FACTORS INFLUENCING QUALITY OF INFORMED CONSENT AMONG GENERAL SURGICAL AND GYNACOLOGICAL PATIENTS AT MUHIMBILI NATIONAL HOSPITAL

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CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: factors influencing quality of informed consent among general surgical and gynacological patients at muhimbili national hospital

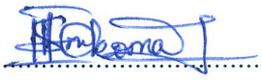
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ABSTRACT

Objectives: A prospective study comprising interviews with patients and then completing standard questionnaires was conducted among surgical patients at Muhimbili National Hospital from April 2009 to January 2010. The aim of the study was to examine the factors influencing quality of informed consent at surgical and gynaecological unit of the largest teaching hospital.

Methods: Two hundred and thirty two (107 men, 125 women) patients undergoing intrathoracic, intraperitoneal and intra pelvic procedures were involved. One patient died before the discharge day. Operation information cards were allocated to 116 patients and the other half of patients received only oral information.

The patients were asked to recall information at various points before and after surgery; this score was compared by age, provision of written information and confidentiality status.

Results: It was observed that the patients were best informed on the day of discharge (81.4%). Old age adversely affected recall of information at all assessment points. Operation information cards improved recall of information. Almost all patients let their relatives to know about their disease status.

Conclution: In conclusion it has identified that the process approach rather than single event approach with regard to procedures of gaining informed consent improves the rate of recall of information. The Junior Doctors are the most effective in imparting information relating to surgical treatment despite the fact that are not the ones carrying out the procedures. Elderly patients are likely to recall information relating to their surgery poorly. It also noted that written information is helpful. Out of culture medical confidentiality is not maintained in daily practice in this setting.

Recommendations: It was stated that the way forward is:

- Extra effort is needed to improve procedures of gaining informed consent from elderly patients which includes , asking patient to recall establishing understanding, adding additional stimuli which includes , providing written information and approach should be process approach rather than single event approach.
- Written information should be given in addition to oral information to all patients.
- Study is needed to evaluate the position and quality of the relatives' opinion in the decision making by the patient during process of obtaining informed consent.

LIST OF ABBREVIATIONS

1.	WMA	-	World Medical Association
2.	CIOMS	-	Council for International Organization of Medical Sciences
3.	CMA	-	Commonwealth Medical Association
4.	MAT	-	Medical Association of Tanzania
5.	MUHAS	-	Muhimbili University of Health and Allied Sciences
6.	AMA	-	The American Medical Association
7.	IQ	-	Intelligence quotient
9.	ACL	-	Anterior Cruciate ligament
10.	ICU	-	Intensive Care Unit

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1. CHAPTER ONE

1.1 INTRODUCTION

Informed consent is an ongoing agreement by a person to receive treatment, undergo procedures or participate in research, after risks, benefits and alternatives have been adequately explained to them [1]. It is consent given by an individual who has received necessary information, has adequately understood the information (comprehension) and after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or intimidation (voluntary decision). Surgical consent is not an event or a signature on a form but is an ongoing process of communication that continues throughout preoperative, perioperative, and postoperative care. In the context of patient-centered medicine, consent is best conceptualized as shared decision making with patients or their surrogates [2]. Valid informed consent represents the culmination of good patient-clinician communication. It is underpinned by the patient's trust in medical professionalism. Patients must trust that their tests are error free, that their diagnosis is correctly made, and that the advice they are given is evidence based.

A more patient-centered method, advocated by Bridson, suggests that clinicians should ask patients their goals for treatment, even before treatment options are discussed. Patient information needs can then be gauged from the start, and the information tailored to fit the context of that particular patient's objectives.

However, the provision of information to patients remains highly problematic, as recent legal precedent has shifted the balance in divulging risk. The previous test for revealing risk to patients was established by the Bolam case, and based on what a consensus of medical opinion would consider should be told to the patient. The Chester v Afshar case in 2004 established the ruling that all material risk, which a reasonable patient would want to know, must be told to them. This creates a tension between responding to patients' individual requirements for information and the onus on the clinician to ensure that all relevant risks are stated and legal

requirements met. Some patients may not want to be informed of the risks and complications of treatment and may prefer to leave the decision entirely to their surgeon, in which case clinicians are advised to document these situations in order to safeguard their position.

In addition, it has been demonstrated that there is variation among clinicians as to what constitutes a significant risk or complication which should be conveyed to the patient, so that the patient may receive consistent information. To counter this, a more universal and systematic process of consent has been suggested, which would provide patients with a preprinted list of significant complications for a particular procedure.

Providing full information to patients means ensuring that patients understand not only the consequences of the treatment options but also have a clear understanding of the impact of potential complications. The use of open questions can check understanding as the consultation progresses, and the verbal process can be supplemented with written information, diagrams and even audio-visual presentations. Written information plays a valuable part in reflection and discussion with family, and patients may need to be given sufficient time to reflect in order to make valid informed consent. In addition, patients expect the person taking consent to be familiar with the procedure and to be able to answer all their questions. Ideally, this should be someone who performs the procedure regularly. [3].

1.2 LITERATURE REVIEW

1.2.1 Overview

The process of obtaining informed consent, whether a written document or an oral communication, is one means of ensuring that patients understand the risks and benefits of a treatment or medical intervention. Rooted in medical ethics and codified as a legal principle, it is based on the assertion that a competent individual has the right to determine what will or will not be done to him or her [4]. The American Medical Association (AMA) Code of Medical Ethics establishes informed consent as an ethical obligation of physicians [5]. Failure to obtain adequate informed consent renders a physician liable for negligence and constitutes medical malpractice.

To date, studies of informed consent have not investigated outcomes related to the adequacy of the communication, insofar as this may impact patient safety [6, 7]. Physician-patient communication styles have been linked to lower rates of malpractice claims [8]. Nonetheless, as noted by Levinson, malpractice claims do not reflect the actual rate of negligence. While some have hypothesized that better informed consent could improve the patient-physician relationship, establish trust, increase patient compliance, and provide information that could reduce medical error, this has not been proved[9 , 10].

1.2.2 Practice Description

Informed consent is a process through which a physician informs a patient about the risks and benefits of a proposed therapy and allows the patient to decide whether the therapy will be undertaken[11]. It may be received in one sitting, or over a period of time, [9] either orally or in writing or a combination of the two. Informed consent procedures have been instituted in both research and clinical medicine. In addition, risks and adverse events that occur while research is in progress are followed closely and reported. As such, informed consent in the research setting differs greatly from informed consent in the clinical setting [12].

In clinical practice, formal efforts, such as the signing of a consent form, (presumably preceded by adequate exchange of information), are only undertaken in some circumstances, notably prior to major invasive procedures such as radiological procedures and surgery. Less well appreciated is that all medical care, including pharmacy prescriptions or laboratory tests, requires informal informed consent, except when the patient is incompetent to make a decision or relinquishes the right to provide it. Studies suggest that in practice only minimal formal efforts are made to obtain informed consent for routine interventions [13,14].

As shown below, procedures to obtain informed consent may not adequately promote the patient's comprehension of the information provided, rendering the consent not truly "informed." Interventions that may prove beneficial in improving and ensuring the patient's understanding include redrafting of consent forms to reduce complexity, providing written materials to accompany oral conversations, using multimedia or other techniques to improve comprehension, and asking patients to recap discussions about the procedure.

1.2.3 Prevalence and Severity of Target Safety Problem

Procedures to obtain consent must ensure that the patient understands his or her condition, as well as the risk and benefits of treatment, and its alternatives. It has been estimated that less than half of the US population understands commonly used medical terms.(13,14) This "health literacy" problem may impact the ability of the patient to understand any attempts to obtain information. In addition to lack of comprehension, procedures to obtain informed consent may be incomplete.

Several studies have noted the various insufficiencies in procedures to obtain informed consent. Three studies examined the completeness of physician-patient conversations in obtaining informed consent. Braddock et al [15] focused on outpatient discussions.

Recognizing that some procedures may require more discussion than others, they created a three-tiered evaluation procedure, in which the completeness of patient-physician discussions differs according to the complexity of the decision being discussed. Basic decisions, such as laboratory tests, require the least in-depth discussion, covering only the patient's role, the clinical nature of the decision, and exploration of patient preferences. Intermediate decisions, such as changes in medication, require a moderate depth of discussion, incorporating the Tier 1 subjects, and adding a discussion of alternative treatments, the risks and benefits of the alternatives, and an assessment of the patients understanding. Complex decisions such as surgery require a discussion of the uncertainties associated with the decision, in addition to all of the aforementioned steps. Analyzing audiotape conversations between 1057 patients and 59 primary-care physicians and 65 surgeons, Braddock et al found that 17.2% of basic decisions contained all required components, while none of the intermediate decisions and only one of the complex decisions contained all of the required components. Applying only the Tier 1 basic consent standards, 20.5% of basic decisions, 21.9% of intermediate decisions, and 38.2% of complex decisions met all the criteria.

In a study of informed consents of surrogates for pediatric patients undergoing surgery, coders examined audiotape conversations with surrogates, as well as structured interview and questionnaire data regarding the conversations. They noted that patients' recall of the conversations with physicians often omitted key components, such as the risks and benefits of the procedures [16].

Bottrell et al [16] examined the completeness of 540 consent forms from 157 hospitals nationwide. Of these, 26.4% included all four of the basic elements (risks, benefits, alternatives, and other important aspects of the procedure). Eighty-seven percent noted the general possibility of risk, but less than half provided specific information. Alternatives were noted in 56.9% of the forms, and benefits appeared in 37%, though most of these were general references rather than specific information. Although 74% of consent forms were deemed

incomplete, it is unknown whether physician-patient discussions that preceded the signing of the consent form included the missing information.

A study by Mark et al [11] found that 82.4% of 102 participants reported that they understood everything that their physicians had described about a procedure and indicated that all of their questions had been answered. Eighteen patients had remaining unanswered questions. Half of this group requested more time to speak with their physicians, while the other 9 felt that their questions were not important.

In a study by Lavelle-Jones [17] 69% of patients admitted that they did not read a consent form before signing it. In addition, approximately half of the patients awaiting treatment were unhappy with the amount of information they received, with 21% stating that most of the information they obtained about their surgical treatment was obtained outside of the hospital.

1.2.4 Opportunities for Impact

While informed consent is a well-established practice, it often fails to meet its stated purpose. Several methods of improving the procedures of obtaining informed consent have been proposed, including improving the readability of consent forms,[18] asking patients for recall to establish understanding,[19] adding additional stimuli, such as multimedia presentations[20] and providing written information[17].

Lavelle-Jones [17] found that elderly patients (0ver 60 years of age) had poorer recall than younger patients. In addition, patients with internal locus of control – those who believed their health was in their own control – were better informed than those with an external locus of control. Patients with above average IQ exhibited better recall. These findings could indicate "at-risk" groups that interventions may target.

One author argues that an important opportunity for impact is to change the model of implementing informed consent from a single event approach to a process approach [9]. Currently obtaining informed consent often revolves around the signing of the consent form. Although this approach clearly delineates the responsibility of healthcare providers, provides documentation of the consent, and fits easily into the current provider structure, it often results in patients failing to actually comprehend the information and reinforces physicians' conception that the consent ritual is futile. In contrast, a process model involves the physician providing information over time, establishing a better patient-physician relationship and better comprehension of medical care. As yet there is no data to support these suppositions.

Since the definition of adequate informed consent is debatable, the number of individuals currently not receiving interventions to obtain adequate informed consent is likely to be quite high, but is not known.

1.2.5 Structured Discussions

Informed consent is often obtained during informal discussion between physicians or nurses and patients, and (as shown above), these discussions frequently do not cover all of the relevant information [15]. Two studies examined the use of a structured interview format in providing information to patients. Solomon et al [21] studied 36 patients receiving cardiac catheterization for the first time at a Veterans hospital. Patients were randomized into two groups. Both groups were briefed by a cardiologist regarding the procedure (standard care). In addition, the experimental group received a 30-minute structured teaching session with a nurse to discuss all aspects of the procedure, including the purposes, techniques, sensations, risks and benefits. Patients in the experimental group also received an illustrated guide to cardiovascular procedures and an educational pamphlet. All subjects were tested using a 13-item questionnaire covering the information that should have been imparted during informed consent procedures. The intervention group scored significantly better than the control group .

In a later study, Dawes et al [22] studied 190 hospitalized patients undergoing ENT surgery. Patients were assigned to one of 4 groups. Groups 1 and 2 were assigned at different times, while groups 3 and 4 were randomly assigned. Group 1 had no consent interview until after assessment at the conclusion of the study. Group 2 engaged in an informal interview with a physician (reflecting current practice), during which the number of complications discussed was recorded. Group 3 engaged in a structured interview with a physician, covering the purpose and technique of the procedure, complications, sensations, alternatives, and benefits (a checklist was used as a guide). The final group, Group 4, engaged in the same structure interview, except that the patient was provided with a copy of the checklist and allowed to take it with them after the interview. Patient anxiety was assessed following consent using a visual analog scale, then reassessed at an interview, given 4 hours later. At the later interview, patients were asked to recount orally the operation name, describe what would be done, list complications, and state whether they understood the information given to them. All but Group 1 (control group) patients showed a drop to normal anxiety after informed consent. Group 2 (informal discussion) remembered proportionately more complications mentioned in the informal interview, although fewer complication were covered. Groups 3 and 4 recalled more total complications than Group 2. There was no difference between Groups 3 and 4 (structured interviews).

1.2.6 Asking for Recall

A simple method of determining whether a patient understands information regarding a procedure is to ask the patient to recount what he or she has been told.

Two studies examined this intervention, using a randomized controlled trial design. In the first study, informed consent was solicited from 50 patients undergoing percutaneous lung biopsy[19] Twenty-seven patients in the control group were offered the standard procedure for obtaining informed consent: approximately 30 minutes prior to the procedure, the physician described the procedure in detail, including its risks and benefits. Four complications were specifically described, along with their relative risks. Patients were asked to sign a standard consent form. Twenty-three patients received the same procedure, but in

addition, they were asked to describe all 4 potential complications. The procedure was repeated until all patients in the intervention group could recount all of the complications. This modified procedure usually took less than 5 minutes extra compared with the traditional approach. Patients were interviewed 2 hours after the procedure was completed. Patients in the modified consent group had better recall than patients in the control group (56% vs. 14%) with high recall (recalling 3-4 out of 4 risks), and 13% vs. 4% with low recall (recalling 0-1 out of 4 risks).

A second study examined verbalization in 20 patients undergoing anterior cruciate ligament (ACL) reconstruction [23]. Patients were randomly assigned to 2 groups. Both groups received the standard education for ACL reconstruction, which included the use of a 3-D model to the knee, discussion with a physician about the procedure, and obtaining informed consent. The experimental group (8 subjects) also was asked to repeat back the risks of the procedure until they could accurately recall all risks discussed. One-month later, recall regarding the information received was tested using a 3-item questionnaire. All 8 in the experimental group answered all questions correctly, while only four out of the 12 in the control group answered all questions correctly ($p=0.03$).

1.2.7 Use of Visual or Auditory Learning Aids

Employing additional stimuli may increase the ability of the patient to understand information being conveyed or increase retention of that information. For instance, use of visual diagrams may make a procedure easier to understand. Multi-media may also promote better comprehension. Three studies have examined the addition of visual stimuli for informed consent. One study of patients undergoing back surgery examined the impact of a diagnosis-specific videodisk program on patient outcomes [20]. Patients ($n=393$) who were candidates for elective back surgery (primarily for herniated disc and spinal stenosis) were randomized to two education groups. The control group received a written booklet regarding the surgical and

non-surgical treatments for herniated disc and spinal stenosis, a description of expected outcomes, and a short self-test on the booklet information. Patients in the experimental group also received the booklet, but in addition viewed a videodisk program. The program allowed a patient to enter their diagnosis and age and receive customized information on the alternative treatments, discussion of the diagnoses (and the ambiguities of diagnosis), and interviews from patients that had been treated surgically and non-surgically. At the end the patient was provided with a printout of outcome probabilities. Patients in the experimental group were slightly more likely to report that they had all the information they wanted. Rates of patients consenting to surgery for herniated disk (32% vs. 47%) and other diagnoses (5.4% vs. 14.0%) were lower in the video disk group.

Hopper et al [24] also tested an interactive computer based video program. One-hundred and sixty outpatients referred for IV contrast media studies were stratified by age, sex, and previous exposure to contrast media, and then randomized to receive either a written consent form, or an interactive computer-based video. Subjects in the control group received a consent form designed to be read at an eighth grade reading level. Subjects in the experimental group viewed a video in which a physician used identical words as the consent form to inform subjects about the procedure and risks. Subjects then had an option of hearing more about the risks. If subjects chose not to hear additional information, they were provided with printouts of the risks (with the minimal information already given). Otherwise, subjects were provided with printouts certifying that they had completed the program. All subjects were tested using a 7-item questionnaire regarding the procedure and risks. Patients that viewed the video responded correctly more often than the control group when asked about general aspects of the procedure. Female patients in the video group also responded correctly more often to questions about risks, although this finding did not hold for male patients. The video did take approximately 1.6 minutes of additional time to complete, and there was no difference in patients' desire for additional knowledge between the groups. One final study did not use an interactive video, but tested whether providing information via video was superior to providing information via an informal discussion with the physician (standard practice [25].

Two-hundred and twenty four subjects referred for colonoscopy were stratified into previous or no previous colonoscopy, and then randomized into 3 groups. The control had a structured discussion with a physician, in which the physician covered the same information covered in the video according to a checklist. The video-only group watched a 5-minute videotape, in which a physician described the procedure, and its risk and benefits. The third group (video and discussion), watched the video and then engaged in a structured discussion with a physician. All patients where tested using a 13-item questionnaire. Both video groups gave more correct responses than the discussion-only group, although they did not differ from each other. In addition, patient anxiety levels were measured using the State-Trait Anxiety Inventory. There were no differences among the 3 groups.

1.2.8 Providing Written Information to Patients.

Providing written information to patients regarding their diagnoses, proposed treatments, and other information given during informed consent discussion allows the patient to refer back to such information, and possibly increases comprehension. One early study compared the then-common practice, informal interview between patient and doctor, with provision of a written consent form [26]. Eighty patients, referred for a first excretory urography, were randomly assigned to 2 groups. The control group received standard care, the informal interview. The experimental group received the same interview along with a detailed written consent form to read and sign. Patient clinical reactions and side effects were monitored. One to 3 days after the procedures, patients retrospectively rated discomfort, fear or apprehension, and understanding of the procedure. Patients also completed an 8-item knowledge examination covering the information of the consent form, or in the informal interview. Experimental subjects scored significantly better ($p=<0.01$) than control subjects for the knowledge exam (scoring 73% vs. 48%), but did not differ in their discomfort, perception of the procedure, or anxiety.

Some investigators have proposed that patients should receive written consent forms days before receiving a procedure. Neptune et al [26] studied 160 subjects referred for a contrast

media radiology exam. The patients were stratified by age, sex, and previous exposure to contrast media, and then were randomized within the strata into 2 groups. The control group received a simple consent form (designed such that it could be read with an eighth grade education), 15-60 minutes before the procedure, consistent with standard care. Patients in the experimental group received the same consent form 24-72 hours before the procedure, and were called one day in advance to remind them to read the form. Subjects' knowledge concerning their procedures was tested using a 7-item questionnaire. Overall, there were no significant differences between the two groups on either a knowledge or satisfaction score.

In a British study, [17] 265 patients undergoing intrathoracic, intraperitoneal, or vascular procedures, were assigned to one of 2 consent groups. The control group was provided with an oral explanation of their disease and the proposed procedures. Members in the experimental group were provided with the same information, and also provided with an "operation card" detailing the same information. Patients were given 30 minutes to review the cards before signing the consent form. Patients were interviewed for recall immediately after consent (1 hour), the day of discharge, 4-6 weeks post-discharge, and at 6 months post-discharge. Control and experimental groups did not differ, except on the day of discharge (p, 0.0001). The only significant factor in predicting recall was the age of the patient, as older patients had poorer recall than younger patients, even when controlling for psychological factors. Written information did not appear to aid in recall for older patients at any time point. While much as been written regarding informed consent and the ethical obligations of providers to obtain proper informed consent, serious shortcomings have been reported. However, very little literature has examined the impact of different procedures for obtaining informed consent on the quality of the consent obtained. The weight of the literature suggests that the value of informed consent can be modestly enhanced by augmenting standard provider-patient discussion with additional learning and retention aids (written or videodisk materials). Moreover, the process of consent can be mildly improved by using structured interviews and by asking patient to recall and re-state key elements of the discussion. More research is needed to establish the best practices to improve informed consent, and to test the impact of such practices on patient safety.

1.2.9 INFORMED CONSENT

1.3.0 THE THEORY OF CONSENT

The legal doctrine of consent was famously articulated by Justice Benjamin Cardozo in Schloendorff v Society of New York Hospital, a case in which a surgeon failed to obtain consent for a hysterectomy, Cardozo, maintaining that surgical consent was mandatory because "every human being of adult years and sound mind has a right to determine what shall be done with his own body, [28] connected consent with the principle of self-determination. The wrong committed in this case was battery by unconsented touching. The emphasis in this ruling was on consent.

In Canterbury v Spence, [29] a federal appeals court addressed physicians duty to disclose information or inform. Surgeons were directed to disclose "material" risks of surgery to the patient. Material facts were defined as the information patients needed to make a medical decision [29]. In Arato v Avedon, [30] the California Supreme Court ruled that a patient's estimated life expectancy is another material fact that surgeons need to communicate preoperatively for valid surgical consent in the setting of critical or terminal illness [31]. These and related cases generated changes in surgical culture by defining the standard of care to which surgeons must adhere. Now, inadequate informed consent is usually considered a tort of negligence rather than battery. The courts enhanced patient self-determination by explicitly requiring and clarifying the nature and content of a patient's informed consent for surgery. Beyond the law, informed consent is the cornerstone of ethical medical and surgical practice because it enshrines respect for patients. It acknowledges that patients are autonomous persons endowed with dignity and the basic human right of self-determination. Informed consent underscores respect for patients' rights to make decisions for themselves according to their own concept of what constitutes the good life, and with freedom to act on their decisions. Because of its legal origins and the requirement for the patient's signature on a printed consent form, some surgeons view consent solely as a legal prerequisite that often is delegated to a junior colleague. But the patient's signature on the surgical consent form is not

the patient's consent. The patient's consent happens during the process of dialogue with the surgeon, during which the patient learns and understands the reasons for the procedure and its risks and benefits, understands alternative courses of action, has questions answered, and agrees that it should be done. The signature on a surgical consent form is merely the culmination and formalization of this preceding consent discussion and agreement. Thus, the signed consent form simply represents evidence of the patient's consent.

A patient's (or surrogate's) informed consent generally is required before diagnostic and treatment interventions, except in cases of emergencies, threats to public health, or danger to self or others. The emergency treatment doctrine authorizes all physicians to provide emergency treatment without explicit consent based on the concept of presumed consent, provided that the emergency treatment administered is the generally accepted treatment for such cases.

Implicit in and intrinsic to the concept of consent for treatment is the option of refusal. In Cruzan v Director, Missouri Department of Health,[32] the US Supreme Court ruled that all US citizens have a constitutional right to refuse unwanted therapy, a right residing in the due process clause of the 14th amendment. Authorized surrogates can exercise this right of refusal on behalf of the incapacitated patients they represent. This right of refusal pertains to all therapies, including life-sustaining therapies and artificial hydration and nutrition, without which patients will die [32, 33]. Without a right to refuse, informed consent is meaningless and self-determination becomes impossible.

In the presence of a patient's or surrogate's refusal of therapy, surgeons may strongly urge the acceptance of recommended therapy by explaining the reasons the patient will be healthier with the recommended treatment and emphasizing the risks of not doing so. Family members and friends may be enlisted to help persuade the patient or surrogate that treatment refusal is a mistake. But there are few instances in which a well-meaning surgeon is ethically or legally justified to coerce a patient or override a patient's valid refusal of surgery. For paternalism to

be ethically justified in this setting, the patient's decision to refuse surgery must be proved to be seriously irrational.

Informed consent is operationalized in surgical practice through the doctrine of shared decision making [34]. In shared decision making, the physician and patient compose a decision-making partnership. The physician contributes information about diagnosis, prognosis, and treatment options, with risks and benefits, and frequently provides and medical opinion and a treatment recommendation. Patients contribute their unique set of values, preferences, and health care goals through which they interpret the treatment recommendation. Together, physicians and patients agree on a course of treatment that is then carried out [35, 36]. The shared decision-making model represents the best blending of physician expertise and patient choice [37]. Informed consent is best viewed as a process, not an event. It is an ongoing dialogue between patient and surgeon throughout the patient's care. It begins with a preoperative examination and continues through surgery and postoperative treatment. At every stage, the surgeon explains the nature of the illness and the recommendations for treatment, with their reasons Good patient-surgeon communication fosters good consent. Patient's condition, and patients may change their minds. Through effective communication, the consent process is sufficiently elastic to permit a wide range of decision making in surgical practice. Thus, informed consent is best viewed as a process of patient-centred decision making.

Practicing informed consent can be viewed as an exercise in communication that challenges professional competence. The goal of communication is mutual understanding. The patient tries to grasp what surgical treatment involves, how it matters to the patient's welfare, and how it will affect the patient's life in the short and long term. The surgeon tries to understand the patient's health goals, preferences, expectations, and fears. Communication requires dialogue, including inviting the patient to ask questions to better comprehend what surgical treatment means and plausible alternatives. In some instances, it takes time to develop understanding, whereas in other, it may happen quickly. Information overload may impair

patient understanding. Knowing what and how to communicate is a skill that surgeons should develop and incorporate in teaching programs for trainees. Deficient skill in communication is a common cause of professional liability.

1.3.1 THE PRACTICE OF CONSENT

Three conditions must be met for valid consent [38, 39] First, the patient must have the capacity to make a health care decision. Incapacitated patients do not lose their right of consent; it is transferred to an authorized surrogate decision maker to exercise on their behalf. Patients with the capacity to provide consent have the following abilities: (1) they understand they are ill and require treatment, (2) they understand their treatment options and the general risks and benefits of each, (3) they have the capacity to make sense of the information presented and can process it rationally to reach a decision that furthers their health care goals, and (4) they have capacity to communicate their wishes.

The second element of valid consent is that patients receive adequate information. The precise amount of information that satisfies this requirement remains controversial. Most jurisdictions apply a reasonable person standard: adequate information is that which a reasonable person requires to make a medical decision. To make a rational health care decision, reasonable people need to know their choices and the general benefits and harms of each choice. Physicians should communicate risks of treatment to the extent that they are common or serious. This practice satisfies the material risk disclosure standard articulated in Canterbury v Spence [29]. Others have advocated community – or specialty-based standards of disclosure or the innovative disclosure standard that patients should be given sufficient information to prevent them from being surprised by a subsequent outcome [40].

The third element of valid consent is that the patient consents freely. Patients should not be coerced into accepting treatment by a physician or agency. Making a strong treatment

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recommendation is persuasion, not coercion. Coercion is the use of threats that a reasonable person would not be expected to resist [39]. It is also subtly coercive to deceive patients through misinformation or by exaggerating the harm of not following the recommended treatment or the benefits of accepting the recommended treatment.

The physician's consent discussion usually should include a treatment recommendation. Some clinical ethicists, devoted to the primacy of respecting patient autonomy, claim that physicians simply should provide a menu of options from which a patient may independently choose. Probably unacceptable. What is known to most physicians is that patients consult physicians for a treatment recommendation and it is appropriate for a physician to make one. Sick patients feel helpless and dependent. There is evidence that hospitalized patients show evidence of childlike judgment impairment that requires careful physician guidance [41]. Sick patients require physicians' assistance and support in reaching the right treatment decisions for them. It is important for physicians to give the reasons for their treatment recommendation to permit a patient the possibility of agreeing with the physician about the facts but disagreeing with the opinion.

The requirement for documenting the consent process varies among hospitals. Most hospitals maintain lists of those procedures requiring a signed consent form. Some operative consent forms contain lengthy descriptions of conceivable risks and outcomes. The use of such forms is based on an older notion of attempting to avoid a charge of battery; they resemble disclaimer statements more than consents. In the modern era, however, consent is more connected with disclosure and risk taking. It is appropriate to document a refusal of surgery when that choice carries considerable risk. In addition to signing a form, surgeons should enter a note in the patient's record documenting that the full range of surgical complications, including death, had been discussed and that all questions had been answered. The inadequacies of relying solely on a consent form were shown in a study [42] that found that most surgical and procedure consent forms in use in US hospitals are not easily understood by patients and fail to list specific risks and benefits of surgery.

Consent for anesthesia and surgery also should include a discussion of the patient's wishes in several foreseen or anticipated situations. The first situation is handling an unexpected finding during surgery. What does the patient want the surgeon to do if, during the operation, something unexpected is discovered that requires additional definitive treatment? The patient should be asked if she or he is willing to authorize the surgeon to perform an additional procedure. The patient's decision usually depends on the patient's health care goals and the extent to which the additional procedure furthers those goals.

A second situation to be anticipated and discussed is whether the patient authorizes the surgeon to treat foreseen complications of the surgical procedure, such as prolonged mechanical ventilation in the intensive care unit (ICU). For example, it has been shown that preoperative pulmonary function testing in patients undergoing abdominal aortic surgery is predictive of postoperative pulmonary complications leading to prolonged ICU stays on ventilators [43]. Is the patient with chronic obstructive lung disease that consents to an elective abdominal aortic aneurysm resection also willing to consent in advance to treatment of the expected postoperative respiratory complications? If so, for how long is the patient willing to receive ICU mechanical ventilatory care postoperatively?

A third issue is determining whom the patient wants to act as a surrogate if the operation or its complications render the patient incapacitated. Ideally, the identified surrogate decision maker should know the patient's values and preferences for treatment, judge how each additional intervention may or may not further them, and be willing to uphold them on the patient's behalf.

There is little empirical literature on physicians' consent behaviors in practice. Several studies [44, 45] have shown that physicians' consent behaviors generally have been poorly integrated into their practices. Furthermore, there remain widespread myths and misunderstandings by physicians of the ethical and legal requirements of informed consent [46]. The amount of

information patients comprehend also has been questioned in a study of patients who consented to carotid endarterectomy. Most patients had false and unrealistic expectations of the benefits and risks of the surgery [(47]. Some surgeons have attempted to enhance consent in elective surgery by creating and distributing thorough, detailed, patient-oriented surgical information leaflets containing essential information [48].

2. CHAPTER TWO

2.1 STATEMENT OF THE PROBLEM

A substantial number of patients are unaware of important details concerning their surgery [49, 50]. Failure of recall may occur because of omission in physician's explanation, or inability of patients to understand, assimilate or recollect the information. Several interventions have been suggested, including use of written explanations [51] or audio-visual materials [52] and asking patients to re-state what they have been told during the informed consent [53]. A few studies have reported on the effect of written as opposed to oral information on the quality of informed consent, [50, 54] but no investigation has assessed the relation of characteristics of individual patients to the appreciation and recall of specific information relating to treatment. Effective strategies to improve this may need to be different in various groups as understanding and recall of medical information may be influenced by age, source of information and confidentiality status. This study was set toll examine prospectively the effect of these variables on recall of medical information by patients before and after elective surgical treatment and to assess the value of reinforcement of verbal communication by information cards.

2.2 STUDY RATIONALE

The concept of research bioethics arose and developed over the last three decades mainly in response to moral crisis created by rapidly advancing medical science and technology. At the heart of the ethical principle of respect for person, lies the informed consent process. Nuremberg Code, Helsinki Declaration of World Medical Association (WMA), Council for International Organizations of Medical Sciences (CIOMS), Commonwealth Medical Association (CMA), and Medical Association of Tanzania (MAT) Guidelines etc. demonstrated the importance of informed consent in biomedical research and medical interventions involving human subjects [55, 57]. Informed consent is an ethical obligation of physicians [5].

However, in practice informed consent has not taken the desired standard especially in our country. In a study by Yongolo CMC et al, they found that all consent forms scrutinized were inadequate. In addition of 112 patients analyzed, no one could be said to have given informed consent [56].

Since the informed consent is culture-dependent and we are unaware of surgical procedures on its implementation in our country, the study is set about to evaluate some aspects of this process at our institution. This study is not intended to define standards for the quality of the informed consent but, the findings may be the basis for the development of tools for that goal.

3. CHAPTER THREE

3.0 STUDY OBJECTIVES

3.1 BROAD OBJECTIVES

To examine the factors inflaming quality of informed consent among general surgical and gynecological patients at Muhimbili National Hospital.

3.2 SPECIFIC OBJECTIVE

- To assess the patient's knowledge on his or her disease (based on six points of score) at various assessment points before and after surgery.
- To determine the source of information according to the patients admitted to hospital for surgery
- To determine the effect of age, operation information card and confidentiality status on recall information at various times before and after surgery

4. CHAPTER FOUR

4.0 PATIENTS AND METHODS (METHODOLOGY)

4.1 STUDY DESIGN

Prospective study comprising interviews with patients and patients completing standard questionnaires.

4.2 SETTING: The study was conducted at Muhimbili National Hospital (MNH). This is referral and teaching Hospital in the country. It is located in the city of Dar es salaam, which has a population of about 3.5 million. A part from serving city residents, the hospital also serves as a National referral Hospital. MNH consist among other departments it has the department of surgery and Obstetrics and Gynacology.
Most of the surgical patients are received at the surgical patients are received at the Causality department where they are sorted and sent either to the wards or scheduled to attend outpatient clinics.

4.3 SAMPLE SIZE

The number of patients undergoing elective intrathoracic, intra abdominal and intrapelvic surgical procedures at MNH in one month is about 60 to 80 patients. In six months are approximately 360 to 480 patients. Based in this fact and by using the formula below sample size formula for estimation of single proportion is.

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

n = desired sample size

z = percentage point of normal distribution corresponding to the level of Significance = 5%=1.96

P = expected prevalence of the condition under the study in the general population (50%)

q = 100 – p = 50%

d = desired precision (5%)

Hence n = 214 patients + 10% = 235 patients

4.4 STUDY POPULATION

Patients undergoing elective intrathoracic, intra abdominal and intrapelvic surgical procedures.

4.5 INCLUSION CRITERIA

- Adult patients undergoing intrathoracic, intraperitoneal and intrapelvic Surgery and have consented to join the study.
- Those patients whose intended operations would not result in an Obvious visible external change.

DETAILS:

INTAKE AND RANDOMIZATION

Patients were entered into the study from the waiting lists of surgical units; general surgery, urology and gynaecology units.

Patients undergoing intrathoracic, intraperitoneal and intrapelvic surgery were included but those whose intended operations would have resulted in an obvious visible external change were excluded – for example, mastectomy, repair of inguinal hernia, removal of subcutaneous and cutaneous lesions etc.

All patients received the same verbal communications throughout their stay in hospital, but half were also randomized to be provided with operation cards (see below). The randomization was performed after entry into the study

An explanation of the operation would personally have been given to some of the patient in the clinic before admission to the hospital.

On the evening before surgery, the consultant/specialist or senior registrar/resident visited the patient and further explained the operation and dealt with any of the patient's questions.

OPERATION INFORMATION CARD

Operation information cards related to specific diseases were designed to contain items of information relating to the nature of the operation and items on recovery, complications and after treatment. An example is shown in the box below.

The information related to the procedure consisted of simple statements on organ to be operated on (for example, the operation is carried out on the large bowel) the nature of the intended procedure on that organ (for example the diseased part of the large bowel will be removed and bowel joined up again) and reasons for the surgery (for example to relieve the symptoms and prevent the disease progression)

The information related to treatment outlined specific details on recovery, complication side effects and follow up (for example some diarrhea when your bowel moves after the operation; your bowel should return to normal within the couple of weeks, you will be in hospital for about seven to ten days after your surgery).

4.6. ASSSSMENT OF PATIENT'S KNOWLEDGE

The same six items of information formed the basis on which the patient's knowledge concerning his/her treatment was assessed on a range of 0-6. Patients who will score 1-3 points considered to be poorly informed, where as those who scored 4-6 points were considered to be well informed.

All the assessment was conducted on the basis of an interview between the patient and the research assistant.

4.7 ETHICAL CONSIDERATIONS

No specific ethical issue was anticipated in this study. However, for any ethical issue that arose in this study was solved accordingly and when necessary by seeking opinion from my supervisor or from Senate Research and Publication Committee (SRPC).

4.8 STATISTICAL ANALYSIS

Statistical comparison of the various groups concerning the amount of information recalled was carried out with appropriate statistical tests including X^2-test and Mann Whitney U-test.

5. CHAPTER FIVE

5.1 RESULTS.

Two hundred and thirty two patients (107 men and 125 women) were recruited and all completed the study except one patient who died before the discharge day. The median (range) age was 49yrs (16 - 85) years. About 77% of patients had completed at least primary school education (Table 1). Operation information cards were allocated to 116 patients the other half of patients receiving only oral information. Almost all patients let their relatives know about their disease status except one patient who confided to no one.

Table 1: Proportion of the patients according to their level of education

Level of Education	N	Percentage (%)
Informal	54	23.3
Primary	138	59.5
Secondary	31	13.3
Graduate	9	3.9
Total	**232**	**100.0**

SEQUENTIAL RECALL, STAFF PERFORMANCE AND EFFECT OF AGE.

For the entire cohort studied the information recall was best on the day of discharge (Table 2). Patients stated that the junior medical staff (junior doctors) gave them most of the information they had acquired during their stay in hospital. The next best were the consultants followed by nursing staff (Table 3).

At all periods of study before and after surgery patients aged 65 years or above had poor recall than younger patients (Table 4).

Table 2: Recall of information by patients at various assessment points before and after surgery. Values are numbers (percentages) of patients.

Assessment point	**Poorly informed (score 0-3)**	**Well informed (score 4-6)**
Admission	145(62.5)	87 (37.5)
Immediately after consent	74 (31.9)	158 (68.1)
Day of discharge	43(18.6)	188 (81.4)*

*One patient died in the ward before the day of discharge.

Table 3: Best sources of information according to patients admitted to hospital for surgery. Values are numbers (percentages) of patients

Source of information	Timing question	
	Immediately after consent signed (n = 232)	On day of discharge (n = 231) *
Junior doctors	198 (85.3)	185 (80.1)
Specialists	28 (12.1)	43 (18.6)
Nursing staff	3 (1.3)	2 (0.9)
All medical staff	1 (0.4)	0 (0.0)
• Others	2 (0.9)	1 (0.4)

- Includes – spouse, friend, videos & news papers

*One patient died in the ward before the day of discharge.

Table 5: Effect of operation information card on recall of information at various times before and after surgery

Assessment point	**Median (range) of information score**		**P - Value***
	Card given (n=116)	**No card given (n=116)**	
Admission	3.00 (1-6)	3.00 (0-6)	0.048
Immediately after consent	6.00 (0-6)	4.00 (0-6)	0.0001
Day of discharge	6.00 (2-6)	5.00 (0-6)	0.0001

*Mann-Whitney U test

Table 6: Effect of someone else incorporated by patient in the process on recall information at various times before and after surgery

Assessment point	Median (range) of information score	
	Confidentiality maintained	Confidentiality broken
Admission	1.00 n=1	3.00 (0-6) n=231
Immediately after consent	2.00 n=1	4.00 (0-6) n=231
Day of discharge	2.00 n=1	5.00 (0-6) n=230

5.2 DISCUSSION

Respect for a patient underlines the duty of the Clinician to obtain informed consent from the patient among other clinician's obligations and should have no age, sex, education, race, religions or other bias. Informed consent of patients undergoing procedures is important not only for ethical and legal reasons but also for the quality of care: patient's understanding allows cooperation, improves results and satisfaction and also helps preventing errors. Procedures to obtain consent must ensure that the patient understands the nature of his or her condition, the risks and benefits of the proposed treatment and its alternatives, and agrees to it voluntarily. However, in practice informed consent has not taken the desired standard. About half of patients awaiting investigation or treatment, or both, are unhappy with the amount of information received [58]. In a study by Yongolo et al, they found that all consent forms scrutinized were inadequate. In addition of 112 patients analyzed, no one could be said to have received adequate information. [56]. Only some patients (14% to 66%) are able to recall basic details of their Surgery [49, 50]. Previous studies have sampled patients' collection of medical information on one occasion only [49, 50] except the British study [17]. In the present study recall was tested at sequential intervals. The patients were best informed on the day of discharge as compared to the admission day. It is observed that the rate of recall of information is directly proportional to the duration of stay in the hospital. The probable reason for this could be once a patient is admitted it is the time for him or her to get adequate information, understand them, assimilate and recollect it. This argument concurs with another finding observed in this study that the junior doctors were the main source of information as perceived by patients. In our setting the junior doctors spend most of their time in the ward as part of their responsibilities and training. In the ward the junior doctors carry out various duties assigned by the senior doctors (specialist) including clerking the patients and doing procedures of obtaining informed consent. In addition in this study most of the patients were clerked after admission.

The Junior Doctors were perceived by the patients as being the most effective in imparting information relating to surgical treatment (Table 3). This finding is consistent with other observations [17] and was most evident immediately after signing the consent form, a

task supervised by the junior doctors during this study in accordance with the routine practice in this setting.

Age was the only variable measured in the study which significantly affected recall at all assessment point. This effect has been documented previously [17, 49]. This may be due to dementia, atherosclerosis, impaired cognitive function and low IQ.

Failure of recall may occur because of omission in physician's explanation, or inability of patients to understand, assimilate or recollect the information. Several interventions have been suggested, including use of written explanations [61] and asking patients to re-state what they have been told during the informed consent [62].In the present study patients who received an operation information card were significantly better informed both immediately after signing the consent form and on the day of discharge. These findings are slightly contrary to findings in a previous report that patients who received an operation information card were significantly better informed only on the day of discharge but seemed to have no advantage immediately after the consent form was signed [17]. Possible reason for this may be patients in our setting are not excessively concerned about their operation such that retention of information is not impaired or as speculated that in our culture patients could be facing operation in a positive manner probably because they are not aware of possible adverse outcomes of operation. They believe operation means cure. Another reason could be in the previous study the patients fail to read the information card. When is the optimal time for patients to receive operation information cards was not a question in the present study. However, patients randomized to receive the cards were given them in the ward after they had received oral information and left to read them for 30 minutes before they signed consent form. In a previous report 86% of patients who were issued with information sheets two weeks before admission were found to be well informed of the basic details of their surgery compared with 55% with no written information [50]. Still this study did not answer when is the optimum time for the patient to receive information cards before operation. Probably another study is needed to evaluate this. However in a previous study they have suggested that the optimal time for patients to receive operation information cards is before admission

either when the patient is put on the waiting list or one week before treatment [17] The formulation of written information should assume that a considerable number of patients will have an IQ below average or impaired cognitive function. An information leaflet that is too complicated or one that uses technical or scientific language will not achieve the desired effect [60].

As the number of comparison group (confidentiality maintained) is too small in the study no analysis of the effect of confidentiality on recall of medical information can be made (Table 6). Almost all patients let their relatives know about their disease status except one patient who confided to himself. This shows that out of our culture medical confidentiality is broken almost in the all patients in daily practice in this setting. This may imply that relatives play an important role in the patients` decision making. But who knows the quality of opinion given by relative to the patient` decision in consideration that relatives are neither suffering nor fed adequate information. If the relative would take the position of the patient would she or he still provide the same opinion? Probably another study is needed to evaluate this.

5.3 CONCLUSION

In conclusion it has identified that the process approach rather than single event approach with regard to procedures of gaining informed consent improves the rate of recall of information. The Junior Doctors are the most effective in imparting information relating to surgical treatment despite the fact that are not the ones carrying out the procedures. Elderly patients are likely to recall information relating to their surgery poorly. It also noted that written information is helpful. Out of culture medical confidentiality is not maintained in daily practice in this setting.

5.4 LIMITATION OF THE STUDY

The present study did not consider other factors which may interfere with the rate of recall information. This includes various pathologies which affect central nervous system like dementia and atherosclerosis; psychiatry related disorders such as change in mood state, impaired cognitive function and health locus of control. The effect of drugs also was not considered.

5.5 RECOMMENDATION

- Extra effort is needed to improve procedures of gaining informed consent from elderly patients which includes:
  - Asking patient to recall to establish understanding
  - Adding additional stimuli which include Multimedia
  - Providing written information and
  - Approach should be process approach rather than single event approach

- Written information should be given in addition to Oral information to all patients.

- Study is needed to evaluate the position and quality of the relatives' opinion in the decision making by the patient during process of obtaining informed consent.

6. CHAPTER SIX

6.1 REFERENCES

1. RCN guidance for nurses. Informed consent in health and social care research. Date of review: November, 2006
2. James LB. Patient-centered informed consent in surgical practice. Arch Surg. 2006; 141: 86-92.
3. Jo Church. Informed consent-a mini topic review. Surgery, Theatres, Anesthesia Specialist Library.
4. Edwards SJ, Lilford RJ, Thornton J, et al. Informed consent for clinical trials: in search of the "best" method. Soc Sci Med 1998; 47: 1825-40
5. American Medical Association. Informed consent. American Medical Association. April 11, 2001.
6. Stewart MA. Effective physician-patient communication and health outcomes: a review. CMAJ 1995; 151: 1423-33
7. Greenfield S, Kaplan S, Ware JE, Jr. Expanding patient involvement in care. Effects on patient outcomes. Ann Intern Med 1985; 102: 520-8
8. Levinson W, Roter DL, Mullooly JP, et al. Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons. JAMA 1997 Feb 19; 277(7): 553-9.
9. Lidz CW, Appelbaum PS, Meisel A. Two models of implementing informed conset. Arch Intern Med 1988; 148: 1385-9
10. Kuyper AR. Patient counseling detects prescription errors. Hosp Pharm 1993; 28: 1180-1, 1184-9
11. Mark JS, Spiro H. Informed consent for colonoscopy. A prospective study. Arch Intern Med 1990; 150:777-80
12. Code of Federal Regulations. Title 45: Public Welfare. Revised June 18, 1991 Effective August 19, 1991.

13. Boyle CM. Difference between patients' and doctors' interpretation of some common medical terms. Br Med J 1970; 1:286-9

14. Cole R. The understanding of medical terminology used in printed health education materials. Health Educ J 1979;38: 111-21

15. Braddock CH, 3rd, Edwards KA, Hasenberg NM, et al. Informed decision making in outpatient practice: time to get back to basics. JAMA 1999;282: 2313-20

16. Bottrell MM, Alpert H, Fischbach RL, et al. Hospital informed consent for procedure forms: facilitating quality paptient-physician interaction. Arch Surg 2000; 135:26-33.

17. Christine Levelle-Jones, Derek J. Byrne, Peter Rice, Alfred Cuschien. Factors affecting quality of informed consent. BMJ 1993; 306:885-890.

18. Hpper KD, TenHave TR, Tully DA, et al The readability of currently used surgical/procedure consent forms in the United States. Surgery 1998; 123:496-5031

19. White CS, Mason AC, Feehan M, et al. Informed consent for percutaneous lung biopsy: comparison of two consent protocols based on patient recall after the procedure. AJR Am J Roentgenol 1995;165:1139-42

20. Deyo RA, Cherkin DC, Weinstein J, et al. Involving patients in clinical decisions : impact of an interactive video program on use of back surgery. Med Care 2000;38:959-69

21. Solomon J, Schwegman-Melton K. Structured teaching and patient understanding of informed consent. Crit Care Nurse 1987;7:74-9

22. Dawes PJ, O'Keefe L, Adcock S. Informed consent: the assessment of two structure interview approaches compared to the current approach. J Laryngol Otol 1992; 106:420-4

23. Wadey V, Frank C. The effectiveness of patient verbalization on informed conset. Can J Surg 1997;40:124-8

24. Hopper KD, Zajdel M, Hulse SF, et al. Interactive method of informing patients of the risks of intravenous contrast media. Radiology 1994;192:67-71

25. Agre P, Kurtz RC, Krauss BJ. A randomized trial using videotape to present consent information for colonoscopy. Gastrointest Endosc 1994;40:271-6.

26. Winfield AC, Ford CV, James AE, et al. Response of patients to informed consent for excretory urography. Urol Radiol 1986;8:35-9.

27. Neptune SM, Hopper KD, Houts PS, et al. Take-home informed consent for intravenous contrast media: do patients learn more? Invest Radiol 1996;31: 109-13.

28. Schloendorff v Society of New York Hospital, 211 NY 125, 105 NE 92 (1914).

29. Canterbury v Spence, 464 F2d 772 (DC Cir 1972), cert denied, 409 US 1064 (1972)

30. Arato v Avedon, 5 CA 4th 1172, 23 Cal Rptr 2d 131, 858 P2d 598 (1993)

31. Annas GJ. Informed consent, cancer, and truth in prognosis. N Engl J Med 1994;330:223-225

32. Cruzan v Harmon, 760 SW2d 408 (mo 1988) (en banc), Cruzan v Director, Missouri Department of Health, 110 SCt 2841 (1990).

33. Lo B, Steinbrook R. Beyond the Cruzan case: the US Supreme Court and medical practice. Ann Intern Med. 1991; 114:895-901

34. Brock DW. The ideal of shared decision making between physicians and patients. Kennedy Inst Ethics J 1991;1:28-47

35. Whitney SN, McGuire AL, McCullough LB. A typology of shared decision making, informed consent, and simple consent. Ann Intern Med. 2004;140:54-59

36. Marzuk PM. The right kind of paternalism. N Engl J Med 1985;313:1474-1476

37. Quill TE, Brody H. Physician recommendations and patient alutonomy: finding a balance between physician power and patient choice. Ann Intern Med 1996;125:763-769

38. Appelbaum PS, Grisso T. Assessing patents' capacities to consent to treatment. N Engl J Med. 1988; 319:1635-1638.

39. Gert B, Culver CM, Clouser KD. Bioethics: A Return to Fundaments. New York, NY:Oxford University Press Inc; 1997:131-250.

40. Gert HJ Avoiding surprises: a model for informing patients. Hastings Cent Rep. 2002;32(5):23-32.

41. Cassell EJ, Leon AC, Jayfnab SG. Preliminary evidence of impaired thinking in

sick patients. Ann Intern Med. 2001;134:1120-1123.

42. Hopper KD, TenHave TR, Tully DA, Hall TE. The readability of currently used surgical/procedure consent forms in the United States. Surgery. 1998;123:496-503

43. Vodinh J, Bonnet F, Toubol C, Lefloch JP, Becquomin JP, Harf F. Risk factors of postoperative pulmonary complications after vascular surgery. Surgery. 1989;105:360-365.

44. Lidz CW, Meisel A, Osterweis M, Holden JL, Marx JH, Munetz MR. Barriers to informed consent. Ann Intern Med. 1983;99:539-543.

45. Sulmasy DP, Lehmann LS, Levine DM, Faden RR. Patients' perceptions of the quality of informed consent for common medical procedures. J Clin Ethics. 1994;5:189-194.

46. Meisel A, Kuczewski M. Legal and ethical myths about informed consent. Arch Intern Med. 1996;156:2521-2526.

47. Lloyd A, Hayes P, Bell PR, The role of risk and benefit perception in informed consent for surgery. Med Decis Making. 2001;21:141-149.

48. Lloyd A, Hayes P, Bell PR,Naylor PR. The role of risk and benefit perception in informed consent for surgery. Med Decis Making 2001;21:141-149

49. Byrne DJ, Naper A, Cuschieri A. How informed is signed consent? BMJ 1988;296:839-40

50. Askew G, Pearson KW, Cryer D. Informed consent: can we educate patients? JR CoU Surg Edinb 1990;35:308-10

51. Stallings SP, Paling JE. New tool for presenting risk in obstetrics and gynecology. Obstet Gynecol 2001;98:345-9

52. Deyo R, Cherkin D, Weinstein J et al. Involving patients in clinical decisions : impact of an interactive video program on use of back surgery. Med Care 2000;38:959-69

53. Edwards MH. Satisfying patients' needs for surgical information. Br J Surg 1990;77:463-5

54. Edwards MH. Satisfying patients' needs for surgical information. Br J Surg 1990;77:463-5.

55. Biswas B, Ahmed R. Critical evaluation of research articles in relation to informed consent. Bangladesh Med Res Counc Bull 2006 Dec;32 (3) : 13-17.

56. Yongolo CMA. Informed consent to patient undergoing surgery in Dar es Salaam. TMJ 1999 March; 14(1):13-17.

57. Guiding Principals on Medical Ethics and Human Rights in Tanzania – MAT (1995).

58. Reynolds M. No news is bad news; patients views about communication in hospital. BMT 1978; - 1673 – 6.

59. Richard J. Mc Donald P. Doctor – patient communication in surgery J R Soc Med 1985; 78; 922 – 4

60. Ley P. Jain VK, Skilbeck CE. A method for decreasing patients' medication errors Psychol Med 1976; 6: 599 – 601.

61. Stallings SP, Paling JE. New tool for presenting risk in obstetrics and ynecology. Obstet Gynecol 2001;98:345–9.

62. White CS, Mason AC, Feehan M et al. Informed consent for percutaneous lung biopsy: comparison of two consent protocols based on patient recall after the procedure. AJR Am J Roentgenol 1995;165:1139–42