAPTER ONE  INTRODUCTION

This chapter presents the background of the study, definition of informed consent, history and development, case law and challenges to informed consent in third world countries. It also provides a statement of the problem, justification, research questions, hypotheses, objectives, significance and anticipated output of the study, definition of terms, assumptions and limitations to the study.

1.1 Background to the study

Consent to medical treatment is widely regarded as the cornerstone of a doctor/patient relationship. Patients cannot be required to accept treatment that they do not want no matter how painless, beneficial and risk free the treatment is (Jones, 1996). It is widely believed that knowledge gives freedom. For one to choose the most appropriate course of action, he/she must appreciate all aspects of a situation and all the possible alternatives. We need information in order to make a right decision, to manage our behaviour and to be independent. To be informed is therefore a fundamental human right since appropriate behaviour depends on information (Rotemberg, 1996). This proposition is recognized as both an ethical principle and a legal rule, and is founded ultimately on the principle of respect for the patient’s autonomy, and on the patient’s ‘right’ to self-determination (Jones, 1996). Thus, the doctrine of informed consent has evolved to facilitate self-determination in a medical setting (Svoboda et al., 2000).

The doctrine of informed consent is a rule of law that requires that no diagnostic or therapeutic procedure shall be performed on a patient without the patient having been told about the risks of the procedure and the alternatives to it prior to giving his/her consent (Bucklin, 1975). Informed Consent is defined as an autonomous authorisation of
medical intervention by individual patients (Ijsselmuiden & Faden, 1999). As a general rule, medical treatment should not proceed unless the doctor has first obtained the patient’s consent which can be expressed or implied, as it is when the patient presents himself to the doctor for examination and acquiesces in the suggested routine (Mason & McCall Smith, 1987).

1.1.2 History and Development of Informed Consent

The evolution of the doctrine of Informed Consent can be traced back to the quiescent period in the transformation of the Hippocratic Oath. During this period the Oath was paternalistic and authoritarian in nature. The patient had no say in clinical decisions and the doctor had all the authority in a doctor-patient relationship (Wekesa & Asiema, 2003). Over the years the Hippocratic Ethic underwent transformation. Factors such as a more educated society, distrust for authority and the spread of participatory democracy led to a demand for alternative ways of practising medical ethics. Principles suitable for medical ethics such as nonmaleficence, beneficence, autonomy and justice were adopted. The principle of autonomy became central to the doctrine of informed consent where a patient was seen to have a right to self-determination (Jones, 1996).

The doctrine of informed consent was elucidated by Justice Cardozo in 1914 in the landmark case of Schloendorff Vs Society of New York Hospital. In this case, a woman had consented to an abdominal examination under anaesthesia, but had not consented to any operation. In spite of this, the doctor found and removed a tumour from the woman’s abdomen and the patient sued. The Judge ruled in favour of the claimant and stated that:
'Every human being of adult years and sound mind has a right to determine what shall be done to his own body and a surgeon who performs an operation without his patients' consent commits an assault for which he is liable to damages.'

This case reinforces the fact that a human being has a right to autonomy and self-determination and cannot be compelled to accept treatment he/she does not want (Bucklin, 1975).

The first major document incorporating human rights principles that centred on the professional responsibility of the physician to the patient was the Nuremberg Code (Annas, 1999). After the Doctors' trial of 1946 - 1947, the Nuremberg Code was developed to guide biomedical research. The Judges decided that for experiments to be carried out, voluntary consent of the human subject was essential. This they said required that:

"The person involved should have legal capacity to consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

The Nuremberg Code abandons the earlier paternalistic view of medicine and research and replaces it with the centrality of patient self determination. The doctrine of informed consent as spelled out in the first principle of the Nuremberg Code above comprises the elements of information, comprehension and volition (Jones, 1996). The requirements of voluntary, competent, informed and understanding consent now generally apply not just to experimentation but treatment as well (Annas, 1999). This Code later became the prototype for many other codes (Belmont Report, 1978). Critics of the Nuremberg Code argue that it was promulgated as a human rights legal document
and that the judges involved made no provisions to deal with clinical research on children (Furlow, 1980), healthy volunteers or mentally impaired people (Annas, 1999). Proponents of the code feel that it should simply be viewed as a universal document and interpreted as a guide to suit varying scenarios (ibid, 1999).

According to the Universal Declaration of Human Rights that was promulgated in 1948, respect for persons is a fundamental human right that relates to the respect for dignity of every individual, protection of the rights and welfare of every human subject. Article 5 provides for seeking of informed consent prior to medical or scientific experimentation and says that:

"...In particular, no one shall be subjected without his free consent to medical or scientific experimentation."

In 1964, The World Medical Council produced the Declaration of Helsinki, which further elaborated on the fundamental guiding principles in research involving human subjects. The Helsinki Declaration, though more paternalistic in nature also seeks to enforce the elements of the doctrine of informed consent. It provides that:

"In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomforts it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring the subject has understood the information, the physician should then obtain the subject's freely - given informed consent preferably in writing. If the consent cannot be obtained in writing, the non written consent must be formally documented and witnessed."

The Helsinki Declaration, unlike the Nuremberg Code, seeks to protect those with diminished autonomy such as the mentally retarded and children by directing that the
investigators obtain informed consent from a legally authorized representative in such cases (Zimmerly, 1973). It further states that:

"In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject ... In any medical study, every patient - including those in the control group, if any - should be assured of the best proven diagnostic method."

The Helsinki Declaration was developed by doctors for doctors and aimed at replacing the Nuremberg Code with a more lenient medical ethics model (Annas, 1999). This Code divided research into therapeutic and non-therapeutic, thus blurring the line between treatment and research (Furlow, 1980). In interpreting the Helsinki Declaration, research becomes treatment, the researcher becomes the healer and the subject becomes the patient. Language is herein used to mask the truth and lend credence to unjustifiable activities (Wekesa, 2004).

The Belmont Report articulated the three basic ethical principles that provide guidelines in resolving ethical problems surrounding research involving human subjects and distinguishes the boundaries between medical practice and research. These principles are largely compatible with the World Medical Association’s Declaration of Helsinki. The principles identified are: respect for persons, beneficence, non-maleficence and justice. The principle of Respect for Persons recognises one’s right to exercise autonomy and encompasses the doctrine of informed consent (Pelias, 2004; Varmus, 1997). It recommends that an individual be treated as an autonomous agent capable of deliberation about personal goals and self-determination. This requires that one be provided with sufficient and accurate information whether for new therapy in cases of treatment, surgical procedures or in clinical research. It also speaks for fairness in
treatment/ research by not restricting the availability of new treatments (National Bioethics Advisory Commission, 2001).

Informed Consent in clinical practice as shown by history has evolved over the years from a situation where the ‘doctor knows best’ to one that requires shared decision making between the doctor and patient (Bailey, 1978).

1.1.3 Cases Studies on Violation of Informed Consent

Although the doctrine of informed consent has been incorporated in many ethical and legal codes over the years, there are cases of violation that have been documented worldwide indicating lack of adherence to the recommended standards. A review of internationally recognized Medical journals showed that 47% of the studies done were published without recording informed consent and 58% did not record approval by an ethics review committee, yet this is a requirement of the Helsinki Declaration (Smith, 1997).

The Tuskegee study of untreated syphilis that lasted 40 years from 1932-1972 in Alabama, USA provides a classical example of unethical research that violated the doctrine of informed consent. In this study, 1,400 poor Afro-American men were used as a control group for monitoring the natural history, side effects and rate of fatality of syphilis. These men were kept in total ignorance of the experiment, their infection, and the seriousness of syphilis. They were not provided with any form of treatment for the entire period of the study, yet there was a professional standard of care that involved treatment of syphilis with heavy metals and later, penicillin. The subjects were told that they were being treated for bad blood and only received money for burial. Three out four participants died from complications of syphilis and many survivors became blind and
crippled. These men, contrary to the requirements of informed consent were provided with insufficient and inaccurate information (Varmus & Satcher, 1997).

During the cold war period of 1940-1970, the US Government via the Atomic Energy Commission conducted radiation experiments without seeking consent from the subjects involved. The US physicians injected hospital patients with radioactive substances to study their effect on the body. In these studies, the doctors involved defended themselves by blurring the distinction between therapy and research (Annas, 1999) and said

‘... palliative therapy was being provided for patients for whom there was no better alternative.’

The Nazi experiments of 1942-1945, later classified as crimes against humanity-involved prisoners in concentration camps, mainly Jews, Gypsies and Slavs (Annas, 1999). These experiments were carried out by Nazi doctors. No consent was sought from those used as guinea pigs in the high altitude, cold and sea water experiments. Neither did the subjects volunteer. Also, no subject was at liberty to withdraw from the experiments. These crimes against humanity occurred yet the Nazis had on 24th November 1933 passed a law for the protection of animals that was explicitly designed to prevent cruelty and indifference by man to animals even when carrying out experiments. This law focused on developing sympathy and understanding for animals as one of the highest moral values of people. With such a law on animals in place, the human beings involved in the Nazi experiments should at least have been treated with equal humanity (Taylor, 1999).

The Cartright Inquiry of 1987 brought to light ‘the unfortunate experiment’ that violated the doctrine of informed consent. This experiment had been carried out at the
National Women’s Hospital in Auckland, New Zealand between 1955 and 1976. The purpose of ‘the unfortunate experiment” was to examine the natural history of cancer in situ of the cervix. Nine hundred and forty eight women who had a positive pap smear were recruited into the study. Out of these, 131 women were enrolled in the control group and were not provided with any form of treatment even though the risk of progression to invasive fatal cancer was known to be 25 times higher in untreated women as compared to women on treatment. Also untreated women had a 12 times greater chance of dying than treated women. Worse still the ‘subjects’ in this study were not told that they were being used as ‘guinea pigs’ in medical research. They were denied the right to individual autonomy and rational decisional making, both basic tenets of informed consent in biomedical research (Young, 2005).

More recently, clinical trials to reduce peri-natal transmission of HIV in developing countries did not follow the laid down guidelines. In these trials where Kenya was among the study countries more than 17,000 pregnant women were enrolled. No antiretroviral drug was provided to those in the control group. This occurred despite the fact that Zidovudine had been shown to reduce the incidence of HIV transmission by two thirds as early as 1994 in a randomized controlled study in United States and France. At that point, the randomized controlled study in United States was terminated in the first interim analysis and Zidovudine became the standard of care for all HIV-infected pregnant women in the United States of America (Lurie & Wolf, 1997). Also, in a Uganda study involving various regimens of prophylaxis against tuberculosis in HIV infected adults, HIV positive patients who tested positive for tuberculin skin tests in the control group were given placebos. However the recommended standard treatment of care provided in the United States at that time was that tuberculin test positive persons
with HIV infection receive prophylaxis against tuberculosis (Varmus & Satcher, 1997).

In 2004, the Human Rights Watch reported cases of women in the Dominican Republic who were sterilized because of their HIV status without receiving full information about their rights and status (www.hrw.org). The patients in these studies were provided with insufficient and inaccurate information, and thus consent obtained from them cannot be said to have been informed.

The foregoing cases took place at a time when there were at least three legal instruments in place, the Universal declaration of Human Rights (1948), the Nuremberg Code (1948) and the Helsinki Declaration (1964) that provided for informed consent had been accepted throughout the world many years earlier.

1.1.4 Challenges to Informed consent in third world countries

In third world countries, where education standards and literacy levels are low, knowledge asymmetry on medicine and health issues exists between patients and health care professionals. However, the doctor has a duty to explain a clinical procedure without turning the patient or his family into medical students (Lore, 1993). The big question is how much information therefore should a doctor give a patient or the patient’s family before they feel informed enough to make a decision?

The ability to use written information is important to comprehension and understanding (Green et al., 2003). Barriers to communication arising from illiteracy and language differences may prevent a common understanding of medical procedures putting a patient at risk of providing consent without comprehension (Richter et al., 1999). How then does a doctor ensure that a patient understands a procedure prior to providing consent?
Presently in Kenya, 46% of the population live on less than a dollar a day (Kenya Integrated Household Budget Survey, 2005/6). Basic health care is therefore unaffordable and out of reach for a large proportion of the population. Any offer of medical assistance among such a vulnerable group is seen as better than nothing thus encouraging undue influence (Annas & Grodin, 1999). Also, some African societies are paternalistic in nature and sometimes require that consent first be obtained from village elders or men as heads of households before the actual subjects provide consent. The challenge here then is to ensure that such consent is not substituted for individuals’ consent which should be obtained voluntarily and not through coercion (Ijsselmuiden & Faden, 1999).

A study carried out at the University of Benin in Nigeria on Current Practices and Medico-Legal aspects of informed Consent revealed that the quality of consent obtained from the average patient fell below the expected standard. Some patients felt that the information provided to them was insufficient since they were not explained to the need of the operation; others were not informed of the nature of the operation while others were not provided the opportunity to ask questions. Use of technical terms by doctors was identified by some patients as a hindrance to understanding the information provided. Also the fact that doctors ‘were in a hurry’ during consultation meant that they had little or no time to explain procedures to the patients (Osime et al., 2004).

In Kenya work has been done to establish the extent of informed consent in biomedical research by KEMRI researchers. In a study carried out in Kilifi district on the Myths and Misunderstanding of informed consent, the researchers sought to investigate whether participants recruited into hospital and community based studies understood the studies and consented voluntarily. They found that most participants did
not distinguish between clinical practice and research and others consented because they thought refusal to do so would deny them access to treatment (Molyneux et al., 2004).

1.2 STATEMENT OF THE PROBLEM

In Kenya, low education standards coupled with high illiteracy levels and the information asymmetry that exists in a doctor-patient relationship may make it difficult for a large proportion of the population to comprehend the medical procedures. Consent forms for treatment procedures often written in a language that is not well understood by a majority of patients may make the situation even worse. Translation on the other hand may not provide an accurate representation of what is at stake. Worse still, voluntary consent is sometimes problematic and difficult to obtain since any promise or offer of medical assistance or other assistance incidental thereto is considered to be better than nothing and may encourage undue influence. Also, the power imbalance that exists between a doctor and a patient may create an intimidating environment that inhibits a patient from refusal to consent. In the light of the foregoing, this study sought to establish whether consent obtained from patients in clinical practice in Kenya is informed, comprehensible and voluntary.
1.3 RESEARCH QUESTIONS

1. Is sufficient information provided to patients involved in clinical practice before consent is obtained in Kenya?

2. Does the patient understand the medical procedure in treatment before he/she provides consent?

3. Do patients involved in medical procedures in Kenya consent voluntarily?

1.4 NULL HYPOTHESES

The study assumed the following hypotheses:

1. Patients in Kenya are not provided with sufficient information in clinical practice prior to providing consent.

2. Patients in Kenya do not comprehend the information given in clinical practice before they provide consent.

3. Patients in Kenya do not consent voluntarily to medical procedures.

1.5 OBJECTIVES OF THE STUDY

The general objective of this study was to establish whether informed consent is obtained from patients prior to involvement in a clinical procedure in Kenya.

The specific objectives of the study were:

1. To determine whether sufficient information is provided to patients in clinical practice before consent is sought.

2. To establish whether patients involved in clinical procedures understand the information given.

3. To establish whether consent is obtained from patients voluntarily.
1.6 JUSTIFICATION FOR THE STUDY

Informed consent is a public health concern that impacts on the population whose health rights and human right must be protected. It also impacts on the quality of health care service delivery in Kenya. No study has been carried out to establish the extent to which the concept of informed consent is applied in clinical practice in Kenya. This study seeks to create new knowledge and to fill the gaps on consent in literature on the subject of informed consent.

1.7 SIGNIFICANCE OF THE STUDY AND ANTICIPATED OUTPUT

The study will be useful in improving the quality of care provided to patients by protecting their autonomy; protection of human rights, dignity and respect for persons; reducing the amount of possible litigation and enhancing the responsibility of health care providers towards the patients. The results of the study will assist in enhancing patient education and awareness; reinforcement of patients' rights and protection; and be beneficial to legislators.

1.8 LIMITATIONS OF THE STUDY

Due to limited financial resources and data collection procedures this study was carried out in two teaching hospitals in Nairobi Province only.

1.9 ASSUMPTIONS OF THE STUDY

It was assumed that patients freely and willingly gave the requisite information. It was further assumed that health care providers gave accurate information.
1.10 DEFINITION OF TERMS

**Information** in this study is defined as sufficient and accurate, including risk, benefits and alternatives to the procedure.

**Comprehension** in this study is defined as the ability to understand, in a language that can be communicated between the doctor and the patient.

**Volition** in this study is defined as free from coercion or undue influence.
CHAPTER TWO  LITERATURE REVIEW

The literature review will focus on past relevant case law, statutes and studies on the concept of informed consent and its constituent elements, which include information, comprehension and volition.

2.1 Concept of Informed Consent

Informed consent is a prerequisite for any medical intervention. Legal and ethical requirements in health care provide qualifications of information disclosure and focus on procedures to obtain a valid consent (Verheggen & Wijmen, 1997). The doctrine of informed consent comprises the elements of information, comprehension and volition (Jones, 1996). A doctor has a medical duty to find the source of malady in a patient if there is any. Once identified, the doctor has an ethical and legal duty to engage the patient in the consent process. The consent process begins when the initial contact is made with the prospective patient and goes on throughout the course of the treatment process. Consent may be oral or written, thus a consent form regardless of detail is only documentary evidence and cannot guarantee consent. It can be rebuffed in a court of law if it is proved that elements of information, comprehension and volition were not provided (Jones, 2000). The only exception is in emergency cases where if a patient presents unconscious, the defence of necessity will be available and in such instances consent is implied. In dealing with minors or adults that are unable to consent, proxy consent should be obtained from the spouse, parents or guardians of the patient (Mason & McCall Smith, 1987).
In Kenya, there are statutes and codes in place that provide for informed consent. The Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004) state clearly the requirements for conducting research. This document emphasizes the paramount need of obtaining informed consent from research participants and highlights the elements of information, comprehension and volition. The HIV and AIDS Prevention and Control Act 2006 of Kenya Part IV, Section 14 provides guidelines for blood testing for HIV purposes and says that, a patient must undergo pre and post test counselling and be provided with sufficient information that will allow him/her to make an informed decision on whether to undergo HIV testing or not. It also stipulates that informed consent be obtained from patients prior to HIV testing. The Anatomy Act Section 5 says that prior to his/her demise a deceased person must give consent for the body to be examined anatomically upon death. The Human Tissue Act requires consent of the deceased prior to his/her demise or of the person in lawful custody of the body before any tissue can be removed.

The Informed consent doctrine seeks as far as is practically possible to ensure that patients take responsibility for ultimate decision making over matters which carry potentially weighty consequences for their future and their lifestyle and is therefore not only relevant to invasive procedures but other clinical decisions as well (Braddock et al., 1997). Emphasis on the process of informed consent should ensure that information is fully disclosed, that competent participants fully understand the treatment in order to make informed choices, and that decisions to participate or not are made voluntarily (National Bioethics Advisory Commission, 2001).

In the classic case of Mohr v. Williams (1905), a physician obtained Ann Mohr's consent to an operation on her right ear. While operating the doctor determined that it
was the left ear that needed surgery and he proceeded to operate on it. A court found that the physician should have obtained the patients consent to surgery on the left ear. The court ruled that:

'...the doctor needs to advise a patient on all information related to a medical procedure and must review all risks and benefits. Only after this exchange does a patient enter into contract, a contract that authorizes the physician to operate only to the extent of the consent.'

Informed consent as shown by the case of *Mohr Vs Williams* (1905) is a process between physician and patient that must contain an information component and a consent component. The information component refers to the full disclosure of information and comprehension of what is disclosed. The consent component refers to a voluntary decision based on competence and agreement to undergo a recommended procedure.

2.2 Information

Information disclosure was explicitly defined in the Nuremberg Code (1949) as follows:

"... Before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected and the effects upon his health or person which may possibly come from his participation in the experiment."

There are two approaches used in providing information in clinical practice. The first is the therapeutic privilege approach which is more paternalistic and accepts that since treatment is meant to be beneficial to patient then it is legitimate to with hold information that would serve to confuse or distress the patient. The second approach
fulfils the requirement of self determination and is of the view that a doctor needs to disclose all the facts about what he/she intends to do and it is not for him/her to determine what the patient needs to hear. The standard of information provided in the latter case must be that of a 'reasonable patient'-rather than that of the 'reasonable doctor'. The requirements of informed consent favour the second approach and emphasize respect for a patients' legitimate interest in totally knowing what he/she is subjecting oneself to. The patient in this case must have sufficient and relevant information. Sufficient information is defined as that which an average person in the patients' position would want to have in reaching an informed decision. Relevant information is that which would have a bearing from the patients' perspective on medical care (Mason & McCall Smith, 1987). The modern approach in clinical practice is patient centred and so this study focuses on the reasonable patient standard.

In *White Vs Turner*, the claimant was unhappy with the large size of her breasts. She requested the doctor to reduce the size through surgery. After the surgery, the incision opened, the patient suffered notable scarring and her breasts were boxy as opposed to round. The patient sued for failure by the doctor to warn of possible risks such as scarring and loss of shape. The doctor was found negligent for failure to fully disclose and the court held that:

"...no longer does the medical profession alone collectively determine by its own practices the amount of information the patient should have in order to decide whether to undergo an operation."

*White* speaks for the modern approach of full disclosure of information based on a reasonable patient rather than a reasonable doctor standard:
A patient bears the risk of incident injury to a procedure and it is therefore his/her prerogative to choose whether or not to accept the risk. On the other hand, the doctor has a duty to provide information based on an objective rather than subjective standard. Although doctors' fears about not wanting to inform patients about risks may be well founded, they may not be accepted not only by the courts but also on ethical grounds due to unjustifiable paternalistic assumptions. Doctors should use communication tools and seek assistance from health communication experts in order to provide patients with the facts needed about the risks, benefits and alternatives to a given medical or surgical procedure (Bucklin, 1975).

A study carried out at University of Umea, Sweden on 'Quality of information and informed consent' examined whether the participants in a clinical trial had perceived adequate information about the trial. Fifty three women drawn from 8 centres were sent a questionnaire focusing on the quality of information given to them 18 months after the trial ended. The researches sought to know whether the participants were aware of the aim of the trials and whether they knew they had the option to withdraw at any time during the trial. Forty three women returned the questionnaire. Seven (16.2%) women said they were not aware of the aim of the trial, 5 (11.6%) women were not aware that a second laparoscopy would be required and 17 (39.5%) said they had no information on the possibility of withdrawing from the study whenever they wanted. Overall, 22 (51.2%) women considered the information they had been given as good or very good. The study concluded that the information provided to the research participants during the trial had been inadequate (Lynoe et al., 1991). Our study also focused on the sufficiency of information provided.
In many African settings the asymmetry of information and knowledge that exists between a physician and his patients acts is a barrier to provision of adequate information. While the doctor is knowledgeable in medicine as a discipline by virtue of his training, patients may be lay members of the community who have no knowledge on medical issues but require to be given information without being turned into medical students in order for them to make informed choices. Thus, doctors have an obligation to provide information in simple language without distortion of medical facts so that the patient makes an intelligent and informed decision. In many African settings provision of sufficient information may not be practical and achievable given limitations of time and cultural issues (Lore, 1993). This study examined the challenges faced by doctors in the process of obtaining informed consent.

Patients generally have a relatively high desire for information. Doctors do not always fulfil the duty of disclosure even when dealing with competent adults. With respect to some procedures it is common practice for patients to be given less information than they would require to enable them participate meaningfully in decision making. Patients should be provided with all information including diagnosis, risks, benefits and alternatives to treatment, otherwise a patient’s discovery that he was not given all information in treatment can undermine his/her ability to deal effectively and positively with any adverse effects of a medical procedure. The duty of disclosure of information on a medical procedure or on the nature of sickness arises from the principle that an individual’s right to self-determination entails a right to know the truth and to receive all information so that the treatment decision is the individual’s own rather than someone else’s decision (Svoboda et al., 2000). Our study examined the sufficiency of
information provided to patients based on diagnosis, risks, benefits, alternatives provided and recommended treatment.

In *Salgo Vs Leland Stanford Jr. University Board of Trustees*, a patient was diagnosed with symptoms of acute arteriosclerosis. The patient was told he required complete examination which would require injection of an anaesthetic into the aorta. He was not informed of the potential risk of paralysis following aortography. Unfortunately after the procedure the patient suffered paralysis from the waist down. The court ruled that:

"...a physician violates his duty to the patient and subjects himself to liability if he withholds any facts that are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."

In *Salgo* the patient was provided with inadequate information and his consent was thus not fully informed.

Also in *Canterbury Vs Spence*, the patients’ mother consented to a surgical procedure that required a laminectomy. The doctor did not disclose the risk of paralysis in such a procedure. The patient suffered paralysis and sued the doctor for lack of complete information disclosure. The court ruled that:

"...respect for the patients right to self-determination on a particular therapy demands a standard set by law for physicians rather than one which physicians may /may not impose upon themselves... the patients' right of self decision shapes the boundaries of the duty to reveal."

The court emphasised the importance of even the slightest risk of a procedure being disclosed to a patient especially if the consequences are severe. It also said that a patient’s true consent to what happens to himself is informed exercise of choice entailing
an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.

In *Haluka Vs. University of Saskatchewan*, a student volunteered to be tested for a new anaesthetic in return for a Canadian $50 payment. He was told the drug was safe. The patient suffered a cardiac arrest that left him with permanently impaired mental ability. The information he was given was inaccurate and insufficient since the drug had not been tested. The doctor was found guilty of negligence. He had violated the doctrine of informed consent by providing false, incorrect and misleading information for a non-therapeutic research procedure. The judge stated that:

‘...there can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary practice’.

The ruling in *Haluka* points to the importance of full information disclosure whether for research or treatment purposes.

The real enemy of proper informed consent in medicine is not the inability of adult patients to engage in the process but the insufficient resources to train doctors to communicate more effectively with their patients and inadequate staff to allow enough time for this essential communication to occur. In practice the boundaries of how much information to reveal should be guided by what the doctors themselves would wish to know in similar circumstances or what they would want to be communicated to their close friends or relatives (Doyal, 2002). In this study the aspect of doctor-patient communication in the process of obtaining informed consent was examined.

Information is important since it enables a patient or guardian to take control and make informed choices. The law is increasingly subjecting health care professionals to greater scrutiny and broader liability. Doctors need to protect themselves from liability
by providing any and all information deemed necessary to allow patients to make an informed choice.

2.3 Comprehension

Comprehension, another key element of informed consent focuses on ensuring that a patient understands the information given. According to the Belmont Report (1979) on ethical principles for the protection of human subjects in research, information must be provided in a language that can be understood bearing in mind the level of intelligence, rationality, education and maturity of the patient. The ability to comprehend the information may be determined by the language of communication and the literacy levels of the patient concerned. Representatives for those with diminished autonomy such as children also need to understand the treatment procedures and act in that persons' best interest. The same applies in cases of persons with mental or behavioural disorders (CIOMS, 1993).

The requirement of comprehension imposes on a doctor the duty to assess whether a person is capable of making a rational decision based upon the information provided by evaluating whether the patient understands the information. While it may be easier to assess the adequacy of information disclosed and imparted, it is far more difficult to assess whether the information is understood. Some authors are of the opinion that a patient's understanding is often limited not so much by his inherent inability to comprehend but by the clinician's inability to convey the information understandably (Richter et al., 1999).

In the case of *Corn Vs French* a patient had signed consent for a mastectomy and haemorrhoidectomy not knowing what those words meant. However she had insisted
that at no stage of surgery should her breasts be removed. The doctor went ahead to remove the plaintiffs' breast. The judge in his ruling said,

"The doctor's removal of the plaintiffs' breast had been contrary to her express oral instructions and could not be protected by the plaintiffs' formal written consent to same."

In the case of Demer Vs Gerety a 40-year-old Mexican man with little education (sixth grade) was to undergo an operation for a hernia. He, however, insisted that the operation should not involve surgery on a previous ileostomy. During the repair of the hernia the doctor revised the ileostomy. In its opinion the court held that the patient who spoke broken English had consented to the hernia operation on condition that the existing ileostomy remain untouched and the patient's wish should thus have been respected. The cases of Demer and Corn emphasize the importance of comprehension by the patient prior to procuring informed consent.

In a cross sectional retrospective study carried out at the University of Washington, Department of Medicine to establish how doctors and patients discuss routine clinical decisions, assessment of patient's understanding was one of the elements categorized. In this study two office visits with different patients for each physician were randomly sampled. Thus, 88 visits involving 44 physician audio taped encounters between doctor and patient were analyzed for elements of informed decision making. Data was analysed using a One-way ANOVA and Non parametric tests, Kruskal Wallis and Cramer's V statistic for nominal variables. The findings of the study showed that the least (2%) frequently discussed element in informed decision making was an assessment of patients' degree of understanding (Braddock et al, 1997). The University of
Washington study focused on assessing comprehension of patients in an out patient setting, our study was carried out on inpatients only.

Courts seem to place more emphasis on disclosure of information at the expense of understanding of the information. Language needs to be used to the advantage of patients to enable them understand the diagnosis, risks, benefits and alternatives in treatment (Annas, 1999). Our study examined the languages used by doctors and patients during consultation.

Disclosure of information requires no special skill. The skill lies in communicating the relevant information to the patient in terms which are reasonably adequate for that purpose-having regard to the patient's apprehended capacity to understand the information. Where a patient has language difficulties the doctor has a special duty to ensure the patient understands a medical procedure before consenting even if it means requesting for an interpreter. Studies have found that some form of written disclosure either alone or in combination with verbal disclosure impart greater comprehension than verbal disclosure alone (Svoboda et al., 2000). This suggests that where practically possible doctors should use other methods in addition to oral presentation to relay information. In this study, methods used to provide information to patients in order to enhance their understanding were examined.

An article on providing insight on ways of enhancing the level of comprehension for purposes of obtaining consent for child related medical research among communities notes that most doctors write and speak at the same level to patients as they do for peers thus making it difficult for patients to provide true consent. Language used in communicating information is important whether it be face to face explanations or printed words. Plain language statements that constitute common every day words,
active rather than passive voice, use of short rather than long sentences and simple rather than technical language that does not sacrifice technical knowledge need to be used to enhance understanding. This is even more important in cases where parents act as proxy decision makers for their children and must bear the consequences for their decision. The blurred line that separates clinical research and treatment advocates for similar requirements of comprehension in procuring informed consent in clinical practice (Green et al., 2003). In our study corroboration of languages used in obtaining informed consent between patients and doctors was examined.

Even when dealing with educated persons no assumptions should be made on comprehension and explanations of the details of an operation are mandatory. The discussion of a clinical procedure needs to be carried out in a non-technical language to allow for maximal interchange of information between a patient and a doctor and ensure that the patient understands the information provided (Kyambi, 2004). This study examined the patients’ level of education as well as ability to understand the information given and whether there was any association between the two variables.

Researchers from the Kenya Medical Research Institute (KEMRI) and the University of Oxford’s Centre for Tropical Medicine carried out a study that examined whether parents’ understood what they were consenting to when they allowed their children to be involved in three different research case studies that required taking blood samples. This study was named the ‘Consent study’. The Consent study was carried out using informal and semi structured interviews as well as structured observations of the consent process. The sample size consisted of a total of 29 staff members, 154 parents and 120 structured observations of the consent process. The findings of the study showed that, some participants were unable to distinguish between clinical practice and
research and the messages about research became distorted or lost along the way in the researcher-communicator-parent chain. This was attributed to cultural differences in concept and terminology and the fact that translators for the study may have simplified the information and focused on aspects that were easier to explain or would persuade people to give consent. The “Consent” study in Kilifi looked at the views and understanding of the participant’s representatives in biomedical research and expressed the difficulty of ascertaining that patients comprehend procedures in research even when translators are availed (Molyneux et al., 2004). Our study examined the element of comprehension in clinical practice and corroboration between doctors and patients understanding was undertaken with an aim of establishing the extent of patient comprehension.

A study carried out at the University of Benin, Nigeria (Osime et al., 2004) sought to evaluate the practice of obtaining informed consent pre operatively. This study involved administration of an interview schedule to 133 patients in the surgical department of the hospital. Data was analyzed using simple percentages, cross tabulation and chi square. The findings of the study showed that only 81 patients (60.9%) were given the opportunity to ask questions or make comments. As a result of not being given the opportunity to ask questions, 50% of the patients claimed that they were not satisfied with the amount of pre-operational information given to them. Nevertheless, only 18(13.5%) out of 133 patients said they had difficulties understanding the information given to them. Five (3.8%) complained that the doctors used technical terms they could not understand, while 8 (6%) said the doctors had little or no time to explain anything to them since they were in a hurry. The patients gave consent, however, to prevent their operations being cancelled. An ideal consent for an operation demands an explanation to
be made to patients in a manner that they understand before consenting. The findings of this study show that some patients provided consent without fully understanding the information provided to them and such consent which falls below the expected requirements and cannot be said to be informed (Osime et al., 2004). The Nigerian study was undertaken only in the surgical department of a teaching hospital and focused on the elements of information, comprehension and volition. This study was carried out in two teaching hospitals and involved inpatients in three departments, namely the surgical, paediatric and obstetrics & gynaecology departments. It also looked at three elements of informed consent.

The above studies present a pertinent issue that focuses on the need to improve the levels of patients' understanding. Medical schools and internship programs need to emphasize better communication skills required to conduct brief, focused and yet comprehensive discussions leading to medical decisions (Braddock et al, 1997).

2.4 Volition

Another component of informed consent is volition. Volition is concerned with the protection of the patient’s right to make health care choices free of coercion or undue influence. Coercion occurs when there is threat of harm to the patient if he/she does not comply. Undue influence occurs through an offer of excessive or improper reward in order to obtain compliance. Any form of inducement can be undue influence if the subject is vulnerable.

In the Nuremberg code (1949), it is stated as follows:

'The duty and responsibility of ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a
personal duty and responsibility, which may not be delegated to another with impunity.

The Helsinki Declaration (1964) also provides for obtaining consent voluntarily for those with capacity and proxy consent for those who lack capacity such as minors. Free choice requires no omission, manipulation or distortion of information. An uninformed decision to follow the recommendation or suggestion of a medical professional is in effect a choice coerced by the medical professional and cannot be said to be voluntary. The Belmont Report (1979) provides for the principle of respect for persons which incorporates two ethical convictions: first, individuals should be treated as autonomous agents and second, persons with diminished autonomy are entitled to protection. This means individuals should be given the freedom to make choices and those incapable of self-determination should be protected. This study examined the aspect of free choice by patients in deciding to undergo a procedure or treatment.

In Africa where most societies are largely paternalistic, men serve as heads of households and village elders in the community. In such instances first person informed consent for research purposes is sought from men even when the research involves competent women. Cultural issues in Africa should not inhibit obtaining informed consent from a competent adult and especially women. Although many customs require men as heads of households and village elders to be informed, their consent should not replace that of an adult woman. When considering outside influences on volition two aspects are of crucial importance; the strength of the will of the patient which is determined by factors such as pain, fatigue or depression and the relationship of the persuader who may be a spouse or parent to the patient (Ijsselmuiden & Faden, 1999). Although a patient has a right to receive advice and assistance from family members
what matters in the end is that the advice does not over bear the independence of the patients’ decision (Jones, 1996; Marshall, 2004).

In the case of *Natanson v Kline*, cobalt radiation caused serious damage to normal chest wall tissues of the patient. Although the possibility of such an injury was foreseeable it was not by any means a certainty. Nevertheless the court held that this should have been explained to the patient before the treatment was undertaken. The Kansas Supreme Court stated that

"... *A man is the master of his own body and he may expressly prohibit the performance of a life saving surgery or other medical treatment. A doctor may well believe that an operation or any other form of treatment is necessary but the law does not permit him to substitute his own judgement for that of the patient...*"

The Kansas case clearly shows that a patients’ decision to undergo a procedure must be a true reflection of his or her autonomy which can only be so if a doctor discloses fully and objectively all information. Doing so encourages a patient to make their decision independently and steers clear of any actions that could amount to undue influence, manipulation or coercion (ibid, 2000).

The findings of a University of Benin, Nigeria study showed that some respondents gave consent without fully understanding what they were signing in order not to be labelled as rude patients with possible attendant consequences. The study concluded that this amounted to intimidation and such patients cannot be said to have consented voluntarily (Osime *et al.*, 2004).

The Myths and Misunderstandings of Informed Consent study carried out in Kilifi concluded that consent provided by the participants was not always voluntary. Some participants consented due to perceived real benefits for the community while
others thought that treatment would be withheld or compromised if they refused to participate (Molyneux et al., 2004). In our study the element of third party influence was examined to ascertain whether it affected volition.

A patient who has capacity to give his consent in law must also have the right to withhold consent. Patients and others who at any time know that they can change their mind about a continuing treatment, about participating in research or about use of tissues they have given, are not coerced and know that they are not coerced. This requires that doctors inform patients of their right to accept or reject treatment Similarly, if a patient does not know that there is no compulsion to participate, it may arguably be assumed that his/her consent was involuntary (O'Neill, 2002). There are exceptions to refusal to treatment that may justify a person being compelled to accept medical treatment that he/she does not want. An example is in cases where it was essential to protect the life or health of a third party- an unborn child, particularly in the case of pregnant women (Jones, 1996). This study sought to examine whether patients were advised of the choice to accept or reject treatment.

In criminal law, consent obtained through threat or intimidation for a clinical procedure is not valid and a doctor can be held liable if anything goes wrong. The real question in volition then, is to establish whether a patients' decision to accept or reject treatment is made freely without coercion or undue influence.

2.5 Summary

Despite the existence of codes and international guidelines, it is clear that there are gaps that exist in the process of obtaining informed consent. Sometimes the information given is not sufficient and/or accurate, in other instances the information is
too technical and cannot be understood by a lay patient. In yet other cases, the patients feel intimidated by either the hospital or home environment so that they are unable to decide whether to provide consent or not. The ideal state in informed consent is that the information provided must be sufficient, accurate and comprehensible and consent given freely. This study sought to investigate how these factors play out on the Kenyan scene.
CHAPTER THREE MATERIALS AND METHODS

This chapter contains a presentation of the research methodology employed in the study. In particular this chapter discusses the following sub topics: research design, study location, target population, sampling techniques and sample size determination, data collection instruments, pilot study and ethical considerations.

3.1 Research Design

The study design was a descriptive cross sectional study. This design was chosen because the time between procuring informed consent and treatment is very short and patients are normally in hospital for a limited time.

3.2 Variables

The independent variables in the study included age, sex, marital status, occupation, languages spoken and education level. The dependent variables included information, comprehension and volition.

3.3 Location of the study

The study was carried out at two teaching hospitals, Aga Khan University Hospital (private) and Kenyatta National Hospital (public) both in Nairobi Province of Kenya.
3.4 Target Population

The Target population comprised of in-patients and doctors in the Surgical, Paediatric and Obstetrics & Gynaecology wards in Kenya. The study population comprised of in-patients and doctors in the Surgical, Paediatric and Obstetrics & Gynaecology wards in of Kenyatta National Hospital and Aga Khan University Hospital.

At Kenyatta National Hospital, the average monthly census for in-patients in the three departments was 1500 (Annual: 18,000) while the average monthly census for in patients at the Aga Khan University Hospital is 500 (Annual: 6,000). The doctor population in the three departments at Kenyatta National Hospital is 150 while at Aga Khan University Hospital is 50.

a) Inclusion criteria: Patients in the selected hospitals in the surgical obstetrics and gynaecological wards. Minors in the paediatric ward whose parents or guardians were present during the study. Doctors treating patients in the selected departments

b) Exclusion criteria: Patients with mental or behavioural disorders and minors whose guardians or parents were absent during the study. Doctors who were not treating patients in the selected departments

3.5 Sampling Procedure and Sample Size

The two teaching hospitals, Kenyatta National Hospital and Aga Khan University Hospital in Nairobi Province were purposively selected for the study. Teaching hospitals are medical institutions for training doctors where the doctrine of informed consent should not only be taught but also applied. These two were selected
for their proximity to one another. Selection of a private and public health institutions was meant to cover a wider spectrum.

Surgical and Obstetrics & Gynaecology departments were chosen because majority of the procedures they handle are either surgical or invasive. The paediatric department was selected for the study because patients here have diminished autonomy and third party consent is required.

Patients were selected purposively depending on their emotional and physical state. The nurses in charge of the various departments provided guidance on the extent of illness, mental, emotional and physical state of the patients and hence their ability to be interviewed.

The required sample size for patients was determined using the Fisher et al., (1983) formula for determining sample size from a target population of more than 10,000 as shown below (Mugenda & Mugenda, 1999).

\[ n = \frac{Z^2pq}{d^2} \]

Where:

- \( n \) = the desired sample size
- \( Z \) = the standard normal deviate (1.96), at a 95% confidence level
- \( p \) = the proportion in the target population having the characteristic being measured (patients in the obstetrics & gynaecology, surgical and paediatric wards).
- \( q = 1-p \)
- \( d \) = the level of statistical significance set (0.05)

\[ n = \frac{(1.96)^2(0.5)(0.5)}{(0.05)^2} = 384. \] To enhance data validity the sample size was increased to 400.
The ratio of patients at Aga Khan University Hospital to Kenyatta National Hospital in the three departments is 1:3.

In relation to Fisher’s formula above, proportionate sampling was used to purposively select 100 patients from Aga Khan University Hospital and 300 patients from Kenyatta National Hospital. The sample size for each department in the two hospitals was obtained using proportionate sampling based on the average monthly census of inpatients in the specific departments as show below.

Table 3.1 Sample size by department in Aga Khan and Kenyatta Hospitals

<table>
<thead>
<tr>
<th>HOSPITAL</th>
<th>Surgical</th>
<th>Paediatric</th>
<th>Obstetrics &amp; Gynaecology</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aga Khan University Hospital</td>
<td>41</td>
<td>32</td>
<td>26</td>
<td>100</td>
</tr>
<tr>
<td>Kenyatta National Hospital</td>
<td>51</td>
<td>100</td>
<td>149</td>
<td>300</td>
</tr>
<tr>
<td>TOTAL</td>
<td>92</td>
<td>132</td>
<td>175</td>
<td>400</td>
</tr>
</tbody>
</table>

The sample size for doctors was determined by obtaining 10% of the doctor population in the three departments within the two hospitals. Ten per cent was deemed to be representative of the doctor population. The doctors were sampled conveniently. The questionnaires were provided to the doctors as they walked in to see the patients. These questionnaires were self administered. Consequently 46 doctors were returned the questionnaires, 27 were from Kenyatta National Hospital and 19 from Aga Khan University Hospital. Doctors were interviewed to confirm the patients’ responses.
3.6 Research Instruments

A face to face interview schedule was conducted for patients. The structure of the research instrument consisted of two parts; part one focused on the respondents' demographic information while part two consisted of questions that sought to collect information on the extent to which information provided to a patient in clinical practice is sufficient; whether patients understand that information and whether they consent without undue influence or coercion. All in all, the interview schedule was made up of 27 questions that were both closed and open ended.

The questionnaire given to doctors was divided into two parts. Part one focused on the respondents' demographics and part two aimed at establishing whether doctors provide sufficient and accurate information to patients and whether they obtain consent prior to treatment. This questionnaire consisted of 16 questions made up of both closed and open ended questions.

Forty five (45) questionnaires were sent out to Doctors at KNH out of which 27 were returned representing 60% return quota. For Aga Khan University Hospital 30 questionnaires were given out and the return quota was 63%. The return quota from both hospitals, 61.5% was well above the 10% required.

3.7 Pilot Study

Pilot testing was carried out using patients and doctors at the Medical Department of Kenyatta National Hospital. The Medical Department as well as the results of the pilot study were excluded from the study. The respondents chosen for pilot testing were encouraged to seek clarification of any unclear questions. After the
questionnaires had been returned, necessary amendments were effected and the questionnaire redesigned. Research assistants were trained by the principal investigator on the administration of the questionnaire to ensure that they had understood the research instrument.

3.8 Data Collection

Primary data was collected using an interview schedule (patients), questionnaire (doctors), case law and statutes. The interview schedule designed for patients was a pre-tested semi-structured one while a questionnaire was designed for doctors. Secondary data was gleaned from books, journals and newspapers. The internet was a valuable resource.

3.9 Data Analysis

Raw Data was coded and analysed using the Statistical Package for Social Sciences (SPSS) program. Data was presented using descriptive statistics such as Bar charts, Frequency tables, Pie charts and Percentages. The Chi- Square test of independence was used to test for relationships between the dependent variables information, comprehension and volition and the independent variables age, gender, level of education, languages spoken, occupation and marital status.

3.10 Ethical Considerations

Permission to carry out research was sought from the Ministry of Education Science and technology (MOEST) before starting the work. Ethical clearance was obtained from Aga Khan University Hospital and Kenyatta National Hospital. Informed
consent was further sought from each of the respondents before issuing the interview schedule. Each participant was adequately informed about the purpose, scope and outcome of the study. Participation was voluntary and willing participants were required to give a written informed consent. Participants were also informed of their freedom to withdraw from the study at any time. Confidentiality was maintained.
CHAPTER FOUR: RESULTS AND DISCUSSION OF RESULTS

4.1 Demographic characteristics of Respondents

4.1.1 Age and Gender Distribution of Respondents

A total of 401 respondent patients participated in the study. Table 4.1 shows that majority (83.1%) of the patients interviewed were aged between 18-40 years. Those over 40 years comprised 16.7%. This confirms the general assertion that the Kenyan population is predominantly youthful (Kenya Demographic and Health Survey, 2003).

Table 4.1 Distribution of respondent patients by age (n=401)

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>No. of Respondents (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30</td>
<td>220 (54.9%)</td>
</tr>
<tr>
<td>31-40</td>
<td>114 (28.4%)</td>
</tr>
<tr>
<td>41-50</td>
<td>38 (9.5%)</td>
</tr>
<tr>
<td>Above 50</td>
<td>29 (7.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>401 (100%)</td>
</tr>
</tbody>
</table>

A total of 46 respondent doctors participated in the study with Kenyatta National Hospital represented by 58.7% (27) and Aga Khan University Hospital represented by 41.3% (19). A majority (91.3%) of the doctors who participated in the study were in the age group of 21-40 years, 8.7% were aged over 40 years (Table 4.2).
Table 4.2   Distribution of respondent doctors by age (n=46)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>No. of Respondents (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-30</td>
<td>22 (47.8%)</td>
</tr>
<tr>
<td>31-40</td>
<td>20 (43.5%)</td>
</tr>
<tr>
<td>41-50</td>
<td>4 (8.7%)</td>
</tr>
<tr>
<td>Above 50</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>46 (100%)</td>
</tr>
</tbody>
</table>

Gender Distribution of Respondents

The number of female respondent patients interviewed was much higher (80.5%) compared to 19.2% male respondents (Figure 4.1). The higher number of female respondents can be attributed to the fact that the research tool was administered in the Obstetrics and Gynaecology Department where there are only female patients. In the paediatric wards where part of the data collection was carried out majority of the children were represented by female respondents as a parent or guardian.
With regard to the doctors, the number of male respondent doctors (73.9%) was much higher as compared to 26.1% female respondent doctors (Figure 4.2). The disparity may be explained by the possibility that there are more males who study medicine than females.
4.1.2 Distribution of Respondents by Department

Table 4.3 shows that the distribution of respondent patients in both hospitals by department was 22.9% for surgical, 33.2% for paediatrics and 43.9% for obstetrics and gynaecology department. Majority (43.9%) of patients interviewed were from the obstetrics and gynaecology department since this department had the highest average monthly census obtained from the hospitals records.

Table 4.3 Distribution of patients by Department (n=401)

<table>
<thead>
<tr>
<th>Department</th>
<th>No. of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical</td>
<td>92</td>
<td>22.9%</td>
</tr>
<tr>
<td>Paediatric</td>
<td>133</td>
<td>33.2%</td>
</tr>
<tr>
<td>Obstetrics &amp; Gynaecology</td>
<td>176</td>
<td>43.9%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>401</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 4.4 shows that the distribution of respondent doctors recruited into the study from both hospitals was 39.1% from surgical department, 28.2% from paediatrics and 32.6% from obstetrics and gynaecology department.

Table 4.4 Distribution of Doctors by Department (n=46)

<table>
<thead>
<tr>
<th>Department</th>
<th>No. of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical</td>
<td>18</td>
<td>39.1%</td>
</tr>
<tr>
<td>Paediatric</td>
<td>13</td>
<td>28.2%</td>
</tr>
<tr>
<td>Obstetrics &amp; Gynaecology</td>
<td>15</td>
<td>32.7%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>46</td>
<td>100%</td>
</tr>
</tbody>
</table>
4.1.3 Marital status of the Respondents

Table 4.5 shows that a majority (73.8%) of the respondent patients interviewed were married.

Table 4.5 Distribution of Patients by Marital Status (n=401)

<table>
<thead>
<tr>
<th>Marital status</th>
<th>No. of respondents (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>296 (73.8%)</td>
</tr>
<tr>
<td>Single</td>
<td>93 (23.2%)</td>
</tr>
<tr>
<td>Other (divorced, widowed, separated)</td>
<td>12 (3%)</td>
</tr>
<tr>
<td>Total</td>
<td>100% (401)</td>
</tr>
</tbody>
</table>

No such information was sought from respondent doctors.

4.1.4 Languages spoken by the Respondents

Figure 4.3 shows that a majority (95.7%) of the respondent patients interviewed in both hospitals spoke Kiswahili while 65% spoke English. The Kiswahili language was predominantly (68%) used by the doctors to provide information to the patients.
In many African countries, most patients live their lives and speak in a different language from researchers and practitioners (Makgoba, 2000). Among the causes of misunderstanding of information in clinical practice are differences in language, culture and lack of a shared understanding between health and disease (Ijjselmuiden & Faden, 1999). It has been suggested that in cases of language differences, doctors should request for interpreters. Even then, translation may distort information provided so that the interpreter focuses on information content that is easier to explain or that which will persuade the patient to give consent. In this study the Kiswahili language was predominantly spoken by patients and used by doctors to provide information which shows that doctors made an effort to reduce the information asymmetry that exists between patients and themselves by predominantly speaking Kiswahili.
4.1.5 Distribution of Respondents according to their level of education, occupation and earnings

A majority (44.6%) of the respondent patients interviewed had attained secondary education with only 19.5% of them having obtained tertiary education (Figure 4.4).

Figure 4.4 Distribution of Patients' by level of education (n=401)
About 40% of the respondent patients interviewed in both hospitals were unemployed, 29.9% were formally employed and 27.7% were self employed (Figure 4.5).

Figure 4.5  Distribution of Patients by occupation (n = 401)

Figure 4.6 shows the earnings of respondent patients interviewed. Over 40% of the patients interviewed had no income, 23.2% earned between 5,001-15,000 Kenya shillings while 13.2% earned over 25,000 Kenya shillings.
Figure 4.6  Distribution of patients’ according to monthly income in Kenya shillings (n =401)

The findings on high levels (40%) of unemployment as well as the fact that a majority (40%) of patients interviewed had no income and 23.2% earned between 5,000 -15,000 Kenya shillings monthly affirms the challenges expressed in ensuring that consent obtained is informed.
4.2 INFORMATION

4.2.1 Information given on the nature of sickness or medical procedure

The findings of this study show that a majority (92.3%) of the respondent patients were provided with some information on the nature of their sickness or medical procedure (Table 4.6).

Table 4.6 Provision of information by doctors to patients (n=401)

<table>
<thead>
<tr>
<th>INFORMATION PROVISION</th>
<th>Respondents (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>370 (92.3%)</td>
</tr>
<tr>
<td>No</td>
<td>19 (4.7%)</td>
</tr>
<tr>
<td>I do not know</td>
<td>8 (2%)</td>
</tr>
<tr>
<td>No response</td>
<td>4 (1%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>401 (100%)</td>
</tr>
</tbody>
</table>

It is probable that among those not provided with information some were admitted to hospital in an unconscious state. Common law provides for emergency cases where when a patient presents unconscious, the defence of necessity is available and in such instances consent is implied (Mason & McCall Smith, 1987).

Table 4.7 A cross tabulation of marital status against information provision

<table>
<thead>
<tr>
<th>MARITAL STATUS</th>
<th>Were you provided with any information on treatment?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES (%)</td>
</tr>
<tr>
<td>Married</td>
<td>280 (94.6%)</td>
</tr>
<tr>
<td>Non-married (Widow, divorced, single, Separated)</td>
<td>90 (85.7%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>370</td>
</tr>
</tbody>
</table>
The Pearson chi square test showed a significant association between marital status and provision of any information. ($\chi^2 = 8.569$, df = 1, p = 0.003). Doctors were more likely to give information to married (94.6%) than non married patients (85.7%). The Pearson chi square test showed no significant association between provision of information and gender ($\chi^2 = 3.517$, df = 1, p = 0.061).

Figure 4.7 shows that the type of information provided to the respondent patients by doctors in both hospitals was mainly on diagnosis (82.7%). Very few respondents were provided with information on risks (23.1%), benefits (31.1%) and alternatives (11.9%) to treatment. These findings show that information provided to patients in this study was insufficient to procure consent since it was not balanced. The information provided focused more on diagnosis and less on risks, benefits and alternatives to treatment.

![Diagram showing type of information provided to patients](image)

**Figure 4.7** Type of information provided to patients
These findings are consistent with those of an American study where only 9% of the respondents were informed of risks and benefits (Braddock et al., 1997) and the Nigerian study (Osime et al., 2004) where 100(75%) patients were not informed of risks. However, risks are a crucial category of information that patients require in order to make appropriate future plans to forgo or undergo the treatment and to act in what they believe is their best interest (Doyal, 2001).

Whereas only 23.1% of the patients' responses show that they were given information on risks, 76.1% of the doctors said they always provide such information. For benefits the results were 31.1% (patients) and 91.3% (doctors). The figures provided by the patients and doctors appear disparate (Table 4.8).

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>Doctors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on Risks</td>
<td>23.1%</td>
<td>76.1%</td>
</tr>
<tr>
<td>Information on Benefits</td>
<td>31.1%</td>
<td>91.3%</td>
</tr>
</tbody>
</table>

A possible reason for the disparity could be that the patients do not understand the medical language in which the information is provided or they do not remember everything they are told. Another explanation could be a possible exaggeration on the part of the respondent doctors. Doctors in this study attributed such disparities to challenges such as low understanding by patients and information asymmetry. A University of Washington study attributed such disparities to imperfect patient recall or
the doctors' self-evaluation that may have resulted in overestimation of performance (Braddock et al., 1997).

The duty of disclosure of information, a key element of informed consent requires that a doctor must fully explain to a patient the proposed procedure, the short-term risks and long-term consequences, the available alternatives, their risks and benefits and the consequences of delaying or declining treatment (Svoboda et al., 2000). This duty is not dependent upon a patient's request for disclosure; rather it is a physician's obligation (Bucklin, 1975). The only generalized exception is in cases where due to a patients' unstable emotional condition, disclosure may cause mental or physical harm (Bailey, 1978). In such instances it is recommended that the doctor explain the risks to the patient's spouse or next of kin and document his decision not to disclose to the patient (Abbuhl & Gerking, 1975).

In the case of Salgo Vs Leland where a patient was not informed of potential risk the court held that '...a physician violates his duty to the patient and subjects himself to liability if he withholds any facts that are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.' In Canterbury Vs Spence where the risk of paralysis was not disclosed to the patient the judge ruled that "...respect for the patients' right to self-determination on a particular therapy demands a standard set by law for physicians rather than one which physicians may /may not impose upon themselves... the patients' right of self decision shapes the boundaries of the duty to reveal." The Case of White Vs Turner where the plaintiff patient was not fully informed ruled that "...no longer does the medical profession alone collectively determine by its own practices the amount of information the patient should have in order to decide
whether to undergo an operation." Legally, securing consent without providing adequate information constitutes redressable negligence (Svoboda et al., 2000).

4.2.2 Average number of patients seen by a doctor per day

Majority (71.1%) of the respondent doctors interviewed said they saw an average of 20 patients on a daily basis, 17.4% of the doctors saw between 20-40 patients and 8.7% of them saw 40-60 patients a day (Figure 4.8).

![Figure 4.8 Average number of patients seen by a doctor per day (n =46)](image)

About 43% of the respondent patients said that the doctors took an average of 10-30 minutes providing information while 52.1% of the respondent doctors reported spending less than 10 minutes giving information on treatment to patients (Figure 4.9).
A possible explanation for the disparities in the reported consultation time by the patients and doctors may be the imperfect patient recall caused by the physical and mental status of the patient while undergoing treatment. Also the fact doctors see as shown in this study saw a minimum of 20 patients a day would mean that if they had to spend up to 30 minutes per patient then they would need to work for 600 minutes (10 hours) per day which may not be feasible. Doctors are alive to and aware of the long patient queues and therefore may shorten consultation time in order to see all patients.

The relationship between age and average consultation time is shown in Table 4.9.
Table 4.9  Cross-tabulation of age against average consultation time

<table>
<thead>
<tr>
<th>AGE</th>
<th>&lt;10 mins</th>
<th>10-30 mins</th>
<th>&gt; 30 mins</th>
<th>Don’t know</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30 years</td>
<td>74 (33.6%)</td>
<td>104 (47.3%)</td>
<td>27 (12.3%)</td>
<td>15 (6.8%)</td>
<td>220</td>
</tr>
<tr>
<td>31-40 years</td>
<td>39 (34.5%)</td>
<td>49 (43.4%)</td>
<td>20 (17.7%)</td>
<td>5  (4.4%)</td>
<td>113</td>
</tr>
<tr>
<td>41 and above</td>
<td>23 (33.8%)</td>
<td>18 (26.5%)</td>
<td>24 (35.3%)</td>
<td>3  (4.4%)</td>
<td>68</td>
</tr>
<tr>
<td>TOTAL</td>
<td>136</td>
<td>171</td>
<td>71</td>
<td>23</td>
<td>401</td>
</tr>
</tbody>
</table>

The Pearson chi square test showed a significant association between age and average consultation time ($\chi^2 = 21.852, df = 6 p=0.001$). Patients aged thirty years and below were more likely to receive attention for 10-30 minutes from the doctors.

Majority (52.1%) of the respondent doctors interviewed felt that the amount of time they spent giving information to patients was sufficient. Thirty seven percent of the doctors in this study indicated that the amount of time they spent with patients was inadequate (Figure 4.10)
Figure 4.10 Reasons why time spent providing information to patients was inadequate (n=17)

Though it may be ethically desirable for patients to be as fully informed as possible, doctors may not have the time to spend on unduly lengthy explanations of all the ramifications of treatment (Mason & McCall Smith, 1987). Among the reasons why doctors may not achieve the ideal level of informed consent are that they are too busy and the pressure to reduce costs of care may be at odds with the need to spend more time in discussion with patients (Braddock et al., 1997). Also doctors possibly presume that the additional time needed for full information disclosure is substantial and would interfere with service delivery yet good communication requires time and resources. When average consultation times are so short and there is a paucity of well designed and produced literature and other informational aids for patients, even the best communicators will be hard pressed to educate patients to their full potential (Elywn et al., 1999). In this study the main reasons for the insufficient time spent by doctors on consultation was that patients have a low understanding of medical information, high
patient load and patient requirement of full disclosure which doctors feel unable to provide during the time they spend with patients.

The findings of this study show that the information provided to patients prior to obtaining informed consent was insufficient since it focused mainly on diagnosis and less frequently on risks, benefits and alternatives to treatment. “Consent” obtained this way cannot be said to be informed. There was no association between the independent variables age, education, gender, income and the dependent variable information. The key recommendations given by the respondent patients were that doctors should spend more time giving information to patients (26%), that doctors should fully disclose the diagnosis, and treatment options as well as risks and benefits (24%) and speak simple language (21%) to explain treatment or medical procedures. Doctors at the two hospitals blamed their inability to provide sufficient information on challenges such as language barrier (33%) and insufficient time (9%).

Language barrier remains a challenge in providing information prior to obtaining consent from patients. This may be as a result of the difficulties doctors face in trying to translate medical terms into simple language in order for patients to understand. However, the doctor has a duty to explain a clinical procedure without turning the patient or his family into medical students (Lore, 1993). Even when dealing with educated persons, doctors must explain the details of an operation in a language that patients can understand even if it means using interpreters (Kyambi, 2004). Some studies have emphasized the need for language used in communicating to patients to be plain simple and to avoid medical jargon in order to enhance patient understanding (Mazur, 2003).
4.3 COMPREHENSION

4.3.1 Methods used by doctors to provide information to patients

The results of the study show that words (80%) were the main method used by doctors to provide information to patients (Figure 4.11). Given the technical nature of the subject matter it would probably be useful if illustrations and other forms of visual aids were used along side words in an effort to provide sufficient and comprehensible information.

![Figure 4.11 Methods used by doctors to provide information to patients](image)

A majority (84.2%) of the respondent patients in both hospitals said they understood the information that was provided by the doctors while only 58.7% of the respondent doctors said they believed patients always understood the information given to them. The results for ability to comprehend the information for doctors and patients do not seem to tally. Either the patients over-rated their ability to comprehend or the
doctors underrated the patients’ ability to comprehend. Whatever the case, over 50% in both cases attest to comprehension of the information provided.

The Pearson chi-square test showed no significant association between the respondent’s level of education and the ability to understand the information provided ($\chi^2 = 6.5 \ df = 3 \ p=0.088$). This result supports the view that even when dealing with educated persons, doctors must explain the details of a medical procedure in a language that patients can understand even if it means using interpreters (Kyambi, 2004). The Pearson chi-square test also showed no significant association between the respondent’s age and the ability to understand the information provided ($\chi^2 = 3.09 \ df = 2 \ p=0.213$) and no significant association between the respondent’s gender and the ability to understand the information provided ($\chi^2 = 0.05 \ df = 1 \ p=0.818$).

The element of comprehension requires that a doctor must fully explain the diagnosis, proposed procedure, the short-term risks and long-term consequences, the available alternatives, their risks and benefits and the consequences of delaying or declining treatment (Svoboda et al., 2000). Any questions put forth by the patient to the doctor on a medical procedure must be truthfully and as fully answered (Mason & McCall Smith, 1987). Ample evidence now exists to confirm the effectiveness of teaching communication skills to medical students and doctors in enabling doctors to better provide information on treatment and educate patients on their treatment choices (Hall, 2000). Such training will ensure that doctors not only speak in a language the patient understands but that patients also understand information provided. It will also narrow the gap between what patients perceive to be the content of information provided to them and the type of information doctors perceive to be providing.
4.3.2 Questions on treatment or medical procedure

A majority (64.8%) of the respondent patients asked questions concerning treatment (Table 4.10).

Table 4.10 Cross-tabulation of income against asking questions on treatment

<table>
<thead>
<tr>
<th>EARNINGS (Kenya Shillings)</th>
<th>Did you ask any questions concerning treatment?</th>
<th>YES (%)</th>
<th>NO (%)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>No earnings</td>
<td></td>
<td>92 (56.4%)</td>
<td>71 (43.6%)</td>
<td>163</td>
</tr>
<tr>
<td>Less than 5,000</td>
<td></td>
<td>41 (56%)</td>
<td>32 (44%)</td>
<td>73</td>
</tr>
<tr>
<td>5,001-15,000</td>
<td></td>
<td>67 (72%)</td>
<td>26 (28%)</td>
<td>93</td>
</tr>
<tr>
<td>15,001-25,000</td>
<td></td>
<td>15 (79%)</td>
<td>4 (21%)</td>
<td>19</td>
</tr>
<tr>
<td>Above 25,000</td>
<td></td>
<td>45 (85%)</td>
<td>8 (15%)</td>
<td>53</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>260</td>
<td>141</td>
<td>401</td>
</tr>
</tbody>
</table>

The Pearson chi square test showed a significant association between a patients' income and whether one asked questions on medical treatment or not ($\chi^2 = 20.59$, df = 4, $p=0.000$). The more money a patient earned the more likely it was for them to ask the doctor questions concerning treatment. A possible explanation for this could be that patients earning a high income are more confident and believe in value for money. They probably feel that their money will only have been well spent if they exhaust whatever questions they have on treatment before they provide consent.
Table 4.11: Cross-tabulation of marital status against asking questions asked on treatment

<table>
<thead>
<tr>
<th>MARITAL STATUS</th>
<th>Did you ask any questions concerning treatment?</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
<td>No</td>
<td>TOTAL</td>
</tr>
<tr>
<td>Married</td>
<td>208 (70.2%)</td>
<td>88 (29.8%)</td>
<td>296</td>
</tr>
<tr>
<td>Other (Single/Widowed, Divorced)</td>
<td>52 (49.5%)</td>
<td>53 (50.5%)</td>
<td>105</td>
</tr>
<tr>
<td>TOTAL</td>
<td>260</td>
<td>141</td>
<td>401</td>
</tr>
</tbody>
</table>

The Pearson chi square test showed a significant association between marital status and whether one asked questions on medical treatment or not ($\chi^2 = 14.633$, df = 1, $p=0.0001$). Married persons (70.2%) were more likely to ask doctors questions concerning treatment than non-married persons (49.5%).

One hundred and forty one (35%) respondents did not ask questions on medical treatment. The findings of the study show that among the reasons given for not asking questions were that some (24%) did not know what to ask and 23% of the respondents were in too much pain (Figure 4.12).

![Figure 4.12 Reasons why patients did not ask questions (n=141)](image-url)
With the exception of emergency situations, sometimes the power imbalance that exists between a doctor and a patient may create an intimidating environment that inhibits a patient from asking questions (Makgoba, 2000). Nevertheless, the duty of a doctor to ensure that a patient understands the information provided is well established in law.

Most respondent patients in this study said they understood the information provided. However, the disparate responses on understanding between the doctors and patients and the oral method predominantly used to provide information make it difficult to establish the true extent of patients' understanding. The results on comprehension in this study are therefore inconclusive.
4.4 VOLITION

4.4.1 Choosing a clinical procedure

Most respondent doctors (60.9%) said they always allowed their patients to choose a clinical procedure. A majority (55.4%) of the respondent patients were however not advised that they had an option of declining or accepting treatment. A cross-tabulation of income against advise is reflected in Table 4.12.

Table 4.12 Cross tabulation of income against advise by the doctor to accept or reject treatment

<table>
<thead>
<tr>
<th>EARNINGS (Kenya Shillings)</th>
<th>Were you advised by the doctor that you could accept or reject treatment?</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>No earnings</td>
<td>68 (42%)</td>
<td>95 (58%)</td>
</tr>
<tr>
<td>Less than 5,000</td>
<td>19 (26%)</td>
<td>54 (74%)</td>
</tr>
<tr>
<td>5,001-15,000</td>
<td>34 (37%)</td>
<td>59 (63%)</td>
</tr>
<tr>
<td>15,001-25,000</td>
<td>12 (63%)</td>
<td>7 (37%)</td>
</tr>
<tr>
<td>Above 25,000</td>
<td>30 (57%)</td>
<td>23 (43%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>163</td>
<td>238</td>
</tr>
</tbody>
</table>

The Pearson Chi Square test showed a significant association between level of income and advise by the doctor on the options of accepting or rejecting treatment ($\chi^2 = 16.8, df = 4, p=0.002$). Patients with high income were more likely to be advised by the doctors that they had an option to accept or reject treatment. A possible explanation could be that since such patients also asked more questions on treatment the doctors may
have felt obligated to provide them with the alternatives of accepting or rejecting treatment.

The relationship between marital status and advise from the doctor on whether to accept or reject treatment is shown in Table 4.13.

Table 4.13 Cross-tabulation of marital status and advise by the doctor to accept or reject treatment

<table>
<thead>
<tr>
<th>MARITAL STATUS</th>
<th>Were you advised by the doctor that you could accept or reject treatment?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>Married</td>
<td>136 (46%)</td>
</tr>
<tr>
<td>Other (Single/Widowed, Divorced)</td>
<td>27 (26%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>163</td>
</tr>
</tbody>
</table>

The Pearson Chi Square test showed a significant association between marital status and advise by the doctor on the options of accepting or rejecting treatment ($\chi^2 = 13.15, df = 1, p<0.0001$). Married persons (46%) were more likely to be advised by the doctors that they had an option of accepting or rejecting treatment than non-married persons (26%).

Although it may not be common practice for doctors to advise patients of their right to accept or reject treatment, informed consent requires that they do so. A Swedish study on Quality of Information provided to patients involved in a clinical trial found that 17 participants (39.5%) had no information on the possibility of withdrawing from the study whenever they wanted to (Lynoe et al., 1991). Patients and others who at any time know that they can change their mind about a continuing treatment, about
participating in research or about use of tissues they have given, are not coerced and know that they are not coerced (O’Neill, 2002). Similarly, if a patient does not know that there is no compulsion to participate, it may arguably be assumed that his/her consent was involuntary (Jones, 1996; Marshall, 2004).

A majority (64%) of the respondent patients in this study did not seek assistance in making a decision to accept or reject treatment. Figure 4.13 shows that among the 134 respondent patients who sought assistance in reaching a decision on whether to accept or reject treatment; assistance was sought from a spouse (45%), friend (24%), family (20%) or a doctor (11%).

![Provision of assistance in deciding to accept or reject treatment](image)

**Figure 4.13** Provision of assistance in deciding to accept or reject treatment (n=134)

In the African context unlike in the West, the appropriateness of first person informed consent has been questioned in the cultural context where one is seen as part of a community and not an individual. Here, consent is first sought from community elders
and in cases of married women; permission is sought from the husband first. However, the principle of respect for persons’ demands that consent be autonomous and free from coercion or undue influence (Ijsselmuïden & Faden, 1999). Individual informed consent cannot be replaced by proxy consent of fathers, government officials, husbands or other traditional male authorities (Richter et al., 1999). Some researchers hold the view that the influence of parents on their children or of one spouse on another may result in coercion (Jones, 1996). The National Bioethics Advisory Commission (2001) recommends that, in no case should permission from a community representative or family member replace the requirement of a competent individual’s voluntary informed consent.

Most (92%) of the respondent patients made their choice to be treated freely without coercion or undue influence (Table 4.14).

| Table 4.14  A cross tabulation of marital status against choice |
|-----------------|-----------------|-----------------|
| MARITAL STATUS  | Did you make a choice to be treated freely? |                     |
|                 | YES             | NO              | TOTAL |
| Married         | 279 (94%)       | 17 (6%)         | 296   |
| Other (Single, divorced, Separated widowed) | 90 (86%)       | 15 (14%)        | 105   |
| TOTAL           | 369             | 32              | 401   |

The Chi-square test showed a highly significant association between volition and marital status ($\chi^2 = 7.702$, df =1, p=0.006). Married persons (94%) were more likely to consent freely to treatment, without coercion or undue influence than non-married persons (86%).
Figure 4.14 shows that among the reasons given for not making a free choice by some respondent patients were; desperation (30%) and that some patients followed whatever advise the doctors had given (25%). Doctors however attribute resistance to providing consent (13%) and the inability of patients to consent voluntarily (11%) as hindrances to volition.

![Bar chart showing reasons for patients not making their choice freely](image)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not understand</td>
<td>20%</td>
</tr>
<tr>
<td>Was afraid</td>
<td>25%</td>
</tr>
<tr>
<td>Was unconscious</td>
<td>10%</td>
</tr>
<tr>
<td>Was desperate</td>
<td>30%</td>
</tr>
<tr>
<td>Was not given an alternative</td>
<td>15%</td>
</tr>
<tr>
<td>Doctor advised</td>
<td>25%</td>
</tr>
</tbody>
</table>

**Figure 4.14  Reasons for patients not making their choice freely (n=32)**

The power imbalance that exists between a patient and a doctor creates a great danger of undue influence. A patient cannot obtain treatment without an agreeable medical professional and, hence, can do little more than respond to treatment offered by the physician. Patients are often anxious at the time consent is sought from them making them even more vulnerable to influence by medical professionals. Also the manner in which a doctor presents information can greatly influence the importance patients attach to different considerations and can intentionally or otherwise persuade the option favoured by the doctor. Doctors must be sensitive to the fact that patients are likely to
interpret a suggestion or a mere mention of an option as a recommendation (Svoboda et al., 2000).

4.4.2 Consent in Emergency cases

A majority (80.4%) of the respondent doctors sought consent in emergency cases. The practice in both hospitals is that, consent is provided by a Consultant or senior doctor on duty in instances where proxy consent is lacking.

Common law requires that medical treatment in the absence of consent be given in an emergency situation when self-evidently necessary. In Kenya, the practice is that in emergency treatment as a life-saving procedure for an unconscious patient, consent should be obtained from an independent senior doctor or Consultant on duty if a next of kin or legal guardian is lacking (Kyambi, 2004). Generally, it is acceptable at common law that a doctor may treat a patient in emergency cases without the patient's consent. In such cases the defence of 'necessity' is available to doctors. The doctor thus can successfully argue that the treatment was necessary and any delay would have led to loss of life (Mason & McCall Smith, 1987). To this extent the practice adopted by both hospitals with respect to informed consent cannot be faulted.

4.4.3 Type of Consent given

The findings of the study show that over 90% of the respondent patients provided either verbal or written consent for treatment. Only 4% of the total number of respondents did not provide any form of consent. This corroborates the findings from doctors who said a majority (99%) of the respondents provide consent prior to treatment.
Table 4.15 Type of Consent given by patients in each department (n=401)

<table>
<thead>
<tr>
<th>DEPARTMENT</th>
<th>TYPE OF CONSENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Verbal</td>
</tr>
<tr>
<td>SURGICAL</td>
<td>20 (22%)</td>
</tr>
<tr>
<td>PAEDIATRIC</td>
<td>102 (77%)</td>
</tr>
<tr>
<td>OBSTETRICS &amp; GYNAECOLOGY</td>
<td>71 (40%)</td>
</tr>
</tbody>
</table>

Written consent was predominantly provided in cases where surgical and invasive procedures were carried in both hospitals (Table 4.15). The Pearson Chi square test showed a highly significant association between department and type of consent given ($\chi^2 = 81.9$, df=2, $p<0.0001$).

In many instances clinicians often equate informed consent with the practice of obtaining signed authorization for surgery or an invasive procedure. Some authors have criticized this limited view and emphasize on the need for informed consent in a much wider range of clinical decisions which include laboratory procedures and prescriptions of medication (Braddock et al., 1997).

Informed consent, as expressed by the findings on volition was obtained freely without coercion or undue influence from the patients in this study. However, the element of persuasion or undue influence may in some instances be difficult to rule out where patients sought the opinion of a third party in deciding whether to accept or reject treatment and in cases where doctors did not allow patients to choose a clinical procedure. The holding of the court in *Natanson Vs Kline* that a patient is the master of his own body and therefore is free to decide on treatment must always find effect.
CHAPTER FIVE

5.1 Introduction

This chapter presents a summary of the findings of the study, conclusions and implications of the findings as well as recommendations and areas for further research.

5.2 Summary of study and findings

The main objective of this study was to establish whether informed consent is obtained from patients in clinical practice in Kenya. In particular the study sought to establish whether patients are provided with sufficient information, whether they understand that information and whether they consent voluntarily without undue influence or coercion. The independent variables in the study were age, sex, marital status, occupation, languages spoken and education level. The dependent variables were information, comprehension and volition.

The study sample comprised of 401 patients drawn from Kenyatta National Hospital (301) and Aga Khan University Hospital (100). Of these 77 (19.2%) were male and 323 (79.6%) were female. For corroboration purposes 46 doctors, 34 (73.9%) males and 12 (26.1%) females in the departments of Surgery, Paediatrics and Obstetrics & Gynaecology from Aga Khan University Hospital (19) and Kenyatta National Hospital (27) were recruited into the study.

5.2.1 Information

A majority (92.3%) of the patients said they were provided with some information on the treatment or medical procedure that was carried out on them. The Pearson chi square test showed a highly significant association between marital status...
and provision of any information. ($\chi^2 = 8.569, \text{df} = 1, p=0.003$). The doctors were more likely to provide information to married than non married persons. The information provided to patients by doctors focused mainly on diagnosis (82.7%) of the respondent patients’ condition. There was little emphasis on risks, benefits and alternatives to treatment.

The average consultation time for a majority (52.1%) of the doctors was less than 10 minutes. The Pearson chi square test showed a highly significant association between age and average consultation time ($\chi^2 = 21.852; \text{df} = 6, p=0.001$). Among the reasons cited by the doctors for insufficiency of consultation time were varied levels of understanding by patients and a high work load.

### 5.2.2 Comprehension

The main method used by doctors to provide information to the patients was oral presentation (80%). Given the technical nature of the subject matter it would have been helpful if illustrations were used more frequently to enhance patient understanding. Although most respondent patients (84.2%) said they understood the information provided, only 58.7% of the respondent doctors said that patients always understood the information provided to them. The disparate responses between patients and doctors and the predominantly oral method of presentation make it difficult to establish the true extent of patient understanding.

The Pearson chi-square test showed no significant association between the respondent’s level of education and the ability to understand the information provided ($\chi^2 = 6.5, \text{df} = 3, p=0.088$), no significant association between respondent’s age and the ability to understand the information provided ($\chi^2 = 3.09, \text{df} = 2, p=0.213$) and no
significant association between the respondent's gender and the ability to understand the information provided ($\chi^2 = 0.05$, df = 1, p = 0.818).

The respondent doctors said that language barrier (33%) represented the biggest challenge in ensuring patient comprehension. Only 260 patients (64.8%) asked questions regarding treatment. The main reasons given by some patients (35%) for not asking questions included fatigue, pain, emergency and not knowing what to ask. The Pearson chi square test showed a significant association between a marital status and whether one asked questions on medical treatment or not ($\chi^2 = 14.633$, df = 1, p < 0.0001). Married persons were more likely to ask the doctors questions concerning treatment than non-married persons. The Pearson chi square test showed a significant association between a respondents’ income and whether one asked questions on medical treatment or not ($\chi^2 = 20.59$, df = 4, p < 0.0001). The more money a patient earned the more likely it was for them to ask questions concerning treatment.

5.2.3 Volition

Three hundred and sixty nine (92%) patients provided consent voluntarily. Twenty one (5.2%) respondent patients sited fear, lack of an alternative, emergency situation, doctor knows best and desperation as reasons for not making a choice to be treated freely.

However, a majority (55.4%) of the respondent patients were not advised that they had an option of declining or accepting treatment. The Chi-square test showed a significant association between volition and marital status ($\chi^2 = 7.702$, df = 1, p = 0.006). Married persons were more likely to make a free choice than non married persons. The Pearson Chi Square test also showed a significant association between level of income
and advise by the doctor on the options of accepting or rejecting treatment ($\chi^2 = 16.8$, df = 4, p=0.002). Patients who earned more money were more likely to be advised by the doctors that they had an option to accept or reject treatment.

Majority (99%) of the respondent doctors said that patients provide verbal or written consent prior to undergoing treatment or a medical procedure. The Pearson Chi square test showed a significant association between department and type of consent given ($\chi^2 = 81.9$, df =2, p=0.000). Written consent was more likely to be provided in the surgical department where invasive procedures are carried out. A majority (80%) of the respondent doctors in both hospitals said they obtained consent in emergency cases so that where a relative or guardian was lacking a consultant or independent senior doctor provided written consent before a medical procedure could be carried out.

5.3 Conclusions and Implications of the Findings

This study concludes that the information provided to patients was not sufficient to procure informed consent since it focused mainly on diagnosis and less on risks, benefits and alternatives to treatment. Although most patients said that they understood the information provided, the use of technical language by doctors and the disparate responses on comprehension and type of information provided by patients and doctors appear to negate this. Also, patients and doctors identified use of medical (technical) language as a barrier to providing and understanding information. In addition, the predominantly oral method used by doctors to provide information makes it difficult to establish the true extent of patients’ understanding. The findings on comprehension in this study are therefore inconclusive In the case of volition where collective decision
making occurred in instances where assistance was sought from family or doctors it may be difficult to exonerate the elements of persuasion or undue influence, however the findings of the study showed that patients consented freely without coercion or undue influence.

The results of this study lead to the inexorable conclusion that although consent is obtained in clinical practice in the two hospitals under study, it is not ‘informed’.

5.4 Recommendations

The results of this study show that there is need for medical schools, hospitals and other employers to offer training to doctors on the art of communicating with patients in order to provide more balanced information on diagnosis, risks, benefits, alternatives, recommended treatment and expected length of stay in hospital where required. The Ministry of Health needs to develop National guidelines for obtaining informed consent in clinical practice and enhance education and awareness of the public on their medical rights in order to protect dignity of patients. This will enable patients to query treatment procedures for clarity and understanding without feeling intimidated. In matters of medical treatment consent needs to be written as part of standard procedure and for purposes of protecting doctors from unforeseen litigation.

5.5 Areas for further study

This study should be extended to non-teaching hospitals in the country. The disparate results obtained in relation to comprehension show there is need to carry out an in depth study to ascertain the extent of patient understanding in relation to informed consent.
REFERENCES


Council for International Organizations of Medical Sciences (CIOMS) 1993, International Ethical Guidelines for Biomedical Research Involving Human Subjects in collaboration with the World Health Organization (WHO).


Doyal, L. (2002). Good Clinical Practice and Informed Consent are inseparable. *Heart* 87:103-105


APPENDICES

APPENDIX I: THE BUDGET

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>AMOUNT IN KSH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection of literature, Internet services, library use, transport cost</td>
<td>50,000</td>
</tr>
<tr>
<td>Proposal writing, typing, printing, photo copying and binding</td>
<td>30,000</td>
</tr>
<tr>
<td>Preparation of research instruments-typing, printing and photo copying</td>
<td>25,000</td>
</tr>
<tr>
<td>Pre-testing of the research instrument, typing, printing and photo copying of the interview schedules.</td>
<td>20,000</td>
</tr>
<tr>
<td>Recruitment and Training of research assistants</td>
<td>20,000</td>
</tr>
<tr>
<td>Data collection</td>
<td>80,000</td>
</tr>
<tr>
<td>Data analysis</td>
<td>40,000</td>
</tr>
<tr>
<td>Thesis, preparation, typing and printing</td>
<td>30,000</td>
</tr>
<tr>
<td>Thesis, photocopying and binding</td>
<td>10,000</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>10,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>315,000</strong></td>
</tr>
</tbody>
</table>
## APPENDIX II: WORK PLAN

<table>
<thead>
<tr>
<th>TIME PERIOD</th>
<th>ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2005 – September 2005</td>
<td>Proposal development, approval and presentation</td>
</tr>
<tr>
<td>October 2005 – December 2005</td>
<td>Pre-testing of research instruments</td>
</tr>
<tr>
<td></td>
<td>Modification of research instruments</td>
</tr>
<tr>
<td>February 2006 – July 2006</td>
<td>Approval from research institutions</td>
</tr>
<tr>
<td>August 2006 – December 2006</td>
<td>Data Collection</td>
</tr>
<tr>
<td>January- February 2007</td>
<td>Data Analysis</td>
</tr>
<tr>
<td>March – April 2007</td>
<td>Draft Thesis writing</td>
</tr>
<tr>
<td>May 2007</td>
<td>Presentation of Findings</td>
</tr>
<tr>
<td>July – October 2007</td>
<td>Correction and finalization of thesis</td>
</tr>
<tr>
<td>November 2007</td>
<td>Submission of Thesis</td>
</tr>
<tr>
<td>January 2008</td>
<td>Thesis Defence</td>
</tr>
<tr>
<td>April 2008</td>
<td>Graduation</td>
</tr>
</tbody>
</table>
APPENDIX IV: INFORMED CONSENT FOR PARTICIPANTS

You are invited to participate in the study on Informed Consent in Clinical Practice in Kenya.

Objectives
The aim of this study is to establish the extent to which consent obtained from patients prior to treatment is based on sufficient, accurate and understandable information and that the consent is given without coercion or undue influence. The information collected will be useful to patients, doctors, health institutions, law makers and the public in general.

Procedures;
This is an interview schedule that requires you to provide answers to questions that you shall be asked. You are required to answer as freely and objectively as possible. The information you provide will be kept confidential and will be used for purposes of the study only.

Benefits of the study
By participating in the study, you will help determine the extent to which consent obtained from patients before treatment in Kenya is informed, comprehensible and voluntary.

Your participation in this study is voluntary and you have a right to refuse to participate or to answer any of the questions that you feel uncomfortable with. If you change your mind about participating you have a right to withdraw at any time. The decision to participate or withdraw will not affect you whatsoever. If there is anything unclear that requires explanation or further clarification I shall be delighted to explain.

Declaration of the volunteer
I have understood that the purpose of this study is to determine the extent to which patients consent prior to treatment is informed, comprehensible and voluntary. I have read the above information, or it has been read to me. I have also had the opportunity to ask questions about the study and have been answered satisfactorily. I also understand that I have a right to withdraw from the study whenever I decide to do so. I therefore consent to participate voluntarily as a subject in this study.

Signature of Volunteer..............................................

Signature of Investigator...........................................

Date.................................................................
Dear Madam

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on ‘Informed Consent in Biomedical Research and Clinical Practice in Kenya’

I am pleased to inform you that you have been authorized to carry out research in Nairobi Province for a period ending 30th August 2007.

You are advised to report to the Provincial Commissioner and the Provincial Director of Education Nairobi before commencing your research project.

On completion of your research, you are expected to submit two copies of your research report to this office.

Yours faithfully

B. O. ADEWA
FOR: PERMANENT SECRETARY

Copy to: The Provincial Commissioner – Nairobi

The Provincial Director of Education Officer – Nairobi

Mildred Shieshia-Oduwori,
Department of Public Health
Kenyatta University
NAIROBI,

Dear Mildred,

RE: INFORMED CONSENT IN CLINICAL PRACTICE IN KENYA

Thank you for submitting your proposal entitled “INFORMED CONSENT IN CLINICAL PRACTICE IN KENYA” to the Institutional Review Committee of the Aga Khan Hospital. This proposal has been reviewed and the comments of the committee are stated below:

1. It is a good study and the committee feels it is reasonably well written.
2. Please note that the poverty line for Kenya is 65% and not 80% as stated in your proposal. Please quote the relevant government publication where such information is obtained. The current Kenya Demographic and Health Survey would be a useful document to quote.
3. Please make necessary corrections of spelling and other words as pointed out.
4. Under references please include relevant local publications in Kenya and East Africa.
5. We shall appreciate very much a copy of your results with regard to Aga Khan Hospital, because this will useful for our learning as well.

Please address these issues clearly and your response will be appreciated. We shall be very grateful if you could please avail to us a copy of your final thesis for our library so that our students can learn from it in future.

This is to inform you that your proposal has been cleared and you may commence the study as soon as possible. Please report to the office of the Medical Director before commencing studies.

DR. M. S. ABDULLAH,
CHAIRMAN, SCIENTIFIC COMMITTEE
AGA KHAN UNIVERSITY HOSPITAL
KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd.
P.O. Box 20723, Nairobi.
Tel: 726300-9
Fax: 725272
Telegrams: "MEDSUP", Nairobi.
Email: KNHplan@Ken.Healthnet.org
Date: 20th February 2006

Ref: KNH-ERC/ 01/ 3290

Mildred Shiesha-Odwori
Dept. of Public Health
Kenyatta University

Dear Mildred

RESEARCH PROPOSAL: "INFORMED CONSENT IN BIOMEDICAL RESEARCH AND CLINICAL PRACTICE IN KENYA" (P96/6/2005)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and approved revised version of your above cited research proposal for the period 20th February 2006 - 19th February 2007.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH-ERC

C.C.  Prof. K.M.Bhatt, Chairperson, KNH-ERC
The Deputy Director CS, KNH
Supervisors: Prof. Moni Wekesa, Dept. of Public Health, Kenyatta University
Dr. Andre Yitambe, Dept. of Public Health, Kenyatta University

THE HDD, MEDICAL RECORDS, KNH
APPENDIX VIII: INTERVIEW SCHEDULE FOR PATIENTS

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient No. ____________________________</td>
</tr>
<tr>
<td>2. Age of respondent</td>
</tr>
<tr>
<td>( ) 18 -30 years</td>
</tr>
<tr>
<td>( ) 41-50 years</td>
</tr>
<tr>
<td>( ) 31-40 years</td>
</tr>
<tr>
<td>( ) above 50 years</td>
</tr>
<tr>
<td>3. Relationship to patient</td>
</tr>
<tr>
<td>( ) Self</td>
</tr>
<tr>
<td>( ) guardian</td>
</tr>
<tr>
<td>( ) Parent</td>
</tr>
<tr>
<td>( ) other</td>
</tr>
<tr>
<td>4. Gender</td>
</tr>
<tr>
<td>( ) Male</td>
</tr>
<tr>
<td>( ) Female</td>
</tr>
<tr>
<td>( ) I don’t know</td>
</tr>
<tr>
<td>5. Marital Status</td>
</tr>
<tr>
<td>( ) Married</td>
</tr>
<tr>
<td>( ) Single</td>
</tr>
<tr>
<td>( ) Divorced</td>
</tr>
<tr>
<td>( ) Separated</td>
</tr>
<tr>
<td>( ) Widowed</td>
</tr>
<tr>
<td>6. Languages spoken</td>
</tr>
<tr>
<td>( ) English</td>
</tr>
<tr>
<td>( ) Kiswahili</td>
</tr>
<tr>
<td>( ) Other – specify _________________________</td>
</tr>
<tr>
<td>7. Level of Education</td>
</tr>
<tr>
<td>( ) None</td>
</tr>
<tr>
<td>( ) Primary</td>
</tr>
<tr>
<td>( ) Secondary</td>
</tr>
<tr>
<td>( ) Tertiary</td>
</tr>
<tr>
<td>8. Occupation</td>
</tr>
<tr>
<td>( ) Unemployed</td>
</tr>
<tr>
<td>( ) Self employed</td>
</tr>
<tr>
<td>( ) Employed</td>
</tr>
<tr>
<td>( ) Other – please specify</td>
</tr>
<tr>
<td>9. How much do you earn in a month?</td>
</tr>
<tr>
<td>( ) Less than Kshs. 5,000</td>
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<td>( ) Between Kshs 5,001 – 15,000</td>
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<td>( ) Between Kshs 15,001 – 25,000</td>
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<td>( ) Over Kshs 25,000</td>
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SECTION B
INFORMED CONSENT

Name of the Department
( ) Surgical
( ) Paediatric
( ) Obstetrics & Gynaecology

1. Did the doctor give you information on the nature of sickness or medical procedure?
   ( ) Yes ( ) No ( ) I do not remember

2. If yes, please tick the information that was provided to you?
   ( ) Diagnosis ( ) Risks
   ( ) alternatives ( ) Benefits
   ( ) Recommended treatment

3. How much time did the doctor take to explain the procedure?
   ( ) <10 mins ( ) None
   ( ) 10-30 mins
   ( ) > 30 mins

4. In what language was information on the procedure provided?
   ( ) English
   ( ) Kiswahili
   ( ) Other, specify ____________________________________________

5. Did the doctor explain the treatment that he/she would provide?
   ( ) Yes ( ) No ( ) I do not remember

6. Which of the following methods did the doctor use to explain the treatment?
   Please tick
   ( ) Words ( ) Pictures
   ( ) Diagrams ( ) None

7. Did you understand the information provided?
   ( ) Yes ( ) No ( ) I do not remember

8. Did you ask any questions concerning your treatment?
   ( ) Yes ( ) No ( ) I do not remember

9. If No, Why? ________________________________________________

10. Were you advised that you could accept or reject the procedure?
    ( ) Yes ( ) No ( ) I do not know
11. Did you seek assistance in reaching a decision whether to accept or reject the procedure?
   () Yes
   () No
   () I do not remember

12. If yes, whom did you seek assistance from and why?

13. Did you make your choice freely?
   () Yes
   () No
   () I do not know

14. If No, Please explain

15. How did you give consent?
   () Verbally
   () Written
   () Not at all

16. What are your recommendations on informed consent?
APPENDIX IX: QUESTIONNAIRE FOR HEALTH CARE PROFESSIONALS

SECTION A
DEMOGRAPHICS
1. Age of the Respondent
   () 21-30 years
   () 31-40 years
   () 41-49 years
   () Above 50 years

2. Gender
   () Male  () Female

3. Area of specialization, please state ____________________________

4. Department in the hospital ________________________________

SECTION B
1. How many patients do you see in a day on average? ____________________________

2. How much time do you spend giving information about a procedure in clinical practice to a patient? ____________________________

3. Do you think this amount of time is sufficient?
   () Yes  () No  () I am not sure

4. If No, why? ________________________________________________

5. Do you think the information you provide is sufficient to procure informed consent?
   () Yes  () No  () I am not sure

6. Do you explain the benefits of the procedure to the patient?  ____________________________

7. Do you explain the risks of the procedure to the patient?  ____________________________

8. Do you allow your patients to choose a procedure?  ____________________________

9. Do you think your patients understand the explanations given to them?
10. Do you obtain consent in emergency cases?

11. How is consent provided?
   ( ) Verbally
   ( ) Written

12. What are the challenges you face in the process of obtaining informed consent from a patient?