INFORMED CONSENT FOR SURGICAL PROCEDURES; ARE ETHICS OBSERVED?

A CROSS-SECTIONAL STUDY AT TERTIARY TEACHING HOSPITALS, AMONG DOCTORS AND ELECTIVE POST-OPERATIVE PATIENTS

RODGERS S. SWAI, (MBBS)

A Dissertation Submitted in (Partial) fulfilment of the requirement for the degree of Master of Medicine in Anaesthesiology of Muhimbili University of Health and Allied Sciences.

October, 2021

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DEPARTMENT OF ANAESTHESIOLOGY

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CERTIFICATION

The undersigned certify that he has read and hereby recommended for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: "**informed consent for surgical procedures; are ethics observed? A cross-sectional study at tertiary teaching hospitals, among doctors and elective post-operative patients**" in (Partial) fulfilment of the requirement for the degree of Master of Medicine in Anaesthesiology of Muhimbili University of Health and Allied Sciences.

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Dr Respicious Boniface

Supervisor

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Date

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Dr. Edwin Lugazia

Co Supervisor

_____

Date

DECLARATION AND COPYRIGHT

I, Rodgers Solomon Swai, declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature: ……Date: ……..

ACKNOWLEDGMENT

First I would like to thank the Almighty God for the strength he has given me for undertaking the postgraduate studies at Muhimbili University of Health and Allied Sciences.

This dissertation could have been impossible if not for the assistance I got from the entire team of the Department Anaesthesia for their supervision and guidance as well as my course colleagues for the support they provided during the study period. God bless all.

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DEDICATIONS

I dedicate this study firstly to all patients and doctors who participated in this study. Secondly to my fellow classmates for their time and commitment they have shown during the entire period of the study.

Thank you.

ABSTRACT

Background

Consent can simply be defined as permission for something to happen or agreement to do something. Important aspect of consent is that a patient voluntarily takes part in the treatment or participation in research.

Informed consent can be defined as willingly and revocable agreement by a mentally competent person to participate in a therapeutic procedure or research study, based on adequate understanding of its nature, intention and implication.

In surgical consent the process involves but is not limited to disclosing to the person the nature of diagnosis, risks and benefits of the procedure, alternative treatments with risks and benefits and lastly the risks and benefits of not receiving or undergoing a treatment or procedure and this should be explained in the language a patient can understand.

Aim/Objective

To evaluate the informed consent process at tertiary teaching hospitals.

Methodology

The study design was a cross-sectional analytical study, involving elective post-operative patients and doctors at JKCI, MOI and MNH between July 2020 and December 2020. The sample size was estimated to be 307 for patients and 123 for doctors, distributed in all three hospitals depending on the number of surgeries performed weekly. Data was collected through a structured questionnaire.

Data was entered in Excel and cleaned. Statistical analysis was performed using R. Data is presented as proportions for categorical variables. The means and standard deviations is used to summarize continuous variables while categorical data is expressed as frequencies with their corresponding percentages.

Statistical association between independent variable (age, sex, level of education, working experience, time spent acquiring consent and the study outcome (ethics observation) will be done using cross tabulation. Chi-square test will be used to compare proportions. P value of <0.05 is considered statistical significant.

Results

Patients

The study enrolled 280 patients from three hospitals, Jakaya Kikwete Cardiac Institute, Muhimbili Orthopaedic institute and Muhimbili National hospital; the distribution is 10.7%, 35.7% and 53.6% respectively. Men were (54.6%) and female (45.7%). Minimum age of the patient seen was 18 years, with a mean of 44.5 years, and maximum age of 85 years. 95.7% had formal education and only 4.3% were illiterate. 76.1% were not adequately informed while only 23.9% (67) were informed. An association between level of education of patients and how informed are the patients when getting consent was calculated by chi square with p value <0.05

Doctors

68 doctors filled the questionnaires in total; 63.2% from Muhimbili National hospital 17% Muhimbili Orthopaedic Institute and 11.8% Jakaya Kikwete Cardiac Institute. Mean age was 33.8 years, minimum 26 years and maximum 45 years. 16.17% doctors had one degree,70.59% either masters or resident students in surgical specialties and 13.24% super specialists. Work experience was categorized into less than 5 years, 42.6%, between 5 and 10 years 41.2% and above 10 years 16.2%.

44.1% had no adequate knowledge on informed consent, while 55.9% had adequate about informed consent process. An association was established between level of knowledge on Informed consent and level of education of doctor as well as work experience.

Conclusion and recommendation

This study concludes that patients are not informed even though there is a signed form for informed consent. Also doctors knowledge is still low on informed consent. There is an association between the level of education of a patient and how informed they can be. Work experience and level of education of doctors influences the level of knowledge on informed consent.

It recommends the use of guideline and capacity building programs to improve services.

Patient education on rights is also important to help improve the services.

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ABBREVIATIONS

HDU	High Dependency Unit
IC	Informed consent
ICU	Intensive Care Unit
JKCI	Jakaya Kikwete Cardiac Institute
MNH	Muhimbili National Hospital
MOI	Muhimbili Orthopaedic Institute
MUHAS	Muhimbili University of Health and Allied sciences
SDS	Same Day Surgery
WHO	World Health Organisation
WHO	World Health Organisation

DEFINITIONS

Consent	Permission for something to happen or agreement to do something.
Informed consent	The willingly given and revocable agreement by a mentally competent person to participate in a therapeutic procedure or research study, based on adequate understanding of its nature, intention and implication.
Research subject	A person who participates in a research study.

CHAPTER ONE

1. INTRODUCTION

1.1 Background

The Nuremberg Code (1947) which was a result of war crimes after World War II laid down ten standards which physicians must abide by when are doing research involving human subjects. Among other things the code highlights the requirement of voluntary informed consent of the human subject. (1) The Declaration of Helsinki (1964) is a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects developed and adopted by the World Medical association (WMA). (2) The Belmont Report (1979) identified the basic ethical principles that should underlie the conduct of biomedical and behavioural research involving human subjects. The peculiar thing of the Belmont report was that it was adopted in its entirety as a policy. (3) All three i.e Nuremberg code, Declaration of Helsinki and Belmont report have one common thing which informed consent before enrolment in research or treatment.

Modern medical ethics is based on four principles which are autonomy meaning a patient has a right to choose what he or she wants; Beneficence meaning we do effort to ensure patient wellbeing; Justice which brings the concept of fairness in distribution and lastly non-maleficence meaning avoid doing harm. (4) The application of these principles can be seen in informed consent which involves two principles of which are autonomy and beneficence which are used in an informed consent. (5) With Informed consent a person has free will to choose i.e. autonomy and we respect their choice. Other scientists have defined this as a shared decision between a clinician and a patient (6). We also inform about the risks and benefits of the procedure i.e. beneficence. Thus, IC is a process that sometimes requires even more than one sitting, for the patient to make sound decisions.

Consent can simply be defined as permission for something to happen or agreement to do something (7). Important aspect of consent is that a patient voluntarily takes part in the treatment or participation in research. There are different types of consent i.e. implied

consent, explicit consent, verbal consent and informed consent. The focus of this study is the informed consent for surgical

Informed consent can be defined as the willing and revocable agreement by a mentally competent person to participate in a therapeutic procedure or research study, based on adequate understanding of its nature, intention and implication. (8) The important things in the definition are willingness, which shows it is not imposed on the person but decided by them and they can withdraw at any time they want. Another important aspect in the definition is understanding, which differentiates the informed consent from all other types. It means that the person has enough information to understand the risks and benefits of the procedure so they can make a decision based on their values and goals.

Implied consent is approval inferred from the patient's conduct; or voluntary submission with apparent knowledge of the nature of the procedure; or presumed consent in a life-threatening emergency. (9) This means is the interpretation of the patient's action by the service provider. For example, if the person is waiting in a line for injection, it simply means the provider assumes that he/she wants the injection and will allow it to happen; otherwise he/she would not be in a line.

Explicit or expressed consent is the type of consent where there is communication between the patient and service provider, with the patient expressing clearly what he or she wants. (10) It is usually verbal but can also be written.

Verbal consent is when a patient gives permission verbally with no written note to proceed with either examination or procedure. (9) For example, when a patient comes into the clinic, and the service provider asks if he/she may do a physical examination and the patient responds yes. Before doing a physical examination, you ask if it is okay and by responding yes, he/she has given verbal consent.

For surgical procedure the standard is informed consent. It should be in writing and should disclose to the person the nature of the diagnosis, the risks and benefits of the procedure, alternative treatments with risks and benefits and lastly the risks and benefits of not receiving or undergoing a treatment or procedure (11) and this should be explained in the language a patient can understand. It should be done by the clinician who has the capacity to do the

procedure or understands the procedure. The explanation is done the moment you plan to do a procedure on a patient; it can be at a clinic, ward or emergency room.

IC is not only a signature to allow a doctor to proceed with a procedure but also a legal document that protects the doctor if done appropriately. (11) A literature review done on different cases of alleged medical negligence, concluded that clinician should change the mind-set and give reasonable information to the patient during getting consent in order to avoid negligence claims. (12)

The World Health Organization has stipulated in its guidelines for safe surgery that informed consent is an important tool for the safety of the patient (13). This is because ensures that every procedure done to the patient, he/she has given permission.

In Tanzania, the National Guideline for Safe Care Standards explains that health facilities should have a clear defined process of getting informed consent. It goes further explaining all parts, and how consent should be attained. In surgical procedures, it directs that the consent form should state the type of anaesthesia and procedure to be performed on the patient. (14) This serves as an important tool to ensure that errors are minimized, if it is followed well.

With all the guidelines and policies in place, still several studies done in IC have highlighted some gaps. A literature searches of articles done in 2010 by Leclercq et al, was able to conclude that there is a big gap between the theoretical/legal best practice and the daily practice of IC (15) and it due to several factors such as physician not knowing the process, patient level of education and language barrier Thus there is a room of research and improvement in order to perfect our informed consent in our setup.

1.2 Problem statement

IC is an important ethical issue that needs to be taken seriously. It involves intense and detailed discussions to ensure the patient understands the procedure planned to be done to him/her with its risks and benefits before giving authorization for treatment.

When IC is not taken properly, the patients' rights to autonomy and beneficence are violated. Not only violation of those rights, but doctors are also at risk of being sued.

Our facilities ensure that it is absolutely necessary to get consent from the patient before any invasive procedure. But is it really informed consent? Or just a signature on a paper? For it to be called informed consent, the patient should be explained in full and understand what he/ she is signing up for. Do we follow the Tanzanian guideline on safe care when getting the informed consent?

There are no published studies from Tanzania which evaluate the IC process in our institutions so we have no information about whether the guidelines are being followed. An audit on surgical patients' understanding and completeness of their informed consent was conducted in Hong Kong on 100 patients; showed only 70% could state at least one complication of the procedure. Hence room for improvement by giving enough information prior getting the consent so that patients can be informed to increase the number to even 100%. (16) Similar findings are seen in an audit in Karachi by Amin et al which was done to find out preoperative informed consent practice in a tertiary care public sector among 200 patients. It was a questionnaire study and showed that 45% were told the about the nature and purpose of procedure and (44.5%) of patients knew about the possible complications of surgery (17).

A study in Nigeria to evaluate the adequacy use of the informed consent in surgical practice among 91 patients through a structured questionnaire revealed among many other findings, that 46% did not understand the content of the consent form even though all patients signed the consent forms (18). The author of this paper concluded that it appears the practice of surgeons is not adequate i.e to ensure the patients understands everything before getting the consent.

This problem seems to be common in different places with different health systems and level of resources, it is possible that the criteria for informed consent are also not being met in Tanzania. Hence we might be facing the same problem at a different magnitude.

1.3 Conceptual framework

The conceptual framework captures the multifaceted realities of the valid informed consent. The shared decision-making model developed by Leon-Carlyle et al (19) for surgical consultation has been modified and applied to the conceptual framework of this study.

Patient factors, physician factors, factors affecting information exchange, patient's deliberation and voluntarism to making treatment decisions and providing consent have been measured. They also have an impact on how the patient will be informed and ethics observed.

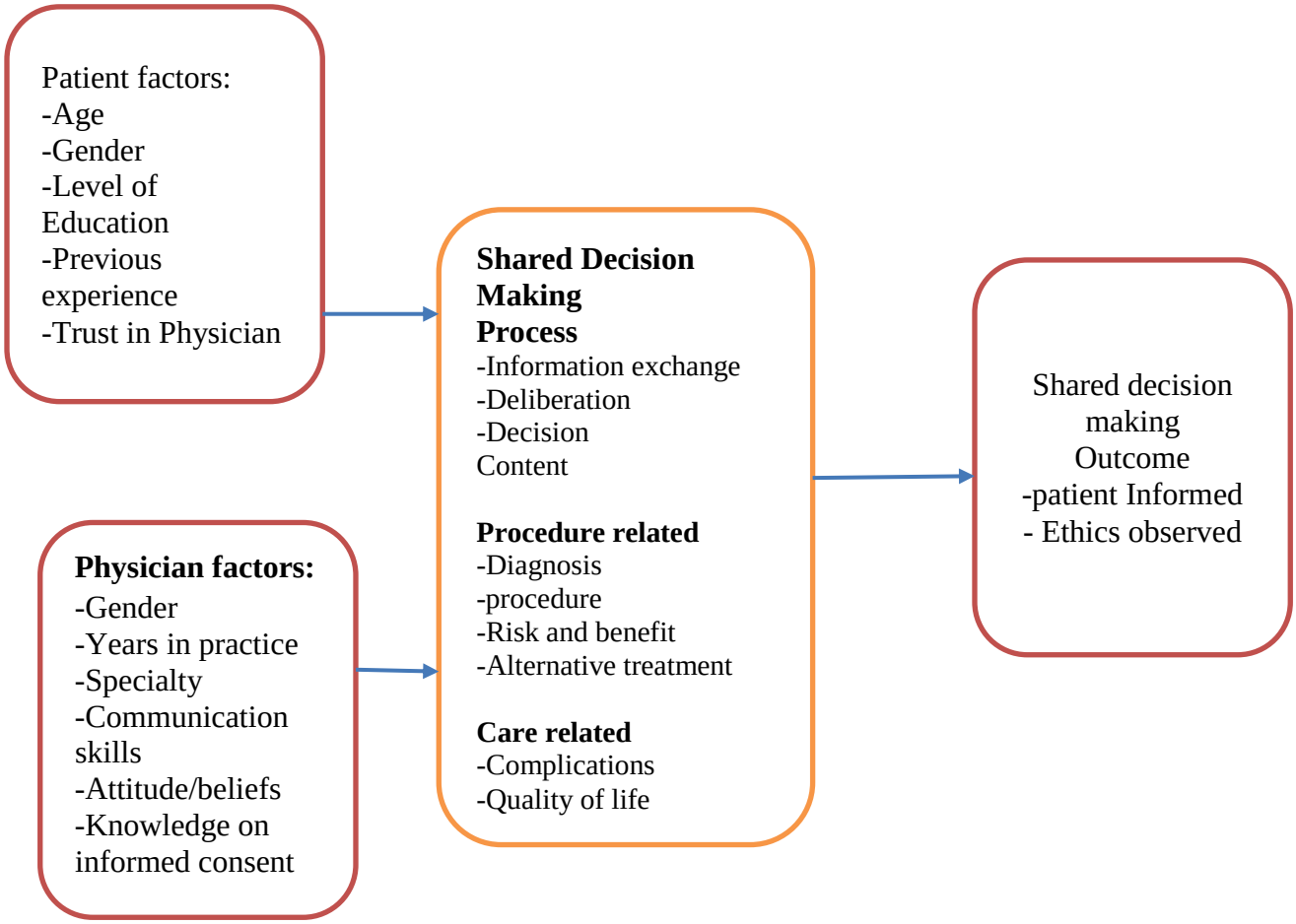

Figure 1: Conceptual Frame work

1.4 Rationale

This research will provide useful information on our current process of IC. It will act as a stepping stone towards a positive change in order to ensure patient centred care, as we practice evidence-based medicine.

The findings from this research will help in changing the mind-set of practitioners in order to protect themselves from being sued for negligence as well as help the patient to make a decision knowing both the risks and benefits of the procedure and choosing according to his own hierarchy of beliefs and needs.

No studies have looked at whether Tanzanian clinicians are familiar with the guidelines. If they are not, educating physicians about the guidelines could help improve the informed consent process.

Doing a research project is also a requirement for my master's program, hence needed. This study will also open doors for further studies in the area of IC.

1.5 Research question

1 Is the informed consent process adequate?
2 What is the knowledge of physicians/doctors on informed consent?

1.6 Broad objective

To evaluate the informed consent process at MOI, MNH and JKCI

1.6.1 Specific objective

1 To determine if the process of obtaining IC is correctly done following the Tanzania guideline among patients undergoing elective procedures.
2 To determine the knowledge of doctors/physician on informed consent process.
3 To identify factors influencing informed consent processes.

1.7 Literature review

1.7.1 Informed consent process.

IC process is mainly based on two principles of medical ethics, autonomy and beneficence. In autonomy we ensure the patient makes their own decision based on enough correct information given observing that you are not persuading the patient with information given. While in beneficence a doctor acts to the best for the patient. (8,20) So it is a mutual decision making where the patient is actively involved. (11)

The process begins by who acquires the consent, a study done in Gulhane Turkey, to look at the quality of informed consent prior surgical procedure; among 400 post-operative patients showed 73% were acquired by physicians (21). A cross-sectional study conducted at 3 university teaching hospitals in Uganda showed only 48.8% of consents from the patients are taken by doctors (22). Another study in Jamaica which was aimed to evaluate the presurgical informed consent process; among 210 patients who participated in the survey 48% of the patients didn't know the title of the one who took the consent (23). All these literatures show that there is a gap in proper introduction of a person who acquires the consent from the patient.

A study in Gulhane Turkey showed 18.3% of Patients did not know their diagnosis and 52.3% were not aware of the kind of surgery that was to be performed on them (21). A study in Jamaica which was evaluating the presurgical informed consent showed similar findings regardless of all the consents being taken by surgical residents (23). In Nigeria, a study done to evaluate the adequacy of the use of informed consents surgical practice among 91 patients who participated in the study, 12.3% of patients did not know the intention of the surgical procedure and it wasn't explained for 27.5% of the patients (18).

An audit of information provided during preoperative surgical consent in Karachi revealed only 45% were told about the nature and purpose of the procedure and only 44.5% knew about the possible complications (17). A study done in seven teaching hospitals in Iran, looking at how well informed with IC the patients were, showed that patients had received an intermediate (a score of 30-45 out of 60) level of information about the nature of the

disease, type of surgery, benefits and importance of the surgery, and complications of rejecting the recommended therapy. They had not received enough information on surgical procedure and complications (24). In Nigeria a study done to audit the process of informed consent for elective and emergency caesarean sections showed only major risks were discussed with the patients (25). In Ghana, in an audit of 100 patients for aspects of surgical informed consent only 13 knew about possible complications. (26) All the above-mentioned studies show that there is gap of information in IC; which means patients are not informed when they give consent. This is backed up by findings from a systematic review by Falagas et al, to evaluate the degree of patients' understanding of various aspects of informed consent, where out of 21 studies, only 6 showed adequate understanding of the surgical procedure, risks and complications (27). But an audit done in Hong Kong revealed astonishing results, 99% could state correctly the name of the surgical procedure and site, and 70% could recall the surgical risks (16). This study shows getting proper informed consent is possible.

1.7.2 Physicians knowledge on IC

For the consent to be informed, a patient should be aware of the risk versus the benefit of the planned procedure. The primary role of a physician is to explain in detail to the patient, answer any questions and ensure that the patient has all the necessary information before getting the consent.

Who then should obtain the consent from the patient? The General Medical council (GMC) of the UK recommends a clinician providing the treatment or investigation is responsible for ensuring that the person has given valid consent before treatment begins (28–30). This is because the doctor providing the treatment is in a better state of explaining the risks, complications and even alternative treatment than a junior doctor. Most times consent is obtained by either residents or junior doctors (22) which might compromise the quality of information a patient receives.

A survey of obstetrics and gynaecology residents' knowledge on IC in Nigeria revealed that not a single resident was able to give all important components of IC (31). These findings

are not far apart from a study in South Africa which examined doctors' practice with regards to IC, which also showed that no single doctor was able to define IC properly. Most of them thought that it included only the condition and recommended treatment (32).

A study done in Uganda to evaluate the informed consent practice of surgeons in three university teaching hospitals, revealed that the majority thought the surgeon performing the procedure should obtain the consent and some thought any admitting personnel even the nurses could do so. About 42% said the consent should be obtained before the surgical procedure but could not specify the exact time. And lastly none of the three hospitals had a proper consent form (22).

The Tanzania guideline for safe care directs the health facility to have a policy on informed consent. The guideline does not specify who should take the consent but emphasizes that the patient should be given information regarding the treatment and make his/her own decision. Evidence of such a decision should be available in the file of the patient (14).

All above still point to the knowledge gap of physicians that if tackled can help improve the informed consent process.

1.7.3 Factors influencing Informed consent

This study aims to identify factors influencing the informed consent process in either positive or negative ways. We want to identify what barriers hinder the patient from being informed before giving consent.

A study done in Iran looking at factors associated with quality of informed consent found that patient level of education and type of surgery affected the quality of informed consent. Patients with low levels of education did not have a quality IC. Also patients undergoing ophthalmology and E.N.T surgeries received high quality IC (33), a factor that has to be studied further to know why these particular patients received high quality level of IC.

A study looking at predictors of comprehension during surgical IC in military veterans from four centres in the USA found that time spent in getting consent was the main predictor of

comprehension (34). This means that more time spent in explaining the information to the patients enables them to really give an informed consent.

A literature review of six databases analysing patients' recollection and understanding of informed consent, reviewing studies from 1995 to 2013 found that the level of understanding of consenting decreased with age. Level of education, literacy and language competency, combined with physicians' ability to effectively explain the medical procedure and the inherent risks and complications, were important determinants of patients' capacity to provide fully informed consent. As a solution, the use of education materials delivered in written form or embedded in an interactive multimedia process led to improvements in patients' understanding of the implications of surgery (35).

CHAPTER TWO

2 METHODOLOGY

2.1 Study design

A cross-sectional analytical study was done, involving elective post-operative patients and doctors at JKCI, MOI and MNH.

2.2 Study area

The study was conducted at Muhimbili Orthopaedic Institute (MOI), Muhimbili National Hospital (MNH) and Jakaya Kikwete Cardiac Institute (JKCI).

The Muhimbili Orthopaedic Institute (MOI) is an autonomous institute established under ACT. No 7 of 1996 with the main objective of providing primary, secondary and tertiary care of preventive and curative health services in the fields of Orthopaedics, Traumatology and Neurosurgery, as well as being a role model for efficient hospital management in Tanzania. Muhimbili Orthopaedic Institute (MOI) is the largest Orthopaedic and Trauma referral centre in Tanzania, with a capacity of 362 beds (260 general beds, 60 private beds, HDU 16 beds, 19 ICU beds, 7 SDS & 2 executive room) It offers both emergent and non-emergent Orthopaedic and Neurosurgery services. It has 9 operating rooms and performs an average of 100-125 procedures a week.

MNH is a National Referral Hospital, Research Centre and University Teaching Hospital with 1,500 bed capacity, attending 1,000 to 1,200 outpatients per day, admitting 1,000 to 1,200 inpatients per week. It has eight operating rooms for general surgery and subspecialties, two operating rooms for paediatrics surgeries, and four rooms for obstetrics and gynaecology. It performs an average of 170 procedures per week.

JKCI is a National Specialized and University Teaching Hospital offering cardiovascular care, training and research services. The Institute has a 103 bed capacity, attending on average 700 outpatients and 100 inpatients per week. It has 2 operating rooms and does at least 10 surgical procedures per week.

2.3 Study duration

The study was conducted from July 2020 to December 2020.

2.4 Study population

The study population included all patients 18 years and above, who consented and underwent elective procedure within the period of July 2020 to December 2020.

It also included all doctors in surgical departments from the three hospitals.

2.5 Sample Size Estimation

Patients

The sample size was estimated to be at least 307 subjects, assuming a 60% of expected prevalence of the adequate ethics observation in IC; this is same as the prevalence found in a study done in Kenya. (36) Precision of 5% and level of significance of 95%. The minimum sample size of this study is calculated using Kish and Lisle formula (1965)

$$N=\frac{Z^2\,P\,(1-P)}{e^2}$$

n = Minimum sample size

Z = point on normal standard distribution (1.96)

e = Margin of tolerable error 5%

p = 60%

Therefore;

n= 1.962 x 0.6(1-0.6)/ (0.05)2

n=307

Doctors

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

$n= (1.96)^2 \times 0.5(1-05)/(0.05)^2$

n= 384

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

nf = n /1+(n/N)

Where

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

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

N= the estimate of the population size, which in this case was the number of physicians (surgeons, residents and registrars) in surgical department in three hospitals (MOI, MNH and JKCI). The total number was estimated to 180.

Therefore: nf= 384/1+(384/180)

nf = 122.5 rounded to 123

Hence sample size for doctors was calculated to 123.

Post-operative patients (elective) treated at JKCI, MOI and MNH from July 2020 to December 2020, who consented, were recruited; and doctors from surgical departments from hospitals. The sample size was distributed in the ration of 3:2:1 for MNH, MOI and JKCI respectively. This distribution is based on numbers of surgical procedures and numbers of doctors in surgical departments of each hospital.

2.6 Inclusion criteria

Patients

- Patients 18 years and above who underwent an elective surgical procedure.

Doctors

Doctors in surgical department's i.e. general surgery and surgical subspecialties' who get consents from patients for surgical procedure

2.7 Exclusion criteria

Patients

Patients who do not consent to be included in the study

Patients admitted in ICU/HDU post operatively

Patients with altered mental status (such as post-operative delirium, chronic and acute dementia, schizophrenic)

Patients who do not understand Kiswahili or English Language

Doctors

- Doctors who do not consent to be included in the study
- Doctors (interns) that have less than 1 month in the surgical department

2.8 Variables

2.8.1 Independent variables

Age

Level of education

Hospital admitted to

Surgical department

Time spent acquiring IC

Operation being performed.

2.8.2 Dependent variable

The outcome of this study was ethics observation. From introduction we saw that IC includes two important pillars of ethics: autonomy and beneficence. So in this study we will have one dependent variable, Ethics observation

2.9 Data collection tool

Pre tested structured questionnaires was used as a data collection tool. It collected quantitative data from the set questions. I used two different questionnaires; one for patients and another one for doctors.

Patient questionnaire

Questionnaire was adopted from a study done in Italy (37), and modified to meet the objectives of this study. It contained seventeen questions, divided into three sections; demographic section containing six questions, written consent containing six questions and last section for oral information containing five questions. Question fourteen had a total score of six depending on the information the patient shares. A score of 6 signified patients are informed before signing the informed consent hence ethics observed. This is mandatory in answering the first specific objective.

Doctors' questionnaire

This will be ten questions, questionnaires divided into two sections. Section one contains demographic data; five questions and section two contains knowledge on informed consent five questions as well. It has some questions with scores which summed to 6 points. A score of five and above was taken as having adequate knowledge on informed consent.

This questionnaire answered the second objective and third objective from finding the association of different variables.

2.10 Data Collection Process

Pre- test for data collection tools was conducted by the researcher for the purpose of finding out if it provides the required information. Necessary changes were made so as to obtain the required information. The researcher provided information about the study to study participants and obtained consents.

A questionnaire was administered by the researcher and research assistant on the first or second postoperative day. Data collection from patients was done when he/she is fully awake in case of same day surgery and pain free to ensure adequate cooperation and concentration. An assessment of mental status was done before administering the questionnaire.

Data from doctors will be collected through a different self-administered questionnaire.

2.11 Research subject enrolment

Patients

All patients 18 years and above who underwent elective surgical procedure from July 2020 to December 2020 will be included.

- Patients were screened for inclusion criteria and those who met them were offered explanations about the study and requested to consent before being enrolled into the study.
- Information was collected using a structured questionnaire.

Doctors

Doctors (interns, registrars, residents and specialists) obtaining informed consent from patients were involved in this study.

- The study was explained to them, and consent requested before being enrolled into the study.
- Data were collected through a self-administered questionnaire.

2.12 Data Management

The data from fully filled-out questionnaires was coded, checked by investigator for accuracy. A Microsoft excel (office 2010) database was developed with logic checks to ensure data quality. Anonymity of the participants was observed at all times as names were not used. The Excel sheet was secured by the password only known to the principal investigator to ensure data safety. The completed database was exported to the R program.

2.13 Data analysis

Descriptive statistics was computed by R program (version 4.0.5) and different prevalence for several questions are shown in either tabular or bar charts to explain the findings.

Data is presented as proportions for categorical variables. The means and standard deviations used to summarize continuous variables while categorical data is expressed as frequencies with their corresponding percentages.

Statistical association between independent variable (age, sex, level of education, working experience, time spent acquiring consent and the study outcome (ethics observation) will be done using cross tabulation. Chi-square test will be used to compare proportions. P value of <0.05 is considered statistical significant.

2.14 Ethical Consideration

Ethical clearance was obtained from MUHAS Institutional Review Board (IRB) and permission from MOI, JKCI and MUHAS research committee was requested. The concept was presented in all institutions for proper understanding and smooth running of the research. The aims of the study were explained to the participants, who were allowed to ask questions about the study. During and after the study period, the patients' confidentiality was maintained. The obtained information was used for research purposes only.

The participants in this study signed an informed consent form to indicate their willingness to participate in the study. The participants were allowed to withdraw from the study at any point during the course of the study.

2.14 Study Limitations

Not all enrolled patients knew how to read and write. Plus, understanding the questions to give appropriate answers was a limitation leading to poor information.

2.15 Study Mitigations

Research assistants were given proper training to understand each question in the questionnaire. Research assistants did data collection from patients and doctors by ensuring patients understand each question before answering it.

CHAPTER THREE

3 RESULTS

3.1 Patient data

3.1.1 Demographic data

310 patients were interviewed, for 6 months, between July and December 2020 in 3 hospitals, i.e. Muhimbili National hospital, Muhimbili orthopaedic institute and Jakaya Kikwete Cardiac institute. 30 questionnaires were excluded from the analysis since due to incompleteness and incorrectness; hence remained with 280.

Patients distribution according to hospitals was as follows:30 (10.7%) patients from JKCI, 100 (35.7%) from MOI and 150 (53.6%) from MNH.

Majority were male 54.6% and the mean age was 45.5 years. Majority had received secondary education 44.3%.

Table 1: Patients characteristics

VARIABLE		FREQUENCY	PERCENTAGE
Hospital	JKCI	30	10.7
	MNH	150	53.6
	MOI	100	35.7
Sex	Female	127	45.4
	Male	153	54.6
Age	Minimum	18	
	Mean	45.5	
	Maximum	85	
Education	College/University	49	17.50%
	Secondary	124	44.30%
	Primary	95	33.90%
	Illiterate	12	4.30%

Time for receiving informed consent form

The time for receiving informed consent forms varied from one patient to another. This is illustrated in the figure below which shows, 3 (1.1%) received the informed consent form in the operating room, 19 (6.8%) in the ward same day of surgery, 64 (22.9%) more than one day before and 194 (69.3%) received the consent a day before surgery.

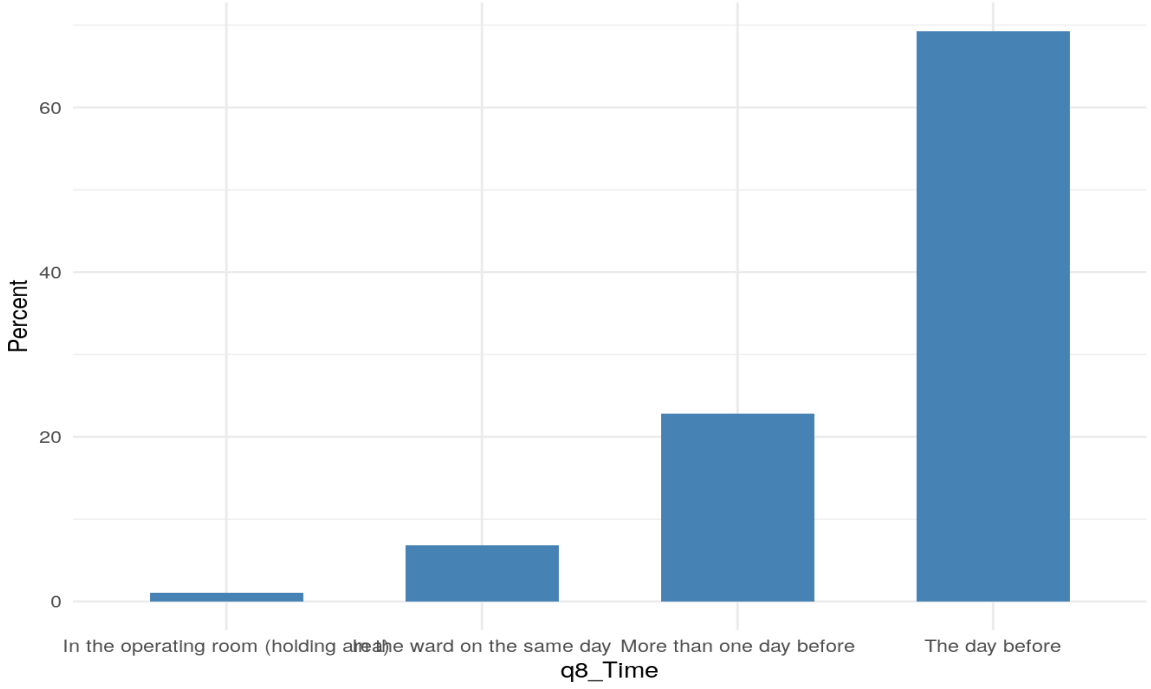

Figure 2: Bar chart showing time patients received the informed consent form

Introduction of health personnel

Patients reported 250 (89.9%) of health personnel introduced themselves by name and title while getting the consent, 10.1% (28%) did not introduce themselves by name and title. 0.7% (2) did not remember.

For those who introduced themselves, 24.3% (68) introduced themselves either as operating surgeons, 75% (210) as other physicians from surgical departments for example, resident and

registrar. Some did not introduce themselves but patients knew them by name and title as they were regular patients.

Reading the consent form

121 (43.2%) of the patients read the form before signing it; 155 (55.4%) did not read it and 4 (1.4%) read it partially. This is shown on the bar graph below.

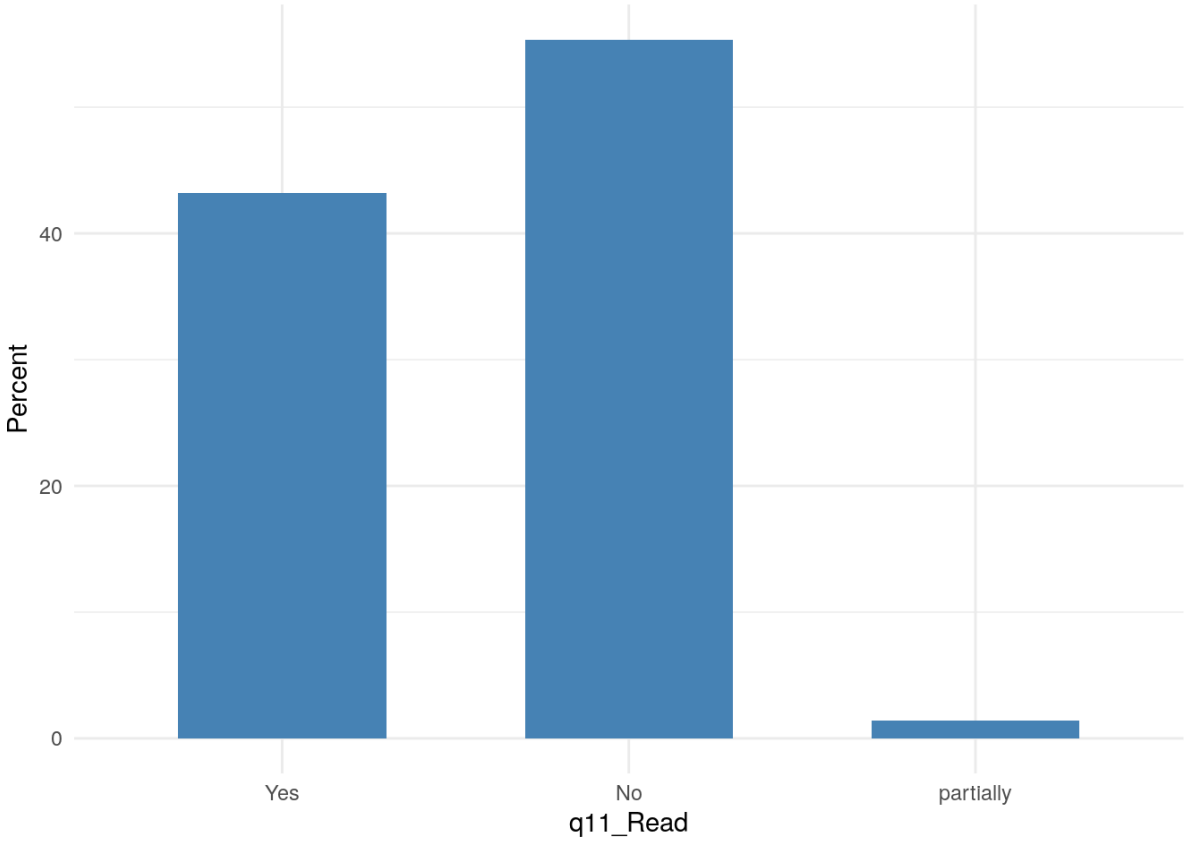

Figure 3: Bar graph showing how many patients read the form before signing it

Understanding the informed consent form

88 (31.4%) patients understood the form; 186 (66.4%) did not understand the form and 6 (2.1%) understood it partially.

Information communicated

This question assessed the information that was communicated to the patients before them giving consent for the planned procedure. The information assessed was diagnosis, prognosis, proposed treatment, expected post-operative progress, benefits of proposed treatment, complications of proposed treatment, alternatives to proposed treatment, chances of success of proposed treatment and possible outcomes of missed treatment. All these are parts of informed consent.

Diagnosis

273 (97.5%) were told their diagnosis while 7 (2.5%) were not told about the diagnosis.

Prognosis

100 (35.8%) were informed about the prognosis while majority i.e 179 (64.2%) were not informed about the diagnosis

Proposed treatment

153 (54.6%) were informed about the proposed treatment; and 127 (45.4%) were not informed about the proposed treatment.

Post-operative progress and possible recovery issues.

This was not communicated to the majority of the patients. Only 44 (15.7 %) were informed about post-operative progress while 236 (84.3%) were not informed.

Benefits of proposed treatment

90 (32.1%) were informed about the benefits of the proposed treatment; and 190 (67.9%) were not informed.

Complications of proposed treatment

Complications were not communicated in the majority of the patients. 243 (86.8%) were not informed about the complications, while only 37 (13.2%) were informed about the complications

Alternatives to proposed treatment

32 (11.4%) patients were informed about alternatives to proposed treatment while 248 (88.6%) had not been informed about alternatives to proposed treatment.

Chances of success

The success of proposed treatment was only communicated to 46 (16.4%) while the majority 234 (83.6%) were not informed about the chances of success.

Outcomes of missed treatment

125 (44.6%) were informed on the outcomes of missed treatment; while 155 (55.4%) were not informed on the outcomes of missed treatment.

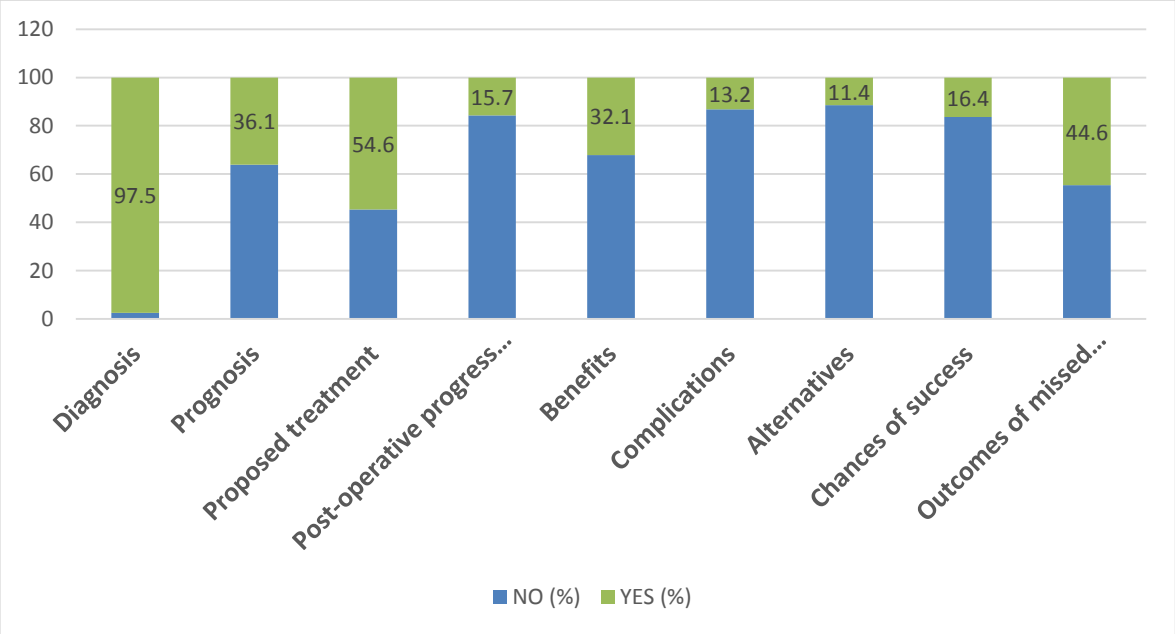

Figure 4: Bar graph summarizing information communicated to patients.

Receiving oral information

This question intended to assess at what particular time was most of the information about consent shared with patients. The bar graph below shows that the majority received the information progress during pre-operative examination i.e during clinic or in the ward when the procedure was planned.

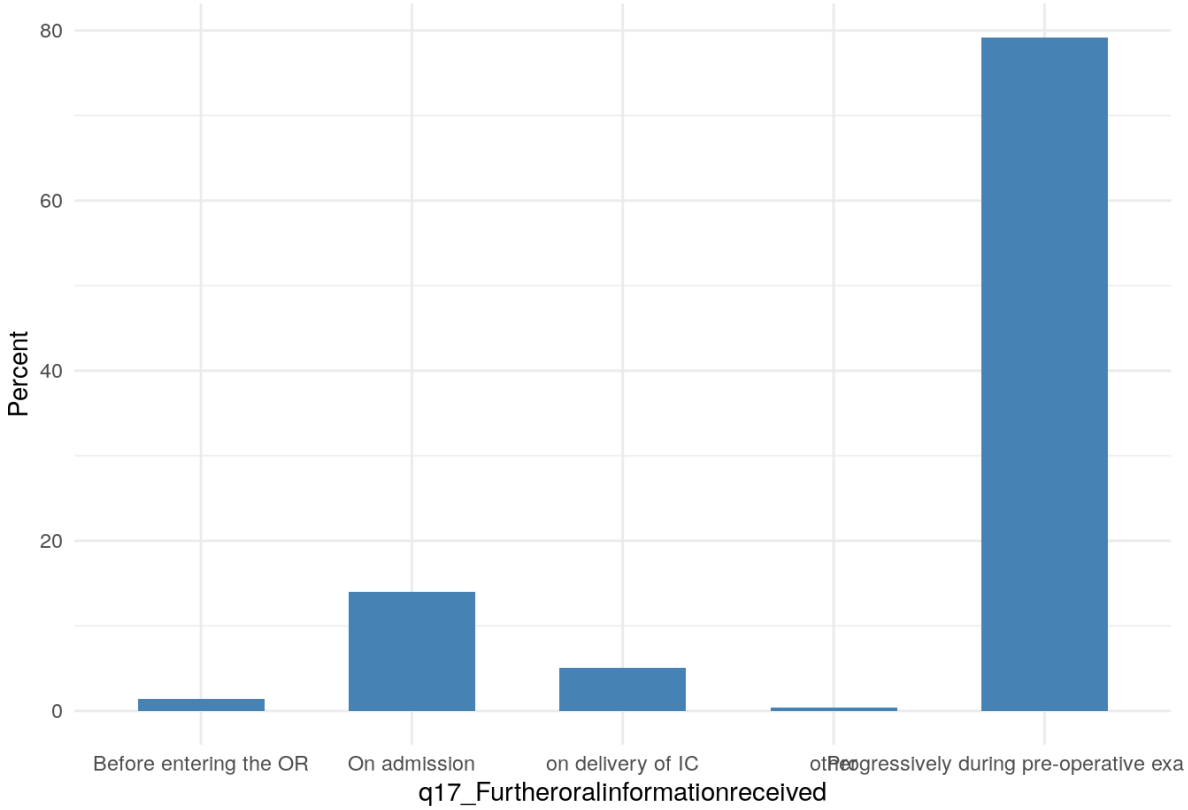

Figure 5: Bar graph showing when patients received further oral information.

Patients understanding

The patients were asked if they understood what was verbally communicated to them; and the majority 274 (98.6%) responded yes, meaning they understood the verbal information. 1 (0.4%) did not understand, and 3 (1.1%) (3) partially understood. This is outlined in the bar graph below:

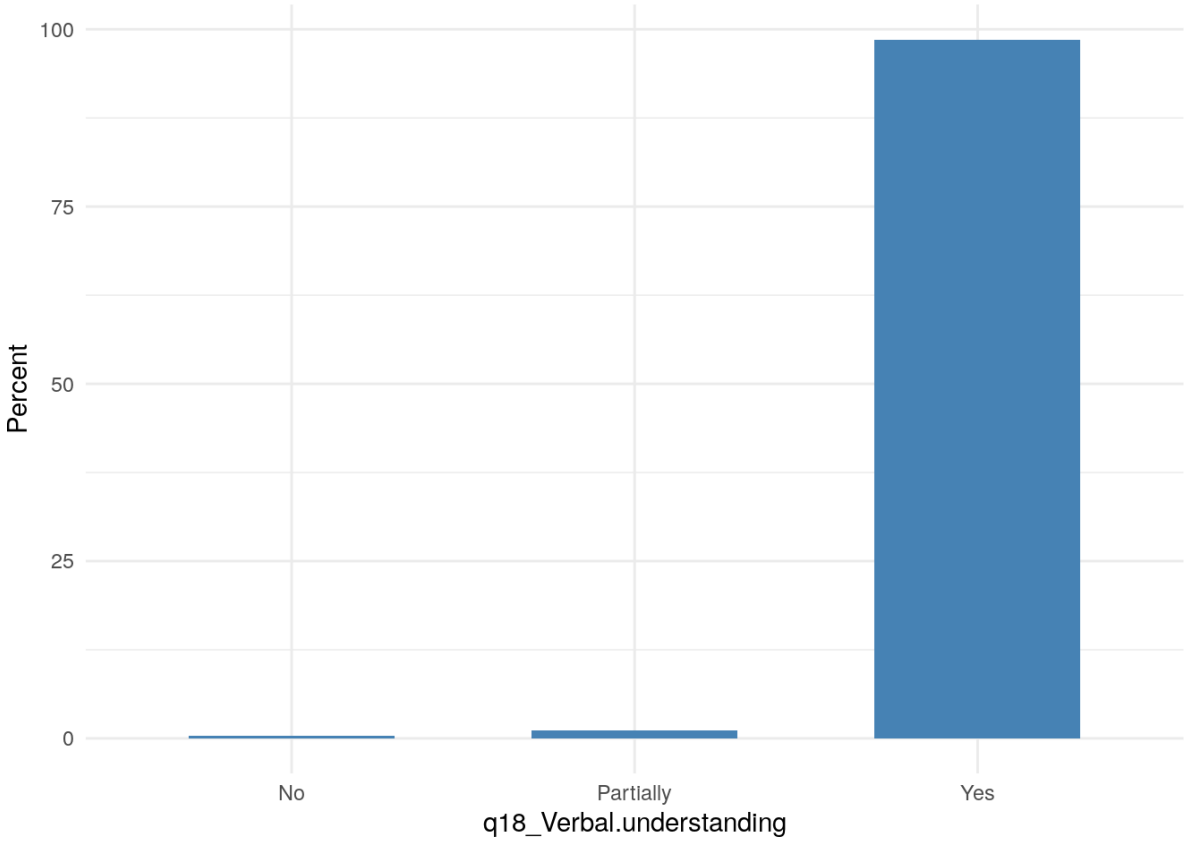

Figure 7: Bar graph showing patient understating verbal information

Anxiety and patients' focus to get well was mentioned as the reason that patients did not understand the verbal information communicated to them.

Opportunity to ask questions

254 (91%) had the opportunity to ask questions which is an important ask question while 26 (9%) had no opportunity to ask questions. This if further elaborated on in the graph below:

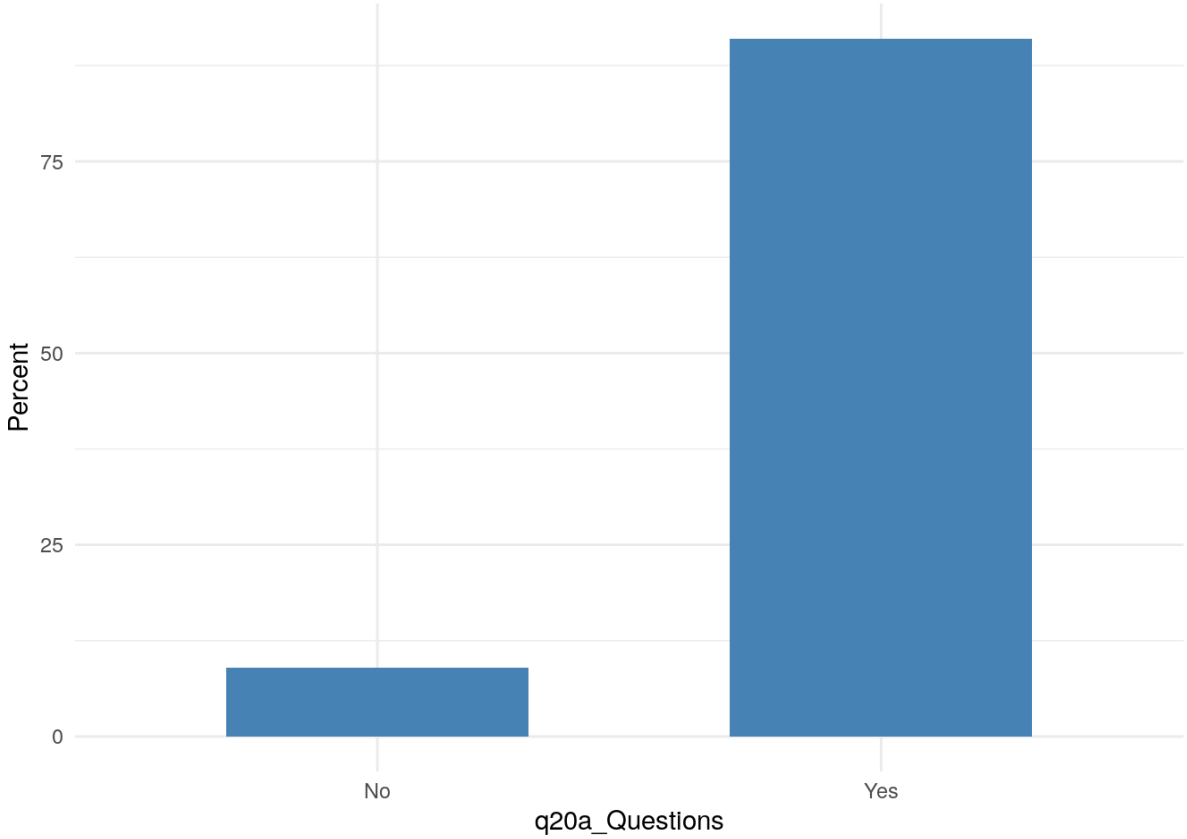

Figure 7: Bar graph showing patients' opportunity to ask questions.

Level of informed

Patients were assessed to determine the level of how informed they are about the surgical procedure by finding a total mark after scoring 1 point for each part they were informed about the consent. The total marks were 9. The average score for patients was 3, with the median of 3, minimum of 0 and maximum of 9. The score of above 4 was taken as at least informed since it was above 50% of the total. 213 (76.1%) were not adequately informed while only 67 (23.9%) were informed.

Association of education and informed.

An association between level of education and how informed are was calculated using chi square.

Table 2: Association between level of education and how informed are the patients.

	Informed		
EDUCATION LEVEL	**No**	**Yes**	**Total**
Illiterate	10 (83.3%)	2 (16.7%)	12 (100%)
Primary/Secondary	180 (82.2%)	39 (17.8%)	219 (100%)
College/University	23 (46.9%)	26 (53.1%)	49 (100%)
Total	213 (76.1%)	67 (23.9%)	280 (100%)

X^2 = 27.7008 df = 2 p = .0000

The above table shows the chi square was 27.7008 with a p value less than 0.05 which shows there is an association between level of education of patients and how informed are the patients when getting consent.

3.1.2 Doctors Results

3.1.2.1 Demographic data

A total of 123 questionnaires were distributed to doctors, unfortunately only 68 returned fully filled by doctors. 63.2% (43) of the total were from MNH, 17% (25) from MOI and 11.8% (8) from JKCI. Majority of the respondents were male 49 (72.1%), and the average age of all respondents was 33.8 years.

Most of the respondents were either residents or specialist 48 (70.6%) and with work experience of less than five years 29 (42.6%) leading followed by between five and ten years 28 (41.2%).

Table 3: Summary of Doctors demographics.

VARIABLE		FREQUENCY	PERCENTAGE
Hospital	MNH	43	63.20%
	MOI	17	25%
	JKCI	8	11.80%
Sex	Male	49	72.10%
	Female	19	27.90%
Age	Minimum	26	
	Mean	33.8	
	Maximum	45	
Level of education	Registrars	11	16.20%
	Resident/Specialist	48	70.60%
	Super specialist	9	13.20%
Work experience	<5 years	29	42.60%
	5-10 years	28	41.20%
	>10 years	11	16.20%

Knowledge on Informed consent

This section had four questions, which tested the knowledge on informed consent if answered correctly. 43 (63%) were able to define informed consent correctly, 25 (37%) were able to identify the correct person to take informed consent who is the specialist and 41 (60%) answered correctly the question regarding the right time to take consent which is in the clinic when planned for surgery. Majority 55 (81%) were able to know which principle of medical ethics is violated in consent is not taken which is autonomy.

Table 4: Summary of doctors' knowledge on informed consent.

VARIABLE		FREQUENCY	PERCENTAGE
Definition IC (score)	Not correct	25	37%
	Correct	43	63%
Responsible person	Specialist	25	37%
	Any health personnel	20	29%
	Any doctor	14	21%
	Registrar	6	9%
	Intern doctor	3	4%
Time to obtain consent	Clinic	41	60%
	On admission	15	22%
	Just before surgery	12	18%
Principle violated	Autonomy	55	81%
	Beneficence	5	7%
	Justice	4	6%
	Non maleficence	4	6%

Consent adequacy

Majority i.e. 55.9% said our current consents are adequate while 44.1% said that they are not adequate.

Some suggested different modifications that can be done to make our forms adequate such as including having different forms for different procedures, including risks and benefits, explanation of the procedure and having forms of English version as well.

Guideline

Majority of the doctors 82.4% have not seen any guideline on informed consent from either the ministry or institution they work for while only 17.6% had seen a guideline on informed consent process.

Capacity building

53 (77.9%) had not received capacity building on informed consent, while 15 (22.1%) had received capacity building on informed consent. This is shown on the graph below:

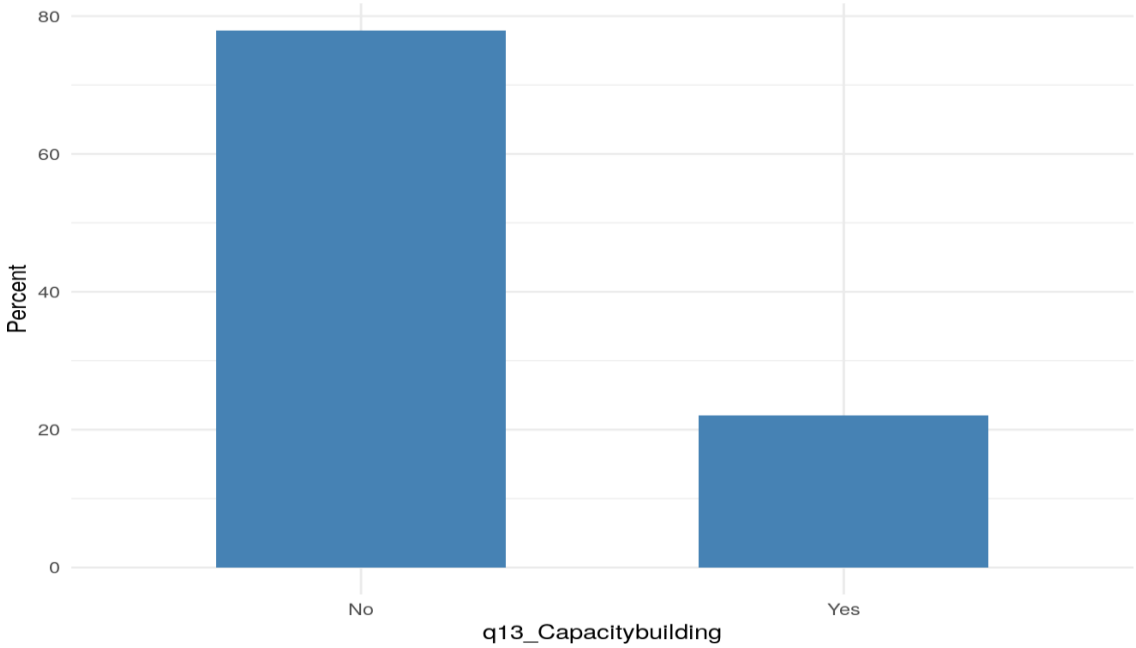

Figure 8: Bar chart showing response of physicians on receiving capacity building on informed consent.

Knowledge

Knowledge was assessed by calculating a total score on 4 questions. i.e definition, responsible person, time and ethical principle violated. A score of 3 and above was considered to be knowledgeable about informed consent process.

30 (44.1%) had inadequate knowledge on informed consent, while 38 (55.9%) had adequate knowledge about informed consent process. This is shown on the bar chart below.

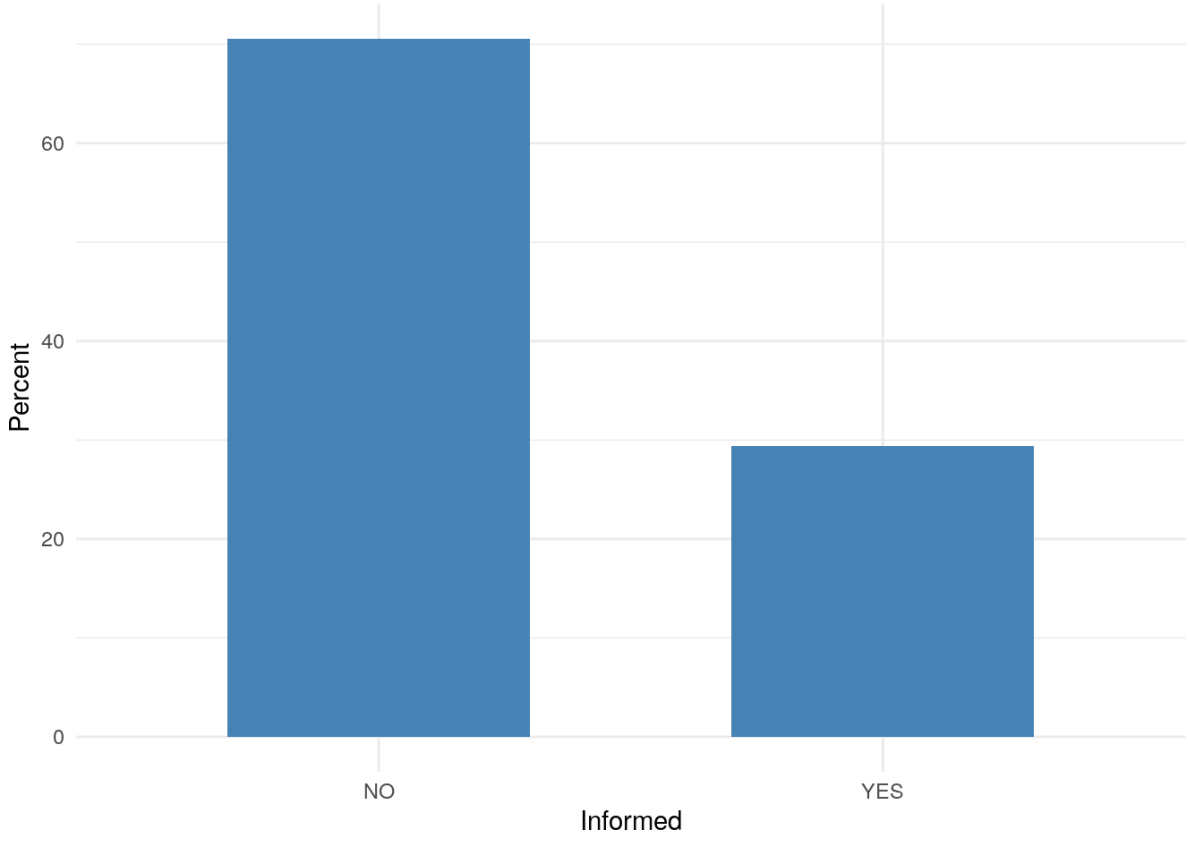

Figure 9: Bar chart showing knowledge distribution of doctors

Association

A relationship between level of education and knowledge of doctors about informed consent process was assessed using chi square test., as the table below shows.

Table 5: Table showing relationship between level of education and Knowledge on informed consent

EDUCATION LEVEL	Knowledge No	Yes	Total
MD/MBBS	10 (90.9%)	1(9.1%)	11 (100%)
MMed/Resident	36 (75%)	12(25%)	48 (100%)
Super specialist/Fellow	2 (22.2%)	7 (77.8%)	9 (100%)
Total	48 (76.1%)	20 (23.9%)	68 (100%)

X^2 = 12.7786 df = 2 p = .0017

From the table above p value calculated is 0.0017 which is below 0.05 hence there is statistical significance between level of education and knowledge of informed consent. As the education level increased i.e. super-specialties had more knowledge on informed consent.

Another relationship that was established is between work experience and level of knowledge on informed consent. Chi square test was calculated as the table below shows:

Table 6: Relationship between work experience and level of knowledge on informed consent

	Knowledge		
Experience	**No**	**Yes**	**Total**
Less than 5 years	27 (93.1%)	2 (6.9%)	29 (100%)
5 to 10 years	18 (64.3%)	10 (35.7%)	28 (100%)
More than 10 years	3 (27.3%)	8 (72.7%)	11 (100%)
Total	48 (70.6%)	20 (29.4%)	68 (100%)

X^2 = 17.5577 df = 2 p = .0002

From the table above chi square calculated was 17.5577 with p value of 0.0002 which is less than 0.05 hence there is statistical significance. This means there is a relationship between work experience and level of knowledge. As the work experience increases, the level of knowledge on informed consent increases.

CHAPTER FOUR

4 DISCUSSION, STRENGTHS AND LIMITATIONS

4.1 Discussion

This study aimed to determine how informed patients are when they give consent for surgical procedures. And in order to assess this, we looked at the process of getting consent before any elective surgery in 3 hospitals

This study shows that only 23.9% of the patient that underwent surgery were informed; this means they at least new information from five parts of the consent example diagnosis, risk, benefits, alternative treatment etc. All patients were informed about the procedure but other information like risks, benefits, post-operative complications were not adequately communicated to all the patients hence lowering the percentage of patients adequately informed.

The process of informed consent involves 4 important steps, delivery, signature, reading and comprehensibility. This study shows that delivery and signature was 100%. This is because it is mandatory for a signed consent form to be in file before patient is taken for surgery. Hence they will sign the form regardless. In this study only 43% read the consent before signing it. Among the reason that were given to why they did not read the form are form being explained to them or doctor being in a hurry. These reasons affect the process hence leading to patients being uninformed. These finding are similar to the study in Kenya and Italy. (36,37)

Almost all patient understood diagnosis and planned procedure. This might be different from a study conducted in Turkey where percentage where 81.7% and 57.7% for diagnosis and procedure respectively. (21) This difference of the finding may be due to the fact that study my study was done immediately after either 1 or 2 days' post procedure hence it is easy to recall. But in assessing comprehensibility it is important that all details are explained to the patient before surgery. The reasons for comprehensibility not being 100% may be cultural where by patients put trust in doctor hence no need to question or demanding any more

information. A study in Italy suggested that the reason for comprehensibility being low is patient and doctors having no interest in informed consent form. (37) which is a bit similar to our study.

According to royal college of surgeon's consent should be taken by a surgeon or person in capacity to do the surgery as they are in better state of explaining the surgical approach, risks and benefits. This study found out that only 24.3% of consents were taken by operating surgeons, while 75% was taken by other physician from surgical department. This is similar to a study in Kenyatta Hospital, where consents were taken by residents by 83%. (36) This means the task of taking consent is shifted from the surgeons to residents and registrars in the surgical department. This is because the study was conducted in 3 teaching hospital with residents who do most of the work as part of the teaching, which was also similar for the case of Kenya. (22,36) Surgical residents are in position to do the procedures so they are okay to take consents from the patients. These finding are also close to findings of a study in Turkey and Iran where by consents was taken by physician by 73.5% and 85% respectively. (21,24) A study in Nigeria found that resident also get consents from the patients (62.6%) and that led to patient not being fully informed since residents cannot have all the information especially in highly specialized procedures. (18) This was a contradicting finding i.e patient not being informed when consents are taken by residents in that study but with truth in it. Residents should be given the responsibilities of getting consents for procedures they have learnt and can perform themselves in order to give all necessary information.

This study showed that there is an association between level of education of the patient and level of informed consent. The level of patients being informed about the procedure increased with increase in level of education. This may be explained by the fact education increases understanding of people hence understand better the information given. This finding is supported by the study in Nigeria which pointed out that educated patients had more information then uneducated patients. It further explained that surgeons tend to prefer getting consents from educated patients than uneducated patients since in uneducated patients it is more difficult and time consuming (38). A review done by Richardson also pointed out level of education as a predictor of patient comprehension. (39) On the hand it can also be

explained by literacy rate of Africans. The literacy rate of sub Saharan Africa is estimated to be 61% which it the world lowest; (40) and this can influence decision making in a large part as rights are not known to them

The knowledge of doctors on informed consent is 55.9% which is boarder line. These results are similar to studies done in Uganda, South Africa and Croatia. (22,32,41) This probably because rate of doctors being sued because of negligence are low in Africa hence doctors don't take it seriously.

Another important finding in this study is doctors are not aware of the presence of guideline on informed consent in their institution. Guideline helps improve doctor's knowledge and practice hence maintain a standard of having knowledge a practice in the institution.

The level of knowledge or consent among doctors increased with level of education. These findings are similar to a study in Pakistan. (42) This means as doctors increase their education i.e. become specialist and super specialist, knowledge on informed consent increases. This may be due to the fact that every time they go to school to attain more education, the subject of consent is brought up again in another dimension making it better understood. Hence junior doctors may benefit by having capacity building on informed consents and close supervision from senior doctors.

4.2 Strengths and Limitations

This study had some strengths as well as some limitations.

Starting with strengths, it is the first institutional study in our set up that as attempted to objectively evaluate how informed are the patients when they sign consent forms by looking at process, doctor's knowledge and associated factors. The findings of this study can be used as the bases for further studies as well as improve our practice by improving the challenges identified and rectifying them and setting a standard of care.

In conjunction to its strength, this study had some limitations; first recall bias may affect the level of informed of patients since they were interviewed several days after consent has been taken. Secondly lack of standardize tool to measure how informed are the patients and level

of knowledge of doctors on informed consent might lead the results to have bias. Thirdly association between patient being informed and level of knowledge of doctors could not be established due to methodology used. Lastly this study did not evaluate the forms used for consent which could confirm details like signature if accurately done, hence it gives room to future studies to evaluate the consent forms used in our institution.

CHAPTER FIVE

5 CONCLUSION AND RECOMMENDATION

5.1 Conclusion

Informed consent is an important tool for communication between patients and doctors. This study concludes that patients are not adequately informed when they are taken to surgery.

There is an association between level of education and how informed the patient can be when they receive informed consents.

Also this study concludes that there is room of improvement on doctors' knowledge on informed consents. It has also established an association between level of education of doctors and level of knowledge on informed consents.

5.2 Recommendation

Institutional guideline on informed consent should be made advocated more to all doctors in order to employ it's use effectively.

Capacity building programs for doctors on informed consent should be employed to reduce the gap of knowledge among doctors on consent in order to improve our services.

Patients should be educated on their rights, i.e. autonomy in order to understand the need of getting all the information before making any decision.

More studies should be done to assess doctors' practice and attitude on informed consent as well as our consent forms.

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APPENDICES

APPENDIX I: QUESTIONNAIRE

Patient Questionnaire:

Informed Consent; Are ethics observed?

A cross-sectional study at MNH/MOI&JKCI among elective post-operative patients

Date of the interview ……..

Hospital ……

Department ……..

DEMOGRAPHIC DATA

1) Sex

☐ M ☐ F

2) Age

_____

3) What is your highest level of education?

☐ Primary School

☐ High School

☐ Middle School (professional qualifications)

☐ College/University

☐ No formal education can read and write

4) Date of surgical procedure _____

5) Surgical Procedure Performed_____

6) Type of admission

☐ Ordinary admission

☐ Same day surgery

WRITTEN INFORMATION

7) Did you receive a written Informed Consent (IC) form?

☐ Yes

☐ No

8) How long before the surgical procedure did you receive the IC form?

☐ In the operating room holding area

☐ In the ward on the same day

☐ The day before

☐ More than one day before

9) Who delivered the IC form?

☐ Operative surgeon

☐ Other physician of the surgical unit

☐ Other_____

☐ I don't know

10) Did he/she introduce themselves by name and title?

☐ Yes

☐ No

11) Did you read the IC form before signing it?

☐ Yes

☐ No

☐ Partially.

IF NO OR PARTIALLY ASK WHY

12) Did you understand the form?

☐ Yes

☐ No

☐ Partially

☐ IF NO OR PARTIALLY ASK WHY _____

ORAL INFORMATION

13) Was the IC form explained during a conversation?

☐ Yes

☐ No

14) What was communicated to you? (Tick appropriate boxes corresponding to the information patient is sharing. Check NB below.)

☐ Diagnosis?

☐ Prognosis?

☐ Type of the proposed treatment?

☐ Expected post-operative progress and possible recovery issues?

☐ Potential benefits of the proposed treatment?

☐ Potential inconveniences (complications) of the proposed treatment?

☐ Alternatives to the proposed treatment?

☐ Chances of success of the proposed treatment?

☐ Possible outcomes of a missed treatment?

☐ OTHERS……..

15) When did you receive the further oral information?

☐ Progressively during pre-operative examination

☐ On admission

☐ Before entering the operating room

☐ On delivery of IC form

☐ Other

16) Did you understand what was proposed to you?

☐ Yes

☐ No

☐ Partially

☐ IF NO OR PARTIALLY WHY? (Probe on barriers such as language, being in pain, anxiety etc. ……

17) Have you had the opportunity to ask any questions?

☐ Yes, I asked questions and I had exhaustive answers

☐ Yes, I asked questions but I didn't have exhaustive answers

☐ No Why? _____

N.B Leading/alternative way to elicit information from the patient for question 14 above
At the time you signed the consent form did you understand

☐ What was wrong with you? (Diagnosis)

☐ What will be done to you? (Procedure)

☐ What are the risks of the operation (Risk)

☐ What are the Benefits of the operation (Benefit)

☐ What could happen to you if you didn't have the operation?

☐ What are the possible complications?

☐ What are the alternatives of to the operation?

QUESTIONNAIRE TO DOCTORS/PHYSICIAN ON IC

Informed Consent; Are ethics observed?

A cross-sectional study at MNH/MOI&JKCI among elective post operative patients

Demographic Data

1) Sex

☐ M ☐ F

2) Age_____

3) What is your highest level of education?

☐ MD/MBBS

☐ ☐Mmed_____

☐ ☐Super specialty/Fellowship_____

4) At what University did you get your medical degree?

_____

5) Working experience

_____

Knowledge about IC

6) Define Informed consent.

_____

_____

_____

_____

_____

7) Who is responsible to get the IC from a surgical patient?

☐ Any health personnel

☐ Intern doctor

☐ Registrar

☐ Specialist

8) When is the right time to get the informed consent from the patient?

☐ In clinic, when you plan for surgery

☐ On admission

☐ Just before surgery

9) When we don't get an IC from patients, what principles of medical ethics do we violate?

☐ Autonomy

☐ Beneficence

☐ Non-maleficence

☐ Justice

10) Do you think our consents are adequate?

☐ Yes

☐ No

If no, what modifications should we make to our forms?

_____
_____
_____
_____
_____

11) Have you see any guideline on consent process at this Hospital?

Yes

No

If Yes who is the author of the guideline?

12) Do you receive any capacity building on CI at this facility? (training/refresher course/sessions in clinical meetings)

Yes

No

Any suggestions ……

APPENDIX II: CONSENT FORM

Title:

Greetings;

My name is Dr Rodgers Solomon Swai, a resident in the Department of Anaesthesiology at Muhimbili University of Health and Allied Sciences. I would like to conduct the study above as a necessary requirement for fulfillment of my postgraduate studies.

Purpose

This study asks you to participate so that important information can be obtained from you regarding the knowledge and importance of informed consent for surgical procedures.

Confidentiality:

All information collected on questionnaires will be entered into computer with an identification number. The questionnaires will be kept in a secure, locked location.

Risk:

There will be no risk associated with this study.

Participation

Your participation in this study is voluntary and therefore any decision you make will be respected. If you agree to participate in the study, you will be interviewed. If you choose not to participate in the study, you will continue to receive all services that are normally provided in our institute.

If you have any question about the study, you can contact Dr Rodgers Solomon Swai 0767062522 and Dr Respecious Boniface 0754270840, Department of Anaesthesiology, MUHAS.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher, you are encouraged to contact **Dr……**, the Chairman of the University Senate research and publications, MUHAS P.O.BOX 65001, Dar es Salaam. Telephone (+255) 222-152-489.

Do you agree?

Participant agrees…….. Participant does NOT agree……

I, _____have read/been told of the contents of this form and understood its meaning; hence, I do agree to participate in this study.

Signature_____ (Participant), Date_____

Signature_____ (Researcher), Date_____

APPENDIX III: FOMU YA RIDHAA (TOLEO LA KISWAHILI)

Kwa wagonjwa wanaotibiwa katika taasisi ya mifupa ya Muhimbili.

Salaaam!

Mimi naitwa Dr Rodgers Soloomon Swai wa udhamili Chuo Kikuu cha Afya na Sayansi shirikishi Muhimbili, idara ya Usingizi ganzi. Ninafanya utafiti huu kama hitaji la lazima ili niweze kumaliza masomo yangu. Pia matokeo ya utafiti huu yatasaidia kufahamu kwa undani zaidi kuhusu tatizo hili hivyo kuboresha zaidi tiba yake.

Jinsi ya kushiriki

Kama utakubali kushiriki katika utafiti huu, nitakuhoji maswali machache kuhusu ulivyopata tatizo na maswali mengine yanayohusu jamii kama vile umri, jinsia, kazi na kadhalika.

Madhara/usiri

Hakuna madhara yoyote yanayotegemewa kutokana na utafiti huu.Taarifa za ugonjwa wako zitatunzwa kwa kutumia herufi maalum ili kuwa na usiri.

Uhuru wa kushiriki ;

Kushiriki kwenye utafiti ni hiari yako.

Unaweza kujitoa wakati wowote. Kama utachagua kutoshiriki, utaendelea kupata huduma kama kawaida hapa hospitalini.

Faida ya utafiti

Ukishiriki kwenye utafiti huu , utapata fursa ya kufahamu kwa undani ukubwa wa tatizo, aina mbalimbali za tiba, pamoja na matokeo baada ya tiba. Pia utapata ushauri wa kitaalamu kwa kipindi chote cha utafiti muda wowote unapohitaji.

Taarifa

Kuna kamati ya kusimamia udhibiti wa utafiti huu.

Endapo unahitaji kupata maelezo kuhusu haki zako au taarifa ,wasiliana na Dr Rodgers Solomon Swai 0767062522 au Dr Respecious Boniface 0754270840, wa chuo kikuu cha Afya na sayansi shirikishi Muhimbili, idara ya Usingizi ganzi.

Kama una swali lolote kuhusu haki yako kama mshiriki na ungependa kuwasiliana na mtu mwingine mbali na mtafiti, wasiliana Mwenyekiti wa Bodi ya Utafiti **Dr…….** chuo kikuu cha Afya na Sayansi shirikishi Muhimbili, kwa S.L.P 65001 numba ya simu +255222152489 Dar es Salaam.

Baada ya maelezo hayo , Je unakubali kushiriki kwenye utafiti? (weka alama) ya vema, Ndiyo.....Hapana.....

Mimi ....., nimeelezwa na nimesoma maelezo haya. Maswali yangu yamejibiwa. Nimekubali kushiriki katika utafiti huu.

Sahihi ya mshiriki..... Tarehe…….

Sahihi ya Mtafiti ..... . Tarehe……

APPENDIX IV: Ethical letter

APPENDIX V: Introduction letter

APPENDIX VI: Permission letter