



COLLEGE OF HEALTH SCIENCE, SCHOOL OF MEDICINE, DEPARTMENT OF ANESTHESIA

ASSESSMENT OF PATIENTS KNOWLEDGE, ATTITUDE, AND
ASSOCIATED FACTOR ON ANESTHESIA INFORMED CONSENT AMONG
ELECTIVE OPERATION AT SELECTED ADDIS ABABA PUBLIC
HOSPITALS.

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Acronyms

AANA; American Association of Nurse Anesthetist

AAU; Addis Ababa university

AIC; Anesthesia informed consent

CHS-IRB; College of Health Sciences-Institutional review Board

EFMHCAC; Ethiopian Food, Medicine and Health Care Administration and Control

ENT; Eye, Nose, Throat

FMOH; Federal Minister of Health

NGO; Non-Governmental Organization

OAU; Organization of African Union

SOP; standard operating procedure

TASH; Tikur Anbesa Specialized Hospital

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Abstract

Background: Informed consent is the backbone for recent medical practice and it is grounded in ethical and legal concept-that patients have the right to understand what is being done to their bodies (personal autonomy) and agree to the potential consequences of the healthcare intervention. Informed consent is considerably beyond putting a signature to the form; the anesthesia professional and the patient develop the anesthesia plan through discussion of alternatives and risks and benefits of the plan.

Objective; The objective of this study was to explore the patient's knowledge, attitude and associated factors on anesthesia informed consent among adult elective surgery at a selected public hospital in Addis Ababa.

Methods; Institutional based Cross-sectional study designed was used with including all elective surgery scheduled patients from December 23/2019 to March 23/2020 with consecutive sampling technique and proportional allocation. A Structured questioner was used with trained data collectors. Data were coded, entered into EPI data v.7 and data was exported to SPSS version 21 statistical package for analysis. Binary logistic regression was used to deal with the response variable. The crude and adjusted odds ratios with their corresponding 95% confidence intervals were computed.

Work plan and budget; The study was conducted from December 23/2019 to March 23/2020 with a total budget of 29, 240 ET

Result; Patient knowledge about the anesthesia informed consent, 65.8% were knowledgeable and 34.2% were not knowledgeable. Marital status, educational level, professionals who provide anesthesia informed consent and place where anesthesia informed consent taken were significantly associated with patient's knowledge. Concerning the attitude of patients, about 44.3% (181) had a positive attitude, and 55.7% (228) had a negative attitude. Sex, marital status, educational level, and place where anesthesia informed consent provided had significantly affected with patient attitude.

Conclusion; Patients who were under the study had limited knowledge and attitude and different factors were affected them.

1. Introduction

1.1 Backgrounds

Anesthesia informed consent is the process, not a form to be signed, and a two-way dialogue between anesthesia professionals and patients is best to ensure that the patient understands all of the risks, no matter how small some of those risks might be.

Now a day informed is the backbone for recent medical practice and it is grounded in ethical and legal concept-that patients have the right to understand what is being done to their bodies (personal autonomy) and agree to the potential consequences of the healthcare intervention (self-determination and self-decision). (1)

Anesthesia informed consent is considerably beyond putting a signature to the form; the anesthesia professional and the patient develop the anesthesia plan through discussion of alternatives and risks and benefits of the plan. (2, 3) The informed consent process delivers the chance for the patient to be an active participant in anesthesia care decision-making and to explain any questions he or she may have or unclear ideas on the discussion. (4-7)

Patients must receive information in a manner that promotes understanding so they can make informed decisions about anesthesia and other medical intervention. While obtaining consent for anesthesia poses unique challenges, the ability of the anesthesiologists/anesthesiologist to engage the patient in meaningful discussion is critical as a means to ensure that the patient is truly informed. It must aim to: discuss the process of informed consent as it applies to anesthesia practice; describe the salient issues related to patient capacity, disclosure, understanding, decision-making, and documentation of the informed consent process; and discuss current strategies to improve the presentation and understanding of consent information. Despite the unique challenges of obtaining consent for anesthesia on the day of surgery, attention to how information for anesthesia care is provided and the adoption of simple strategies to enhance understanding can go a long way to ensure that decision-makers are appropriately informed. (8)

What to consider during obtaining anesthesia informed consent? General considerations to facilitate clear communication with the patient during the informed consent process including, engaging the patients on consenting processes, assess the patient understanding of the information provided, and Consent Document and Process Completion. (9)

1.2 Statement of the problem

Informed consent was a part of the routine practice of pre-operative care before any anesthesia as a matter of hospital policy, legal requirement, and ethical obligation.

Patients have an interest in knowing what is going to happen to them and what they should expect during a course of anesthesia (autonomy).

Elective surgery patients should be provided with information before admission, preferably at pre-assessment. Preoperative assessment clinics are specifically designed to stratify patients' risk to identify and justify the effect of risk factors associated with high perioperative morbidity and mortality.

Preoperative patient education should recognize that different patients have various misconceptions, expectations, and needs. Therefore multiple ways of education can be required to increase the patient's knowledge and attitude on anesthesia informed consent and to decrease patient anxiety as well as to increase patients satisfaction. (10)

The legal requirements for valid consent reflect the ethical ones: it must be given voluntarily by an appropriately informed patient, who can exercise a choice, without any enforcement or push.

A patient's decision to consent anesthesia needs to be grounded on an adequate basis of relevant information on benefits, risks, complications, and alternatives. Without such a basis, a patient's decision to consent anesthesia is not effective informed consent.

In Ethiopian context legal requirements of any medical treatment and procedure, needs can be provided on beside patient's informed consent. (11)

The Addis Ababa university College of Health Sciences-Institutional review Board (CHS-IRB) is one of the first IRBs in Africa that received international recognition from WHO/SIDCER/FERCAP. The IRB adheres to specific policies for ethical review and follow up as per its standard operating procedure (SOP). In addition to its daily activities, the IRB has provided trainings for its members, members of Departmental Research Ethics Committees, and other academic staff and make efforts in research ethics capacity building. IRB has a comprehensive list of Standard Operating Procedures (SOPs) and submission developed with support from the WHO/SIDCER in 2009 and reviewed in 2015.

The IRB currently has 12 members (5 women and 7 men) with varied backgrounds including physicians, pharmacologists, microbiologists, biostatistician, and community representative.(36)

TASH and other hospitals tried to improve the anesthesia consent by separating it from surgical consent, both have different concerns related with their field of practice, and by establishing preoperative clinic at their institution, but some hospitals didn't try anything, as it was a routine preoperative practice it raises the question of quality implementation of anesthesia informed consent. The reason behind were hidden either staff or intuition related. This study aimed to identify the level of patient's knowledge, attitude, and the associated problems on anesthesia informed consent.

1.3 Significance of the study

The Federal Ministry of Health (FMOH) focused on improving the quality of care one of the targets was working on community and patient awareness to demand quality health services. Therefore the proper implementation of anesthesia informed consent can improve the quality of health service on the anesthesia and surgical health services. (12)

The reason to conduct this study was on our attachment rotations at attachment sites most patients are on anxiety and fear at the operating room (operating tables) as well as they are reacting on anesthesia-related incidents and postoperatively dissatisfied, this forced me to assess the patient's knowledge, attitude and associated factors at our attachment sites elective surgery patients.

The study might bring patient-centered informed consent process as a model of shared decision-making that enhances patient safety, improves patient satisfaction, Increase patients trust to the anesthesia professionals, meets ethical and legal duty to the patient, increases staff morale, reduces legal risk to the healthcare provider and organization, and helps ensure compliance with regulatory and accreditation requirements, Decreases patients intraoperative hemodynamic changes which is directly related anxiety and fear due to lack of full information during surgery. (10) Therefore the study can benefit patients, anesthesia professionals as well as the health organization as a whole.

I hope the finding might improve the implementation of anesthesia informed consent and mention the institution the way how to fill the gaps and make the implementation standard. The study was not conducted yet in Ethiopia on anesthesia informed consent even if, in Africa as published

material. Whatever, it has valuable importance and influence on patient safety and legal and ethical implications on surgical services.

2. Literature review

A literature review conducted at southern Australia, on six databases were searched from January 1995 to March 2013 for articles using the terms informed consent, patient comprehension, and patient understanding. They identified 354 articles and analyzed them. Finally, they resulted in, the degree of understanding of the consenting process decreased with age. Some patients believed that the primary purpose of the consent procedure was to protect hospitals and doctors. Level of education, literacy, and language competency, combined with physicians' ability to effectively explain the medical procedure and the inherent risks and complications, were important determinants of patients' capacity to provide fully informed consent. The review found that patient's recall and understanding of the medical procedure, risks, and complications are often low, particularly among older individuals. (13)

A survey study conducted at America on Patient perspectives on informed consent for anesthesia and surgery: American attitudes on Five hundred patients by investigators C. M. Burkle et al. A majority of respondents (92% and 80%, respectively) believed the risk of common but less consequential complications and rare yet severe complications should be discussed. Only 21% agreed that anxiety generated by discussion of risks outweighed the benefit and only 6% agreed that discussion of risks should be restricted based on the patient's inability to appreciate complexities of care. Participants preferred consenting on the day of surgery, 1 week before, and 1 month before in 46%, 35%, and 16% of respondents, respectively, and they also favored discussion with their anesthesia provider alone (44%) or in combination with written information (52%) as compared with written information only (4%). This shows that Greater awareness of patient preferences and expectations may result in better information exchange between anesthesia providers and their patients. (14)

A cross-sectional study investigated at Italy's Campania Region on "does written informed consent adequately informs surgical patients? " By Erminia Agozzino et al, from January 2016 to June 2016. The investigation showed that about 13.9% of the respondents can't know to have surgery, 51.8% are read IC thoroughly. Of those who reported having read it, 90.9% judged it to be clear.

Of those receiving the written consent form, 52.0% had gotten it the day before the surgery at the earliest 41.1% received it some hours or immediately before the procedure.

The written IC form was explained to 65.6% of the patients and 93.9% of them received further oral information that deemed understandable. Most attention was given to the diagnosis and the type of surgical procedure, which was communicated respectively to 92.8 and 88.2% of the patients. Almost one in two patients believed that the information provided some emotional relief, while 23.2% experienced increased anxiety. Younger patients (age≤60) and patients with higher levels of education were more likely to read the written IC form. Investigators concluded that the written IC form is not sufficient in assuring patients and making them fully aware of choices they made for their health; pre-operative information that was delivered orally better served the patients' needs. (15)

Great Britain National Health Service Litigation Authority reviewed claims related to anesthesia from 1995–2007 about 841 relevant claims, a result shows 3% of litigations related to anesthesia informed consent. (16)

A hospital-based, cross-sectional study at Pakistan at a tertiary-care hospital in Karachi by F. Jahan et al, on Factors affecting the process of obtaining informed consent to surgery among patients and relatives conducted between July and October 2010 in Aga Khan University Hospital on 400 post-surgery adult patients. Their study result shows Overall, 233 patients (58.3%) had signed the surgery consent form themselves, while 167 relatives (41.7%) had signed on behalf of the patient. Perceived factors significantly associated with patients not signing the consent form themselves were: the language used, medical terminology used, insufficient time allocation, cultural/traditional reasons, and low education. Inappropriate timing for taking consent and not being informed or asked about consent were not statistically significant factors. Health-care practitioners should encourage patients to sign the consent form themselves. (17)

A Cross-sectional Study conducted at Istanbul, Cerrahpasa Medical Faculty Hospital of Istanbul University in 2015 by Itir Erkan. et al, on Assessment of patients' knowledge level regarding the informed consent from the ethical aspect of the research, was conducted on 102 hospitalized patients. The result shows of the participants, 63 declared that they know what the informed consent means, 39 (38.1%) declared that they have not sufficient knowledge on this subject, while 74 (72.5%) of participants stated that they were informed about the risks and adverse effects of

operation to be performed and 28 (27.4%) were not sufficiently informed. The study concluded that patients were not sufficiently informed about the informed consent and that there still are words, the meaning of which is not known by the patients. (18)

A mixed qualitative and quantitative cross-sectional study at Teheran military hospital in 2016 by Vajihah Meysami .etal on quality of receiving patient's informed consent in the surgical wards with a stratified random sampling of 120 subjects. The researchers also used expert panel methods experts. The study Resulted with the average score in the dimension of providing information with 18.93%, compliance with patients decision-making competence with 7.48%, and how to get written consent with 5.47%, was lower than the expected average, and the average score of patient comprehension with 9.77%, Volunteerism with 8.16 and Interaction between physician and patient with 16.02%, were in an acceptable level. The most important was providing information to patients in the preparation clinic and giving patients enough time to choose a therapeutic approach. (19)

A cross-sectional study conducted at Inkosi Albert Luthuli Central Hospital, Durban, South Africa from September 5–16, 2011 on the informed consent process for anesthesia: perspectives of elective surgical patients by S Naidu and PD Gopalan on 143 patients their study shows as only 57% of patients were given information about their anesthetic preoperatively. Concerning complications experienced during anesthesia, 36% of patients preferred not to be informed of any possible sequelae, while 17% wanted to be informed of all possible complications. 83% of patients who had signed the surgical consent form with the surgeon thought that they had signed an anesthetic form with the anesthetist. Some 56% of patients felt that written consent on a specific standardized anesthetic consent form should be introduced. Finally, they concluded that Even though the majority of patients are being seen preoperatively by the anesthetist, the quality of their assessment is concerning, in terms of the amount and depth of information imparted and lack of standardization of information given. (20)

A cross-sectional study conducted at South Africa from March–June 2012 on "Patients' insights on informed consent practices by healthcare professionals" investigated by Wolters Kluwer on randomly selected public hospitals. He got the results Patients were generally informed about the diagnosis (81%), risks (57%), and benefits of treatment (61%). Few were informed about treatment

options (41%), recommended treatment (28%), and right of refusal (25%). Patients favored disclosure of all material risks (78%) and few consulted surrogates before decision-making (76%).

There was an association between the participant's age and knowledge of consent. Most patients were satisfied with the information disclosed (91%) and did not feel coerced. Some were afraid to ask questions for fear of losing free treatment (8%). Barriers to IC include poverty, language, and low educational level. South African patients prefer to disclose all material risks, better communication skills by healthcare workers. (21)

A descriptive correlation study conducted at Rwanda military hospital in 2017 by Felix Mbonera and Geldine Chirona on the relationship between knowledge and perception of patients regarding informed consent. They Come-up with 83% had low knowledge, 12% moderate and only 5% had a high level of knowledge. 23% had a low perception, 50% moderate and 31% had high level of perception towards informed consent. The researchers revealed that the patient's knowledge towards informed consent for surgical procedures is limited and their perception towards informed consent is poor. (22)

A cross-sectional studied on Nigeria at Aminu Kano Teaching Hospital by Abubakar Idris Sulaiman, et al. The study assessed knowledge, attitude, and perception of women towards informed consent between 1st July and 30th September 2013. All respondents believed signing consent before surgery was important and believed it was a legal document involved in the decision-making process. 97% of the respondents were satisfied with the explanation given to them before the surgery however, 15.8% had some reservations to the explanations while 3% were not completely satisfied with the explanations. They conclude that Awareness and knowledge of consent were high in the study and the respondents had a positive attitude towards signing consent. (23)

A prospective, descriptive, questionnaire-based study conducted at Ladoke Akintola University of Technology Teaching Hospital Osogbo, Osun State, Nigeria in 2010 by Atanda.etal on How informed are our patients? They revealed that patients had limited knowledge of the legal implications of consent before surgery. More than half 55.6% of the patients strongly agreed that the main purpose of the consent is to protect the hospital against litigation. Over two-thirds of 69.2% of the patients have strongly believed that consent allows doctors unnecessary control over what happens during surgery. However, highproportion of the participants 71.8% and

66.7% strongly agreed that signing the consent form made them more aware of what was going to happen during surgery and the risk of surgery respectively.

They concluded that patients have limited knowledge of the legal implications of signing or not signing consent forms, and they failed to identify that written consent primarily serve their interests. Existing consent form signing appeared inadequate as a way for the expression of patients' autonomy. (24)

A cross-sectional study conducted at Enugu, the capital of Enugu State in southeast Nigeria in October 2014 by Kenneth Amaechi Agu et al, on Attitude towards informed consent practice in a developing country. They come-up with Approximately 70% of those who had tertiary education indicated that informed consent was necessary for procedures on children, while the greater number of those with primary (64.4%) and no formal education (76.4%) indicated that informed consent was not necessary for procedures on children. Finally, they concluded that knowledge of the informed consent practice increased with the level of educational attainment but most of the participants irrespective of educational status would want to be involved in decisions about their healthcare. (25)

A a cross sectional study design conducted at Addis Ababa selected hospitals in Ethiopia from May14, to June 14, 2017 by Meaza Birile on Perception about informed consent for surgical procedures as part of patient safety practice among service providers and patients. The author come up with regarding participation on decision for surgical procedure were physicians 212(63.5%), patient himself 92(27.5%) and patient family/friends 30(9.0%) and knowledge of patients related with risk 118(35.3%) and alternatives 95 (28.4%) of surgery.(36)

The ability of the patients to obtain, read, understand, and use healthcare information to make appropriate health decisions. To have a patient that understands health terms and can make proper health decisions, the language used by health professionals has to be at a level that others who are not in the medical field can understand. Health professionals must know their audience to better serve their patients. The language used by these professionals should be plain. Plain language is a strategy for making written and oral information easier to understand; it is communication that users can understand the first time they read or hear it. (26)

Preoperative clinics are specifically designed to stratify patients' risk to identify and mitigate the effect of risk factors associated with high perioperative morbidity and mortality. The clinician participating in a Preoperative clinic should do so with clear goals in mind. First, it is important to create an open environment for the patient by building rapport with the patient and their relatives, to address the anxiety associated with invasive surgical/anesthesia procedures. The patient should be assessed in a systematic and focused manner following evidenced-based established guidelines to reduce the morbidity and mortality of the surgery. (27)

Conceptual framework

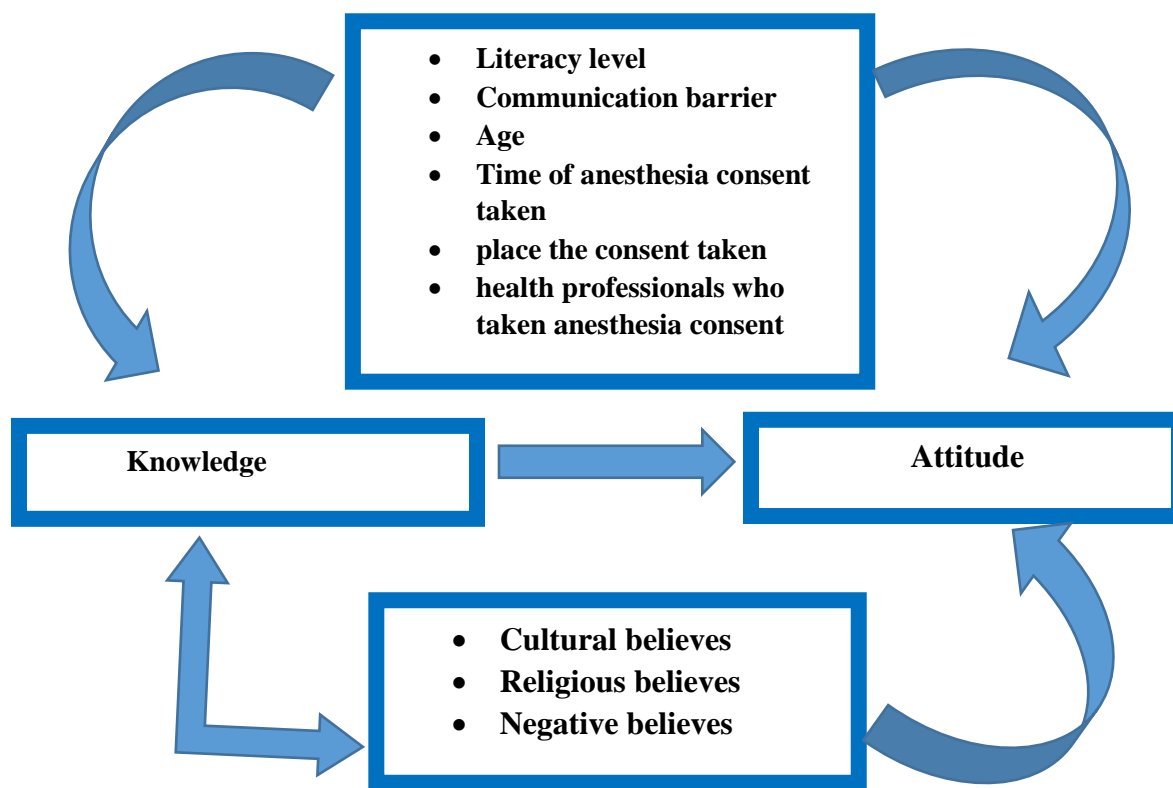


Figure 1. Factors affecting patient knowledge and attitude

3. Objective

3.1 General objectives

To evaluate patients Attitude, knowledge, and associated factors affecting anesthesia informed consent among elective surgical procedures at Addis Ababa public hospitals from December 23/2019 to March 23/2020.

3.2 Specific objectives

- To assess patient knowledge on anesthesia informed consent
- To assess patients attitude towards anesthesia informed consent
- To assess associated factors that affect a patient's knowledge and attitude on anesthesia informed consent.

4. Methods and material

4.1 Study area and period

Addis Ababa is the capital city of the Federal Democratic Republic of Ethiopia has the status of both a city and a state. Apart from this, the city is also host to foreign embassies and heads of a diplomatic mission, international, regional and sub-regional organizations and several international NGOs, it is the place the African Union is and it's antecedent the OAU was based. It likewise has the central station of the United Nations Economic Commission for Africa and various other international. The whole city is divided into 10 'kifleketmas' (sub-cities) and 116 woredas with a total area of 520sq.Km. The population of Addis Ababa from 2013 estimates 4,156,251 to be in 2020 is 4,970,983 based on the 2007 population census with an annual growth rate of 2.9 % (CSA, 2007). A total of 58 hospitals and 90 health centers are available in Addis Ababa city administration (Addis Ababa city land administration atlas 2015).

There are thirteen public hospitals and 31 private hospitals are found (registered) in Addis Ababa according to information obtained from Addis Ababa Health Bureau in the year 2017. The study was conducted from December 23/2019 to March 23/2020.

4.2 Study Design.

Institutional based cross-sectional study design was used.

4.3 Study population.

4.3.1 Source of population.

All surgery patients who undergo an operation at Addis Ababa public hospitals

4.3.2 Study population.

Elective surgical patients who undergo an elective operation in Addis Ababa public hospitals

4.3.3 study unit

Elective operation in selected Addis Ababa public hospitals in the specified time.

4.4 Study variables

4.4.1 Dependant variable.

Knowledge and attitude

4.4.2 Independent variable

Socio-demographic: Age, sex, educational status (literacy), language, religion

Time of anesthesia consent taken, place the consent taken, health professionals who taken anesthesia consent

4.5 Eligibility Criteria

- **Inclusion:** - Adult patients Age greater than 18yrs and admitted in hospital of different units where an elective operation was performed.
- **Exclusion:-** mentally ill patients

4.6 Sample size

The sample size was calculated by taking 50% population proportion to calculate the sample size with a single proportion formula. With 95% Confidence interval (1.96), and margin of error (5%)

$$d= 0.05 \quad p= 50\% (0.5)$$

$$n = \left(\frac{1.96}{d}\right)^2 p(1 - p) = \left(\frac{1.96}{0.05}\right)^2 0.5(1 - 0.5) = 385$$

With a 10% non-response rate, $n= 385 + 39 = \underline{424}$

4.7 Sampling technique/procedure

Non probability Consecutive sampling technique was used for scheduled elective surgery as calculated by a single population proportion formula at a specific period, from selected Addis Ababa public hospitals. The sample was collected from December 23/2019 to March 23/2020 and Sample size was allocated to the selected hospitals by probability proportional to size using last year's performance report from selected hospital, here hospitals served as strata, the patients wherever they appear are similar in terms of the operation being done, so no design effect was used.

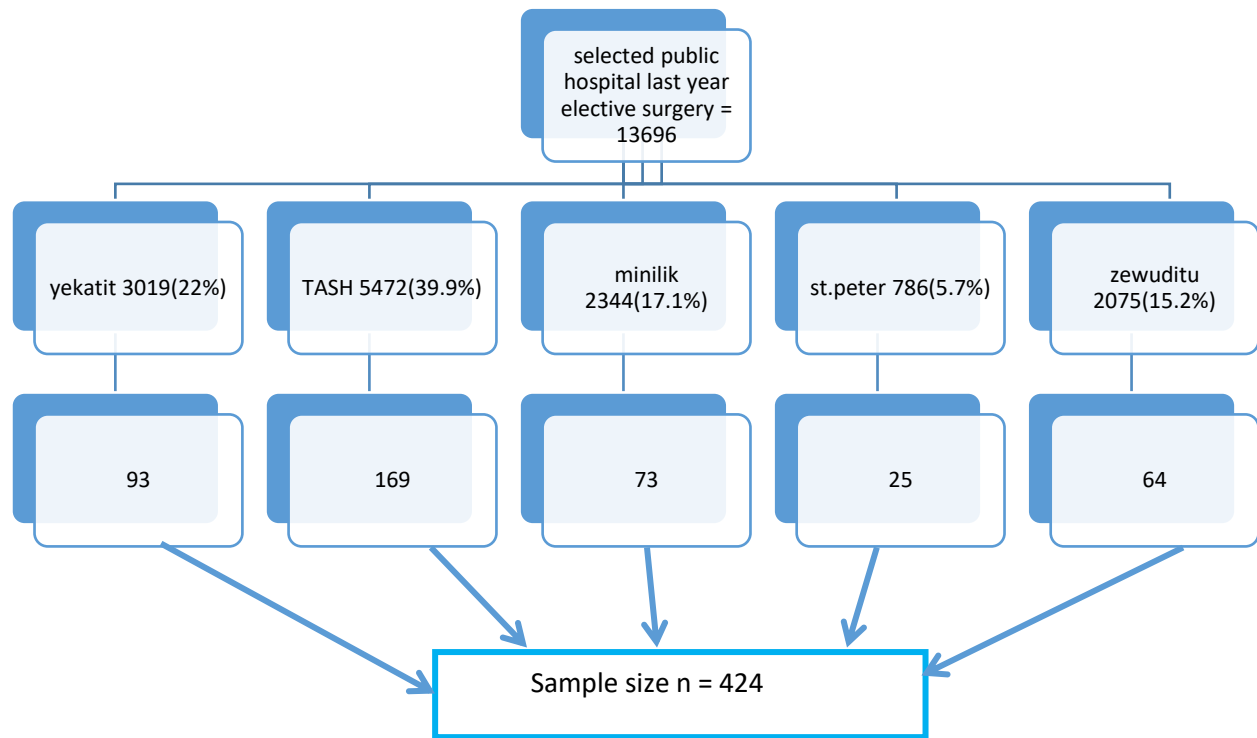


Figure 2 Schematic representations of the selection of samples.

4.8 Data collection Tool and procedure

4.8.1 Data Collection Tool

Data were collected using interviewer-administered a structured pre-tested questionnaire. The questionnaire was prepared in English and then translated to Amharic. Close-ended questions were used. The questionnaire contains four sections: socio-demographic data, Patients knowledge, patient attitude towards anesthesia informed consent, and associated Factors on anesthesia informed consent, and parts 2 and 3 of the questioners were prepared by using two and five point linkart scale respectively and the for the purpose of analysis it was recoded to a two-point Likert scale system for both. (28)

4.8.2 Validity and reliability of data collection tools

Face validity measures the construct of the study using facial looking of the tools in this study the face validity of the questionnaire was determined by asking questions to my classmate to verify whether they are clear. Face validity was achieved by structuring the research tool into three separate sections: knowledge regarding anesthesia informed consent, attitude on anesthesia informed consent, and socio-demographic characteristics. (29)

Content validity of this study tool was developed after reviewing different literature on the topic besides adopting from the related researches and guidelines which was done on patient knowledge, attitude, and factors affecting the process of informed consent.(17, 18, 23)

Construct validity was the level to which a tool measures the construct it was aimed to measure. (30) The construct validity was determined by assessing whether the knowledge and attitude of the patient towards anesthesia informed consent are measured in the conceptual framework and research instrument tool. Criterion validity evidence on the relationship between the concepts under study with other variables. In this study, criterion validity was explained by the relationship between knowledge and attitude towards anesthesia informed consent with other variables. (31)

Reliability describes how far a given tool like questionnaire can lead to similar results in different situations. To achieve reliability, a closed-ended questionnaire with similar words, similar structure, and a similar format for each participant, was used to ensure consistency and accuracy of the tool. The reliability coefficient analysis of the research instrument will show that the instrument was a very good measure of the concepts under study.

4.8.2 Data collection procedure

The pretest of the structured questioners has conducted at St. Paul hospital before the administration of questionnaires to patients, and then ethical clearance was obtained from the Addis Ababa University Department of anesthesia before the actual data collection period. Consent was provided after detailed information on the study topic and the objectives of the study for patients.

The structured questioner which assesses patient knowledge and attitude of anesthesia informed consent were administered after signing of anesthesia informed consent. The data collection

process was taken from December 23/2019 to March 23/2020 by using structured questionnaires and reviewing of each hospital consent form.

Measuring patients knowledge and attitude

Section; 2 Assess the level of knowledge of patients towards anesthesia informed consent for elective surgical Procedures in the selected Addis Ababa public hospital. The response was rated on a Likert scale whereby the most favorable answer got a higher score and less favorable a lower score and the overall score will be calculated. The minimum possible total score for level of knowledge was 8 and the maximum possible score will be 16. Dividing the attained score on this section by the maximum possible attainable score 16 and multiplying by a hundred came up with a percentage calculated knowledge for anesthesia informed consent of elective surgical procedures. (22)

Section; 3 Assess the level of attitude of patients towards anesthesia informed consent for elective surgical procedures in the selected Addis Ababa public hospital. The response was rated on a Likert scale whereby the most favorable answer got a higher score and less favorable a lower score and the overall score was calculated. The minimum possible total score for level of attitude was 9 and the maximum possible score was 18. Dividing the attained score on this section by the maximum possible attainable score 18 and multiplying by a hundred came up with a percentage calculated level of attitude towards anesthesia informed consent of elective surgical procedures. (22)

4.9 Data Quality control

The English version of the developed questionnaire was translated to Amharic and back-translated to English to ensure its consistency. Thorough one-day orientation was given for data collectors and supervisors on data collection tools, cleaning, and precautions to be taken while collection to ensure data quality, the approach and different experiences, and the most common mistakes committed during data collection. Then after, using the Amharic version questionnaire five BSc level Nurses and two supervisors were used on the data collection process.

Internal consistency (the reliability, validity, accuracy) was measured by Cronbach's Alpha Reliability Coefficient(28). The reliability coefficient of this study tool was $\alpha = 0.72$. and Data consistency and completeness were checked and data entry was done daily and the immediate correction was taken. For non-respondents three times revisit was done and consider as no-

respondent. Moreover, principal investigator and supervisors were made supervision on the data collection process to check the accuracy and validity of the questionnaire, Objective-based, logically sequenced, free of scientific terms and structured questionnaire was prepared, pre-testing of the questionnaire was done on five percent (5%) of the sample before the actual study period.

4.10 Data analysis

Data were coded, entered into EPI data v.7, and exported to SPSS version 25 statistical package for analysis. A descriptive statistical analysis was used to show the characteristics of the participants. Data cleanup was performed by checking for frequencies, accuracy, outliers, and consistencies and missed values and variables. Binary logistic regression was used to identify factors associated with the patient's level of knowledge and attitude on anesthesia informed consent. The cut point used during bivariate analysis was a p-value of less than 0.25 considered as fit for multivariate analysis. The crude and adjusted odds ratios with their corresponding 95% confidence intervals were computed. A comparison of variables was done using the Chi-Square test while P-values of 0.05 or less were considered significant. The results will be presented in text and tables based on the type of data.

4.11 Operational Definition

Attitude: patients belief and feeling about the anesthesia informed consent; it can be determined by using questioner's cumulative result of response alternative as shown below. ([22](#), [23](#))

- 0-50% poor level of attitude
- 51-100% good/high level of attitude

Knowledge: Real information that a person knows about anesthesia informed consent; it can be determined by using questioner's cumulative result of response alternative as shown below. ([22](#), [23](#))

- 0-50% poor level of knowledge
- 51-100% good/high level of knowledge

Competent: when the patient's age >18 years and able to decide for anesthesia to be given to him/her during surgery.

Preoperative assessment: is an assessment which gives opportunity to identify co-morbidities that may lead the patient to complication during anesthesia, surgery, and post operative period.

Preoperative care: is preparation and management of the patient prior to anesthesia.

Preoperative clinic: is a speciality clinic where patients are evaluated before surgery to establish a data base upon risk assessment and preoperative management decision can be made.

4.12. Ethical Considerations

Ethical clearance was obtained from the ethical clearance institutional review board (IRBs) from the department of anesthesia. Informed consent was taken from the study participants. Privacy and confidentiality were maintained throughout the study period; each questionnaire was coded without any personal identification.

4.13. Dissemination of result

The final report of the study will be presented and submitted to Addis Ababa University College of Health Sciences department of anesthesia for the fulfillment of the requirement and the paper will be sent for peer-reviewed publication.

5. Result

5.1 Socio-demographic characteristics of the patients

In this study, 409 (96.5%) patients participated in a response rate of 96.5%. The majority of the patients 158 (38.6%) were age above 35 years with the mean age of 35 ± 12 SD years. Two hundred thirteen (52.1%) and one hundred ninety-six (47.9%) participants are male and female respectively. Most participants are single (58.9%) and the rest were married (41.1%).

Orthodox Christianity was the most dominant religion 219 (53.5%) followed by protestant 144 (35.2%). Regarding educational status, majorities were illiterate about 149 (36.4%) and the remaining were below certificate 45 (11%), diploma 119 (29.1%), and above degree 96 (23.5%) (Table 1).

Table 1:- Sociodemographic characteristics of patients among elective surgery at selected public hospitals in Addis Ababa, in 2020. (n=409)

Variables	Category	Frequency(n)	Percent (%)
Age (years)	19-24	72	17.6
	25-30	114	27.9
	31-35	65	15.9
	>35	158	38.6
Sex	Male	213	52.1
	Female	196	47.9
Marital Status	Married	168	41.1
	Single	241	58.9
Religion	Christianity	219	53.5
	Protestant	144	35.2
	Jovawitnes	2	0.5
	Muslim	44	10.8
Educational level	Illiterate	149	36.4
	Below certificate	45	11.0
	Diploma	119	29.1
	Above degree	96	23.5
Types of surgery	Gynecology	98	24.0
	Obstetrics	100	24.4
	General	98	24.0
	Urologic	23	5.6
	ENT/Maxillofacial	45	11.0
	Others	45	11.0

5.2 Knowledge of patients on anesthesia informed consent

In this study, patient knowledge about the anesthesia informed consent, 65.8% were knowledgeable and 34.2% were not knowledgeable (fig; 1).

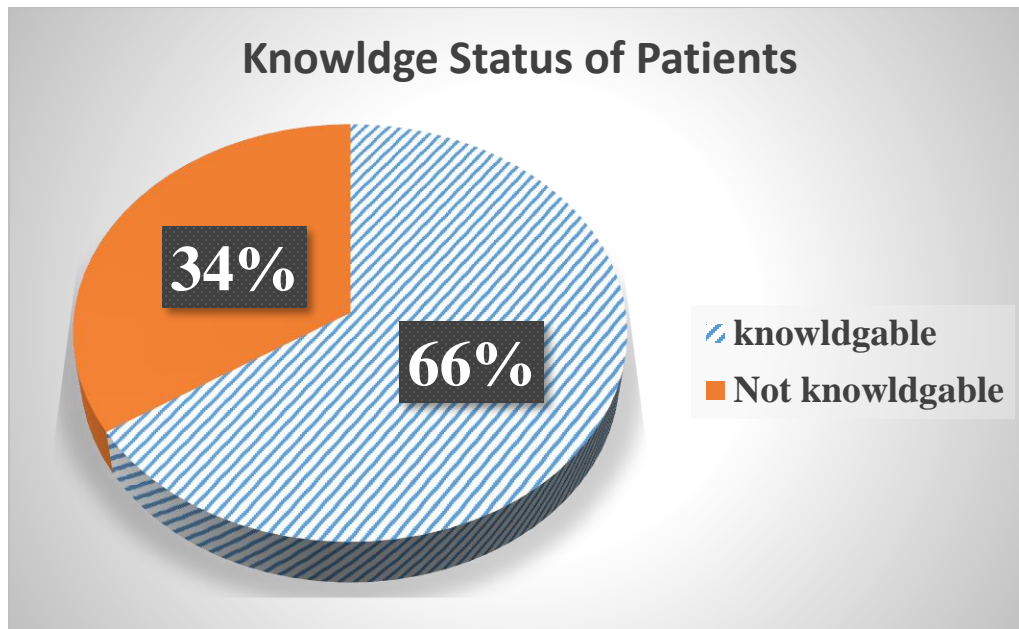


Figure:-1 knowledge status of the patients

A significant number of the patients did not know the reason for signing the anesthesia informed consent 174(42.5%). Also, most patients did not know who explain anesthesia informed consent 284(69.4%). The majority of the patients had no information about the benefit, alternatives, and risks/complications of anesthesia to be given at the day of surgery, 235(57.5), 315(77%), and 294(71.9%), respectively.

Related with the rights of patients most of them were did not know their right on asking unclear opinions regarding anesthesia and on their participation in the decision of their anesthesia, 277(67.7%), and 243 (59.4%) respectively (Table 2).

Table 2:- Knowledge of patients on anesthesia informed consent among elective surgery at selected public hospitals in Addis Ababa in 2020. (n=409)

Variables	Category	Frequency(n)	Percent (%)
Do you know about anesthesia informed consent?	Yes	207	50.6
	No	202	49.4
Do you know the reason for signing anesthesia informed consent?	Yes	235	57.5
	No	174	42.5
Do you know who can explain about the proposed anesthesia?	Yes	125	30.6
	No	284	69.4
Do you know the alternatives to your anesthesia?	Yes	94	23.0
	No	315	77.0
Do you know the benefits of anesthesia?	Yes	174	42.5
	No	235	57.5
Do you know the complication/risks of anesthesia?	Yes	115	28.1
	No	294	71.9
Do you know your right to ask questions on vague things related to anesthesia?	Yes	132	32.3
	No	277	67.7
Do you know your right to participate in the decision of anesthesia care?	Yes	166	40.6
	No	243	59.4

5.3 Attitude of the patient on anesthesia informed consent

In this study concerning the attitude of a patient, about 44.3% (181) had a good attitude, and 55.7% (228) had a poor attitude (fig 2).

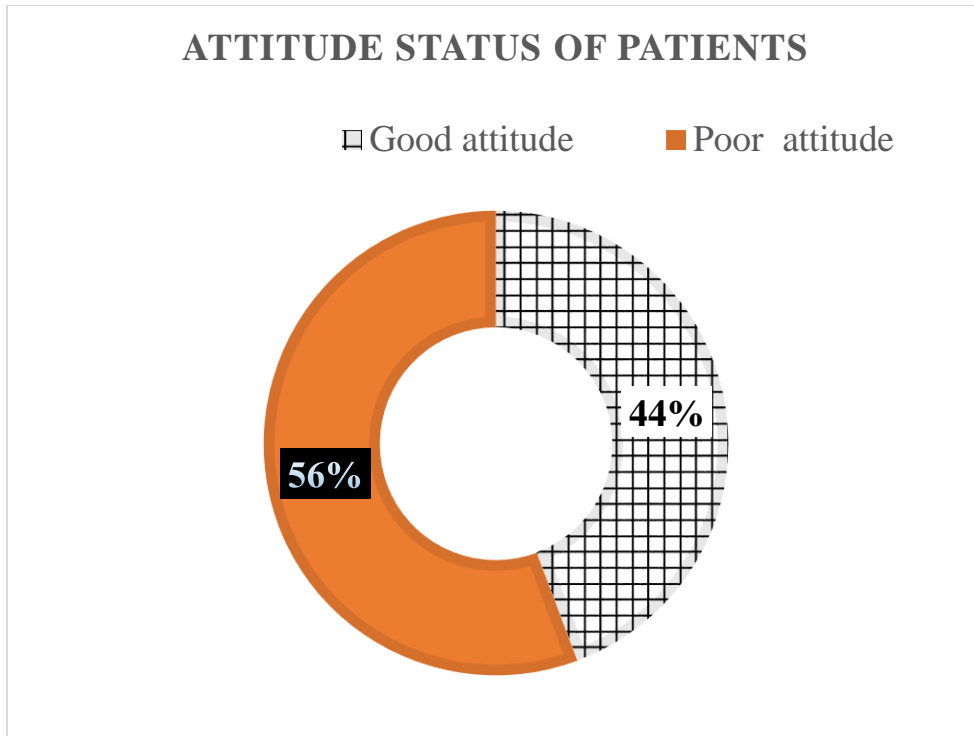


Figure 3 Attitude status of the patients.

Whatever most patients 219(53.5%) saying anesthesia informed consent was important. Greatest patients 265(64.8%) disagreed about anesthesia professional responsibility on providing information regarding anesthesia and about 144(35.2%) of patients were agreed anesthesia professionals were responsible for providing information related to anesthesia on consenting. Related with Anesthesia informed consent protection of anesthesia professional from being sue or reduction of family/relatives reaction to anesthesia and surgery outcome, majority patients disagreed 276(67.5%) and 133(32.5%) agreed.

Regarding on legality of anesthesia informed consent, Here also the same is true a majority of patients 291(71.1%) were disagree about the legality of anesthesia informed consent, others 118(28.9%). Related with the importance of knowing anesthesia benefits, alternatives, and risks/complication of anesthesia, patients were 260(63.6%) disagree, and 149(36.4%) agreed.

Regarding the rights of patients majorly on decision making, on the protection of their right, on their right to refuse after consenting anesthesia informed consent and lastly their right to change planed anesthesia after consenting majorities have disagreed about their right, 74.1%, 72%, 61.9%, and 79.5% respectively(Table 3).

Table 3:- Attitude of a patient on anesthesia informed consent among elective surgery at selected public hospitals in Addis Ababa in 2020. (n=409)

Variables	Category	Frequency(n)	Percent (%)
Is anesthesia informed consent important?	Yes	219	53.5
	No	190	46.5
Do you agree that anesthetists are responsible for providing information on anesthesia?	Disagree	265	64.8
	Agree	144	35.2
Do you agree anesthesia informed consent is a part of legal document?	Disagree	291	71.1
	Agree	118	28.9
Do you agree you are a part of the decision making for your anesthesia?	Disagree	303	74.1
	Agree	106	25.9
Do you agree with knowledge of anesthesia, alternatives, benefits, risks, and complications are very important?	Disagree	260	63.6
	Agree	149	36.4
Do you agree anesthesia consent protects the patient right?	Disagree	296	72.4
	Agree	113	27.6
Do you agree anesthesia informed consent protects the anesthesia professionals from sued?	Disagree	276	67.5
	Agree	133	32.5
Do you agree if you cannot sign the anesthesia informed consent the operation cannot take place?	Disagree	253	61.9
	Agree	156	38.1
Do you agree you have a right to change your mind after signing anesthesia informed consent?	Disagree	325	79.5
	Agree	84	20.5

5.4 Factors that affect patient knowledge on anesthesia informed consent

Sex, marital status, educational status, health professionals who provide anesthesia informed consent, place where anesthesia informed consent signed, a time when anesthesia informed consent signed and communication barriers had a significant association with patient's knowledge on anesthesia informed consent during bivariate analysis. However, marital status, educational level, professionals who provide anesthesia informed consent and place where anesthesia informed consent taken were significantly associated with patient's knowledge during the multivariate analysis. Patients who were single 50% more likely knowledgeable than married patients (AOR=.5, 95%CI; 0.06, 0.8). Patients who were educational status above degree had 2.1 times more knowledgeable than illiterates (AOR= 2.1, 95%CI; 0.04, 0.64). Patients who got anesthesia informed consent from surgeons 2.5 times have more knowledge than those who get from ward nurses (AOR= 2.5, 95%CI; 5.8,46.2). Patients who were signed anesthesia informed consent at the preoperative clinic were 99% more knowledgeable than those signed at ward (AOR= 0.1, 95%CI; 0.001,0.07) (Table 4).

Table 4:- Determinants of patient knowledge on anesthesia informed consent among elective surgery at selected public hospitals in Addis Ababa in 2020. (n=409)

Variable	Category	Known ged	Not knowled ged	COR (95%CI)	PV	AOR(95%CI)	PV
Sex	Male	120	93	0.4(0.26-0.6)	.001		
	Female	149	47	1		1	
Marital status	Married	54	86	.27(0.18-0.4)	.001	.5(0.06-0.8)	.023
	Single	187	82	1		1	
Educational status	Illiterate	13	83	1		1	
	Below certificate	84	35	1.06(.03-.13)	.001	1.16(.04-.64)	.009
	Diploma	38	7	3.7(1.9-7.2)	.001	2.8(.9-8.4)	.054
	Above degree	134	15	2.2(.9-5.5)	.075	3.1(.8-11.9)	.099
Who provides AIC	Anesthesia professionals	39	58	1.5(.87-2.5)	.14	1.74(.35-1.5)	.4
	Doctor surgeon	63	63	31.6(13.4-74.8)	.001	2.5(5.8-46.2)	.001
	operation nurse	18	12	2.2(.96-5.1)	.060	.23(.06-.82)	.024
	ward nurse	149	7	1		1	
Where AIC signed	Preoperative clinic	17	75	1		1	
	At Ward	117	33	.02(.01-.07)	.001	.01(.001-.07)	.001
	Operation Theater	103	29	.3(.09-1.1)	.083	.01(.001-.08)	.001
	Operation table	32	3	.3(.09-1.1)	.085	.02(.002-.19)	.001
When AIC signed	>2 days before surgery	19	32	.2(.09-.36)	.001		
	2 days before surgery	46	67	12.8(3-54.6)	.001		
	1 day before surgery	123	39	.2(.13-.36)	.001		
	At the day of surgery	81	2	1		1	
Translator needed (communication)	Yes	32	83	10.7(6.5-18)	.001		
	No	237	57	1		1	

Key AIC – anesthesia informed consent

5.5 Factors affecting patient attitude towards anesthesia informed consent.

Sex, marital status, educational status, health professionals who provide anesthesia informed consent, place where anesthesia informed consent signed, a time when anesthesia informed consent signed and communication barriers had a significant association with patient's attitude on anesthesia informed consent during bivariate analysis. However, sex, marital status, educational level, and place where an anesthesia informed consent provided were significantly associated with patient attitude during multivariate analysis. Female patients were 68% more likely to have a better attitude towards anesthesia informed consent than males. Single patients 25% more likely to have a better attitude than married patients (AOR=.75, 0.02, 0.23).

Patients who were educational status above degree holders had about 4.3 times a better attitude than illiterates (AOR=4.3, 95%CI; 0.05, 0.82). Patients who were signed anesthesia informed consent at the preoperative clinic were 99% had a better attitude than those signed at the ward (AOR= 0.01, 95%CI; 0.00, 0.06) (Table 5).

Table 5:- Determinants of patient attitude on anesthesia informed consent among elective surgery at selected public hospitals in Addis Ababa in 2020. (n=409)

Variable	Category	Positive attitude	Negative attitude	COR(95%CI)	PV	AOR(95%CI)	PV
Sex	Male	77	136	.50(.33-.74)	.001	.32(.12-.80)	.015
	Female	104	92	1		1	
Age	19-24	23	49	.43(.24-.78)	.005		
	25-30	43	71	.56(.34-.91)	.021		
	31-35	33	32	.95(.53-1.70)	.87		
	>35	82	76	1		1	
Marital status	Married	37	131	.19(.12-.29)	.001	.75(.02-.23)	.001
	Single	144	97	1		1	
Educational status	Illiterate	14	82	1		1	
	Below certificate	39	110	0.75(.02-.10)	.001	1.22(.05-.82)	.025
	Diploma	91	28	1.11(.06-.19)	.001	2.22(.08-.57)	.002
	Above degree	37	8	1.42(.59-3.4)	.429	4.3(1.3-14)	.016
Who provide AIC	Anesthesia professionals	32	65	1.29(.74-2.25)	.36		
	Doctor surgeon	49	77	2.03(1.19-3.4)	.001		
	operation nurse	78	78	5.58(2.24-13.9)	.001		
	ward nurse	22	8	1		1	
Where AIC signed	Preoperative clinic	18	74	1		1	
	At Ward	52	98	0.01(.00-.06)	.001	0.03(.00-.08)	.001
	Operation Theater	78	54	0.03(.00-.13)	.001	0.07(.03-.11)	.001
	Operation table	33	2	0.08(.02-.38)	.001	0.01(.00-.06)	.001
When AIC signed	>2 days before surgery	9	74	0.44(.23-.84)	.013		
	2 days before surgery	21	30	0.07(.03-.16)	.001		
	1 day before surgery	52	61	0.54(.33-.88)	.014		
	At the day of surgery	99	63	1		1	
Translator needed (communication)	Yes	31	84	2.82(1.76-4.52)	.001		
	No	150	144	1		1	

Key: AIC- anesthesia informed consent.

5.6 Relationship between knowledge, attitude and associated factors towards anesthesia informed consent.

it was found that Pearson's coefficient ($r= 0.228, (-1 \leq r \leq 1)$) by taking knowledge as dependant variable, and attitude independent variable the patients have a small positive correlation (i.e. knowledge of the patients towards anesthesia informed consent increases with the increasing patients attitude).(Table 6)

Table 6: Correlations between knowledge(dependant) and attitude(independant) towards anesthesia informed consent

		Knowledge status of the respondent	Attitude status of the respondents
knowledge status of the respondent	Pearson Correlation	1	.228**
	Sig. (2-tailed)		.000
	N	409	409
Attitude status of the respondents	Pearson Correlation	.228**	1
	Sig. (2-tailed)	.000	
	N	409	409

Key **. Correlation is significant at the 0.01 level (2-tailed).

5.7 Relationship between knowledge, and associated factors towards anesthesia informed consent.

The relationship of patient’s knowledge and factors marital status, educational level, professionals, and places were 0.3, 0.32, -0.14, and 0.4 Pearson's coefficient(r) respectively. Almost all have Positive except place were anesthesia informed consent which have weake negative relationship bettewen patients knowledge.

5.8 Relationship between attitude, and associated factors towards anesthesia informed consent.

Regarding relation of attitude with determinants sex, marital status, educational level, and place (0.2, 0.4, 0.5, & 0.4) got Pearson's correlation coefficient of positive relation, They have positive correlation.

6. Discussion

This research study showed as our patient's level of knowledge, level of attitude, and some factors which affected them as well as it also gives us a hint on our institution's practice on anesthesia informed consent.

It was found that 34.2% of patients had poor knowledge about anesthesia informed consent. This finding was supported by the same study conducted in Istanbul(18). Another study conducted in Rwanda showed that 83% of study participants had poor knowledge of informed consent(22). This might be related to cultural and traditional, facility setup, and information system of the country.

As multivariable analysis results showed that marital status, educational level, professionals who provide anesthesia informed consent and place where anesthesia informed consent was taken were significantly associated with patient knowledge. For instance, patients with marital status single were 50% more likely to know anesthesia informed consent as compared to married patients. This finding did not have any published supporting study it was the finding of this study.

It was difficult for justification, but the finding might be related to a marital status single had time to explore extra/additional information on anesthesia when compared with married patients they had extra responsibility to their children and family members (social role theory).(32)

Also, those who had educational status above degree were 2.1 times more knowledgeable as compared to illiterates, therefore, patients who have higher the level of education have a higher level of knowledge. This outcome respects a similar study conducted in Rwanda(22) and southeast Nigeria(25). This might be due to their literacy level and their habit of reading may be better than other patients.

Patients who got anesthesia informed consent from surgeons were 2.5 times had more knowledge about the anesthesia informed consent as compared to those who got from ward nurses. And Patients who got anesthesia informed consent from anesthesia professionals were 1.74 times more knowledgeable as compared with those who got from ward nurses. This study supported by research conducted in South Africa (20, 33). This might be due to the reason for anesthesia informed consent be signed by anesthesia professionals because they are the owner of the field of study and it believed that they have a better understanding of anesthesia than other professionals and surgeons also somehow have near to the anesthesia practice than ward nurses.

Patients who obtained anesthesia informed consent at the preoperative clinics were 99% more knew about the consent as compared to those who informed at Operation Theater. This study supported by the study conducted in the USA (27) and Portugal (34). This might be for the reason of having sufficient time to discuss the anesthesia, and also it gives time to think and ask questions regarding anesthesia than ward and other areas.

Regarding the attitude of patients 44.3% had a better attitude on anesthesia informed consent. This result of the study was supported by the study conducted in Nigeria(23). This might be a result of insufficient patient education on anesthesia informed consent at a perioperative time by anesthesia professionals or the poor practice of the anesthesia professionals on informed consent or might be a poor institutional policy on anesthesia informed consent.

By way of a multivariable analysis suggesting that Sex, marital status, educational level, and place where anesthesia informed consent was provided was significantly associated with patient attitude. For example, Female patients had 68% more likely to have a better attitude towards anesthesia informed consent than males. There were no supporting articles on the marital status of this outcome of the study. It might be because of social role theory.(32)

Patients who were single 25% had a better attitude than married patients on the anesthesia informed consent. Also, this outcome had no similar study which supports it. It was challenging to justify, it might be a marital status single had time to explore extra/additional information on anesthesia when compared with married patients they had extra responsibility to their children and family members (social role theory).(32)

Patients whose educational status above degree were found that 4.3 times had a better attitude than illiterates towards anesthesia informed consent. This outcome has supported the study conducted in the UK(35) and Nigeria(23). As it was known that more educated persons are near to the information Medias and search.

Patients who were signed anesthesia informed consent at the preoperative clinics were 99% more likely had a better attitude compared with those who signed at the ward on anesthesia informed consent. Here also no published materials which support the outcome of the study. It was really that patients and professionals have enough time to discuss and plan what is going on perioperatively in detail there, this might favor their better attitude.

7. Conclusion

The study showed that the knowledge and attitude of the patients under the investigation were limited to anesthesia informed consent. The main factors marital status, educational level, professional who provides anesthesia informed consent, and a place where anesthesia informed consent taken were significantly affected patient's knowledge of the study. And sex, marital status, educational level, and place where anesthesia informed consent also affected a patient's attitudes similarly. Preoperative education promotion anesthesia informed consent, the establishment of the preoperative clinic, and assigning senior professionals were needed before consenting the patient.

8. Recommendations and Limitations

- If the study design were observational the study might show us the most real finding.
- Its better every hospital recruit translators for each language.
- It was ideal for each institution to establish preoperative clinics
- The informed consent must be separated from others or anesthesia informed consent must be signed separately.
- The informed consent must be prepared again to the standard.

8.1 Limitation

- Corona pandemic
- Limited supporting articles

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Annex 1 English version

Consent

My name is and I am MSC student in anesthesia at Addis Ababa University. Now I am working as investigator for the research being conducted to assess patient's knowledge, attitude and associated factors on anesthesia informed consent at selected public hospital at Addis Ababa. Purpose of the study was evidence and input for high decision makers at hospitals and country level, participating on the study not have any risks also the information provided from you confidential. Giving permission for this study is fully voluntary. I kindly request you to express your understanding freely about your anesthesia informed consent for the planed anesthesia.

Are you voluntary?

1. Yes
2. No

Contacts:-Tamrat kelelegn (BSc in anesthesia), Addis Ababa

Mobile phone: +251984203089 E-mail: tkelelegn@gmail.com

Self-administered/interview Questionnaires

Section 1:- Demographic data

- 1.1 Sex 1. Male 2. Female
- 1.2 Age
- 1.3 Marital status 1. Married 2. Single 3. Divorce
- 1.4 Literacy level 1. Illiterate 2. High school 3. College diploma 4. University degree
5. Master's degree 6. Others
- 1.5 Religion 1. Christianity 2. Protestant 3. Jehovah witness 4. Islam 5. Other
.....
- 1.6 Types of surgery (data collectors) 1. Gynecologic 2. Obstetric 3. General 4.
Urologic 5. ENT/maxillofacial 6. Cardiothoracic 7. Neurologic 8. Other

Section 2:- Questions to assess patient knowledge of anesthesia informed consent.

- 2.1 Do you know about anesthesia informed consent? 1. Yes, 2. No
- 1.1 Source of information 1. Anesthesia professionals
2. Surgeons 3. Media 4. Another source.....
- 2.2 Do you know the reason for signing anesthesia informed consent? 1. Yes, 2. No
- 2.3 Do you know who can explain about the proposed anesthesia? 1. Yes, 2. No
- 2.4 Do you know the alternatives to anesthesia? 1. Yes, 2. No
- 2.5 Do you know the benefits of anesthesia? 1. Yes, 2. No
- 2.6 Do you know the complication/risks of anesthesia? 1. Yes, 2. No
- 2.7 Do you know your right to ask questions on vague things related to anesthesia? 1. Yes, 2.
No
- 2.8 Do you know your right to participate in the decision of anesthesia care? 1. Yes, 2. No

Section 3:- Questions to assess patient attitude towards anesthesia informed consent

- 3.1 Is anesthesia informed consent important? 1. Yes, 2. No
- 3.2 If your answer for Q# 3.1 is yes, do you agree that anesthetists are responsible for
providing information on anesthesia? 1. Strongly agree 2. Agree 3. Not sure 4.
Disagree 5. Strongly disagree

- 3.3 Do you agree anesthesia informed consent is a part of legal document? 1. Strongly agree
2. Agree 3. Not sure 4. Disagree 5. Strongly disagree
- 3.4 Do you agree you are a part of the decision making for your anesthesia? 1. Strongly agree
2. Agree 3. Not sure 4. Disagree 5. Strongly disagree
- 3.5 Do you agree with knowledge of anesthesia, alternatives, benefits, risks, and complications are very important? 1. Strongly agree 2. Agree 3. Not sure 4. Disagree
5. Strongly disagree
- 3.6 Do you agree anesthesia consent protects the patient right? 1. Strongly agree 2. Agree
3. Not sure 4. Disagree 5. Strongly disagree
- 3.7 Do you agree anesthesia consent protects the anesthesia professionals from sued? 1.
Strongly agree 2. Agree 3. Not sure 4. Disagree 5. Strongly disagree
- 3.8 Do you agree if you cannot sign the anesthesia informed consent the operation cannot take place? 1. Strongly agree 2. Agree 3. Not sure 4. Disagree 5. Strongly disagree
- 3.9 Do you agree you have a right to change your mind after signing anesthesia informed consent? 1. Strongly agree 2. Agree 3. Not sure 4. Disagree 5. Strongly disagree

Section 4: Questions on factors which affects the patient's knowledge and attitude

- 4.1 Who will sign the anesthesia informed consent? 1. Self 2. Sister/brother 3.
Mother/father 4. Wife/husband 5.other
- 4.2 Who gives you anesthesia informed consent? 1. Anesthesia professionals 2. Surgeons
3. Operation nurses 4. Ward nurses 5. Physician
- 4.3 Where did the anesthesia informed consent take? 1. Preoperative clinic 2. Ward 3.
Operation Theater 4. Operation table
- 4.4 When had the anesthesia informed consent taken? 1. More than two days before surgery
2. Two days before surgery 3. One day before surgery 4. At the day of surgery
- 4.5 Do you need a translator to communicate with anesthetists? 1. Yes, 2. No

Annex 2 Amharic version

የስምምነት ዉል፤

ስሜ ታራምት ከለላኝ ይባላል በአድስ አበባ ዩንቨርስቲ የአንስቴዥያ ህክምና ማስተርስ ተማሪ ነኝ። አሁን ለመመረቅ ጥናት ለማድረግ የታካምዎችን እዉቀት፣ አመለካከት እና የአንስቴዥያ ዉል አወሳሰድ ዙሪያ ያሉ ችግሮች ለማጥናት መረጃ እየሰበሰብኩኝ እገኛለዉ። መረጃዉ የምሰበሰበዉ በተመረጡ ሆስፒታሎች ላይ። የጥናቱ ዉጤት ለሆስፒታሎች እና ለከፍተኛ ዉሳኔ ሰጭዎች እንዴ ግባዔት ያገለግላል፤ የጥናቱ ተሳታፊዎች ላይ ምንም አይነት ጉዳት አያመጥም እናም ምሰጥራውንም የተጠበቀ ስሆን፤ በሙሉ ፍቃደኝነት ላይ የተመሰረተ ነዉ። ስለ አንስቴዥያ ዉል በተዘጋጅዉ መጠይቅ ዙርያ ያሉትን ምልክታ አዉቀት በነጻነት እንድመልሱ በትህተና እጠይቃለሁ።

ፍቃደኛ ኖት?

1. አዉ

2. አይ

መጠይቅ

MRN:

code

ክፍል:-1 ስነ-ህዝባዊ መረጃ

1.1 ጾታ 1. ወንድ 2. ሴት

1.2 እድሜ

1.3 የጋብቻ ሁኔታ 1. ያላግባ 2. ያገባ 3. አግብቶ/አግብታ የፈታች 4. ሌላ

1.4 የትምህርት ደረጃ 1. ያልተማሬ 2. ሁለተኛ/ከፍተኛ ደረጃ ትምህርት 3. ድፕሎማ 4. ድግር 5. ማስተርስ 6. ሌላ

1.5 ሀይማኖት 1. ኦርቶዶክስ 2. ፕሮተስታንት 3. ጆሻ 4. እስላም 5. ሌላ

1.6 Types of surgery (data collectors) 1. Gynecologic 2. Obstetric 3. General 4. Urologic 5. ENT/maxillofacial 6. Cardiothoracic 7. Neurologic 8. Other

ክፍል:-2 ስለ ሰሙሙን ዉል ታካምዉ ያለዉ እዉቀት

2.1 ስለ አንስቴዥያ ዉል/ፍቃድ ያቃሉ? 1. አዉ 2. በክፍል 3. አይ

2.1.1 አዉ ካሉ ከየት ሰሙ? 1. ከአንስቴዥያ ባለሙያ 2. ከቀድሞ-ሀኪምና ሀኪም 3. ከመረጃ ጣብያዎች 4. ከሌላ አካላት

2.2 የአንስቴዥያ ዉል/ፍቃድ የምፈርሙበትን ምክንያት ያቃሉ? 1. አዉ 2. በክፍል 3. አይ

2.3 ስለ ምታቀደዉ አንስቴዥያ ማን ማብራሪያ እንደምሰጡት ያቃሉ? 1. አዉ 2. በክፍል 3. አይ

2.4 ሌላ የአንስቴዥያ አማራጮችን ያቃሉ? 1. አዉ 2. በክፍል 3. አይ

2.5 የአንስቴዥያ ጥቅሞችን ያቃሉ? 1. አዉ 2. በክፍል 3. አይ

2.6 ከአንስቴዥያ ጋር ተያይዘዉ ልመጡ ስለምችሉ ጉዳዮች/ችግሮች ያቃሉ? 1. አዉ 2. በክፍል 3. አይ

2.7 ከአንስቴዥያ የተያያዙ ግልፅ ያልሆነ ነገር ካለ መጠየቅ እንደምችሉ ያቃሉ? 1. አዉ 2. በክፍል 3. አይ

2.8 ስለምሰጡት አንስቼዥ ዉሳኔ ላይ የመሳተፍ መብት እንዳሉት ያቃሉ? 1. አዉ 2. በከፍል 3. አይ

ክፍል:-3 ስለ አንስቼዥ ዉል ታካምዉ ያለዉ አመለካከት (ጠባይ) ፣

3.1 የአንስቼዥ ዉል/ፍቃድ ጠቃም ነዉ? 1. አዉ 2. አይ

አዉ ካሉ፣

3.2 የአንስቼዥ ባለሞያዎች ስለ አንስቼዥ መረጃዎችን የመስጠት ሀላፊነት አላቸዉ ብለዉ ይስማማሉ?

- 1. በጣም እስማማለሁ
- 2. እስማማለሁ
- 3. እርግጠኛ አይደለሁም
- 4. አልስማማም
- 5. በጣም አልስማማም

3.3 የአንስቼዥ ዉል/ፍቃድ የህጋዊ ሰነድ አካል ነዉ ብለዉ ይስማማሉ? 1. በጣም እስማማለሁ 2.

- እስማማለሁ
- 3. እርግጠኛ አይደለሁም
- 4. አልስማማም
- 5. በጣም አልስማማም

3.4 ስለምሰጡት አንስቼዥ ዉሳኔ አካል በመሆኖ ይስማማሉ? 1. በጣም እስማማለሁ 2. እስማማለሁ

- 3. እርግጠኛ አይደለሁም
- 4. አልስማማም
- 5. በጣም አልስማማም

3.5 በአንስቼዥ ጥቅሞች እና ጉዳዮች/ችግሮች ላይ ያሉት/የምኖሮት እዉቀት ጠቃም ነዉ ብለዉ

ይስማማሉ? 1. በጣም እስማማለሁ 2. እስማማለሁ 3. እርግጠኛ አይደለሁም 4. አልስማማም 5.

በጣም አልስማማም

3.6 የአንስቼዥ ዉል/ፍቃድ የህሙማንን መብት ይጠብቃል ብለዉ ይስማማሉ? 1. በጣም እስማማለሁ

- 2. እስማማለሁ
- 3. እርግጠኛ አይደለሁም
- 4. አልስማማም
- 5. በጣም አልስማማም

3.7 የአንስቼዥ ዉል/ፍቃድ የሰመመን ባለሞያዎችን መብት ይጠብቃል ብለዉ ይስማማሉ? 1. በጣም

- እስማማለሁ
- 2. እስማማለሁ
- 3. እርግጠኛ አይደለሁም
- 4. አልስማማም
- 5. በጣም አልስማማም

3.8 የአንስቼዥ ዉል/ፍቃድ ካልፈረምኩኝ የቀድሞ-ህክምናዉ አይሰራም ብለዉ ይስማማሉ? 1.

- በጣም እስማማለሁ
- 2. እስማማለሁ
- 3. እርግጠኛ አይደለሁም
- 4. አልስማማም
- 5. በጣም

አልስማማም

3.9 የአንስቴዥያ ዉል/ፍቃድ ተስማምተዉ ከፈረሙ በኋላ እቅድን መቀየር እችላለሁ ብለዉ ይስማማሉ? 1. በጣም እስማማለሁ 2. እስማማለሁ 3. እርግጠኛ አይደለሁም 4. አልስማማም 5. በጣም አልስማማም

ክፍል:-4 የታካሚዉን እዉቀት እና አመለካከት ላይ ጫና የምያደርጉ ነገሮች

4.1 ማን ነዉ የአንስቴዥያ ዉል/ፍቃድ የምፈረምሎት? 1. እኔ 2. እህቴ/ወንድሜ 3. አባቴ/እናቴ 4. ባሌ/ምስቴ 5. ሌላ

4.2 የአንስቴዥያ ዉል/ፍቃድ የምያስፈርምህ ማን ነዉ? 1. የቀዶ-ህክምናዉ ሀኪም 2. የአንስቴዥያ ባለሞያዉ 3. የአፕራስዮን ክፍል ነርሶች 4. የተኝቶ ሀኪምና ክፍል ነርሶች

4.3 የት ነዉ የአንስቴዥያ ዉል/ፍቃድ የምወሰደዉ? 1. ቅድመ ቀዶ-ህክምና ምርመራ ክፍል 2. ተኝተዉ የምታከሙበት ክፍል 3. ቀዶ-ህክምና ክፍል 4. ቀዶ-ህክምና አልጋ ላይ 5. ሌላ

4.4 መች ነዉ የአንስቴዥያ ዉል/ፍቃድ የተወሰደዉ? 1. ከአንድ ቀን በፍት 2. ከሁለት ቀን በፍት 3. ከሶስት ቀን በፍት 4. በቀዶ-ህክምናዉ ቀን 5. ሌላ

4.5 አስተርጓሚ ፈልገዉ ነበር ከአንስቴዥያ ባለሞያዎች ለመግባባት? 1. አዉ 2. አይ አዉ ካሉ የየትኛዉ ቋንቋ?

ስለ ትብብር በጣም አመሰግናለሁ!!!!

Meeting NO. 6/2019

IRB'S Decision

Protocol Number-- 22

Date (D/M/y) Dec 16/2019

Protocol title – Assessment of Patient's Knowledge attitude and associated factors on anesthesia informed consent among elective operation at Addis Ababa Public Hospital from October 30 2019 – January 30 2020	
Principal Investigator	Tamirat Kelelegn Bekele
Institute	AAU-SOM Department of Anesthesia
Elements reviewed (AAUMF 01-008)	<input checked="" type="checkbox"/> Attached <input type="checkbox"/> not Attached
Review of Reviewed Application <input type="checkbox"/> YES <input type="checkbox"/> NO	Date of previous Review
Decision of the meeting	<input checked="" type="checkbox"/> Approved <input type="checkbox"/> Approved with recommendation <input type="checkbox"/> Resubmission <input type="checkbox"/> Disapproved

Assigned No – 22/ 2019

I Elements approved

1. Protocol version no
2. Protocol version Date
3. Informed consent version NO
4. Informed consent

V obligations of the PI –

I. Obligations of the PI-

1. Should comply with the national and international standards of scientific and ethical guidelines
2. If the PI makes any changes to the protocol during the period of this approval he/she must submit a revised protocol to the IRB for approval before implementing the change
3. The approval process is for a period of time not to exceed one year from the date of the approval
4. A report requesting an extension is required for all activities that exceed one year
5. The PI is responsible for providing the IRB with findings and/or notification of the status of the research at the completion of the project

Institution review board (IRB) approval: period from December to June follow up report export expected in 3months _____
6month _____ 9month_ one year _____

IRB Coordinator

Signature

[Handwritten signature]

Director

signature

[Handwritten signature]

*Luliyayitu Akalu
Head of Anesthesia*



ዲግሞዊ ምኒሊክ ሪፈራ ሆስፒታል የቀዳሚ ህክምና ለማድረግ የፈቃደኝነት መግለጫ ቅፅ

እኔ እድሜ ያለ የክርድ ቁጥር
በደ/ር በአንስቴቲስት (የቀዳሚ ህክምና/የማህንጃር ጸንሰ
ቀዳሚ ህክምና/ገለጅ/ቀዳሚ ህክምና በራሴ/በልጅ/በሌላ ላይ እንዲደረግ
እንዲሁም ህክምናውን ለማካሄድ የሚያስፈልገውን የአንስቴዲያ መድሀኒት እንዲሰጠኝ በፈቃደኝነት
ተስማምቼአለሁ። የሚሰራው የአፕራሲዮን እይነት (Pain Management) [ጥቅም ጉዳት ሌላ የህክምና አማራጭ
ወይንም ወይም አለመኖር ተብራርቶልኝ ለነገራዬ ጥያቄዎች በሚገባ መልስ ተሰጥቶልኝ።

ህክምናው የሚደረገው ታካሚው በአንስቴዲያ ተጽዕኖ ስር እያለ በመሆኑ በቅድሚያ ያልተወቀ ግን በአፕራሲዮን ወቅት የታየና
መሰተካክል የሚገባው የጤና ችግር ካጋጠመኝ ታካሚው ቀድሞ አልተገኘውም ተብሎ ሳይሰተካክል መተው ስለሌለበት
የህክምና ውይይት ስነ ምግባር በሚፈቅደው መሰረት ባለሞያዎቹ ሙሉ ዕውቀታቸውንና ችሎታውን በመጠቀም አስፈላጊ ነው
ራሴ ላይ ስለሚደረገው ህክምናውን እንዲያሻሽሉኝ እንዲጨምሩ ወይም እንዲለውጡ ሙሉ ጋላፊነት ሰጥቼአለሁ።

በቀዳሚ ህክምና ሂደት ለማንም ባለውያን በእርግጠኝነት መተንበይ ስለሚያዳግት የትኛውም የህክምና ባለሙያም ሆነ
ሆስፒታል ለውጤቱ ዋስትና ሊሰጥ አይችልም፤ በመሆኑም ቀድሞ ያልተገመቱ ነገር ግን በቀዳሚ ህክምና ሰዓት የሚከሰቱ
በቀዳሚ ህክምና ወይም ከአንስቴዲያው ወይም ከታካሚው የጤና ሁኔታ ጋር በተያያዘ ለህይወት የሚያሰኑ ክፍትም በላይ
የሆኑ ውርቅና የሌላቸው ችግሮች ሊያጋጥሙ እንደሚችሉ ተገልጿል።

በቀዳሚ ህክምና ለምርመራ ከሰውነት የሚወጡ የአካል ክፍሎች እንደሁኔታው በላቡራቶሪ ከተመረመሩ በሃላ ሆስፒታል
እንዲወገድ ያደርጋል። አስፈላጊ ሲሆን ማንነታቸው በሰም ሳይገለጹ ለሌላ ምርመራ ለምርመራ ለማስተማሪያነት ሊቀመጡ
እንደሚችሉ እና ይህም በታካሚው ላይ የሚያመጣው ምንም ዓይነት ጉዳት እንደሌለው ተገልጿልና ተቀብያለሁ።

የምና የደም ውጤቶችን በተመለከተ

የደም ስርዓት ጊዜ ከፍተኛ የደም መፍሰስ ቢያጋጥም ደምና የደም ውጤቶችን መውሰድ ያለውን ጥቅምና ጉዳት ተነግሮኝ
ፈለጠኝ የሚገባ መሆኑን ባለሙያው ካመነበት ሊሰጠኝ እንደሚችል (ይከበብ) ተስማምቼአለሁ / አልተስማማሁም።

የጥንቅቅ እካልን ቆርጦ ማስወገድ የሚያስፈልግ ህክምናን በተመለከተ

የሚደረግ የህክምና ዓይነት እካልን ቆርጦ ማስወገድ እንደሚያስፈልግ በሀኪሜ በተገለጸልኝ መሰረት (ይከበብ) (የግራ
ቶች) (አጂ/አግር) ሌላ ይገለጻል ተቆርጦ እንዲወገድ (ይከበብ)
ተስማምቼአለሁ / አልተስማማሁም።

ታካሚው ወይም የቤተሰብ ስም ፊርማ ቀን 16 ወር 23 9.ም

- የሰዓቶች 1ኛ ፊርማ
- 2ኛ ፊርማ
- 3ኛ ፊርማ

- ማሳሰቢያ**
1. የሰዓቶች ስልጣን ደርሞ በታካሚው መፈረም አለበት። ነገር ግን ታካሚው ከህመሙ የተነሳ ለመፈረም
 በማይችልበት ጊዜ የቅርብ ዘመዶች መፈረም አለበት።
 2. ታካሚው ዕድሜ ከ 18 ዓመት በታች ለሆኑ ህፃናት ወላጆቻቸው ወይም በህግ የተወከለ አሳዳጊ ሕጋዊ ውክልና
 ያለው የመንግስት አካል ሊፈረም ይችላል።
 3. ሕሊናውን ለየተ ታካሚ ከሆነ ህጋዊ ተወካይ ወይም በህግ የተወከለ የመንግስት ተወካይ ወይም ዋናው ህኪምና
 የሰራ ስልጣን አብረው ሊፈረሙለት ይችላሉ።

የካቲት 12 ሆ/ል ሜ/ኮሌጅ

የአንስቲኛርያ (ማደንዘዣ፣ ሰመመን)

ስምምነት ቅፅ

ቀን:	_____
ስም:	_____
የክርድቁጥር:	_____
ዕድሜ:	_____
ፆታ:	_____
አድራሻ:	_____
መኝታ ክፍል:	_____

እኔ ስሜ ከላይ የተጠቀሰው ታካሚ ለሰራሳዊ ለታተደው የተደረገ ህክምና ወይም ለሌላ የህክምና ምርመራ የሚያስፈልገውን የአንስቲኛርያ (ማደንዘዣ፣ ሰመመን) አይነት መርጠው ወር/ክፍ/ወት/ደ/ር _____ እና የሰራ-ባልደረቦቻቸው እንዲሰጡኝ ፈቅጃለሁ። ያሉትም የአንስቲኛርያ (ማደንዘዣ፣ ሰመመን) አማራጮች፣ ጥቅማቸውና ጉዳታቸው፣ ሊያጋጥሙ የሚችሉ የሚጠበቁና የማይጠበቁ ውጤቶች በዝርዝር ተነግሮኝ ለመወሰን ዕድል ተሰጥቶኛል።

ታካሚ ወይም ታካሚውን የሚወክል ሰው ስም: _____

ታካሚ ወይም ታካሚውን የሚወክል ሰው ፊርማ: _____ ቀን _____

ታካሚውን የሚወክለው ሰው የዝምድና ሁኔታ: _____

ቅጹን ያስፈረመው ባለሙያ ስምና ፊርማ: ቀን _____

የዘውዲቱ መታሰቢያ ሆስፒታል
የቀዶ ህክምና እና የአካላዊ ስምምነት ቅጽ

የታካሚዎ/ሰም _____
 እና ስሜ ከዚህ በላይ የተጠቀሰው በዶክተር _____
 እንዲደረግልኝ ተስማምቻለሁ። ዶክተር _____
 የመረጣቸው ሀኪሞች ቀዶ ህክምናውን ካለ ምንም መዘግየት እንዲያደርጉልኝ እንዲወሰኑ ፈቅጃለሁ።
 እና በሰራ ባልደረገባቸው የቀዶ ህክምና
 ቀዶ ህክምናውን ለማከናወን ባይችሉ ሌሎች አላቸው
 ከዚህ በታች የተገለጹት መረጃዎች እንደቀረቡልኝ እና እየተሰማግጡ አረጋግጣለሁ።

1. በሽታው ዓይነት _____
2. የቀዶ ህክምናው የሚደረግበት ምክንያት _____
3. የቀዶ ህክምናው ሊያመጣው የሚችለው ችግር _____
4. ለበሽታዬ ህክምና ባይደረግ ሊመጣ የሚችለውን ችግር _____

5. በቀዶ ህክምና ወቅት በሚገኙ ተጨማሪ በሽታዎች ወይም በሚደገቡ ተጋዳሪ ችግሮች ላይ ተጨማሪ ህክምና ወይም ሐኪም አስፈላጊ ሆኖ ቢገኝ ምንም እንኳን አስቸኳይ ባይሆንም ከላይ በተጠቀሰው ዶክተር ወይም በሰራ ባልደረገባቸው ህክምናው እንዲደረግልኝ ፈቅጃለሁ። ይህ ተጨማሪ ቀዶ ህክምና እሁን ከተገኘኝ አደጋዎች የተለየ አደጋዎች ሊኖሩት እንደሚችሉ ተገልጿል። ሆኖም ግን ከላይ ለተጠቀሰው ዶክተር እና ባልደረገባቸው ተጨማሪውን ህክምና እንዲያደርጉልኝ ፈቅጃለሁ።

6. በቀዶ ህክምናው ወቅት ወይም ከቀዶ ህክምናው በኋላ የደም ልጎ ሲያሰረድ ለምሳሌ ለመሰንጠን አስማግለሁ _____

አልሰማግጥም _____ የማልሰማግጥበት ምክንያት _____
 ነው። ደም ከወሰድኩ _____

ሊያመጣቸው የሚችላቸው ችግሮች _____ መሆኑ ተነግሮኝ ተረድቻለሁ።

7. ለህክምናና ለሳይንስ ትምህርት ቀዶ ህክምናዬ በማካሄድበት ሰአት ተመሳሳዮች እንዲኖሩ ፈቅጃለሁ። ከዚህም በተጨማሪ በህክምና ትምህርትና ለሳይንስ ሚጠቅሙ ፎተግራፎች፣ የቃል መገለጫዎች እንዲሁም በመታዘብ መጽሐፎች ላይ ህትመት እንዲደረግ ፈቅጃለሁ። ነገር ግን በፎቶ ግራፎችም በቃል መገለጫዎችም ሆነ በህትመቶች ላይ ስሜን ማንኛውንም የሚገልጽ መገለጫዎች እንዲደገቡ ተስማምቻለሁ።

8. በቀዶ ህክምናው ጊዜ የሚወጡ የሰውነት ክፍሎች እንደ አስፈላጊነቱ ለተጨማሪ ምርመራ እንዲሉ ወይም እንዲለሉ ተስማምቻለሁ። በማንኛውም ቀዶ ህክምና ወቅት እርግጠኛ የሆነ ውጤት ሊኖር እንደማይችል እና በዚህ ቀዶ ህክምና ላይም ከቀዶ ህክምናው በፊት እንደዚህ እርግጠኛ የሆነ ውጤት እንደሌለ ተገንዝቻለሁ።

በተጨማሪ ቀዶ ህክምናውን በተመለከተ ከዶክተር እና ከሰራ ባልደረገባቸው ወይም ከሚተኩት ባለሙያዎች ጋር ውይይት ለማድረግ እድል እንደተሰጠኝና የተነገረኝን መረጃ ሁሉ እንደገባኝ አገልግላለሁ። የተነገረኝ መረጃ ገልፅ ሆኖልኝ ይህንን ቅጽ ለመሙላት ምርጫ እንዳለኝ አውቃለሁ።

9. ይህንን ቀዶ ህክምና ለማካሄድ አንስቲዲያ እንደሚለጠኝ አውቃለሁ። አስፈላጊ የሆነውን የአካላዊ ስምምነት የአካላዊ ባለሙያው መርጦ እንዲጠቀም አረጋግጣለሁ። በዚህ ሰዓት የምወሰደው አካላዊ ስምምነት ምን ዓይነት እንደሚሆን ምን ችግር ሊያመጣ እንደሚችል ከአካላዊ ስምምነት በአካላዊ ባለሙያው ገለጻ ተደርጎልኝልኝ።

የታካሚዎ/ሰም ስም እና ፊርማ _____ ቀን _____

ስምምነት ላደረግ ችግር የሌለውን ስምምነት/የሚወክል ሰው ስምና ፊርማ _____

ትውልድ ያስፈረመው ህኪም ስምና ፊርማ _____ ቀን _____

የምስክርነት ስም እና ፊርማ _____ ቀን _____

_____ ቀን _____



ማስታወሻ፡- ለደንገተኛ በሽታ ታካሚዎች እንደበሽተኛው ሁኔታና እንደበሽታው ክብደት ከዚህ ወረቀት ደርባ በላይ ጸሁፍ ያስፈርሙ።