PATIENTS' COMPREHENSION. COMPARING ENHANCED VERSUS CONVENTIONAL INFORMED CONSENT FORMS FOR SURGICAL PROCEDURES AMONG PATIENTS UNDERGOING ELECTIVE SURGERIES.

DR. ANTHONY MGENGI MAPANDE, MD

MMed (Surgery) Dissertation

Muhimbili University of Health and Allied Sciences

October, 2021

Muhimbili University of Health and Allied Sciences

School of Medicine

Department of Surgery

PATIENTS' COMPREHENSION. COMPARING ENHANCED VERSUS CONVENTIONAL INFORMED CONSENT FORMS FOR SURGICAL PROCEDURES AMONG PATIENTS UNDERGOING ELECTIVE SURGERIES

BY:

ANTHONY MGENGI MAPANDE, MD

A Dissertation Submitted in Partial Fulfillment of the Requirements of the Degree of Master of Medicine (Surgery) of

Muhimbili University of Health and Allied Sciences

October, 2021

CERTIFICATION

The undersigned certify they have read and hereby recommend for examination of a dissertation entitled: "**Patients' comprehension. Comparing Enhanced versus Conventional informed consent forms for surgical procedures among patients undergoing elective surgeries"** in partial fulfillment of the requirements for the degree of Master of Medicine (General Surgery) of Muhimbili University of Health and Allied Sciences (MUHAS), Dar es Salaam, Tanzania.

…….

Dr Ramadhani H Khamisi

(Supervisor)

Date…….

DECLARATION AND COPYRIGHT

I, **Dr**. **Anthony Mgengi Mapande,** declare that this dissertation is my 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……...

ACKNOWLEDGEMENT

First and foremost, praises and thanks be to the Almighty God, for His showers of abundant blessings throughout the time that I have been working to accomplish this work. With the guidance of His Holy Spirit, I have been able to make it through this successfully.

I would like to extend my heartfelt appreciations to our head of the department of General Surgery (MUHAS), Dr. Obadia Nyongole, and other members of the department in their totality for their contributions, guidance, encouragement, and for providing a conducive environment for my research work to be accomplished. Furthermore, may I extend my appreciation to the MNH research unit & records departments and the Directorate of surgical services for their cooperation in providing my research work with all the information I needed during data collection.

Last but not least, may I express my unfeigned gratitude to my family and friends at large for their illimitable support, prayers, and encouragement throughout the accomplishment of this research work.

DEDICATION

This study is wholeheartedly dedicated to my mother; Mrs. Agatha Mapande, and my brothers for their inestimable understanding and support during the whole period of this research project and my residency at large.

In a special way; I further dedicate this dissertation to my late father, Mr. Joseph Mapande, and grandfather; Ambrose Malembeka for their nurturing which has made me the way I am and it's my hope that they are proud of their product whenever they are.

ABSTRACT

Background

Comprehension is an essential element in truly informed consent and well-informed patients are proactive and compliant. Poor comprehension among patients after offering consent is a global problem with African countries noted with worse situation. Several interventions have been designed and proved to improve patients' comprehension but applicability depend on social-cultural settings. This study assessed the impact of locally designed enhanced informed consent form for surgical procedures on patients' compression who underwent electives surgeries at Muhimbili national hospital, Tanzania.

Method

A hospital-based, randomized, double blinded, interventional study. The study population was patients admitted for elective surgical procedures. 212 participants randomly assigned into two groups; Interventional and Control groups. The interventional group used the Enhanced informed consent form while the control group used the Conventional informed consent form. Enhanced informed consent form is a locally designed form with a conversation checklist intended to properly guide clinician on the consenting process. Interviewer-administered questionnaire was used to assess the level of comprehension in both groups post-surgery. Patients' comprehension described using proportion and computed for differences using Chi-square with P-value set at 0.05.

Results

No statistically significant differences in patient demographics were observed between groups. A significantly greater proportion of patients demonstrated a good comprehension in the enhanced informed consent form group while none had good comprehension in the conventional informed consent form group (71.7% Vs 0%, $P < 0.001$).

Conclusion

Enhanced informed consent form for surgical procedures is a locally designed, cost effective and user-friendly intervention that imparts more comprehension to patients than Conventional informed consent form for surgical procedures.

LIST OF ABBREVIATIONS

AMA	American Medical Association
CMA	Commonwealth Medical Association
CICF	Convectional Informed Consent form
EICF	Enhanced Informed Consent Form
IC	Informed Consent
ICF	Informed Consent Form for surgical procedures
IRB	Institutional Review Board
MAT	Medical Association of Tanzania
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
UK	United Kingdom
USA	United States of America
SPSS	Statistical Package for Social Sciences
WHO	World Health Organization

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

DEFINITION OF TERM

Consent: Permission or agreement[1].

Comprehension: Ability of understanding something complete and be familiar with a situation[2].

Informed consent: The process by which a patient learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial. Informed consent generally requires the patient or responsible party to sign a statement confirming that they understand the risks and benefits of the procedure or treatment[3]. The concept of informed consent may also apply to refusal of treatment[4].

Informed consent process: Involves all elements of informed consent that need to fulfill, information, comprehension and consent[5]. The elements of informed consent that need to be satisfied are “threshold elements, information elements and consent elements. Competence to understand and decide and voluntariness in deciding without coercion are the threshold elements. Information elements are made up of disclosure (of information), recommendation (of a plan), and understanding of the information. Consent elements are decision (in favor or against the plan) and the authorization of the chosen plan[6]”.

Valid informed consent: This applies when the patient:

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

Consent form: A legal document, dated and signed by patient and his/her health care provider, designating that the patient has been advised about the care to be received[59].

Conventional informed consent form for surgical procedures: Refers to the current consent form used at MNH for consenting prior to surgical procedure, diagnostic procedures and anesthesia.

Enhanced informed consent form for surgical procedures: Refers to a newly designed and quality improved consent form, which incorporates elements required during informed consent process. It will be used for consenting prior to surgical and diagnostic procedures.

1. INTRODUCTION

Informed consent is a cornerstone of modern medical practice[11,12]. Patient involvement in decision-making regarding their health-related issues, even in routine acts is a fundamental aspect of patient-centered care[13-17]. There is a rising body of literature that supports the observation that the majority of patients desire to be involved in making decision affecting their wellbeing[13,15,16,17,20,21,22]. Patient involvement is justified by the ethical principle of autonomy, and the role of informed consent to treatment is meant to protect this autonomy[13-16]. Informed consent is defined as the process by which a patient learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial. Informed consent generally requires the patient or responsible party to sign a statement confirming that they understand the risks and benefits of the procedure or treatment[3]. The concept of informed consent may also apply to refusal of treatment[4]. It is seen as not only a matter of signing a form but a collaborative procedure between healthcare provider and patient[18,19]. A patient's informed consent process requires adequate information, capacity to make informed decision and the absence of any coercion[23]. IC is a doctrine that helps patients to protect themselves from unwanted medical/surgical interventions and allow patients to take responsibility of their own health issues.

IC is an ethical concept that is most relevant to surgery[24]. In all institutions, it is mandatory to take informed consent prior to establishment of any intervention or procedure done on the patient. Recent studies have questioned whether informed consent is being taken in true spirit or it is being adhered to as a medico-legal formality[25]. Professional performance is influenced by many factors including clinical values, beliefs, knowledge of ethics and legal contracts, ability to recognize and analyze ethical problems, inter personal relationships and communication skills[26, 27].

In their daily practice, clinicians perform medical and surgical interventions in various

specialties and therefore have an ethical obligation of observing these principles, including that of obtaining informed consent from patients. Obtaining consent should be seen as a process, not a discrete event and it is important to remember that patients have two options open to them to accept or refuse the suggested interventions[28].

Clinicians have the duty to provide information (disclosure) so that patient can make a decision and give informed consent[29]. The process of disclosure requires good communication skills. The patient should have the capacity to understand the relevant information and appreciate those consequences for his/her decision that may reasonably be foreseeable consequences on decision or lack of it[30]. In case of a minor or a person with incapacity then a substitute makes a decision therefore the information delivered by the doctor must be sufficiently clear for the substitute decision maker to comprehend and make a decision in the best interest of patient[31].

The decision of the patient must be voluntary, free of external forces of coercion, manipulation or persuasion[32]. External influences like pain, limitation of choices because of nature of the illness and emotional factors should be minimized by such measures as alleviation of pain and counseling. Needless to say, the physician should tell the patient nothing but the truth. When all these issues have been addressed; the patient makes a decision and this can be considered to be an Informed Consent[31].

The consent form serves to document the informed consent but it does not replace the process. The physician has to prove that he has made efforts to ensure that the patient understands the information provided. As an expert of his field, the physician must provide his patient with all the necessary information required to make a well-informed decision. Furthermore, it was proven that a well-informed patient is more proactive and compliant[4]. However, Aroori and Spence, in United Kingdom, have demonstrated that less than half of resident surgeons were able to answer all the

questions posed by patients. Only few residents correctly listed all risks, benefits and alternatives for informed consent[35]**.**

Since the medico-legal requirement concerns the doctor's interest more than the information component, it is hypothesized that doctors may secure documentation of informed consent without sincerely ensuring that the patient has received and understood the appropriate information[36].

Patient comprehension is fundamental to valid informed consent. A systematic review in 2020 in interventions to improve patient comprehension in informed consent for medical and surgical procedures revealed that current practices often result in inadequate patient comprehension[37]. One study conducted in India revealed that the level of understanding was 44.6% for both illiterate and primary education patients and 68.2% for people with a high level of education[38]. Another study in Botswana, assessed comprehension of informed consent using a 20-questions true or false quiz administered in 6-months intervals in the context of a placebo-controlled randomized trial for the prevention of tuberculosis among HIV-infected adults. This study revealed that participants with low comprehension of informed consent were those with low education and language problems[39]. The lower illiteracy level alone does not necessarily result in decreased comprehension. However, in resource-poor countries, higher rates of illiteracy may contribute to the challenges associated with comprehension of informed consent document[40].

2. LITERATURE REVIEW

2.1. Overview

Informed consent has become the primary paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine. Informed consent may be used for different purposes in different contexts: legal, ethical or administrative purposes. Although these purposes overlap, they are not identical, thus leading to different standards and criteria for what constitutes “adequate” informed consent. The ethical purpose of informed consent is somewhat more abstract and ideological; seeking to respect patient autonomy by ensuring that treatment is directed toward the desired ends and is chosen by the patient. The ethics literature regarding informed consent emphasizes that it is not an event, but rather a process that precedes the “signing” of the document and continues for as long as the choice remains relevant[46].

The American Medical Association (AMA) code of ethics establishes informed consent as an ethical obligation of physicians[47]. Two and half decades ago Medical Association of Tanzania (MAT) in collaboration with Commonwealth Medical Association (CMA) produced the first edition of Guidelines for Medical Ethics[48] aiming to raise awareness on ethical issues and to assist the medical professionals to integrate bioethical knowledge into daily practice, which in turn supports and safeguards professional performances[27]. Among others these Guidelines demand the physician to disclose relevant information and ensure the patient comprehends before consenting for any medical interventions.

2.2. Informed Consent process and Patient’s Comprehension

Comprehension empowers patient participation in decision-making process, which is a matter of concern for ethics committees on research trials but also in clinical practice[46] yet most studies done reports inadequate comprehension among patients consented for various medical interventions.

A study done in UK by Worthington reports that, physicians were concerned about not having enough time to spend discussing about personal values and patients' preferences since they had to operate and save lives[51]. Many doctors still perceived their interactions with patients as limited. They gave scanty information and offered less decision-making authority to patients[52], keeping Comprehension in doubts. Moreover, he observed that obtaining the consent for surgical procedures was delegated to the junior surgeons or interns at most of the times; who did not perform/participate in such surgeries. It turns out that most of them could not explain properly to patients what to expect in terms of risks and complications of operations[51]. This rendered these consents legally invalid because of lack of better understanding to meet, what Perry called" a requirement of adequate information for a patient to act voluntarily"[53]. This also raises doubts if clinicians have adequate skills in obtaining informed consents and if they do; then pose another query if they perform it in true spirit rather than aiming at getting the signature down on the consent form.

A study conducted in India reveals limited knowledge of patients towards informed consent where some of them perceived it as a legal obligation for physicians while others thought it entailed them the right to some compensation. Besides, a great number of patients had unsatisfactory comprehension while a few of them had poor comprehension[49]. Another study conducted in Saudi Arabia had comparatively same findings, where almost half of patients participated believe that surgical procedures wouldn't have been performed without signing the consent forms while others signed the forms because they were afraid of destroying the relationship with their physicians if they wouldn't have signed the consent forms[50].

A study conducted in Nigeria by Siddiqui et al. reports patients to have poor information retention after obtaining informed consent. Furthermore, it reveals that current consent process in Nigeria seems inadequate as a means of expression of independent choice as patients have limited knowledge of legal importance of signing or reject signing the informed consent[49]. Another study done in Ghana by Clegg-Lamptey et al, emphasized that, "Doctors have been accused of arrogance at times,

since they dictate treatment even when there are other relevant available options". Even though the lack of formal education is to blame for poor understanding, health care workers are too; they do not provide the necessary information or talk about relevant alternatives that are available to patients[54].

Like Ghana, the underdeveloped world including South Africa, experiences even more problems due perhaps to lack of knowledge on the part of patients about the entire decision– making process. Dhai noticed by the way that; "South Africa is home to a large number of vulnerable groups of poor populations who have limited or no access to education and health services and who accept authority without question"[55]. This reveals that most of patients sign the consent forms as a formality without comprehending the delivered information.

Two decades ago, Yongolo et al scrutinized informed consent forms from a number of health facilities in Dar es Salaam, Tanzania and found that all the consents were inadequate; lacking important elements of standard informed consent, yet the study revealed that out of all forms analyzed, none of them found to have given informed consent[31]. This gives clues that quality and format of the consent form might have impact on patient comprehension, but this is not proven.

An unpublished study conducted at MNH in Dar es Salaam, Tanzania, one decade ago by Mkoma I.S, revealed inadequate patients' comprehension. Out of 232 patients interviewed, 158 patients (68.1%) were well informed regarding the details of the surgical procedures they underwent. This study also revealed that higher level of comprehension was associated with younger age and higher level of education. It further revealed that intern doctors were most effective in imparting information related to surgical treatments despite being not the ones who did the surgery or rarely participate in the named procedures. The study also reports that intern doctors were the ones obtained informed consents form patients most of the times[42].

Another unpublished study that was done in 2017 at Mwananyamala Hospital in Dar es Salaam, Tanzania by Harun S, revealed half of participants to have good comprehension about their treatment preliminary information. Participants

comprehended well about purpose, procedure, benefits and time duration more well than risks, voluntariness and side effects. The study also reports significant association between higher education level and more sources of information (other than doctors and nurses) with increased comprehension. However, the study reports no significant association between age and patient's comprehension[45].

2.3. Interventions and Patient's Comprehension

Respect for a patient underlines the duty of the clinician to obtain informed consent from the patient among other clinician's ethical obligations and should have no age, sex, education, religious or any other form of bias[56]. The ethics of both surgical research and interventions necessitates all participants/patients to provide valid consents, which require patient capacity, adequate disclosure of information and voluntariness. Therefore, a valid informed consent for a surgical procedure; patient must be provided with sufficient information to make an informed decision, be competent to give consent, be aware of the right to refuse surgery or voluntarily agrees to the procedure. Inadequacy in obtaining consent in many countries has resulted in poor patient's comprehension and is potentially subject to malpractice litigations[24].

A study conducted in USA in 1990 revealed an improved comprehension level with reducing reading level of informed consent forms. In this study a delay of 15 minutes in answering questions or consenting was assessed as well but reports to have no significant impact on comprehension. Higher education level revealed to have increased comprehension[58].

A comparative study done in USA in 1998 revealed no significant improvement of comprehension among patients who used simplified compared to standard informed consent forms for surgical procedures. The standard informed consent forms for surgical procedures seemed too difficult for many patients to read and to comprehend especially those with low literacy skills. However, most of the patients preferred and also report to be comfortable using the simplified than the standard ones[57].

A prospective randomized study done in UK, Manchester City in 2016, comparing the current/standard surgical informed consent form with a modified consent form revealed the modified consent form to have a significant impact in enhancing understanding among patients. Significantly greater proportion of patients demonstrated a good understanding of their procedures in the modified consent form group than those receiving the standard form following surgery. Moreover, Patients in modified consent form group expressed greater satisfaction with the consent process post-operatively compared to standard consent form group[44].

A systematic review of randomized controlled trials of informed consent interventions done in USA in 2013 revealed some of interventions to have significant impact on patients' knowledge. The findings of the study revealed that enhanced informed consent form and extended discussions to be the most effective in improving participants' understanding. Multimedia and test/feedback quizzes seemed less effective and statistically did not prove to have significant impact on patients' knowledge. Furthermore, the study findings pointed out that patient' satisfaction improved or unchanged by interventions in all categories[12].

Another systematic review on randomized and non-randomized clinical trials conducted in 2020 on interventions to improve patient comprehension in informed consent for medical and surgical procedures revealed that interactive interventions, particularly with test/feedback or teach-back components appeared to be superior to other interventions. The magnitude of impact of the interventions as compared with standard informed consent had a statistically significant improvement in patient comprehension with written interventions, audiovisual interventions, multicomponent interventions, interactive digital interventions and verbal discussion including test/feedback or teach-back interventions respectively[37].

An unpublished study done at MNH, Dar es Salaam, Tanzania on 2010 by Mkoma I.S revealed the operation information cards to have significant impact on imparting knowledge among patient who underwent elective surgical procedures[42]. The operation information cards contained information specific to a particular surgical

procedure and were given to patients prior to surgery.

Another study conducted on 2019 in Pemba, Tanzania revealed the information sessions to have significant impact in improving knowledge as compared to pamphlets. The study further emphasized that; a communication tool differs among cultural settings so different methods should be tested in different regions. In many African settings oral communication seems to have more value than written communication, most likely due to the low literacy levels, particularly in adults[43]

3. PROBLEM STATEMENT

A patient needs an adequate disclosure before making an informed consent yet studies on the quality of informed consent have shown, in some cases, that physicians are not meeting the requirements for an adequate informed consent[33, 34]. Moreover, the informed consent forms used are inadequately worded, lacking important information, and are sometimes ambiguous and confusing[31].

Most of the studies done globally and in local settings revealed poor patients' comprehension of the elements of informed consent after they have offered their consent[31,42,43]. The inadequacy in comprehension is even worse in the developing world, and Tanzania is not excluded from the long list[31,42]. An unpublished study done at MNH by Mkoma and colleagues, a decade ago reports 31.9% of patients had poor knowledge after they had consented using conventional informed consent forms for surgical procedures[42].

Therefore, this study was designed to assess the impact of the Enhanced informed consent form for surgical procedures as a means of a designed intervention to improve patients' comprehension.

4. RATIONALE

It is proven that a well-informed patient is more proactive and compliant[4] therefore interventions considering available resources and social-cultural settings needed to be set up to address the challenge of poor patients' comprehension to improve patients' participation in decision making and compliance of the treatment offered. This study was set to explore the impact of Enhanced informed consent form for surgical procedures on patients' comprehension at our institution. The EICF is a modified consent form designed to properly guide a clinician to take a meaningful informed consent from patients hence expected to improve comprehension. The findings of this study would provide basis of developing more fairly effective interventions to improve comprehension but also would provide knowledge that will offer avenues for more researches to be done on the topic.

5. CONCEPTUAL FRAMEWORK

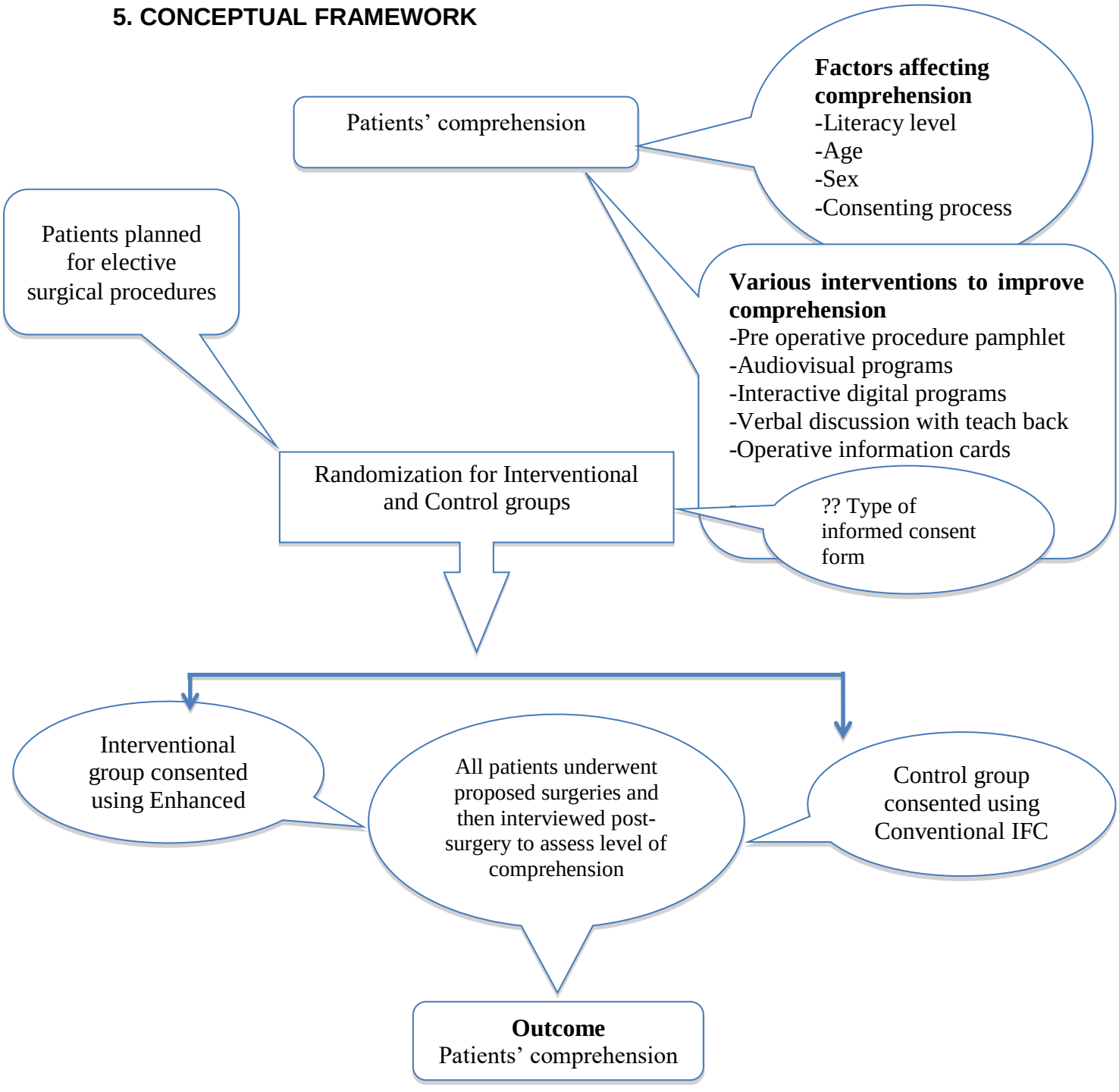

Figure 1: Conceptual framework

CONCEPTUAL FRAMEWORK ILLUSTRATES FACTORS ASSOCIATED WITH PATIENTS' COMPREHENSION.

Patient comprehension is affected by a number of factors mostly the socio-demographics such as education level, age and sex[45]. Moreover, the comprehension seems to be also affected by poorly conducted consenting process.[51, 52]

As illustrated in the conceptual framework above, a number of interventions have been studied trying to check their impacts on patient's comprehension and some of them have proved to be able to improve comprehension. These interventions also seemed to be more effective depending on socio-economic settings.[12,37,42,43,57]

Enhanced informed consent form for surgical procedures was one of the interventions that was developed considering the socio-economic settings which was studied to assess its impact on patients' comprehension.

6. RESEARCH QUESTION

Does the type of informed consent form influence patient's comprehension?

Specific question

What proportions of patients would have good comprehension on the elements of informed consent among those who used Enhanced versus Conventional informed consent form for surgical procedures?

7. HYPOTHESIS

Null hypothesis (H_o): Enhanced informed consent form for surgical procedures imparts the same comprehension to patients as the conventional informed consent form for surgical procedures.

Alternative hypothesis (H_1): Enhanced informed consent form for surgical procedures imparts more comprehension to patients than conventional informed consent form for surgical procedures.

8. OBJECTIVES

8.1. Broad objective

To assess the impact of Enhanced informed consent form for surgical procedures on comprehension among patients undergoing elective surgical procedures at MNH

8.2. Specific objective

To analyze the proportion of patients with good comprehension on elements of informed consent among those who used Enhanced versus Conventional informed consent form for surgical procedures.

9. METHODOLOGY

9.1. Study design

The study was a hospital-based, randomized, double-blinded interventional study; because the aim was to assess the level of comprehension on elements of informed consent among patients who underwent elective surgical procedures at MNH, and was implemented from December 2020 to April 2021. The double blinding was achieved by recruiting clinicians (Intern doctors) who had never seen an MNH informed consent form for surgical procedures to take consents during the study and each group of intern doctors did it once to reduce bias. Some of the intern doctors used the Enhanced while others used the Conventional informed consent forms. (New intern doctors who had not rotated in any department under directorate of surgical services were recruited to take consent, assuming they had never used a MNH informed consent form before). A quantitative approach was used because measuring participants' comprehension needed a standardized tool, which included numerical measurements.

9.2. Study area

The study was set at Muhimbili National Hospital (MNH). This is the National referral and major teaching hospital in Tanzania and is located in the city of Dar es Salaam. Apart from serving city residents, the hospital also serves as a national referral hospital and teaching Hospital for MUHAS and other various Universities. MNH consists among others the Directorate of Surgical Services, which comprises several Departments; General surgery, Urology, and Obstetrics & Gynecology. Most surgical patients are received at the Emergency Department where they are sorted and send either to the respective departments or scheduled to attend the Outpatients clinics, and approximately 45 elective surgeries are done per day.

9.3. Study population

The study population was the list of admitted patients who underwent elective surgical procedures from Departments of General Surgery, Urology, and Obstetrics &

Gynecology. These are among the departments under the Surgical services Directorate which comprise most of the patients undergoing electives surgical procedures.

9.4. Study sample and Randomization

The study sample comprised of randomly selected patients who underwent elective surgical procedures from selected departments under the Directorate of Surgical Services. Simple random sampling was employed to select participants. Simple random sampling is a probability sampling in which all members of the population have an equal chance of being selected[8]. A lottery technique was used to select participants in which eligible patients admitted in the selected departments for elective surgical procedures were assigned with numbers, then allocated into either control or interventional groups. For credibility the numbers were subjected to the online computer software namely; http://www.randomresult.com which generated numbers of participants to be allocated to interventional group and the rest were allocated in the control group[10].

Recruitment of participants was done during day hours (0800hrs to 1800hrs) along the whole week with references to elective operation lists. Those who were found in the wards and listed for elective surgical procedures and consent to participate in the study were recruited.

Patients were randomly allocated into Interventional and Control groups, and allocations were concealed in sequentially numbered sealed envelopes. The sealed envelopes with patients' details were given to the research assistant, Ward Nurse in charge, and the clinician taking consent just before the consenting process.

All patients were asked to complete a questionnaire which assessed their level of comprehension approximately after 48 hours post-surgery but before to their discharge.

9.5. Variables

The following were the study variables categorized as dependent and independent as shown below: -

9.5.1 Dependent variable

Patients' comprehension on elements of Informed Consent

9.5.2 Independent variable

Type of Informed Consent form for surgical procedures used

9.6. Inclusion and exclusion criteria

9.6.1 Inclusion criteria

-Patients listed for elective Surgical procedures

-Aged 18 - 70 years

-Patients capable of giving consent.

9.6.2 Exclusion criteria

-Day surgical procedures

-Unconscious patients post-surgery

-Psychiatric patients

9.7. Sample size

- Comparison for two-proportion formula was used; obtained from online source; **Select Statistical Services**[50]

- Study done at MNH in 2010, reports a proportion of 68.1% to be well informed after consenting for surgical procedures[42].

$$n = (Z_{\alpha/2} + Z_{\beta})^2 \times \{P_1(1-P_1) + P_2(1-P_2)\} / (P_1-P_2)^2$$

Where:

n = Sample size for each group

P_1 = Proportion of patients with good comprehension from previous study done at MNH; 68.1%

$1\text{-}P_1$ = (100% - 68.1%) = Proportion of patients with poor comprehension from previous study done at MNH; 31.9%

P_2 = Proportion of patients expected to have good comprehension after implementation of an intervention; 85%

$1\text{-}P_2$ = (100% - 85%) = Proportion of patients expected to have poor comprehension after implementation of an intervention; 15%

$Z_{\alpha/2}$ = Value of standard normal distribution corresponding to a significance level of $\propto$ at 95%; 1.96

Z_{β} = Value of the standard normal distribution corresponding to a desired level of power at 80%; 0.84

Therefore, sample size will be of 95 for each group.

For non-response rate of 10%, the adjusted sample size will be 106 for each group.

9.8. Data collection

To achieve the set objectives, Interviewer administered questionnaire with open-ended and closed-ended questions was used for data collection. The questionnaire was available in English and Swahili versions.

The questionnaires were divided into two Sections: -

Section A: Aimed at obtaining the socio-demographic profile of participants and source of health information.

Section B: Aimed at obtaining comprehension on elements of the informed consent process. A scale of 0-22 was used. Higher scores ranged 16-22 (≥73%) indicating adequate or good comprehension, the moderate score ranged between 10-15 for moderate comprehension and the lower score was 0-9 (≤ 41%) for poor comprehension on elements of informed consent[9]**.**

Information given on the informed consent process consisted of 11 elements and each element had a maximum of 2 scores. (Diagnosis, type of surgery done, Purpose of procedure done, Likelihood of success, Specific potential risks, Risks of not carrying out the procedure, Possible problems related to recovery, Possible alternative treatment modalities and risks, Opportunity for asking for clarifications, Voluntariness, and Opportunity of revising decision made). Ability to answer a question well scored 2, average answer scored 1, and wrong or no response scored 0. In the end, scores were summed up to obtain a total score for each participant.

9. 9. Validity of tools.

The Enhanced informed consent form for surgical procedures is a modified informed consent form with the addition of some items, which was developed after an extensive review of different consent forms from various hospitals within and some out of the country.

The comprehension assessment tool used had been adapted from tools used in completed trials within multiple levels of international ethics and regulatory review. The tool was initially developed from the VAXGEN phase III HIV vaccine trial conducted in Bangkok. This was modified and used in hypothetical Pre-exposure prophylaxis trial consent form and then the tool was used on comparison of close-ended, open-ended, and perceived informed consent comprehension measures for a MOCK HIV prevention trial among women in Mwanza, Tanzania[9] and was further modified and used to assess comprehension among HIV patients attending the clinic at Mwananyamala Hospital[45]. The assessment was comprehensive and detailed to include all the elements of informed consent.

9.10. Pretesting of data collection tools

A pilot study was conducted at Otorhinolaryngology Department. The enhanced informed consent form for surgical procedures was pretested on a random sample of 10 patients who were then interviewed post-surgery using the questionnaire. This pilot pretest provided clear applicability of the consent form and questionnaire and resulted in some more modifications of both the form and questionnaire.

9.11. Data Management

The principal investigator supervised the filling of questionnaires. This ensured that the data collected were correct and answers/responses were well understood by participants. The filled questionnaires were examined on daily basis to check for the quality of the questionnaire conducted on that particular day to trackback missed responses from the participants.

The data collected using the questionnaire were verified for completeness of filling. The data were coded before entering and feeding the information into statistical package SPSS version 25 to run frequencies of the data. Data cleaning was done to ensure there was no information missing.

9.12. Data analysis

Data were checked for completeness, coded, and then entered into Statistical Package for Social Scientists IBM (SPSS) version 25. The sample demographic characteristics of the participants were described using frequency distribution and percentages. Continuous variables were summarized to means, range, and standard deviations, while categorical variables into proportions and computed for differences using Chi-square with a P-value set of less than 0.05.

10. ETHICAL CONSIDERATIONS

Participants were informed about the study; purpose, their voluntariness in participation, risks, benefits, and their rights to withdrawal at any point of the study. Written informed consents were obtained from participants. Confidentiality of gathered information was maintained during and after the study. Data collected was only used for research purposes including publication of findings in research journals and dissemination in scientific forums.

Ethical clearance to carry out this study was sought from Muhimbili University of Health and Allied Sciences (MUHAS) Research and Publication Committee. Permission to conduct the study at Muhimbili National Hospital (MNH) was sought from the MNH Research and Consultancy unit and the Directorate of Surgical services.

10.1. Results dissemination

The findings of this study shall be published in academic journals and presented at scientific conferences. Electronic copies shall be given to the MUHAS repository. Department of surgery MUHAS shall receive a briefing of the report and a recommendation summary for addressing patient-centred care issues.

11. RESULTS

RECRUITMENT AND ASSIGNMENT OF PATIENTS

A total of 212 patients consented to enroll into the study and randomly assigned into either control (conventional) or interventional(enhanced) groups. Control and interventional groups had 106 participants each.

DEMOGRAPHICS

No statistically significant differences in patient demographics were observed between groups. Equivalence of the two groups is demonstrated in Table 1.

Variable		Type of consent used		P – value
		Conventional	Enhanced	
Sex	Female	69 (54.3%)	58 (45.7%)	
	Male	37 (43.5%)	48 (56.5%)	0.123
Age	18 - 27	15 (45.5%)	18 (54.5%)	
	28 - 37	21 (51.2%)	20 (48.8%)	
	38 - 47	22 (39.3%)	34 (60.7%)	0.206
	48 - 57	21 (53.8%)	18 (46.2%)	
	>58	27 (62.8%)	16 (37.2%)	
Education level	Informal	12 (63.2%)	7 (36.8%)	
	Primary	42 (48.8%)	44 (51.2%)	
	Secondary	38 (52.1%)	35 (47.9%)	0.467
	Tertiary	14 (41.2%)	20 (58.8%)	
Marital status	Married	1 (50.0%)	1 (50.0%)	
	Widowed	78 (51.7%)	73 (48.3%)	
	Divorced	23 (42.6%)	31 (57.4%)	0.369
	Single	4 (80.0%)	1 (20.0%)	
Residency	Central zone	4 (44.4%)	5 (55.6%)	
	Coastal zone	90 (52.3%)	82 (47.7%)	
	Lake zone	5 (45.5%)	6 (54.5%)	
	Northern Highland zone	4 (50.0%)	4 (50.0%)	0.407
	Southern Highland zone	3 (37.5%)	5 (62.5%)	
	Southern zone	0 (0.0%)	4 (100.0%)	

Table 1 : Shows the social-demographic characteristics of the study sample.

PROPORTION OF PATIENTS' COMPREHENSION ON THE ELEMENTS OF INFORMED CONSENT

A significantly greater proportion of patients demonstrated a good comprehension in the enhanced consent form group while none had good comprehension in the conventional consent form group (71.7% Vs 0%, P < 0.001). Table 2 demonstrates the proportion of patients' comprehension in each group.

Type of informed consent form	Patients' Comprehension level			P-value
	Poor	Moderate	Good	
Conventional consent form	86 (81.1%)	20 (18.9%)	0 (0.0%)	<0.001
Enhanced consent form	3 (2.8%)	27 (25.5%)	76 (71.7%)	
Total	89 (42%)	47 (22.2%)	76 (35.8%)	

Table 2: illustrating proportion of patients' comprehension between conventional and enhanced consent form groups.

12. DISCUSSION

Our study involved 212 participants who underwent elective surgeries at MNH. The interventional and control groups were comparable. Enhanced consent form imparted more comprehension to patients than conventional consent form. This deference is statistically significant.

Enhanced informed consent form for surgical procedure is a simple, cost effective, user-friendly and local design of intervention to improve patients' comprehension. Its designing considered the social-cultural values of our settings. Its design facilitates interactive session by having a conservation checklist which guides the clinician on things to consider before, during and after taking consent from patients. The checklist helps the clinician on things to emphasize and check instant understanding of the patient during the consenting process.

A significant improvement in patients' comprehension is observed after using the enhanced consent form. Same findings were seen a decade ago at MNH by introduction of specific operation information cards as means of intervention to improve patients understanding[42] but high illiteracy level and high costs were the major challenges. Most studies done in African settings revealed interactive session design of interventions to have power to impart more knowledge to patients than non-interactive interventions[12,37,43]. Different designs of interventions have proved to improve patients' comprehension globally, but the question of social-cultural values play a vital role in having a significant impact.

Our study revealed an increase of patients with poor comprehension than it was observed a decade ago from an unpublished study done at MNH[42]. The increase seen might be due to differences in assessment tool and grading of comprehension level. It might also be due some structural and policy modifications that MNH has

undergone in a previous decade where individualized specialists' clinics were introduced. These clinics, health insured or cash paid patient are permitted to visit MNH without referrals, and most of these patients come to MNH as their first visit for medical consultations. These patients are less likely to be aware of their conditions unlikely those who came only by referrals a decade ago where most of them had chronic conditions. Patients with chronic conditions had the advantage of been informed on their illnesses at multiple level before referred to MNH than those coming to MNH for first visit. Patients' first visit to MNH broadens up the applicability of the enhanced consent form to lower health facilities where many times patients go for first visit in the health system.

During the study, intern doctors took consent for surgical procedures and surgery residents interviewed the participants post-surgery. This points out that junior doctors who are considered inexperienced with less knowledge, can impart adequate knowledge to patients when guided properly on the consenting process. Unpublished study conducted at MNH 10 years ago by Mkoma and colleagues revealed the same findings[42]. Junior doctors provided information to patients but the study could not ascertain the adequacy of information disclosed.

We found some factors which may have influence in enhancing patients' comprehension but their assessment was beyond the scope of this study. Patients were counseled less than 24 hours prior to execution of proposed surgeries. This queries the ability of adequate assimilation of the information disclosed yet patients had to sign the consent forms. Some patients requested the presence of their significant ones due to different reasons. This brings query on the influence of significant ones on patients' comprehension. Moreover, some patients requested for more privacy during the consenting process. Patients were counseled in the wards at their beds so we think privacy might also affect patients' comprehension.

Limitation

The study was a randomized double blinded interventional study. Both participants and intern doctors who were instituting the intervention were blinded. Despite intern doctors enrolled in the study never rotated to any department under surgical service directory, we could not ascertain if they ever came across the conventional informed consent form.

13. CONCLUSION AND RECOMMENDATIONS

13. 1. CONCLUSION

Enhanced informed consent form for surgical procedures is a locally designed, cost effective and user-friendly intervention that has proved to impart more comprehension to patients than Conventional informed consent form.

13.2. RECOMMENDATIONS

1. Enhanced informed consent form for surgical procedures can be adopted for clinical use at MNH and other health facilities.

2. Further studies should be done to establish other factors that affect the consenting process like the influence of family/friends, consenting environment, and duration of consenting to the execution of a proposed procedure for designing more effective interventions to improve patients' comprehension.

14. REFERENCES

1. Appelbaum PS. Assessment of Patients' Competence to Consent to Treatment. N Engl J Med. 2007 Nov; 357(18): 1834–40.

2. Elizabeth Imperio I, Button K. Teachers' Responses to Teacher Images in Picture books. Lang Lit. 2016; 18(3): 33-49. https://doi.org/10.20360/G27G74

3. Beauchamp T.C.J. Principles of Biomedical Ethics. Oxford University Press: 2013; 10(7) 348-54.

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

5. Panting G. Informed consent. Orthop Trauma. 2010; 24(6): 441–6.

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

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

8. Singh S, Singh R. Generalized franklin's model for randomized response sampling. Commun Stat - Theory Methods. 1993 Jan; 22(3): 741–55.

9. MacQueen KM, Chen M, Ramirez C, Nnko SEA, Earp KM. Comparison of closed- ended, open-ended, and perceived informed consent comprehension measures for a mock HIV prevention trial among women in Tanzania. PLoS One. 2014; 9(8): e105720.

10. Randomresult.com. Random Result - Generator. Randomresult.com. 2017; 2. (Accessed on June 11st, 2020)

11. Richardson V. Patient comprehension of informed consent. J Perioper Pract. 2013; 23(1–2): 26 –30.

12. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: A systematic review of 54 interventions tested in randomized control trials. BMC Med Ethics [Internet]. 2013;14(1):28. Available from: BMC Medical Ethics

13. Cook SA, Damato B, Marshall E, Salmon P. Reconciling the principle of patient autonomy with the practice of informed consent: decision-making about prognostication in uveal melanoma. Health Expect. 2011; 14(4): 383-396.

14. Redley M, Keeley H, Clare I, Hinds D, and Luke L, Holland A. Respecting patient autonomy: understanding the impact on NHS hospital in-patients of legislation and guidance relating to patient capacity and consent. J Health Serv Res Policy. 2011; 16(1): 13-20.

15. Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. BMJ. 1993; 306(6882): 885- 890.

16. Akkad A, Jackson C, Kenyon S, Dixon-Woods M, Taub N, Habiba M. Patients' perceptions of written consent: questionnaire study. BMJ. 2006; 333(7567): 528.

17. Guadagnoli E, Ward P. Patient participation in decision-making. Soc Sci Med. 1998; 47(3): 329-339.

18. WHO. "Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis''. WHO Geneva. 2015; 93(2): 12.

19. O'Daniel M, Rosenstein AH. Professional Communication and Team Collaboration. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Agency for Healthcare Research and Quality (US); 2008.

20. Perneger TV, Charvet-Bérard A, Perrier A. Patient assessments of the most important medical decision during a hospitalization. J Gen Intern Med. 2008; 23(10): 1659-1665.

21. Say R, Murtagh M, Thomson R. Patients' preference for involvement in medical decision-making: a narrative review. Patient Educ Couns. 2006; 60(2): 102-114.

22. Deber RB, Kraetschmer N, Irvine J. What role do patients wish to play in treatment decision-making? Arch Intern Med. 1996; 156(13): 1414-20.

23. Krumholz HM. Informed consent to promote patient-centered care. JAMA. 2010; 303(12): 1190 –1. Doi: 10.100.1/jama.2010.309

24. Carneiro PMR. Ethics of surgical research in Tanzania. Tanzania Medical Journal. Sept 2006; 21(1): 28-32.

25. Mazur DJ. What should patients be told prior to a medical procedure? Ethical and legal perspectives on medical informed consent. *Am J Med*. 1986; 81(6): 1051-1054. Doi: 10.1016/0002-9343(86) 90405-5

26. Medical Association of Tanzania (MAT), guiding principles on Medical Ethics and Human Rights in Tanzania. MAT 1995.

27. Peter A Singer. Bioethics for Clinicians. Can. Med Assoc. J. July 1996; 155(2): 189.

28. Etchells E, Sharper G, Walsh P William JR, Singer PA. Bioethics for clinicians: 1 Consent; Can. Med. Assoc. J. July 1996; (2): 177-80.

29. Etchells E, Sharper G, Burgess MM, Singer PA. Bioethics for clinicians: Discloser. Can. Med. Assoc. J. Aug1996; 155(4): 387-90.

30. Etchells E, Sharper G, Elliott C, Singer P.A. Bioethics for clinicians: 3 Capacity. Can. Med. Assoc. J. Sept 1996; 155 (6): 657-61.

31. Yongolo CMA, Ngoloi P, Mselle J, Mkony C.A, Kabote, Mstapha M. Informed consent to patients undergoing surgery in Dar es Salaam. Tanzania Medical Journal; March 1999; 14(1): 13-17

32. Etchells E, Sharper G, Dykeman MJ, Meslin EM, Singer PA. Bioethics for clinicians: 4 Voluntariness. Can. Med. Assoc. J. Oct 1996; 155 (8): 1083-1086.

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

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

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

36. White G. Obtaining Informed Consent: It's more than a signature. Am J Nursing 2000; 100 (9)

37. Glaser J, Nouri S, Fernandez A, Sudore RL, Schillinger D, Klein-Fedyshin M, et al. Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: An Updated Systematic Review. Med Decis Mak. 2020;40(2):119–43.

38. Singh A, Chopra M, Singh GP, Bhardwaj A, Kaur B, Aggarwal O. Perceptions towards Legal Nature of Informed Consent. J Indian Acad Forensic Med [Internet]. 2013;35(1):2011–4. Available from: http://medind.nic.in/jal/t13/i1/jalt13i1p40.pdf

39. Chaisson LH, Kass NE, Chengeta B, Mathebula U, Samandari T. Repeated assessments of informed consent comprehension among HIV-infected participants of a three-year clinical trial in Botswana. *PLoS One*. 2011; 6(10): e22696. Doi: 10.1371/journal.pone.0022696

40. Davis TC, Berkel HJ, Holcombe RF, Pramanik S, Divers SG. Informed Consent for Clinical Trials: a Comparative Study of Standard Versus Simplified Forms. JNCI J Natl Cancer Inst. 1998 May 6; 90(9): 668–74.

41. Patrica A. Marshall. Ethical challenges in study design and informed consent for health research in resource-poor settings. Soc Econ Behav Res. 2007.

42. Mkoma I.S. Factors influencing quality of informed consent among general surgical and gynecological patients at MNH, Oct 2010; 28-34.

43. Palmeirim MS, Ross A, Obrist B, Mohammed UA, Ame SM, Ali SM, et al. Informed consent procedure in a double blind randomized anthelminthic trial on Pemba Island, Tanzania: Do pamphlet and information session increase caregivers knowledge? BMC Med Ethics. 2020;21(1):1–9.

44. Krishnamoorthy B, Yap K-H, R Critchley W, Nair J, Devan N, Barnard J, et al. A prospective randomised study comparing the current surgical informed consent form with a modified, pre-printed consent form. Heal Educ Care. 2016;1(1):17–21.

45. Harun S. Comprehension in doubt: An informed consent towards treatment among people living with HIV and AIDS at Mwananyamala hospital. Oct 2017

46. Hall DE, Prochazka A V, Fink AS. Informed consent for clinical treatment. CMAJ. 2012 Mar 20; 184(5): 533–40.

47. American Medical Association (AMA). Informed Consent. American Medical Association. April 11, 2001.

48. Medical Association of Tanzania (MAT), Guiding principles on Medical Ethics and Human Rights in Tanzania. MAT 1995.

49. Siddiqui F.G, Shaikh J.M, Memon M.M. An audit of informed consent in surgical patients. December 2007.

50. Sulaiman A, Ayyuba R, Diggol I, Haruna I. Knowledge, attitude and perception of patients towards informed consent in obstetric surgical procedures at Aminu Kano Teaching Hospital. Niger J Basic Clin Sci. 2015;12(1):45 -50.

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

52. Whitney SN, McGuire AL, McCullough LB. A typology of shared decision making, informed consent and simple consent. Ann Intern Med 2004; 140(1): 54-9.

53. Perry C. Negligence in securing informed consent and medical malpractice. J Med Humanit Bioethics. 1988; 9(2): 111-120

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

55. Dhai A. Research ethics review-protecting participants in research. South Africa Med J; Aug 2005: 95(8)595-7

56. Lazer M.N, Greiner G.G, Robertson G, Singer P.A. Bioethics for clinicians: 5 substitute decision-making. Can Med Assoc. J. Nov 1996; (10)1435-37.

57. Davis TC, Holcombe RF, Berkel HJ, Pramanik S, Divers SG. Informed consent for clinical trials: A comparative study of standard versus simplified forms. J Natl Cancer Inst. 1998;90(9):668–74.

58. Young DR, Hooker DT, Freeberg FE. Informed consent documents: increasing comprehension by reducing reading level. IRB; a Rev Hum Subj Res. 1990;12(3):1–5.

59. http://medical-dictionary.thefreedictionary.com (accessed on June 11st, 2020)

60. https://select-statistics.co.uk (assessed on Sept 28th, 2020)

15. APPENDICES

Appendix I: Informed Consent (English Version)

Introduction

You are invited to participate in a research study conducted by Surgery Resident from Muhimbili University of Health and allied Sciences (MUHAS). You must be 18 years or older to participate in the study. Your participation is voluntary. Please take as much time as time as you need to read the information in this form. You may also decide to discuss it with your family or friends. You will be given a copy of this form.

Background information

Comprehension is an essential element of patient centered care. It is reported that patients who have good comprehension are proactive and more compliant but it is noted that most patients have poor comprehension and even poorer in Sub Sahara African countries, Tanzania being one of them. The most effective interventions to improve comprehension have not been identified and therefore there is a need to design interventions based on our settings to improve patients' comprehension.

Purpose of the research

This study is set to assess the impact of Enhanced Informed Consent form for surgical procedures on Patients' comprehension as compared to the Conventional Informed consent form for surgical procedures.

Study procedures

This study is expected to involve participants who are patients admitted at MNH and listed to undergo elective surgical procedures. You are asked to participate in this study because you are among the patients planned for elective surgery. Participants will be randomly grouped into two groups; one group will use the Enhanced/Modified informed consent form for surgical procedures while the other group will use the Conventional/Current informed consent form for surgical procedures when consenting for the planned surgeries. 2-3 days after surgery you will be interviewed to answer some questions regarding the surgical procedure done and other basic information. The expected time to spend to answer questionnaire will be from 10 minutes to 15

minutes depending on an individual participation.

Participation

Participation into the study is voluntary. You have the right to decline participation or withdraw from the study at any point during the process of consenting or answering questions. Your decision to participate or not will not in any way interfere the services at the ward, theater or other place within and outside the hospital. Moreover, you are not subjected to say why you are quitting the study.

Confidentiality

Any information obtained from you will be kept confidential. Only research team will access the information. In any way, information will not be linked to your individual name and will have no any implication to your current and future status to social services including health services in this hospital. Your name will not be mentioned in any paper or report about this study. Your identity to this study will base on the agreed identification item (ID).

Costs

You do not need to pay anything to be involved in this study. Otherwise, any payment towards the cost of your treatment, which was explained to you at admission, will be paid as determined by hospital policy.

Benefits

There is no direct benefit for you participating into this study. However, the information that you are going to provide to us will help in improving the format of informed consent form for surgical procedures and design other more interventions that will improve patients' comprehension hence improve patient centered health services.

Risks

There are no anticipated risks to your participation. When you feel some discomfort at responding to some questions, please feel free to ask to skip particular question(s).

Contact details

For further information or reporting of study related adverse events, contact me or my supervisors on the following address and numbers:

1) Investigator: Dr. Anthony M. Mapande;
   P. O. Box 65001 Dar es salaam,
   Mobile: +255 762 711 371,
   Email:anthonymapande@yahoo.com
2) Supervisor: Dr Ramadhan H. Khamisi
   Mobile: +255 784 657 037.
   Email: hassanramadhan@yahoo.com
3) Supervisor: Dr Andrew Swallow
   Mobile +255 785 075 403.
   Email: swallowandrew@yahoo.com

4) Supervisor: Dr. Jahanarah Graf
   Mobile: +1(202) 550 0274.
   Email: jahanara.j.graf@gmail.com

In case of any information about your rights as a participant in this study, please contact: Dr. Bruno Sunguya, Chairperson-MUHAS IRB, P. O. Box 65001, Dar es Salaam; Telephone: +255 22 2152489/0302-6. Email address: drp@muhas.ac.tz

Consent to participate

Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep.

Subject's Signature: ..... Date: .....

Researcher's Signature: ..... Date: .....

Thanks for participating

Appendix II: Consent Form (Swahili Version)

HATI YA RIDHAA YA USHIRIKI KATIKA UTAFITI

Utanglizi

Unaalikwa kushiriki katika utafiti unaofanywa na Daktari katika mafunzo ya upasuaji toka Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Unatakiwa uwe na umri kuanzia miaka 18 na kuaendelea ili kushiriki katika utafiti huu. Ushiriki wako ni huru na wa hiari. Tafadhali soma vizuri taarifa katika hati hii, pia unaweza kujadili na ndugu au rafiki kabla ya kufanya maamuzi. Utapatiwa nakala ya hati hii.

Taarifa za awali kuhusu utafiti.

Uelewa wa mgonjwa ni sehemu muhimu katika huduma za matibabu. Inasemekana kuwa mgonjwa mwenye uelewa mzuri kuhusu matibabu yake huwa na ushiriki mzuri na mtiifu katika huduma za matibabu anazopewa, lakini imeonekana wagonjwa wengi wana uelewa hafifu hasa katika nchi chini ya jangwa la Sahara, Tanzania ikiwa mojawapo ya nchi hizo. Njia nzuri na bora zaidi ya kuongeza uelewa kwa wagonjwa bado haijapatikana hivyo kuna hitajika kufanyika tafiti katika mazingira yetu ili kuweza kupata namna nyepesi na bora zaidi ya kuongeza uelewa wa wagonjwa kuhusu matibabu wanayopatiwa.

Dhumuni la utafiti.

Utafiti huu utatathimini uwezo wa **fomu mpya ya idhini ya matibabu ya upasuaji** katika kuongeza uelewa kwa mgonjwa ikilinganishwa na **fomu ya idhini ya matibabu ya upasuaji** inayotumika kwa sasa.

Utaratibu wa ushiriki.

Utafiti huu utahususha jumla ya washiriki 212 ambao ni wagonjwa waliolazwa katika Hospitali ya Taifa Muhimbili wanaotegemea kufanyiwa upasuaji wa hiari. Unaombwa kushiriki kwa kuwa uko katika orodha ya wanaofanyiwa upasiaji wa hiari. Washiriki watagawanywa katika makundi mawili; kundi moja watatumia fomu mpya ya idhini ya matibabu ya upasuji na kundi lingine watafumia fomu ya idhini ya matibabu ya upasuaji inayotumika kwa sasa katika kutoa idhini ya kupatiwa matibabu. Siku 2-3 baada ya upasuaji utaombwa kuulizwa maswali kuhusu upasuaji uliofanyiwa. Muda

utakaotumia kijibu masawali hayo unakadiriwa kuwa kati dakika 10 -15.

Ushiriki

Ushiriki wako ni huru na hiari. Una haki ya kukataa kushiriki au kijitoa katika utafiti katika hatua yoyote ya utafiti. Uamuzi wako wa kushiriki au kutoshiriki katika utafiti huu hautaingiliana kwa jinsi yoyote na utaratibu kwa kupata huduma za matibabu katika wodi, chumba cha upasuaji au katika mazingira yoyote ndani na nje ya Hospitali. Pia, hutatakiwa kusema kwa nini umeamua kujitoa katika utafiti endapo utafanya uamuzi huo.

Usiri

Taarifa zote utakazotoa zitatunzwa kwa usiri mkubwa. Taarifa zako zitaweza kuonwa na wahusika wa utafiti huu tuu. Kwa namna yoyote, taarifa zako hazitahusishwa na jina lako na pia hazitakuwa na athari yoyote katika huduma za kijamii pamoja na huduma za matibabu katika Hospitali hii. Jina lako halitatumika katika sehemu yoyote kwenye utafiti huu.

Gharama

Hutakiwi kulipa gharama yoyote kushiriki katika utafiti huu. Gharama ya matibabu utakayopatiwa italipwa kulingana na taratibu za Hospitali na kama ulivyoelezwa kipindi unalazwa.

Faida

Hakuna faida ya moja kwa moja kushiriki katika utafiti huu. Taarifa utakazotoa zitasaidia kuboresha hati ya idhini ya matibabu ya upasuaji na ubunifu wa njia nyingine bora zaidi za kuongeza uelewa wa wagonjwa kuhusu matibabu wanayopatiwa hasa ya upasuaji.

Athari

Hakuna athari zozote katika kushiriki utafiti huu. Endapo utahisi hauko vizuri kujibu baadhi ya maswali, tafadhari kuwa huru kutojibu swali/maswali husika.

Mawasiliano

Kwa ajili ya maelezo ya ziada kuhusu utafiti huu au kutoa taarifa zozote za athari kutokana na utafiti, tafadhari wasiliana na wafuatao.

1) Mtafiti: Dkt. Anthony M. Mapande;
   S.L.P 65001 Dar es salaam; Simu: +255 762 711 371;
   Barua pepe:anthonymapande@yahoo.com
2) Msimamizi: Dkt Ramadhan H. Khamisi
   Simu: +255 784 657 037:
   Barua pepe: hassanramadhan@yahoo.com
3) Msimamizi: Dkt. Andrew Swallow
   Simu: +255 785 075 403:
   Barua pepe: swallowandrew@yahoo.com
4) Msimamizi: Dkt. Jahanarah Graf
   Simu: +1(202) 550 0274
   Barua pepe: jahanara.j.graf@gmail.com

Kwa taarifa zozote kuhusu haki zako kama mshiriki, Tafadhali wasiliana na Dkt Bruno Sunguya, Mwenyekiti- Kamati ya maadili ya tafiti ya Chuo Kikuu Muhimbili, S. L. P 65000 Dar es Salaam; Simu +255 22 2152489/0302-6. Barua pepe: drp@muhas.ac.tz

Idinini ya Kushiriki

Saini yako hapa inaonyesha umekubali kushiriki katika utafiti huu, umesoma na kuelewa taarifa zilizoandikwa katika hati hii. Utapewa nakala ya hati ya idhini hii iliyotiwa saini na yenye tarehe uitunze.

Saini ya Mshiriki: ..... Tarehe: .....

Saini ya Mtafiti: ..... arehe: .....

Asante kwa kushiriki

Appendix III: Conventional Informed Consent Form for surgical procedures (English Version)

MUHIMBILI NATIONAL HOSPITAL

Cables: "MUHIMBILI"
Telephones: 266-22-2151367-9
Fax: 255-22-2150534
Website: www.mnh.or.tz
Email: info@mnh.or.tz

Postal Address:
P.O. Box 65000
DAR ES SALAAM
Tanzania

CONSENT FORM

Hospital number: ..... Sex: .....

Name: ..... Address: .....

Age: .....

THIS CONSENT IS FOR SURGICAL PROCEDURE, DIAGNOSTIC PROCEDURES AND ANETHESIA.

I ..... I give the consent to Dr. ..... and other supporting staff to perform operation /diagnostic procedure.

I have been told by the Dr that during the procedure anything may happen as they may find other problems than the one that I was told before. I give the consent to the doctor to do whatever he/she can for my benefit.

I also give the consent to be given

Anesthesia of any kind before the procedure
Blood or its product if it will be needed

I .....I confirm and declare that I had a clear explanation from the doctor/Anesthetist /Anaesthestologist, I have also read and understood all the explanations above;

I have had the opportunity to ask questions and have had these answered clearly. I give the consent for the procedure to be done.

Name of the patient: ..... Date: ..... Time: .....
Signature: .....

Name of the Doctor: .....
Signature: ..... Date: .....
Anesthetist /Anaesthestologist

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

Witness

1. Name: ..... Date: .....(Relative)
Time: .....
Signature: .....

2. Name: .....(Health personnel)
Date: ..... Time: .....
Signature: .....

Appendix IV: Convectional Informed Consent Form for surgical procedures (Swahili Version)

MUHIMBILI NATIONAL HOSPITAL

Cables: "MUHIMBILI"
Telephones: +266-22-2151367-9
FAX +255-22-2150534
Web: www.mnh.or.tz

Postal Address:
P.O. Box 65000
DAR ES SALAAM
Tanzania

FOMU YA IDHINI YA MATIBABU (INFORMED CONSENT) UTOAJI WA DAWA YA USINGIZI (NUSU KAPUTI), GANZI NA KUFANYIWA HUDUMA YA UPASUAJI NA/AU TIBA UCHUNGUZI

Tarehe: .....

Mimi ..... Namba ya Usajili .....
Wodi ..... Jinsi ..... Umri ..... namruhusu
(i) Dk. ..... na jopo la wataalam wengine wataomsaidia katika kufanyia huduma ya upasuaji/au matibabu na uchunguzi wa ugonjwa wangu
wa ..... Aina ya upasuaji .....
.....

Nimekwisha elezwa aina upasuaji/uchunguzi utakaofanyika, na kwamba wakati wa huduma ya upasuaji matatizo mengine ambayo hayakuonekana kabla ya kupewa dawa ya usingizi na kupasuliwa yanaweza kuonekana/kujitokeza na ikihitajika kufanyiwa upasuaji tofauti na nilivyoelezwa awali. Kwa hiyo nitatoa idhini ya kumuomba daktari aliyetajwa hapo juu kufanya upasuaji kama itakavyohitajika.

(ii) Naidhinisha kupewa dawa, damu, kwa njia zote za kitaalamu kadri itakavyohitajika pamoja na drip kama tiba au huduma yoyote itakavyoonekana ya lazima au muhimu kwa hali yangu kutokana na uamuzi wa wataalamu.

(iii) Nathibitisha kuwa nimeelezwa na kuelewa aina na lengo la upasuaji na nimeelezwa kuhusu matibabu mbadala yaliyopo na uwezekano wa matatizo au madhara yanayoweza kutokea wakati wa huduma ya upasuaji.

Jina la Mgonjwa/Mbadala .....
Saini ya Mgonjwa/Mbadala ..... Tarehe: .....

Jina la Daktari .....
Saini ya Daktari ..... Tarehe: .....

Jina la Shahidi ..... (Mtaalam yeyote wa Afya eg. muuguzi, daktari, etc)
Saini ya Shahidi ..... Tarehe: .....

Jina la Ndugu .....
Saini ya Ndugu ..... Tarehe: .....

Appendix V: Enhanced Informed Consent Form for surgical procedures (English Version)

MUHIMBILI NATIONAL HOSPITAL

Cables: "MUHIMBILI"
Telephones: +266-22-215136-9
FAX +255-22-2150534
Web: www.mnh.or.tz

Postal Address:
P.O Box 65000
DAR ES SALAAM
Tanzania

DIRECTORATE OF SURGICAL SERVICES

INFORMED CONSENT FORM FOR SURGICAL PROCEDURE

DETAILS OF PROCEDURE	PATIENT IDENTIFICATION
Diagnosis……	Hospital Reg Number……
Name of Procedure ……..	Surname……..
……	Other names……
Surgeon's name……	Residential address…….
Department……	Date of Birth ……../……../……
Date of Surgery ……/……../……	Sex M / F
Date of Admission……/……/……..	Religion …….

INFORMED CONSENT FOR SURGICAL PROCEDURE

Note:

For the purpose of this consent form, this operation/treatment/test is referred as procedure

i. For elective surgical procedure this consent form will be valid for 15 days
ii. To be signed by parent/guardian in case of minor and by next of kin in case a Physically Disabled or Mentally Incompetent or an unconscious person
iii. Surgical Services Director/ Head of department or Designee can sign for an unaccompanied, incapable person's emergency management.

Consent by: Patient ☐ Next of Kin ☐ Surgical Director/Designee ☐

I ……hereby authorize Dr……

Of Muhimbili National Hospital, and his/her team to perform upon me/my patient the following procedure;

Procedure name……

Diagnosis …….

1. My doctor/team has discussed with me the following aspects in details (as applicable)
    a) The nature, purpose, benefits of the proposed procedure and likelihood of success……..
    b) Specific Potential Risks involved; like ……
    c) Type of Anesthesia expected to be given……..
    d) Possible specific problems related to recovery ……..
    e) Duration to full recovery and when to resume normal duty ……..
    f) Potential risk of not carrying out the proposed procedure

……..

g) Possible alternative treatment modalities and the risks involved

……..

2. I further consent to the performance of such surgical and/or other procedure as may be deemed necessary by the above-mentioned doctors to correct the existing or unforeseen conditions, which may be revealed during the above-mentioned procedure.
3. I also consent the use of other drugs or any other treatment procedures deemed necessary or advisable for the above-mentioned procedure.
4. I also allow the use of contrast media as deemed necessary by performing doctor or associates or assistants. Therefore, I have informed the doctor of all allergies I/my patient have/has, including any previous reaction to contrast media.
5. The medical staff of Muhimbili National Hospital **IS / NOT** authorized to obtain photographic or other pictorial representations of the procedure.
6. In the course of my treatment, I further consent transfusion of blood and blood products if deemed necessary or advisable. The purpose, benefits, risks, complications and alternatives of such transfusion have been explained to me.
7. In the event that the above procedure involves the removal or disposition of dismembered tissue, parts or organs; The Muhimbili National Hospital **IS AUTHORIZED** / **NOT AUTHORIZED** to use these for scientific or teaching purpose or otherwise dispose these in a suitable manner. The limbs/fetus/other acceptable organs, unless infectious and/or pose a health hazard, are to be delivered for burial to

   Name of the person……..…….....

   Mobile……
8. I acknowledge that the above information has been given to me in the language that I understand and is sufficient for me to consent and to authorize the “procedure” prescribed above. I have had the opportunity to ask questions

concerning my/ my patient's condition and about the procedure and all questions have been answered to my satisfaction. I also certify that all the blanks or statements requiring insertion or completion were filled in and any inapplicable paragraph stricken before I signed.

……
Name of the Doctor whom consent is accorded
Signature…….
Designation…….
Date ……...Time…….

……
Name of the Patient/Next of kin
Signature……..
Date……Time……

Relationship to the patient, if applicable……..

TO BE FILLED BY WITNESSES

Health Personnel.

Name……..
Signature …….
Designation …….
Date ……. Time……

Patient Next of Kin/Relative

Name…….
Signature…….
Relationship……...
Date……. Time……...

CLINICIAN INFORMED CONSENT CONVERSATION CHECKLIST

Please go through the checklist before starting the process of taking consent and make sure you follow the required steps and be marking each step: Only if you have done it.

NB: Do no harm

1. **Preparation**

   ☐ Review the patient's medical records including History, Physical findings, Diagnosis, Investigations done and proposed procedure.

   ☐ Determine if the patient needs an interpreter or other communication aid.

   ☐ Prepare a conducive environment for taking consent.

2. **Introduction**

   ☐ Introduce yourself and state your role in the patient's care including the proposed procedure

   ☐ Encourage active patient participation and shared communication with open-ended questions

3. **Core**

   ☐ First; re-check patient understanding on his/her Diagnosis, then go on discuss the diagnosis as it relates to the proposed procedure.

   ☐ Explain the procedure (Indication, nature, purpose, benefits and likelihood of success) including who will perform it, and how long it might take.

   ☐ Explain the potential specific risk related to the proposed procedure, Alert on unforeseen conditions, and possibility of Blood Transfusion with its benefits and risks

   ☐ Describe the risk and consequences of rejecting the proposed procedure

   ☐ Describe the relevant alternatives to the proposed procedure

☐ Describe what to expect following the procedure (Eg. Amount and duration of pain, length of recuperation, limitations on activities of daily living, quality of life)

4. Review

☐ Elicit questions and concerns

☐ Check for patient understanding through “teach back”

☐ Review the consent form with the patient; consider reading the form out loud or giving the patient the opportunity to read the form alone

☐ Allow time for additional discussion with family members

☐ Emphasize that it is the patient’s choice whether or not to consent to the procedure, make sure the patient understands that the procedure cannot be done without his/her consent

Appendix VI: Enhanced Informed Consent Form for surgical procedures (Swahili Version)

MUHIMBILI NATIONAL HOSPITAL

Cables: **"MUHIMBILI"**

Telephones: **+266-22-215136-9**

FAX **+255-22-2150534**

Web: **www.mnh.or.tz**

Postal Address:

P.O Box 65000

DAR ES SALAAM

Tanzania

KURUGENZI YA HUDUMA ZA UPASUAJI

HATI YA IDHINI YA MATIBABU YA UPASUAJI

TAARIFA ZA UPASUAJI	TAARIFA ZA MGONJWA
Ugonjwa……	**Namba ya usajili…….**
Aina ya upasuaji …….	**Jina la ukoo…….**
……	**Majina mengine……**
Jina la Daktari…….	**Anuani ya makazi…….**
Idara……..	**Tarehe ya kuzaliwa ……/…. /……**
Tarehe ya upasuaji ……/……../…….	**Jinsi ME / KE**
Tarehe ya kulazwa……/……/…….	**Dini …….**

IDHINI YA MATIBABU YA UPASUAJI

Nukuu:

Kwa matumizi ya hati hii ya idhini, neno “utaratibu” linaamanisha upasuaji/matibabu/kipimo husika

i. Kwa upasuaji usio wa dharura, idhini hii itadumu kwa siku 15.
ii. Hati hii isainiwe na Mzazi/Mlezi endapo mgonjwa ni mtoto chini ya miaka 18 na isainiwe na ndugu/jamaa wa karibu endapo mgonjwa ni mlemavu/hana akili timamu/hana fahamu
iii. Mkurugenzi wa huduma za upasuaji/Mkuu wa idara au wakala wake anaweza kutoa idhini kwa mgonjwa asiye na hafamu/hana uwezo wa kutoa idhini na hana ndugu/jamaa wa karibu kwa ajili ya matibabu ya dharura.

Anaetoa idhini: Mgonjwa ☐ Jamaa wa karibu ☐ Mkurugenzi wa huduma za upasuaji/Wakala ☐

Mimi…….natoa idhini yangu kwa Dkt……
wa Hospitali ya Taifa Muhimbili na wasaidizi wake kunifanyia/kumfanyia mgonjwa wangu utaratibu ufuatao wa upasuaji

Jina la utaratibu…….

Ugonjwa……

1. Daktari wangu/Wasaidizi wake wamenieleza na kujadili nami kwa kina mambo muhimu yafuatayo
    a) Namna, lengo, faida za kufanya utaratibu pendekezwa na uwezokano wa mafanikio…….
    b) Athari maalum zinazoweza kuzitokeza kama utaratibu huu utafanyika; mfano……
    c) Aina ya dawa za usingizi zitakazotumika……..
    d) Matatizo yanayoweza kujitokeza katika hatua za kupona …….

e) Muda unaotegemewa mpaka kupona kabisa na kuanza shughuri za kawaida…….

f) Athari na matatizo yanayoweza kujitokeza kama utaratibu pendekezwa hautafanyika…….

g) Matibabu mbadala yanayoweza kufanyika; faida na hatari zake …….

2. Natoa pia idhini ya kufanyiwa taratibu zingine za upasuaji zitakazojitokeza kwa maoni ya madaktari husika kwa lengo la kurekebisha hitilafu za ziada zitakazojitokeza kwenye utaratibu uliyokusudiwa.

3. Natoa idhini pia kwa matumizi ya dawa au namna nyingine ya matibabu yatakayopendekezwa kwenye utekelezaji wa utaratibu huu.

4. Natoa idhini pia kwa matumizi ya mionzi na dawa maalumu zinazosadia kutambulisha viungo kwenye picha iwapo yatahitajika. Nimemueleza Daktari/wasaidizi wake kuhusu mizio yote niliyonayo.

5. **Natoa idhini** / **Sitoi idhini** kwa wahudumu wa afya wa Hospitali ya Taifa Muhimbili kupiga picha wakati utaratibu huu unaendelea

6. Katika zoezi la matibabu yangu, naidhinisha pia uwekwaji wa damu na/au mazao yake kama itahitajika. Nimeelezwa lengo, faida, hatari, matatizo na mbadala wa uwekwaji damu na/au mazao yake.

7. Endapo utaratibu huu utahusisha utoaji/kukata kipande cha kiungo au sehemu ya mwili; Hospitali ya Taifa Muhimbili **Itaruhusiwa /Haitaruhusiwa** kutumia kiungo hicho kwa ajili ya shughuri za kitafiti / mafunzo au kuhifadhi kwa namna nzuri yenye heshima. Mguu/Mkono/Kijusi au kiungo chochote kinachoruhusiwa, endapo

hakina hatari ya maambukizi / madhara ya kiafya; vikabidhiwe kwa ndugu zangu kwa ajili ya mazishi.

Jina la liyeidhinishwa……..Simu…….

8. Nathibitisha kuwa taarifa zote tajwa katika hati hii zimetolewa katika lugha ninayoielewa kuniwezesha kufanya maamuzi ya kutoa idhini kwa utaratatibu pendekezwa. Nimepata fursa ya kuuliza kuhusu ugonjwa wangu na utaratatibu pendekezwa na nimeridhika na majibu/maelezo niliyopata. Nathibitisha pia vipengele vyote vilivyo wazi vilijazwa na vipengele visivyohusika vilifutwa kabla sijaweka saini yangu.

……
Jina la Daktari
Saini……..
Cheo……..
Tarehe……Saa……..

……..
Jina la Mgonjwa/Ndugu
Saini…….
Tarehe……Saa…….
Uhusiano na Mgonjwa…….

IJAZWE NA SHAHIDI

Mtalaam wa Afya

Jina……..
Saini…….
Cheo…….
Tarehe……Saa……

Ndugu wa Mgonjwa

Jina ……
Saini……
Uhusiano…….
Tarehe……Saa……

CLINICIAN INFORMED CONSENT CONVERSATION CHECKLIST

Please go through the checklist before starting the process of taking consent and make sure you follow the required steps and be marking each step: Only if you have done it.

NB: Do no harm

1. **Preparation**

   ☐ Review the patient's medical records including History, Physical findings, Diagnosis, Investigations done and proposed procedure.

   ☐ Determine if the patient needs an interpreter or other communication aid.

   ☐ Prepare a conducive environment for taking consent.

2. **Introduction**

   ☐ Introduce yourself and state your role in the patient's care including the proposed procedure

   ☐ Encourage active patient participation and shared communication with open-ended questions

3. **Core**

   ☐ First; re-check patient understanding on his/her Diagnosis, then go on discuss the diagnosis as it relates to the proposed procedure.

   ☐ Explain the procedure (Indication, nature, purpose, benefits and likelihood of success) including who will perform it, and how long it might take.

   ☐ Explain the potential specific risk related to the proposed procedure, Alert on unforeseen conditions, and possibility of Blood Transfusion with its benefits and risks

   ☐ Describe the risk and consequences of rejecting the proposed procedure

   ☐ Describe the relevant alternatives to the proposed procedure

   ☐ Describe what to expect following the procedure (Eg. Amount and duration of pain, length of recuperation, limitations on activities of daily living, quality of life)

4. Review

☐ Elicit questions and concerns

☐ Check for patient understanding through “teach back”

☐ Review the consent form with the patient; consider reading the form out loud or giving the patient the opportunity to read the form alone

☐ Allow time for additional discussion with family members

☐ Emphasize that it is the patient’s choice whether or not to consent to the procedure, make sure the patient understands that the procedure cannot be done without his/her consent

Appendix VII: Questionnaire (English Version)

Questionnaire number ……

Sex: F / M

SECTION A: Demographic details

1. What is your age? ……
2. Where do you live?
    2.1.1. Region …….
    2.1.2. District …….
3. What is your education level?
    3.1 Informal education
    3.2 Primary level
    3.3 Secondary level
    3.4 Tertiary level (Collage / University)
4. What is your occupation?
    4.1 Self employed
    4.2 Employed
    4.3 Unemployed
    4.4 Retired
5. What is your marital status?
    5.1 Married
    5.2 Widowed
    5.3 Divorced
    5.4 Single
6. Where do you get your health information? – *Tick one/more option as applicable*
    6.1 Health Personnel
    6.2 Significant others
    6.3 Other sources. eg internet, Journals, Newspapers etc

SECTION B: Comprehension on elements of informed consent process

Ability to respond well to a question will score 2, respond to a question score 1 and wrong/no response score 0

	Questions	Response rate		
		Wrong/No response	Average response	Good response
1	Do you know your illness?	0	1	2
2	Do you have any idea of the surgery you underwent?	0	1	2
3	Do have any idea of the purpose of the surgery you underwent?	0	1	2
4	Do you have any idea of the chances of success of the surgery you underwent?	0	1	2
5	Do you know any risks you could have got from the surgery you underwent?	0	1	2
6	Do have any idea of what could have happened (risks & consequences) if you would have rejected the surgery you underwent?	0	1	2
7	Do you have any idea of the problems that might happen to you during your recovery?	0	1	2
8	Do you have any idea of any other alterative treatment(s) that you might have undergone and the related risks?	0	1	2
9	Do you know you could ask for any clarifications from the doctor before consenting for surgery?	No 0	I don't know 0	Yes 2
10	Do you know that you could reject the proposed surgery or ask for alternative treatment?	No 0	I don't know 0	Yes 2
11	Would you reconsider your decision if you were to sign now? If No then why?? ……..	No 0	-	Yes 2

Appendix VIII: Questionnaire (Swahili Version)

Namba ya dososo .....…

Jinsi: ME / KE

SEHEMU A: Utangulizi

1. Una miaka mingapi? ……
2. Unaishi wapi?
    2.1.1. Mkoa …….
    2.1.2. Wilaya ……
3. Una kiwango gani cha elimu?
    3.1 Sijasoma
    3.2 Elimu ya msingi
    3.3 Elimu ya Sekondari
    3.4 Elimu ya chuo na kuendelea

4. Ufanya kazi gani?
    4.1 Nimejiajiri
    4.2 Nimeajiriwa
    4.3 Sijaajiriwa
    4.4 Mstafuu

5. Hali yako ya mahusiano ikoje?
    5.1 Niko kwenye ndoa
    5.2 Mwenza amefariki
    5.3 Nimeachwa
    5.4 Siko kwenye ndoa

6. Unapata wapi taarifa kuhusu maswala ya afya? – *Chagua moja au zaidi kadri inavyohusika*
    6.1 Mtoa huduma za afya
    6.2 Ndugu/Jamaa wa karibu
    6.3 Vyanzo vingine, Mfano; Mtandaoni, Majarida, Magazeti n.k

SEHEMU B: Uelewa juu ya vipengele katika mchakato wa kutoa idhini ya matibabu

Uwezo wa kujibu swali kwa usahihi mzuri atapata alama 2, kujibu swali sahihi atapata alama 1 na kushindwa kujibu/jibu lisilo sahihi atapata alama 0

	Swali	**Alama za majibu**		
		Jibu lisilo sahihi	Jibu sahihi (wastani)	Jibu sahihi (Zuri)
1	Unafahamu una ugonjwa gani?	0	1	2
2	Unafahamu kitu chochote kuhusu upasuaji uliofanyiwa?	0	1	2
3	Unafahamu upasuaji uliofanyiwa una malengo yapi?	0	1	2
4	Unafahamu upasuaji uliofanyiwa una asilimia kiasi gani cha kufanikiwa?	0	1	2
5	Unafahamu hatari na madhara yoyote ambayo ungeweza kupata kutokana na upasuaji uliofanyiwa?	0	1	2
6	Je! Unafahamu hatari/madhara yoyote ambayo ungeweza kupata kwa kutofanyiwa upasuaji uliofanyika?	0	1	2
7	Unafahamu matatizo yoyote unayoweza kupata katika hatua za uponaji wako?	0	1	2
8	Unafahamu aina yoyote nyingine ya matibabu ambayo ungeweza kupatiwa na hatari zinazoambatana na matibabu hayo?	0	1	2
9	Je! unafahamu kuwa unaweza kuomba maelezo ya ziada au ufafanuzi kuhusu ugonjwa au matibabu yako kabla ya kutoa idhini yako?	Hapana 0	Sijui 0	Ndio 2
10	Je! Unafahamu kuwa unaweza kukataa matibabu yalipendekezwa na/au kuomba kuapatiwa matibabu mbadala?	Hapana 0	Sijui 0	Ndio 2
11	Je! Ungefanya maamuzi ulifanya kama ungetakiwa kutoa idhini yako sasa hivi? Kama ni hapana ni kwa sababu gani?.....	Hapana 0	-	Ndio 2