KNOWLEDGE REGARDING INFORMED CONSENT AMONG SURGICAL PATIENTS AT HOSPITAL UNIVERSITI SAINS MALAYSIA (HOSPITAL USM), KUBANG KERIAN, KELANTAN

By

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Dissertation submitted in partial fulfillment of the requirements for the degree of Bachelor of Health Sciences (Nursing)

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DECLARATION

I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

CERTIFICATE

This is to certify that the dissertation entitled "Knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia (Hospital USM), Kubang Kerian, Kelantan" is the bona fide record of research work done by Siti Noorain Binti Mohd Hashim, Matric Number: 108663 during the period of December 2013 to June 2014 under my supervision. This dissertation is submitted in partial fulfillment for the degree of Bachelor of Health Sciences (Nursing). Research work and collection of data belong to Universiti Sains Malaysia.

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LIST OF ABBREVIATION

ACS	: American Cancer Society
HBM	: Health Belief Model
HPV	: Human Papillomavirus
SMSH	: Sri Maharaja Hari Sigh
SPSS	: Statistical Package for Social Science

KNOWLEDGE REGARDING INFORMED CONSENT AMONG SURGICAL PATIENTS AT HOSPITAL UNIVERSITI SAINS MALAYSIA (HOSPITAL USM), KUBANG KERIAN, KELANTAN

ABSTRACT

Patients often feel powerless and vulnerable and it is a proven fact that patient's awareness of legal and ethical issues related to the consent process is often limited. The goal of this descriptive cross-sectional study was to determine the level of knowledge regarding informed consent among surgical patients. This study also examined the differences of knowledge regarding informed consent with educational level, between male and female patients and also between frequencies of surgery. 112 surgical patients who were hospitalized in the five surgical wards Hospital USM were recruited in this study using purposive sampling. Data were collected from February to March 2014 using self-administered questionnaire and analyzed using SPSS version 20 for frequency, percentage, mean, standard deviation and p-value. Ethical approval was obtained from Research Ethics Committee (Human), USM. The results revealed overall level of knowledge regarding informed consent among surgical patients was at high level of knowledge (71.4%). However, surgical patients would like to have more information on information especially regarding any special precaution to be taken after operation, important risk and possible complication involved in having the operation and recurrence, any special dietary advice to be considered after operation, chance of successful result of the operation, for how much time operation will be done and the reason for operation. This study also found that there was significant differences of knowledge regarding informed consent with level of education (p=0.046), no differences of knowledge between male and female (p=0.225), and frequency of surgeries that they had attend (p=0.500). As conclusion, surgical patients knowledge level regarding informed consent were highly satisfactory, however they need further understanding in certain information, thus the information's will helps patients to cope with treatment and to achieve better surgical outcome.

Key words: knowledge, informed consent

PENGETAHUAN MENGENAI PEMBERIAN KEIZINAN DALAM KALANGAN PESAKIT SURGIKAL DI HOSPITAL UNIVERSITI SAINS MALAYSIA (HOSPITAL USM), KUBANG KERIAN, KELANTAN

ABSTRAK

Pesakit selalunya berasa tidak berdaya dan lemah dan ia adalah suatu hakikat yang membuktikan bahawa kesedaran pesakit mengenai isu undang-undang dan etika yang berkaitan dengan proses pemberian keizinan selalunya terhad. Matlamat kajian keratan rentas deskriptif ini ialah untuk menentukan tahap pengetahuan mengenai pemberian keizinan di kalangan pesakit surgikal. Kajian ini juga bertujuan untuk melihat perbezaan pengetahuan mengenai pemberian keizinan dengan tahap pendidikan, antara pesakit lelaki dan perempuan dan juga antara frekuensi pembedahan. 112 pesakit surgikal yang dimasukkan ke hospital dalam lima wad surgical di Hospital USM telah diambil dalam kajian ini menggunakan kaedah persampelan bertujuan. Data telah dikumpulkan dari Februari hingga Mac 2014 dengan menggunakan soal selidik yang ditadbir sendiri dan dianalisis menggunakan perisian SPSS versi 20 untuk frekuensi, peratusan, min, sisihan piawai dan nilai-p. Kelulusan etika telah diperolehi daripada Jawatankuasa Etika Penyelidikan (Manusia) , USM. Keputusan menunjukkan tahap keseluruhan pengetahuan mengenai pemberian keizinan di kalangan pesakit surgikal adalah pada tahap yang tinggi (71.4%). Walau bagaimanapun, pesakit surgikal ingin mempunyai maklumat lanjut terutama mengenai langkah-langkah penjagaan yang perlu diambil selepas pembedahan , risiko penting dan komplikasi yang mungkin terlibat ketika menjalani pembedahan dan berulang, nasihat-nasihat pemakanan yang khusus untuk dipertimbangkan selepas pembedahan , peluang pembedahan akan berjaya, untuk berapa lama tempoh masa pembedahan akan dilakukan dan sebab untuk pembedahan. Kajian ini juga mendapati bahawa terdapat perbezaan yang signifikan untuk pengetahuan mengenai pemberian keizinan dengan tahap pendidikan (p=0.046), tiada perbezaan pengetahuan antara lelaki dan perempuan (p=0.225), dan kekerapan pembedahan yang telah dijalani (p=0.500). Kesimpulannya, tahap pengetahuan pesakit surgical mengenai pemberian keizinan sangat memuaskan, namun mereka memerlukan pemahaman lanjut dalam maklumat tertentu,

dengan itu maklumat ini akan membantu pesakit untuk menjalani rawatan dan untuk mencapai hasil pembedahan lebih baik.

Kata kunci: pengetahuan, pemberian keizinan

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment. It originates from the legal and ethical right the patient has to direct what happens to her body and from the ethical duty of the physician to involve the patient in her health care. The most important goal of informed consent is that the patient has an opportunity to be an informed participant in her health care decisions. In addition, comprehension on the part of the patient is equally as important as the information provided. Consequently, the discussion should be carried on in layperson's terms and the patient's understanding should be assessed along the way (Bord, 2014).

It is a vital document while performing all surgical and aesthetic procedures, particularly in the current day practice. Proper documentation and counseling of patients is important in any informed consent. Today, patients tend to be well- or ill-informed about the disease and health. Therefore, providing adequate information and educating the patient about realities and obtaining informed consent before subjecting a patient to any test, procedure or surgery is very essential (Rao, 2008). Informed consent is the permission given by the patient or relatives after being given appropriate information about the proposed medical or surgical intervention. The process is called the informed consent process (Bikash, 2010).

In addition, it is the fundamental mechanism whereby the physician informs the patient about the options for the diagnosis and treatment of the patient's illness. It is not just a form to be signed as a hospital formality, but a process, which ensures respect for persons through provision of thoughtful consent for an option to decide on the best possible treatment in disease processes. It originates from the legal and ethical rights of the patient who have to direct what happens to her body and from the ethical duty of physicians to involve the patient in her health care. The most important goal of informed

consent is that the patient should have an opportunity to be an informed participant in his health care decisions so it acts as a safeguard to ensure the preservation of individual rights (Bhurgri & Qidwai, 2004).

Physicians are required by law and medical ethics to obtain the informed consent of their patients before initiating treatment. Valid informed consent is premised on the disclosure of appropriate information to a competent patient who is permitted to make a voluntary choice. When patients lack the competence to make a decision about treatment, substitute decision makers must be sought. Apart from that, in emergencies, physicians can provide appropriate care under the presumption that a reasonable person would have consented to such treatment. For patients with advance directives, either the treatment choice that the patient made in advance or the choice of a surrogate decision maker may be indicated. In the absence of an advance directive and when time is available, the recourse is usually to contact family members (Appelbaum, 2007).

The patient or the surrogate should adequately inform about the nature of medical condition, the objective of the proposed treatment, possible alternatives, and possible outcomes. It is good practice for the healthcare team to involve those close to her in order to find out about her values and preferences before a loss of capacity ensues. When a patient lacks the decision making capacity, an appropriate surrogate should make the decisions on her behalf, ideally one who knows the patient's preferences and acts in her best interest. But in extreme emergency situations where a patient is unable to consent, such as due to unconsciousness, a doctor may perform emergency treatment based on the doctrine of necessity to save lives (Yousuf, Fauzi, How, Rasool & Rehana, 2007).

Patients often feel powerless and vulnerable and it is a proven fact that patient's awareness of legal and ethical issues related to the consent process is often limited. Apart from that, informed consent process should be seen as an invitation to her to participate in her health care decisions so that her knowledge and attitude regarding informed consent increased (Rajesh, Abhishek, Mukul, Gaurav, Venkteshan, Anu, Balbir & Aggarwal, 2013). It must be preceded by disclosure of sufficient information. Consent can be challenged on the ground that adequate information has not been revealed to enable the patient to take a proper and knowledgeable decision. Therefore, accurate, adequate and relevant information must be provided truthfully in a form using non-scientific terms and

language that the patient can understand. It cannot be a patient's signature on a dotted line obtained routinely by a staff member (Rao, 2008).

The legal aspects of consent are based around the rights of the patients to make their own decision and ethical aspects of the concept of the shared decision making. Thus, shared decision making allows both patients' autonomy and physician responsibility (Marasini, Kaiti, Mahato, Gyawali & Nepal, 2013). The understanding shown by the patient is very important before signing the informed consent and before he undergoes any surgery. Everyday there will be a surgery done and the percentage is quite large and increase over time. So, it is important for us to know how far their knowledge regarding it and how was their understanding regarding the informed consent. Apart from that, it shows that the requirement of knowledge regarding informed consent is essential.

1.2 Problem statement

Patients will be asked to sign a consent form that says they have agreed to the treatment and that they understand the benefits, risks and alternatives. Patients surely may ask anything that they don't understand to the physician or if they had more time to think about it. Apart from that, it must be remembered that signing the consent form is the patients' decision and they can change their mind at any time, even if they have signed the consent form. Despite everything, let physician know immediately if they changed their mind. Patients' wishes will be respected at all times (Guy's & Thomas, 2013).

In the study by Marasini, Kaiti, Mahato, Gyawali and Nepal (2013), it is stated that the majority (61.9%) of the patients were not sure if they could withdraw the surgery at any time if they wished so. Furthermore, from the ethical point of view, the consent will be valid only when the patient feels that it would have been possible to refuse and change their mind. It is possible only when patients understand the meaning and the significance of consent. Besides that, many patients (69%) thought that to sign the consent form was equivalent to agree for surgery. It reflects that these patients allow doctor to determine the treatment without blaming them of possible adverse effects. In

spite of that, a few (16.7%) patients considered the consent form as a medico-legal document which is, in fact, true from the doctor's perspective.

Many patients wanted to know about the disease process, treatment involved and the success rate of surgery. Most patients did not know what actually consent meant and why they were signing it. However, it must be recognized that most patients want to know what their treatment involves and all the information regarding informed consent. They wanted to know about the disease process, treatment involved and the success rate of surgery. Apart from that, by explaining all the desired information to the patients before surgery, it helps establish a trustful relationship between patients and physician and also helpful in order to achieve better surgical outcome (Marasini, Kaiti, Mahato, Gyawali & Nepal, 2013).

Seventy percent, mostly from higher educational level considered the impact of information provided by the doctors completely convincing for decision making while 30%, mostly from lower educational level only found the information partly convincing (Bikash, 2010). Signing the consent form is the patients' decision and they can change their mind at any time, even if they have signed the consent form. However, majority (69%) of the patients were not sure if they could withdraw the surgery at any time if they wished so. Furthermore, from the ethical point of view, the consent will be valid only when the patient feels that it would have been possible to refuse and change their mind. It is possible only when patients understand the meaning and the significance of consent (Marisini, et al., 2013).

Respondent from Hospital Tengku Ampuan Afzan, Kuantan accepted that disclosing diagnosis was in the patient's best interest but respondents from Sri Maharaja Hari Sigh (SMHS) Hospital, Kashmir, India regarded patients as generally less willing to be told the whole truth. Respondent from SMHS showed tendency to reservedly disclose medical information and would withhold it, if it was deemed potentially harmful or requested so by relatives (Yousuf, Fauzi, How, Rasool & Rehana, 2007).

Even within the same culture or society, patient's preferences differ in information disclosure. Not all patients want to know everything all the time. Older, illiterate, socially conservative patients and those with serious illnesses prefer less information and avoid decision-making as they think it is the doctor's job to advise them.

In contrast, younger and more educated patients show greater interest to know the details and want active participation in decisions regarding their care (Yousuf, Fauzi, How, Rasool & Rehana, 2007).

Despite the legal importance of the consent and its presence in the signed documents as a standard procedure yet 75.0% patients falsely believed that it was a legal requirement. An almost similar percentage of respondent (68.8%) thought that signing the consent meant waving their rights to any compensation. Most (88.0%) of the patients under study thought that they had no right to change their minds after signing the consent. Many the patients (75.2%) believed that they would be left to die hadn't they signed the consent. 83.8% signed consent form so that they can undergo required operative procedure (Rajesh, et al., 2013).

Therefore, researcher aims to identify the level of knowledge regarding informed consent among surgical patients. The researcher aimed to focus on the information that patients wanted to know regarding informed consent because when patients have knowledge regarding informed consent, understanding of the surgery will be increased. The researcher intends to use results and also information gathered for education purpose in the hospital department and the university for nursing students. The Health Belief Model was used as a guideline throughout this study as a conceptual framework. This model is focusing on the attitude and beliefs of individual. The differences between knowledge and the modifying factors (educational level) will be determined in this study.

1.3 Objectives of the study

1.3.1 General objective

The general objective of the study is to determine the knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia.

1.3.2 Specific objectives

The specific objectives for the study are:

1. To determine the knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia.

2. To determine the difference between patients's educational levels and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia.
3. To determine the difference between male and female knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia.
4. To determine the difference between frequency of surgery and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia.

1.4 Research Questions

The research questions are as follow:

1. What is the knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia?
2. Is there any difference between patient's educational levels and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia?
3. Is there any difference between male and female knowledge regarding informed consent among surgical patients' at Hospital Universiti Sains Malaysia?
4. Is there any difference between frequency of surgery and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia?

1.5 Research Hypothesis

A p-value of ≤ 0.05 was considered significant for all statistical analyses.

1. **Null Hypothesis, Ho**: There is no significant difference between patients' educational levels and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia.

   Alternative Hypothesis, HA: There is a significant difference between patient's educational levels and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia.
2. **Null Hypothesis, Ho**: There is no significant difference between male and female knowledge regarding informed consent among surgical patients' at Hospital Universiti Sains Malaysia.

   Alternative Hypothesis, HA: There is a significant difference between male and

female knowledge regarding informed consent among surgical patients' at Hospital Universiti Sains Malaysia.

3. **Null Hypothesis, Ho**: There is no significant difference between frequency of surgery and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia

   Alternative Hypothesis, HA: There is a significant difference between frequency of surgery and knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia

1.6 Operational Definition

1.6.1 Informed Consent

Informed consent refers to the process whereby patients are provided with all the necessary information about health care and subsequent treatment plans. It has many benefits including patient cooperation, thus minimizing surgical complications and increasing the chances of successful defense against possible medico-legal cases (Marisini, Kaiti, Mahato, Gyawali & Nepal, 2013).

1.6.2 Knowledge regarding informed consent among surgical patient.

The knowledge regarding informed consent among surgical patient refers to how patients' knowledge corresponds to informed consent procedure which are related to the understanding the concept of informed consent, management of the informed consent and the effect of understanding the informed consent by learning a predisposition to think, feel and act in a particular way towards a given object or class of objects regarding the process. In addition, patients are provided with all the necessary information about health care and subsequent treatment plans that has many benefits including patient cooperation, thus minimizing surgical complications and increasing the chances of successful defense against possible medico-legal cases (Marisini, et al., 2013 & Rajesh, et al., 2013). Measurement of knowledge regarding informed consent, each correct answer will be given 1 point and no point will be deducted for the incorrect answer (Vodopivec et at., 2002). The patients' knowledge regarding informed consent were categorized into three level which are low (score 0-5), average (score 6-10), and high (score 11-15). The maximun is 15 and the minimum score is 0.

1.7 Significance of study

This study will determine knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia. The study contributed to patients, nurses and the Hospital organization. The findings of this study will be a guideline to the nurses and the physician to build a good cooperation between patients, nurses and physician throughout the surgery. In addition, postoperative management will also become better once a good relationship was build between them.

Apart from that, after surgery, the patient may have problems with management of their health, pain management and also a good post-operative care. All of these things are relate to each other if patients just take an easy step when giving consent because of not having a good knowledge regarding consent. Whereas, during the consent process, patients are encouraged to ask any questions arise.

As a nurse, the finding of this study will help in treatment of the patients. The nurses will help the doctor by doing the reinforcement when the patients are not able to understand well or they have no adequate knowledge regarding informed consent. In addition, if there is a patient who are refused to give the consent, the nurse may help by doing the reinforcement back to the patients so that he understood well and agree to undergo the surgery.

CHAPTER TWO

LITERATURE RIVIEW

2.1 Introduction

In this chapter, the literature review consist information regarding informed consent. The information of knowledge regarding informed consent was discussed in details. The differences of knowledge regarding informed consent with level of education, gender and frequency of surgery were discussed in details. The conceptual framework by using Health Belief Model was discussed.

2.2 Informed Consent

Informed consent is the process and actions that take place as patients learn about a treatment before they agree to it. Patient's signature on the form is taken to be evidence that this took place. If patients decide that he do not want the procedure or treatment, he should not sign the consent form. In this case, he may be asked to sign an informed refusal form or a form that states he is choosing not to follow medical advice. Patient's signature on this form implies that he knows the risks of refusing (American Cancer Society (ACS), 2012). The informed consent process for surgery usually begins long before the patient enters the operating room environment, with the patient's first visit to the surgeon's office. In contrast, the informed consent for anesthesia is often obtained in the minutes before surgery in which the anesthesiologist and patient meet for the first time (Norman, 2008).

It is the right and responsibility of every competent individual to advance his or her own welfare. This right and responsibility is exercised by freely and voluntarily consenting or refusing consent to recommended medical procedures, based on a sufficient knowledge of the benefits, burdens and risks involved. The ability to give informed consent depends on adequate disclosure of information, patient freedom of choice, patient comprehension of information and patient capacity for decision making. By meeting these four requirements, three necessary conditions are satisfied which are that the individual's decision is voluntary, that this decision is made with an appropriate

understanding of the circumstances and that the patient's choice is deliberate insofar as the patients has carefully considered all of the expected benefits, burdens, risks and reasonable alternatives. Legally, adequate disclosure includes information concerning diagnosis, nature and purpose of treatment, risks of treatment and treatment alternatives (Ascension Health, 2013).

Generally, no procedure, surgery, treatment or examination may be undertaken on patient without the consent of the patient, if he or she is a competent person. Such consent may be expressed or implied and may be verbal or in writing. Obtaining a patient's consent is an important component of good medical practice, and also carries specific legal requirements to do so. Except in an emergency where the need to save life is of paramount importance, the consent of the patient must be obtained before the proposed procedure, surgery, treatment or examination is undertaken. Failure to do so may result in legal action for assault and battery instituted against the medical practitioner (Mahmud, et al., 2010).

From the doctor's viewpoint, informed consent means that a doctor or nurse must make every effort to be sure the patient understands the purpose, benefits, risks and other options of the test or treatment. Then the doctors or nurse must get the patient's consent before starting. In some cases, even a simple blood test or an injection requires written consent from the patient. Apart from that, as long as adult patients are mentally able to make their own decisions, medical care cannot begin unless they give informed consent. If the patient is a minor (under age), has a serious mental disability, or cannot give consent, then the parent, legal guardian, or a person authorized by the court must give consent before treatment can start. This is usually a close family member who has reason to know what the patient would want (ACS, 2012).

Informed consent is processes that includes all of these steps in which are patients are told or get information in some way about the possible risks and benefits of the treatment, patients are told about the risks and benefits of other option, including not getting treatment, patients have the chance to ask questions and get them answered to your satisfaction, patient have had time if needed to discuss the plan with family or advisors, patients are able to use the information to make a decision that he think is in his

own best interest and patients share his decision with his doctor or treatment team (ACS, 2012).

If patients have gone through these all these steps and decide to agree to the treatment or procedure, patients are usually asked to sign a paper called a consent form. The completed and signed consent form is a legal document that lets your doctor go ahead with the treatment plan. The consent form names the procedure or treatment to be done. The rest of the form may be very general, stating only that patients have been told about the risks of the treatment and other available options. In cases where there are larger possible risks, patients may be asked to agree in writing to the doctor's plan for their care. This is part of informed consent. It recognizes their need to know about a procedure, surgery, or treatment, before they decides whether to have it. After they first talked with doctor, they may have only a general idea of the treatment plan. Patient's will likely to know more so that he can think about the ways this plan may affect his health and his life. In order to freely decide whether the risks are worth the benefits he expects to get from the treatment plan, he must understand the risks and drawbacks of the plan. Most people find that they need to get some questions answered before they can decide on a treatment plan that carries some risk for them (ACS, 2012).

The concept of consent arises from the ethical principle of patient autonomy and basic human rights. Patient's has all the freedom to decide what should or should not happen to his or her body and to gather information before undergoing a treatment, procedure or surgery. No one else has the right to coerce the patient to act in a particular way. Even a doctor can only act as a facilitator in patient's decision making. Besides that, there is also a legal angle to this concept. No one has the right to even touch, let alone treat another person. Any such act, done without permission, is classified as physical assault and is punishable. Hence, obtaining consent is a must for anything other than a routine physical examination (Rao, 2008).

Besides that, an explanation regarding the procedure of an operation should be explained wisely. Consent should begin with a brief explanation of the planned operation. It is good to describe what the patient may expect to experience during surgery especially if under local anesthetic. Apart from that, medical term should be avoided as it may reduce patients' understanding. In addition, sufficient information to

make a decision should include an explanation of the risks and benefits involved any alternatives treatment available and the risks and benefits of doing nothing (Anderson & Wearne, 2007).

2.3 Knowledge Regarding Informed Consent

Informed consent is the process of agreeing that the patient will have an operation as one of the treatment based on access to all relevant and easily digestible information about what is going on throughout the operation, in terms of harms and benefits (Rajesh, et al., 2013). In a simple term, it can be defined as an instrument of mutual communication between doctor and patient with an expression of authorization or permission or choice by the letter for the doctor to act in a particular way (Rao, 2008).

Nowadays, informed consent consists of five principles which are voluntariness, disclosure, understanding, competence, and consent. First, it were voluntariness which is referred to when the patients giving their agreement without any of coercion or pressure. Besides that, disclosure is one of the burdens to the person who ask for consent because he needs to explain everything related to the operation especially the risks of the operation. Next, understanding of the informed consent refers to the patients' comprehension of the information given to them. Means that, they are well understood all the information related with the operation given to them. In addition, the patients' ability to understand all the important information refers to the competence of the informed consent. Finally, when the patients agree to the proposed medical treatment, event of consent occur (Knifed, Lipsman, Mason, & Bernstein, 2008).

Informed consent is legally valid and professionally acceptable only if patients' have the capacity to decide whether to take part in the operation, have been properly informed about the procedure of the operation, and have agreed to had the operation without pressure or coercion. It is the process by which a patient freely agrees to undergo an operation and all the information needed to make a decision must be told to the patient (Pick, Berry, Gilbert, & McGaul, 2013). Informed consent of patients undergoing procedure is very important especially for the quality of care of the patients rather than for ethical and legal reasons. Patients' understanding of the informed consent will allow

good cooperation, improves results and satisfaction and also helps preventing errors perioperative care (Brezis, Israel, Birenshtock, Pogoda, Sharon, & Tauber, 2008).

Providing the pertinent information in a manner the patient can understand is very important. Patients often forget even the most basic information once the possibility of surgery is raised. The most effective way to provide informed consent is to talk to the patient and give him something in writing. The use of diagrams, models, handouts and language appropriate to the patient's education or ethnic background can heighten the ability of the patient to understand. Physicians must make it clear to patients that informed consent is not only about signing a form, but is about making a decision. It is an invitation for the patient to participate in the process and ask questions about the procedure and more than just a description of risks and complication (Fleeter, 2010).

General rules to follow in consent for surgery and anesthesia are to inform the patient of common risks even if they are not serious and very serious risks, such as death, even if they are not common. By asking the patient if they have any specific concerns, you can invite the patient to let you know of any "special" informational needs that they may have which are not obvious to you. When discussing risks with patients, understand that mere recitation of statistical risks may mean little to patients, and it can be helpful to relate the information to risks which have some meaning for the patient. The approximately one in 50,000 risk of death during general anesthesia in a healthy patient can be compared to that of the risk of death in an automobile accident (about twice that), as a way of putting perspective on the information being provided (Norman, 2008).

More substantively, patients need to understand that they are being asked to authorize surgical management. Patient must understand that by consenting to surgical management the patient authorizes the surgeon and surgical team to perform the procedure that the surgeon has described to the patient. The patients must also understand that the surgery cannot proceed without the patient's permission. In addition, the patient should understand what is being authorized. The patient needs to grasp the nature of the procedure, its goals, its expected duration, and what can be expected during the near-term and long-term recovery process. After completion of surgery, particularly functional changes that affect job, performance, valued activities, or sexuality and

aesthetic changes, such as the length and appearance of scar tissue, must be understood well by the patients (Jones, McCullough & Richman, 2007).

Patients will be asked to sign a consent form that says they have agreed to the treatment and that they understand the benefits, risks and alternatives. Patients surely may ask anything that they don't understand to the physician or if they had more time to think about it. Apart from that, it must be remembered that signing the consent form is the patients' decision and they can change their mind at any time, even if they have signed the consent form. Despites, let physician know immediately if they change their mind. Patients' wishes will be respected at all times (Guy's & Thomas, 2013).

In the study by Marasini, Kaiti, Mahato, Gyawali and Nepal (2013), state that the majority (61.9%) of the patients were not sure if they could withdraw the surgery at any time if they wished so. Furthermore, from the ethical point of view, the consent will be valid only when the patient feels that it would have been possible to refuse and change their mind. It is possible only when patients understand the meaning and the significance of consent. Besides that, many patients (69%) thought that to sign the consent form was equivalent to agree for surgery. It reflects that these patients allow doctor to determine the treatment without blaming them of possible adverse effects. Despite, few (16.7%) patients considered the consent form as a medico-legal document which is, in fact, true from the doctor's perspective.

From that study, it shows that explaining all the desired information to the patients before surgery helps establish a trustful relationship. Many of patients wanted to know about the disease process, treatment involved and the success rate of surgery. Most of patients did not know what actually consent meant and why they were signing it. However, it must be recognized that most of patients want to know what their treatment involves. Apart from that, it can be concluded that the information's helps patients to cope with treatment and helps to achieve better surgical outcome (Marasini, Kaiti, Mahato, Gyawali & Nepal, 2013). Most of the patients were interested to know about the duration of the operation, possible risks and complication involved if they undergo the operation, chances of successful operation and cost of treatment (Rajesh, et al., 2013).

In addition, the goal by explaining all the potential risks of the surgery is to inform patients well enough to allow them to make a balanced decision. If they received

too little information regarding the operation, it will fail to inform while if they receive too much information, it may be counter-productive and only lead to confusion. Apart from that, patients feel more meaningful if the doctors just explain the complication that may affect them in the future such as permanently worse vision or even blind rather than explanation of all those potential surgical complication such as infection instead of endophthalmitis (Anderson & Wearne, 2007).

In most instances, the informed consent process flows naturally from the "partnership" between the doctor and patient; however, when this does not occur, serious legal and ethical consequences may result. Let's say that hypothetically, a patient becomes injured as the result of a medical procedure; we understand the concept of an informed consent requirement that would likely arise in any malpractice claim for injuries. If a doctor does not get informed consent from a patients and the patient is injured, the patient may have the ground to sue the doctor for medical malpractice (Molina, 2013).

Whether or not a patient gave their informed consent to a treatment is crucial in the law of medical malpractice. If a doctor does not get a patient's informed consent and the patient would not have opted for the treatment if they knew about the risks, the patient may be able to sue the doctor for medical malpractice. The informed consent process has been criticized as concentrating more on avoidance of doctor liability than on truly educating patients so as to make self-determined medical decisions. Besides that, doctors typically require patients to sign a consent form detailing the risks of any given treatment or procedure. But signing a form alone does not necessarily prove that the patient gave informed consent. The doctor must actually discuss the procedure and risks with the patient. Then, the patient must understand, to the extent possible, the risk they will face (Molina, 2013).

Study done by Jukic, Kozina, Kardum, Hogg & Kvolik (2011) found that there is a great discrepancy between physicians and patients concerning both understanding and knowledge of the informed consent process. The physicians have evaluated their practice of giving information and obtaining informed consent to be more detailed than their patients. Based on that study, it shows that, most of the responses between physicians and patients were significantly different regarding their knowledge of informed consent

process. Result shows that, among a total of 31% physicians reported that they personally informed patients about their medical condition and forthcoming clinical procedures in detail and 55% informed patients as much as necessary. Then, only 11% patients reported being informed in detail and 71% reported that they received only basic information. Besides that, although 53% physicians reported that their patients received sufficient information to be able to decide on their treatment but only 12% reported the same while others are not.

2.3.1 Measurements of knowledge regarding informed consent among surgical patients

The research instrument in this study was constructed from two resources name Rajesh, Singh, Chopra, Singh, Venkteshan, Bhardwaj, et al, 2013 and Marasini, Kait, Mahato, Gyawali, & Nepal, 2013). It was organized into three parts which are: 1) socio-demographic data that consist of 8 items, 2) surgical patients' knowledge regarding informed consent that consist of 15 items and 3) information that patients wanted to know that consist of 12 items.

The original instrument regarding surgical patients' knowledge regarding informed consent was adopted by Rajesh, Singh, Chopra, Singh, Venkteshan, Bhardwaj, et al, 2013 from study of patient's awareness, attitude, understanding and perceptions towards legal nature of informed consent. The original instrument had 38 items representing 5 dimensions of an evaluation of patient's awareness, attitude, understanding and perceptions towards legal nature of informed consent which are: 1) socio-demographic profile that consist of 8 items, 2) information regarding patient's awareness, attitude & understanding towards consent and the legal issues that consist of 10 items, 3) response of subjects to determine what do they wanted to know about their treatment that consist of 12 items, 4) opinion of patients regarding their role in decision making about the treatment that consist of 3 items, and 5) patients understanding to what has been explained to them. Only 22 items were selected as essential information for the study and respondents need to choose one answer.

Apart from that, there was a question regarding surgical patients' knowledge regarding informed consent that was adopted by Marasini, Kait, Mahato, Gyawali, and Nepal, 2013 from study of informed consent in patients undergoing eye surgery: a

qualitative study assessing their attitude, knowledge and anxiety level in a community based hospital of Nepal. The original instrument consists of two parts.

The first part of the questionnaire included 12 items which were developed based on the publications by Elder and Dawes. It was translated into Nepali language and pretesting was done in twenty patients attending the ophthalmology department. The questions were revised and modified to ensure the ease of comprehension and completeness. The questions in the interview covered three aspects of the consent: preoperative information provide, patient's decision and the attitude towards consent. The second part of the questionnaire included eight questions to respond to the extent they agree. Respondents were offered a choice of five pre-coded respondents which ranged from strongly disagree with the neutral point being neither agree nor disagree. Apart from that, only 5 items will be selected as essential information for the study.

All together 27 questions was constructed. Each item was rated using a 'Yes', 'No', and 'Don't Know' to determine the level of knowledge regarding informed consent among surgical patients. Fifteen multiple choice items is then will be calculated to a percentage score from 0 to 100%. The more questions answered correctly will result in a higher score. If all questions are answered correctly, the score would be 100% (McMillan et al., 2005). Each correct answer will be given 1 point and no point will be given for the incorrect answer. The patients' knowledge regarding informed consent are categorized into three level which are low (score 0-5), average (score 6-10) and high (score 11-15) (Vodopivec, et al., 2002).

2.3.2 The differences of Knowledge Regarding Informed Consent with Level of Education

Education level plays a major role in the ability of patients to understand and recall the information presented to them, no matter how the information is presented. Lower education level has been shown to have a direct negative effect on patients' comprehension and memory (Johnson, Singh, Stewart & Gioe, 2011). In addition, Rossi et al. (2005), found that adjuncts such as video in the informed consent process has a greater effect on improving understanding in patients with less than or equal to 12 years of formal education.

Based on Falagas et al. study's (2009), many patients fail to recall major portions of information on consent. Patients' educational background is related to the level of attention they give to information provided by the physician and their ability to describe this information when asked. Apart from that, participants with higher education grasped more information compared to patients with lower education. Despite, one cannot assume that a patient with a higher education level is necessarily literate regarding written forms or verbal information received.

Besides that, almost half, 43% of the patients, mainly those with no formal education and educational levels of primary or high school could not list even a single complication while 33% who listed one complication only mainly had a primary or high school and certificate level education. Only 3% listed 3 complications and they had either master or baccalaureate level education. It's showed that better levels of understanding in patients who had higher education (Bikash, 2010).

2.3.3 The differences of Knowledge Regarding Informed Consent with gender

Male gave more importance on knowing the surgical doctor while females reported high scale grades on fear of the operation. From this study, it can be observed that more males wanted to know about the surgical doctor. This could be because of the male dominated society where the family head (senior male) makes the decision regarding all the family members. This leads the doctor to act in a paternalistic way in our society where doctor decides everything for the better management of patient. Despite, in contrast, in developed countries, it is now accepted that a competent individual may go as far as to refuse any treatment even if as a result the may die (Marisini, et al., 2013).

Besides that, female patients were statistically more anxious than male patients on the day of surgery and their anxiety began statistically significantly sooner. Female patients experience higher levels of anxiety than male patients. Anxiety was expressed more by female patients, younger and novice patients. However, female patients are suggested to be more truthful when completing preoperative anxiety measures and not necessarily more anxious (Mitchell, 2011).

Study done by Medeiros and Ramada (2011) regarding knowledge differences between male and female university students about human papillomavirus (HPV) and cervical cancer: implications for health strategies and vaccination state that female students revealed to have more and accurate knowledge's than male students. Female students have higher knowledge than male students because of cervical cancer are developed in women, and they have access to more an accurate information given by physicians.

2.3.4 The differences of Knowledge Regarding Informed Consent with frequency of Surgery.

Frequency of surgery refers to how many times a person have undergone surgery before. According to the theory, the more frequently a person is doing a thing; an understanding of these things will be much improved. So, patients who often undergo surgery are more often faced with the consent form. Therefore, the more frequently a person undergoing surgery, the understanding of the consent form will be higher than someone who first undergoes surgery.

Regarding this study, patients will have to answer whether they had undergone previous surgery or not. If they had undergone previous surgery, they should state this time is to what number of surgery they will be undergoing.

2.4 Conceptual/ Theoretical Framework

The theoretical framework for this study is based on the health belief model by Hochbaum (1958).

The Health Belief Model (HBM) is by far the most commonly used theory in health education and health promotion (Glannz, Rimer & Lewis, 2002). The underlying concept of the original HBM is that health behavior is determined by personal beliefs or perceptions about a disease and the strategies available to decrease its occurrence (Hochbaum, 1958). They are four perceptions which serve as the main constructs of the model which are perceived seriousness, perceived susceptibility, perceived benefits, and perceived barriers.

More recently, other constructs have been added to HBM; thus, the model has been expanded to include cues to action, motivating factors, and self-efficacy. The

construct of perceived seriousness speaks to an individual's belief about the seriousness or severity of a disease. While the perception of seriousness is often based on medical information or knowledge, it may also come from beliefs a person has about the difficulties a disease would create or the effects it would have on his or her life in general. Majority (61.9%) of the patients were not sure if they could withdraw the surgery at any time if they wished so (Marasini, Kaiti, Mahato, Gyawali & Nepal, 2013).

Personal risks or susceptibility is one of the more powerful perceptions in prompting people to adopt healthier behaviors. The greater they perceived risk, the greater the likelihood of engaging in behaviors to decrease risk. Despites, it is only logical that when people believe they are at risk for a disease, they will be more likely to do something to prevent it from happening. Unfortunately, the opposite also occurs. When people believe they are not at risk or have a low risk of susceptibility, unhealthy behaviors tend to result (Maes & Louis, 2003).

Besides, when the perception of susceptibility is combined with seriousness, it results in perceived threat. If the perception of threat is to a serious disease for which there is a real risk, behavior often changes (Glannz, Rimer & Lewis, 2002). Male patients gave more importance on knowing the surgical doctor whiles females reported high scale grades on fear of the operation. Apart from that, more males are concern regarding giving the consent and also the procedure that he will undergo (Marasini, et al., 2013).

The construct of perceived benefits is a person's opinion of the value or usefulness of a new behavior in decreasing the risk of developing a disease. People tend to adopt healthier behaviors when they believe that new behavior will decrease their chances of developing disease. Besides, perceived benefits play an important role in the adaptation of secondary prevention behaviors (Frank & Swedmark, 2004). The informed consent process may be influenced by the educational level of the patient. Patients with higher education levels tended to have better knowledge of informed consent, grasped more information and also had better recall than those with no formal education (Bikash, 2010).

Since change is not something that comes easily to most people, the last construct of the HBM address the issue of perceived barriers to change. This is an individual's

own evaluation of the obstacles in the way of him or her adopting a new behavior. Of the entire construct, perceived barriers are the most significant in determining behavior change (Janz & Becker, 1984). Many patients (69%) thought that to sign the consent form was equivalent to agree for surgery. It reflects that these patients allow doctor to determine the treatment without blaming them of possible adverse effect (Marasini, et al., 2013). Despites, it must be remembered that signing the consent form is the patients' decision and they can change their mind at any time, even if they have signed the consent form (Guy's & Thomas, 2013).

In addition to the four beliefs or perceptions and modifying variables, the HBM suggests that behavior is also influenced by cues to actions. Cues to action are vents, people, or things that move people to change their behavior (Graham, 2002). In 1988, self-efficacy was added to the original four beliefs of the HBM (Rosenstock, Strecher & Becker, 1988). People generally do not try to do something new unless they think they can do it. If someone believes a new behavior is useful (perceived benefit), but does not think he or she is capable of doing it (perceived barrier), chances are that it will not be tried.

Conceptual Framework of the study

The conceptual framework of this study is based from health belief model (Figure 2.1). In the health belief model, if a person has a higher level of education, he will have high knowledge of certain issue especially regarding his health. Apart from that, in this study will look at whether there is a different of level of knowledge between levels of education.

Male gave more importance on knowing the surgical doctor while females reported high scale grades on fear of the operation (Marisini, et al., 2013). Apart from that, with regard to gender and waiting activities a number of differences were established. Female patients, in comparison to male patients, statistically significantly indicated preference to spend their time waiting by talking with other patients, passing the time with a partner or friend and did not wish to be informed that 'the chance of the anesthetic not working properly is rare' (Mitchell, 2011). This model will also look at whether a difference in knowledge towards informed consent between male and female.

According to the theory, the more frequently a person is doing a thing; an understanding of these things will be much improved. So, patients who undergo surgery are more often faced with the consent form. Therefore, the more frequently a person undergoing surgery, the understanding of the consent form will be higher than someone who first undergoes surgery. Based on this conceptual framework, researcher wants to find out if there is a different between frequencies of surgery with the knowledge regarding informed consent. Overall, this conceptual framework will be a guidance to determine the knowledge regarding informed consent among surgical patients.

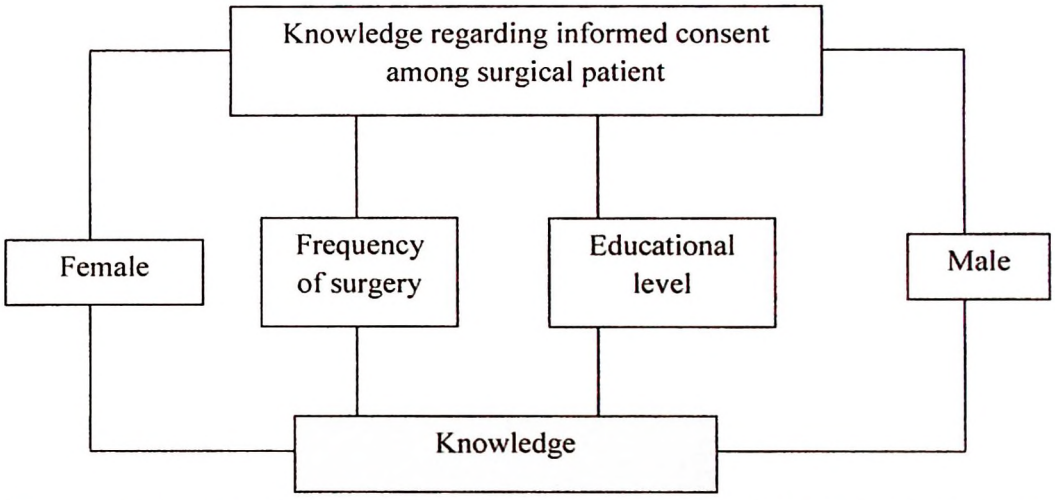

Figure 2.1: Conceptual Framework of Knowledge regarding informed consent among surgical patients adapted from Health Belief Model

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Research Design

The research design used in this study was cross-sectional design. The data was obtained through a set of self administered questionnaire. This is a useful way to gather information on knowledge regarding informed consent among surgical patients at Hospital Universiti Sains Malaysia (Hospital USM) and also to examine the different between these variables.

3.2 Population and Setting

The target populations were hospitalized surgical patients in surgical wards at the Hospital USM. They were patients in general surgery wards: 2 Intan and 3 Utara, otorhinolaryngology ward: 4 Timur Depan, and orthopedic surgery wards: 4 Utara and 4 Selatan.

3.3 Sampling Plan

3.3.1 Sample size

The research used Raosoft sample size calculation software to calculate the sample size and to ensure the accuracy by avoiding sampling error during representatives and parameters of the sample. By entering all these values, the software were calculated the recommended sample size for the study. An analysis is conduct by using Raosoft software with a confidence level 95%, a margin of error that can be tolerated amount 0.05, with the population size of 138 from the average number of cases for elective surgery at Hospital USM in operation theater from January to September 2013 (Table 3.1) and the response distribution of 50%, thus the recommended sample size for the surgical patients undergoing the selected surgery are 102. Then, the drop out for this study, 10% of calculated sample size is recorded. Therefore, the total patients involved for this study was:

= 102 patients + drop out of 10%

= 102 patients +10 patients

= 112 patients

Table 3.1: Operation cases for elective unit at Hospital USM in Operation Theater January to September 2013

Type of surgery	JAN		FEB		MAR		APRIL		MAY		JUNE		JULY		AUG		SEPT	
	M	MI	M	MI	M	MI	M	MI	M	MI	M	MI	M	MI	M	MI	M	MI
General surgery	31	7	11	21	22	14	19	20	7	14	15	8	12	13	12	12	6	16
Orthopedic	55	30	48	32	42	41	61	43	20	27	58	29	51	30	33	19	42	16
ORL	6	29	14	25	8	22	6	39	22	8	9	23	3	20	10	23	6	30
Total by month	158		151		149		189		99		142		129		109		116	
TOTAL	1242																	

M: Major surgery, MI: Minor surgery

Source: Operation Theater Hospital USM

3.3.2 Sample Design Method

Non-probability, purposive sampling procedure were used to recruited the sample. However, a number of inclusion criteria and exclusion criteria were used to control the homogeneity of surgical patients for the study. The inclusion criteria and exclusion criteria were as follows:

Inclusion Criteria

1. Patients who will undergo general surgery, orthopedic and otorhinolaryngology surgery in Hospital USM.
2. Patients age 18 years or more, capable of giving consent and with acceptable knowledge of the chosen language of questionnaire (Bahasa Malaysia).
3. Patients had received information regarding surgery and had signed consent form for surgery in their files.
4. Patients who agreed to participate in research.