



St. Paul's Hospital Millennium Medical College

Graduate Study Program

**Informed consent practice and factors affecting the process for surgical
procedures among Physicians in a Tertiary Care Hospital, Addis Ababa,
Ethiopia.**

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**A thesis report for partial fulfillment of a specialty certificate in Obstetrics
and Gynecology surgery**

September, 2023

Addis Ababa, Ethiopia

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Addis Ababa, Ethiopia

September 2023

Abstract

Introduction Informed consent is essential in all patient-physician relationships and is more than simply paperwork. It should be understood as an ongoing bidirectional process of communication and education with the patient or surrogate that continue through the medical care. Studies indicate that the use of Surgical Informed Practice in surgical practice is still not at its optimum level.

Objectives To assess surgical informed consent practice and factors affecting the process for surgical procedures among Physicians at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, September to November 2022.

Methods A cross sectional analytic study was used to assess level of Surgical informed practice among surgical and residents and associated factors. An online survey was conducted using Google form from August 2022 to September 2023. All 484 surgical consultants and residents were invited with their respective department's Telegram group. Binary logistic regression analysis was employed. The selection of variables was made by backward elimination and then the selected variables were included in the final multivariate logistic regression model. The adjusted odds ratio with a 95% confidence interval and P-value < 0.05 was used to determine the magnitude of the association and statistical significance.

Result: A total of 154 questionnaires were completed from consultants and residents with a response rate of 32%. Two-third (66.6%) practiced proper informed consent during major surgical procedures. Among the respondents, only 33.3% had good knowledge about the informed consent process. Above five years of working experience (AOR= 4.25, 95% CI= 1.68, 10.75) and training (AOR= 2.52, 95% CI= 1.04, 6.08) on SIC were statistically, and positively associated with satisfactory knowledge of Surgical Informed Practice. Moreover, those who are married (AOR= 2.39, 95% CI= 1.09, 5.23) and satisfactory Surgical Informed Practice knowledge (AOR= 3.37, 95% CI= 1.39, 8.15) were significantly associated with good informed consent practice.

Conclusion The practice of informed consent process is suboptimal. The SIC process may be enhanced by giving physicians with training aimed at improving their understanding and properly structuring the procedure.

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List of Acronyms and Abbreviations

MD: Medical Doctor

OBGYN: Obstetrics and Gynecology

PI: Principal Investigator

DC: Data Collectors

DS: Data Supervisors

SPHMMC: St. Paul Millennium Medical College

1. Introduction

1.1 Background

Patients have a basic legal and ethical right to control what happens to their bodies. Consent refers to patients' right to choose what, if any, clinical care they receive, as well as surgeons' responsibility to ensure that patients have given their permission prior to any treatment, examination, or intervention(1).

Informed consent forms the foundation for the modern practices of shared decision making and patient-centered care (2). It is primarily a legal and ethical concept that protects the legal rights of patients and guide the ethical practice of medicine(3). It also includes the administrative goal of providing efficient health care and the interpersonal goal of building the trust needed to proceed with therapeutic interventions.

Informed consent is not just a form rather it is an interactive process that is critical in all patient-physician relationships (4). It should be understood as an ongoing bidirectional process of communication and education with the patient or surrogate that continue through the medical care (2). The consent form should be signed only after reaching a mutual understanding (5).

A mentally competent adult patient has the right to information regarding any diagnostic procedure or therapy and has the right to receive the information in a way that the patient can understand easily. The patient should be aware of the type of surgery, alternative treatments, identifying the operating surgeon, anesthesia-related risks, complications of surgery and postoperative care (6).

Several well-documented constraints hamper the practice of informed consent. Patient comprehension, patient use of given information, patient autonomy, the obligations placed on health care providers, and how effectively physicians achieve the minimum disclosure standards are all examples of these limitations(3).

Informed consent practice is a complicated process that necessitates flexibility in order to achieve its numerous objectives. The legal goal of protecting patients' rights, the ethical goal of

supporting autonomous decision-making, the administrative goal of providing efficient health care, and the interpersonal goal of establishing the trust necessary to proceed with therapeutic interventions are all among these objectives(3).

While signing a consent form prior to a surgical treatment is a legal necessity, it does not guarantee that the patient is completely informed of the treatment's details (7). An important factor in informed consent is a clearly communicating doctor that transfers focused information about the planned surgical procedure. The operating surgeon must provide all required information to the patient in order for him to make an informed decision regarding his treatment. A well-defined treatment plan integrating the surgeon's counsel should be discussed, and the patient's understanding of all of this information must be ensured (8). Clinicians should involve patients in decision-making by ensuring that the discussion contains pertinent details about the expected benefits, viable alternatives, and what to expect before and after the operation, in addition to the disclosure of risks(3).

According to researches, physicians rarely fulfill even the most basic disclosure standards in order to acquire informed consent, and there is little high-quality (i.e., level 1) data to guide practice (3). There is need for organizing objective training in creating awareness among healthcare professionals in this crucial but neglected area of doctor-patient communication. There is little in the literature regarding on how to teach healthcare professionals about giving patients appropriate informed consent(5,9).

1.2 Statement of the problem

The SIC process has significant flaws and omissions, and the basic aspects of the SIC process are largely ignored in everyday practice. It is an underappreciated aspect of surgery, and neither surgeons nor patients recognize its significance (10). Patients' perspectives on informed consent have previously indicated that they do not feel fully informed about the risks and advantages of operations, as well as available alternatives (11, 12).

People are encouraged to "sue for any fault their doctors make," which leads to a rise in medico-legal claims (13). It should be noted, however, that the majority of legal issues are the result of communication failures rather than therapeutic failures(10, 13) Because a well-informed patient has more reasonable expectations about a medical operation and its hazards, he or she will be happier and make fewer legal claims(10).

According to studies from institutions in western countries such as the United States, Europe, the Netherlands, and New Zealand, doctors have limitation of awareness of SIC procedure(8). Surgeons are not specially trained or qualified and lack the knowledge to take patients through the legally sound SIC process(10). In the USA and other developed countries, there are currently no uniform, globally approved techniques to teaching or evaluating informed consent skills (11).

Residents lack confidence in their understanding of all risks and benefits associated with routine operations, and they are uneasy about gaining informed permission. During their residency in the United States, up to 60% of residents reported they never received any feedback on these difficulties. According to existing literature, health care staff, particularly residents, usually lack basic informed consent training, resulting in insufficient knowledge, abilities and practice (11).

There is a gap in evidence collected on surgical informed consent practice among physicians in Ethiopia. There is no study done in a tertiary care hospital in Ethiopia with the author only identifying one institutional-based cross-sectional study aimed to assess practice and factors associated with the informed consenting process among all nurses, midwives, doctors (general physicians, surgeons, gynecologists), emergency surgery officers, anesthetists) who were working in public hospitals of Bale Zone, South Eastern Ethiopia. This study showed that only

half, (50.1%), of the health-care providers practiced adequate informed consent(14). Thus, more research is necessary to improve the SIC process in daily practice.

1.3 Justification of the study

Despite the importance of informed consent as a theoretical idea in surgical practice, practical issues with the process persist(3). Patients' perspectives on informed consent have previously revealed that they were not fully informed about the risks and benefits of operations, as well as other alternatives (15-18). Studies have also looked at the content of consent forms and offered improvements to them (19).

Although current informed consent processes have been challenged, few research have looked at the viewpoints of individuals who obtain consent. According to the current literature, more research is needed to better understand the limitations of current physicians SIC practice and to make recommendations for improving the process. This is especially true in Ethiopia. To the best of the authors knowledge only one prior study has been conducted in Ethiopia to investigate surgical informed consent practice from the perspectives of individuals who obtain consents and non in SPHMMC. So, this study will fill this gap and lay the ground or further studies.

1.4 Significance of the study

The study will provide information regarding the current surgical informed consent practice among physicians and the existing gap in a tertiary care hospital. The study will also identify factors affecting surgical informed consent practice and their association with the process. The result of the study provides impute for the institution and policy makers. Moreover, it will also guide the beneficiaries if the current practice is adequate or not and on which areas to intervene.

2 Literature review

Various studies conducted in various countries across the world found that healthcare practitioners' knowledge and practice of effective surgical informed consent (SIC) was suboptimal, and they did not satisfy the minimum standards while conducting informed consent with patients (10).

According to a survey of the practice of the informed consent process in general surgery in the Netherlands the quality of the SIC process is far from optimal. Only 55% were familiar with all three basic elements of SIC ('assessment of preconditions,' 'provision of information,' and 'stage of consent'). One out of every six surgeons (17%) have experienced a SIC-related complaint, presumably indicating poor SIC application in regular surgical practice (20).

A study was done in Northwestern University Medical School, Chicago, Illinois which sought to answer whether residents are adequately knowledgeable about the risks, benefits, and alternatives of the procedures that they commonly obtain consent for and whether they answer common questions that patients may ask about these procedures. Few residents were able to correctly list all risks, benefits, and alternatives of any of the procedures and less than one-half of the questions that patients may ask about the procedures were correctly answered (21).

According to a cross sectional study done in Pakistan Doctors' knowledge and attitudes toward the SIC are less than ideal, especially among junior doctors. Instead of the operating surgeon obtaining the SIC personally, the majority of responders entrusted the task to the staff nurse or junior doctors. Communication of the anticipated consequences as well as alternative treatment was severely lacking. Doctors underestimate their patients' information requirements (8).

In Africa, effective informed consent is not often practiced. In a study conducted in Egypt significant differences were found between physicians and patients regarding their knowledge, practice and perception of the informed consent process which highlight the need for establishing better communication channels. Nearly half of the physicians (49.4%) reported that they informed patients about their medical condition in details, while 65.7% of the patients mentioned being not informed at all. A significantly higher percentage of physicians than patients reported

that they thoroughly explained to their patients the potential complications of their planned treatment (50% vs. 18.5%) (22).

A cross-sectional study conducted at three Ugandan university teaching hospitals found that In Uganda's university teaching hospitals, informed consent administration and documentation for surgical health services are still lacking. Despite the fact that 99.2% of respondents agreed that informed consent is required before every surgical procedure, just 48.8% said they routinely acquire consent every time they do surgery. Moreover, 34% of the respondents did not know the definition of informed consent (19).

A Nigerian based cross-sectional study conducted in University of Ibadan and University College Hospital concluded that most Nigerian surgeons seemed to have a good knowledge of the informed consent requirements and process but fall short in practice. More than half of the physicians (54.9 percent) agreed with the notion that patients are not given enough information when consenting to surgical operations. The majority of respondents (61.8 percent) believe that surgeons do not provide enough information to patients about their illnesses before treatment initiation. Most respondents thought that informed consent is mostly used as a medicolegal ritual (42.2%) rather than a truly participatory decision-making process (51.0%) (23).

In Ethiopia there are several studies done to assess SIC process but there is a paucity of studies assessing knowledge, attitude and practice of SIC process from the perspective of people who obtain consents.

Wogene Negash et al. conducted an institutional-based cross-sectional study from March 9 to 24, 2020, among all nurses, midwives, doctors (general physicians, surgeons, gynecologists), emergency surgery officers, anesthetists) who were working at Bale Zone public hospitals during the study period. The practice and factors connected with the informed consent process were examined in this study, and the findings revealed that only half of the health-care professionals, or 50.1 percent, practiced adequate informed consent. 52% of the respondents had good knowledge about informed consent process and more than half, 58%, had a favorable attitude. In this study, the health-care workers who had good knowledge and those with favorable attitudes toward informed consent practice were more likely to practice adequate informed consent than

those who had poor knowledge. Moreover, adequate informed consent practice was higher among health-care workers who had training on consenting than those with no training (14).

Pre-intervention and post-intervention surveys were conducted at Hawassa University Comprehensive Specialized Hospital, Ethiopia among women who underwent obstetric or gynecologic surgeries. The purpose of this study was to see if an intervention designed to improve SIC in obstetric and gynecologic surgeries is associated with the receipt of SIC components. A three-day training on routine counseling for surgical procedures was provided to health workers as part of the intervention. After controlling for effects of potential confounders, the number of SIC components reported by post-intervention survey participants was 16% higher than what is received by pre-intervention ones. Acquiring a higher number of standard counseling components is linked to training in the delivery of standard SIC (24).

In another institution-based prospective cross-sectional study done at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia from March 4 to April 12, 2019, G.C. Chane et al. reviewed 135 patients. Only 8.1 percent of the 135 patients who responded obtained the minimal required components of informed consent (a good quality informed consent) (25).

Conceptual Frame Work

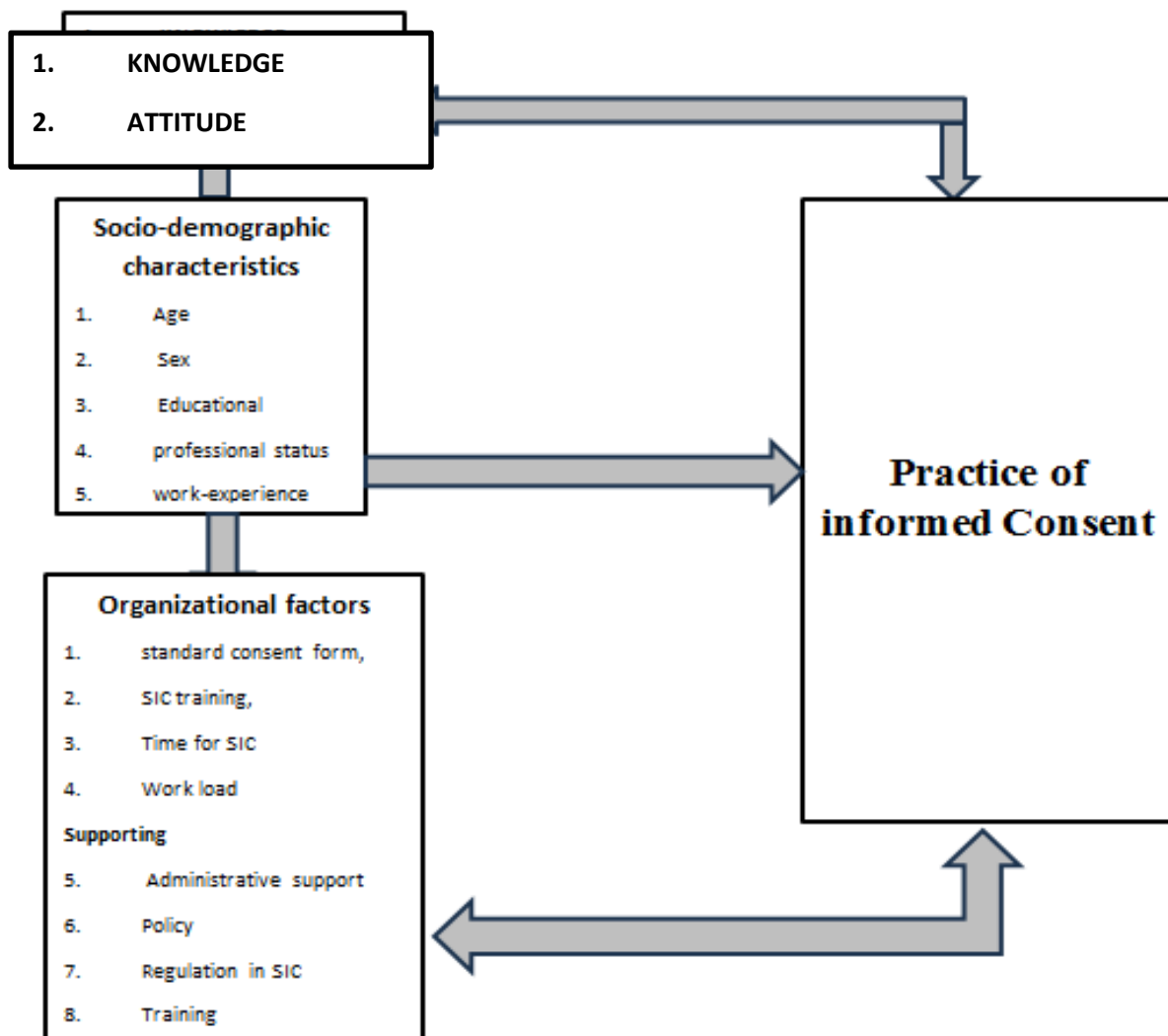


Figure 1: Conceptual framework

3. Objectives

3.1 General objectives

- To assess surgical informed consent knowledge, attitude and practice and factors affecting the process for surgical procedures among Physicians at SPHMMC Addis Ababa, Ethiopia, September to November 2023.

3.2 Specific objectives

- To determine the level of surgical informed consent practice among physicians working at SPHMMC in the year 2023.
- To assess the level of surgical informed consent knowledge among physicians working at SPHMMC in the year 2023.
- To determine the attitude of surgical physicians working at SPHMMC towards surgical informed consent in the year 2023.
- To identify factors affecting the knowledge, attitude and practice of surgical informed consent among physicians working at SPHMMC in the year 2023.

4. Method

4.1 Study area and study period

The study was conducted from April to September, 2023 in St. Paul's Hospital Millennium Medical College, the second-largest governmental tertiary care hospital located in Gulele sub-city, Addis Ababa, Ethiopia. It is a medical center for a catchment area of more than 5 million population. On average, daily, the hospital gives medical service for 1,200 patients with diversified complaints, in several specialty and subspecialty fields.

4.2 Study design

An institutional-based cross-sectional study design was employed

4.3 Source Population

All Residents and consultant in SPHMMC.

4.4 Study population

All residents and consultants from surgical specialties including general surgery, orthopedics surgery, plastic surgery, neurosurgery, Ophthalmology, maxillofacial surgery, otorhinolaryngology, urology, and Obstetrics and Gynecology departments working in SPHMMC who consented to participate in the study.

4.5 Eligibility criteria

4.5.1 Inclusion Criteria

All surgical residents and specialists from general surgery, orthopedics surgery, plastic surgery, neurosurgery, Ophthalmology, maxillofacial surgery, otorhinolaryngology, urology, and Obstetrics and Gynecology who were working during the study period in the hospital were included.

4.5.2 Exclusion criteria

Those who are suspended or dismissed from the surgical specialty training program.

4.6 Sampling Procedure

A survey was administered to all residents and consultants from all surgical fields using each department's Telegram group which is widely used for the surgical residency training program.

4.7 Study Variables

4.7.1 Dependent Variable

Knowledge of surgical informed consent (Satisfactory, Unsatisfactory)

Attitude of surgical informed consent (Favorable, Unfavorable)

Practice of surgical informed consent (Poor, Good)

4.7.2 Independent Variables

Sex, age, marital status, academic rank, specialty, work-experience, knowledge, attitude, and

Standard SIC training.

4.8 Operational Definition

A mean score of the knowledge, attitude and practice variables were used to dichotomize the variables.

Good practice: - a score of 6 or more

Poor practice: - a score of 5 or less

Satisfactory knowledge: - a score of 7 or more.

Unsatisfactory knowledge: - a score of 6 or less.

Favorable attitude: - a score of 7 or 8

Unfavorable attitude: - a score of 6 or less

4.9 Data collection tool and procedure

The questionnaire was developed through literature review (1, 2, 8, 10, 14, 20, 26, 27). It was prepared in English which is the language of instruction higher education in Ethiopia and had 43 items with five parts. Part I had 6 questions regarding socio-demographic characteristics of the study participants. Part II with 6 items of organizational factors of informed consent practice. Part III and IV had 8 questions each assessing respondents' knowledge of the informed consent process and attitude towards the practice of informed consent respectively. The attitude questions contained questions with Likert scale responses which ranged from strongly disagree to strongly agree. Part V: contained 10 questions to assess the respondents' practice of the informed consent process with response options of "never", "sometimes" and "always".

The questionnaire was then converted in to an online Google form. Physicians were invited via a link to the Google form on their respective department's Telegram channel. Invitations included information about the study and encouraged physicians to participate. Multiple extra invitations were made to non-responders in an effort to increase recruitment. Those who chose to participate were asked to complete a structured online, a pretested self-administered questionnaire.

4.10 Data Quality assurance

The questionnaire was piloted on 12 physicians from different surgical departments to check clarity and reliability of the questions. The pre-test data was analyzed and Cronbach's α value=87.9%, indicating high degree of internal consistency. Those who took part in the pilot

study were excluded from the actual study. The feedback from the pilot was used to make adjustments on the questions. The study participants were encouraged to answer the questions as honestly as possible. The returned questionnaires were checked for completeness and consistency on the same day. A double data entry was carried out to ensure accuracy.

4.11 Data Analysis

The collected data were checked for completeness and consistency. The excel file of the Google form was cleaned and exported into Social Sciences (SPSS window version 26) for analysis. Categorical variables were summarized by frequency and percentage. Numerical values were summarized with mean and standard deviation.

For knowledge items a score of 1(correct) and 0(incorrect) was given. For attitude questions a score of 1(agree/strongly agree) and 0(neutral/disagree/strongly disagree), for practice part a score of 1 for those who responded (always) answer and 0(sometimes/never) was given. The scores were summed into total. Then the total score was used to construct the indices. The association between personal characteristic of the physicians and the dependent variables was analyzed using binary logistic regression. The selection of variables was made by backward elimination model and then the selected variables were included in the final multivariate binary logistic regression model. The adjusted odds ratio (AOR) with a 95% confidence interval (CI) and P-value <.05 was used to determine the magnitude of the association and statistical significance.

4.12 Ethical Consideration

Ethical clearance was obtained from the Institutional Review Board of St. Paul's Hospital Millennium Medical College, and then permission was sought from the school administration through the academic provost of the school to carry out the study. All participants were asked to consent before proceeding with the survey, and confidentiality of all information was ensured by the removing an identifying information from the data. The collected information was only used for this particular study and was kept confidential.

5. Results

Out of 484 surgical consultants and residents representing almost all departments that give major surgical services in SPHMMC invited to participate in the online survey, a total of 154 completed the questionnaire with a response rate of 32%.

5.1 Socio-Demographic Characteristics of the Respondents

The respondents' mean age was 30.4 years ± 3.6 , ranging from. More than half, 114 (74%) of the respondents were male, and over half, 93 (60.8%) were unmarried. Of the 154 participant physicians most 138 (89.6%) were residents and 16(10.4%) were consultants. Nearly half of the respondents 65(42.5%) were from the department of Obstetrics and Gynecology and the lowest is from Otorhinolaryngology. Among the participants 130 (84.4%) of the respondents had less than 5 years working experience.

Table 1: Socio-demographic of participants

Variables		N	Percent
Age category	26-28	47	30.5
	29-31	64	41.6
	32-34	29	18.8
	>35	14	9.1
Gender	Male	114	74.0
	Female	40	26.0
Marital status	Married	60	39.2
	Single	93	60.8
Academic Rank	Resident	138	89.6
	Consultant	16	10.4
Specialty	General surgery	24	15.7%
	Maxillofacial surgery	10	6.5%
	Neurosurgery	6	3.9%
	Obstetrics and Gynecology	65	42.5%
	Ophthalmology	2	1.3%
	Orthopedics surgery	32	20.9%
	Otorhinolaryngology	4	2.6%
	Plastic surgery	5	3.3%
	Urology	5	3.3%
Experience	<5 years	130	84.4
	>5 years	24	15.6

5.2 Organizational Factors

Nearly half, 76 (51.4%) of the respondents operate on average of 3-4 patients in a day/per shift during their stay in an operating theatre and in response to a question regarding how long they spent informing their patients during the professional interaction, over half (53.9%) said they did it in less than 5 minutes. Nearly half (49.4%) said the informed consent form's information was sufficient for them to obtain a valid consent. The majority of respondents 130 (84.5%) did not have administrative assistance (such as interpreters and only 66 (42.9%) reported that their institution had a policy or legislation that supports the practice of informed consent. Only 27 people (17.6%) had taken part in in-service training on the surgical informed consent process.

Almost half 83(53.9) spent less than 5 minutes to provide information to their patients about the procedure during the professional encounter.

Table 2: Organizational Factors

Questions		N (%)
How many patients do you operate on average in a day/per shift during your stay in an operating theatre?	1-2	53 (35.8)
	3-4	76 (51.4)
	>5	19 (12.8)
Do you think the consent form contents currently used in your hospital is adequate to obtain valid informed consent from patients?	Yes	76 (49.4)
	No	78 (50.6)
Is there a policy or regulations that support practice of informed consent process in your institution that u know of?	Yes	66 (42.9)
	No	27 (17.5)
	I don't know	61 (39.6)
Do you have had administrative support like interpreters available?	Yes	22 (14.5)
	No	130 (84.5)
Have you had training on the process of Surgical informed consent?	Yes	27 (17.6)
	No	126 (82.4)
How much time do you spend giving information about a treatment or procedure to a patient during a professional encounter?	< 5 minutes	83 (53.9)
	6-10 minutes	58 (37.7)
	11-30 minutes	13 (8.4)

5.3 Knowledge and Attitude of Physicians about the Informed Consent Process

The median score of study participants' knowledge was seven, and only one third, 51 (33.3%), of the respondents had good knowledge about the informed consent process.

Table 3: knowledge related questions

Questions		N (%)
Do you know the elements informed consent process?	Yes	101(66.0)
	No	52(34.0)
Do you know all the contents of informed consent?	Yes	88(57.1)
	No	66(42.9)
For which type of surgical procedure the SIC should be sought?	For emergency	1(0.6)
	For elective ones	2(1.3)
	For all procedures	151(98.1)
Patient of what age do you think is able to give a valid SIC?	All ages	5(3.2)
	Depending on clinical judgment of maturity	8(5.2)
	Depending on the individual's intelligence	2(1.3)
	Patients aged above 14	7(4.5)
	Patients aged above 16	7(4.5)
	Patients aged above 18	125(81.2)
Who should obtain the SIC?	The whole team, including anesthesiologists	1(0.6)
	The operating surgeon himself	145(94.2)
	The junior doctor on duty	5(3.2)
	Staff nurse on duty	2(1.3)
	Operating surgeon and Anesthesiologist	1(0.6)
From whom do you obtain the SIC?	The patient	154(100.0)
What is the best way to ensure that the patient understood the information?	Repeat back	57(37.0)
	Judged on the basis of one's own intuition	1(0.6)
	Asking if there are any questions	42(27.3)
	Asking if everything was understood	54(35.1)
Which time do you obtain the SIC?	The night before surgery	55(35.7)
	On the admission encounter	53(34.4)
	Just before the surgery	1(0.6)
	It depends on the type of the procedure and the time when surgery is decided.	1(0.6)
	In the ward	22(14.3)
	In the operating theatre	21(13.6)
	At or corridor	1(0.6)
	Repeat back	57(37.0)
What is the best way to ensure that the patient understood the information?	Judged on the basis of one's own intuition	1(0.6)
	Asking if there are any questions	42(27.3)
	Asking if everything was understood	54(35.1)

5.4 Attitude towards Surgical informed process

The mean attitude score of study participants' was six, and majority, 137 (90.7%), had a favorable attitude towards the informed consent process.

Table 4: Attitude related questions

Question	Strongly disagree	Disagree	Neutral	Agree	strongly agree
Informed consent is not just about signature of the patients and health care providers	1(0.6%)	0(0.0%)	0(0.0%)	29(18.8%)	124(80.5%)
Informed consent signifies shared decision making	1(0.6%)	2(1.3%)	1(0.6%)	38(24.7%)	112(72.7%)
Decision making about proposed treatment/procedure does not belongs only to health care provider.	(0.6%)	0(0.0%)	5(3.2%)	35(22.7)	112(72.7%)
All risks need to be explained to the patient	0(0.0%)	1(0.6%)	2(1.3%)	32(20.8%)	118(76.6%)
It is important to repeat the explanation if the patient demands it.	0(0.0%)	0(0.0%)	1(0.6%)	22(14.3%)	130(84.4%)
The duty of obtaining informed consent is belongs to health care provider who is doing the procedure	0(0.0%)	1(0.6%)	9(5.8%)	33(21.4%)	109(70.8%)
Informed consent Improve the patient's compliance with medical care	0(0.0%)	2(1.3%)	3(1.9%)	35(22.7%)	113(73.4%)
Informed consent process that starts as soon as the doctor meets the patient and should continue after the operation	4(2.6)	13(8.4%)	17(11.0%)	41(26.6%)	77(50.0%)

5.5 Practice of Informed Consent Process

The majority of respondents, 123 (80.4%), said they always told the patient about the purpose or indication for the surgery, while more than two-thirds, 116 (76.8%), said they always acquired informed permission for major surgical procedures.

113 (74.8%) of respondents said they always describe the procedure's benefits to the patient, and just over half, 92 (60.1%) said they always mentioned the procedure's risks or potential consequences. Only few 16(10.5%) mentioned that they provided supporting tools like leaflets, websites, soft wares, information personnel for patient's education and guidance. Half of the respondents (50.7%) stated they gave patients the chance to ask questions, and 50.3% claimed they assessed their patients' competency to consent to treatment/procedure.

90 percent (59.6%) of the participants said they make sure their patients comprehend the explanations they give. Nearly half 75(49.7%) claim they inform their patients about presence/absence of alternative treatment option/s to surgery. Almost half (49.7%) said they educate their patients about the availability or absence of other treatment alternatives for surgery. Less than one-third 171 (27.5%) of participants discussed the presence of any favorable environment and the possibility to say no to the proposed surgery (Table 3). The median score of study participants' informed consent practice was five, and two-third, 94 (66.6%) had good practice towards the informed consent process.

Table 5: Practice related questions

Question	Never	Sometimes	Always
I obtain informed consent from patients for major surgical procedures	12(7.9%)	23(15.2%)	116(76.8%)
I inform the patients why the surgery will be performed	9(5.9%)	21(13.7%)	123(80.4%)
I explain the benefit of the procedure to the patient	9(6.0%)	29(19.2%)	113(74.8%)
I explain the risks or potential complication/s related to the procedure to the patient	12(7.8%)	49(32.0%)	92(60.1%)
I inform the patients about type of anesthesia to be used	24(15.8%)	61(40.1%)	67(44.1%)
I provide supporting tools like leaflets, websites, soft wares, information personnel for patient's education and guidance	101(66.0%)	36(23.5%)	16(10.5%)
I provide an opportunity to ask questions to the patients	23(15.3%)	51(34.0%)	76(50.7%)
I assess the competence of my patients to give consent to treatment/procedure	24(15.9%)	51(33.8%)	76(50.3%)
I check that my patients understand the explanations I provided to them	16(10.6%)	45(29.8%)	90(59.6%)
I inform the patients about presence/absence of alternative treatment option/s to surgery	17(11.3%)	59(39.1%)	75(49.7%)

5.6 Factors Associated with Knowledge of surgical informed consent

The selection of variables was made by backward elimination model and age, gender, marital status, academic rank, experience, training on SIC were included in the final multivariate binary logistic regression model based on the inclusion criteria. On multivariable binary logistic regression analysis model, after adjusting for other covariates experience and training on SIC were statistically, and positively associated with knowledge of SIC.

The odds of satisfactory SIC knowledge among those who had more than five years of work experience are 4.25 times higher than those who had less than five years' experience (AOR= 4.25, 95% CI= 1.68,10.75 p-value=0.02) . Likewise, the odds of high knowledge among those who had training on SIC are 2.52 times higher than those who have not been trained (AOR= 2.52, 95% CI= 1.04, 6.08, p-value=0.04).

Table 6: The relation between knowledge, practice, and attitude and demographic variables.

Variable		Knowledge			Attitude			Practice		
		Unsatisfactory	Satisfactory	P-value	Unfavorable	Favorable	P-value	Poor	Good	P-value
Age	<30	70	31	0.33	8	92	NA	34	60	0.31
	>30	32	20		6	45		13	34	
Gender	Female	25	15	0.52	1	38	NA	10	28	0.28
	Male	77	36		13	99		37	66	
Marital status	Single	62	30	0.93	8	84	0.74	34	51	0.04
	Married	40	20		6	52		13	42	
Academic rank	Consultant	9	7	0.35	1	17	NA	3	13	0.19
	Resident	93	44		13	122		44	81	
Experience	<5 years	93	36	0.001	11	116	NA	43	76	0.10
	>5 years	9	15		3	21		4	18	
Training on SIC	Yes	13	14	0.03	3	24	NA	6	18	0.33
	No	88	37		11	112		41	75	
Knowledge	Unsatisfactory	-			10	89	NA	39	56	0.006
	Satisfactory				4	47		8	37	
Attitude	Unfavorable	-			-			6	6	NA
	Favorable							41	86	

NA= cells expected count less than 5 is > 20%.

5.7 Factors Associated with Practice of surgical informed consent

Similarly on multivariable binary logistic regression analysis model, after adjusting for other covariates marital status and knowledge were statistically, and positively associated with good SIC practice. After adjusting for other covariates, the odds of good practice among those who are married is 2.4 times higher than in those who are not married (AOR=2.4, 95% CI=1.09, 5.23, p-value=0.03) while the odds of good practice among those who had satisfactory knowledge is 3.4 times higher than those who had poor knowledge (AOR=3.4, 95% CI=1.39, 8.15, p value=0.01).

Table 7: Multivariate binary logistic analysis of the likelihood of having satisfactory knowledge, favorable knowledge and good practice of surgical informed consent.

Variable		Knowledge			Attitude			Practice		
		OR	95%CI	P-value	OR	95%CI	P-value	OR	95%CI	P-value
Age	<30 years	0.9	0.39-2.46	0.97	1.42	0.93-5.16	0.60	0.94	0.37-2.41	0.90
	>30 years	1			1			1		
Gender	Male	1.03	0.45-2.35	0.95	0.20	0.024-1.56	0.12	0.65	0.28-1.55	0.34
	Female	1			1			1		
Marital status	Married	1.56	0.70-3.44	0.28	0.92	0.27-3.14	0.90	2.39	1.09-5.23	0.03
	Single	1			1			1		
Academic rank	Resident	1.11	0.31-3.92	0.87	0.61	0.07-5.67	0.67	0.72	0.17-3.03	0.65
	Consultant	1			1			1		
Experience	>5years	4.25	1.68-10.75	0.002	1			0.69	1.98-2.41	0.56
	<5 years	1			1.67	0.42-6.64	0.47	1		
Training on SIC	Yes	2.52	1.04-6.08	0.04	0.77	0.19-3.02	0.70	1.27	0.44-3.66	0.66
	No	1			1			1		
Knowledge	Low	NA			NA			1		
	High							3.37	1.39-8.15	0.01

6. Discussion

A total of 154 questionnaires obtained from surgeons and residents representing almost all departments that give major surgical services in SPHMMC with a response rate of 32%. This response rate was comparable to response rate with the study done in the Netherlands to assess practice of the informed consent process which was 30% (20).

Numerous studies from throughout the world have suggested that informed consent process practices are suboptimal and that this number even declines further in developing nations (10,14,19, 20). Surgical informed consent does not pertain to a ritual; rather, it refers to patients' right to choose what, if any, therapeutic care they receive, as well as surgeons' obligation to ensure that patients have given their consent prior to any treatment, assessment, or intervention(1). Few studies have been conducted to assess practice level of informed consent process from the perspective of health professionals (14, 17, 24). This is the first research of its kind to analyze the SIC process from the perspective of consultants and residents undergoing surgical specialty training. On the contrary, several research on trainees and consultants have been undertaken in different countries (8, 19, 22, 28).

Among 484 invited physicians, 154 completed the questionnaire with a response rate of 32%.

Our study showed that the current surgical informed consent knowledge was 33.3%. In contrast, a study conducted in Netherlands was found to be 55%. This might be attributable to the respondents' degree of work experience and training. In our study, 89.6% of participants were surgical specialty trainee residents with little experience, compared to only 35% in the study from the Netherlands (20).

Physicians who did receive SIC training exhibit greater knowledge of SIC than those who did not. Furthermore, our research showed that doctors with greater SIC knowledge had better practices than those who did not. This was supported by a studies conducted in Bale and Hawassa, where informed consent training was substantially related to better informed consent practice ($P < 0.001$) (14, 24). Also, a survey of obstetrics and gynecology residents in the United States showed that most residents lack confidence when it comes to obtaining SIC and observation is how they develop the majority of their SIC practice. In addition, more than half

(61.6%) said they would want to receive additional SIC training (29). Similarly, a study in the Netherlands indicated that although doctors were familiar with some SIC components, it was clear that they lacked practical knowledge and SIC practice on many aspects. It was suggested in these studies that incorporating educational SIC training in residency programs would improve many aspects of surgical informed consent practice(20). As it includes the basic elements of informed consent ('assessment of preconditions', 'provision of information' and 'stage of consent'), training may enhance current knowledge and practices.

Less than half (49%) of the physicians in our study reported that they inform the patients about presence/absence of alternative treatment option/s to surgery. While significantly higher percent of physicians reported explaining to their patients the alternative lines of treatment (89.5%) in a study conducted in Cairo University Hospitals. This shows lack of understanding of important components of the SIC practice and the obligation to provide their patients with pivotal information about the process (22).

It is crucial how a doctor presents information to a patient since research has shown that many patients might fail to recall what a doctor tells them. This was demonstrated by a study done in Israel which indicated two thirds of the patients did not remember discussions of other alternatives treatments, and fifty percent of the patients did not remember hearing risk explanations (30). This theoretically can be improved by implementing modern supporting tools like leaflets, websites, software's, information personnel for patient's education and guidance to facilitate SIC (10). In our study only 10.5% reported that they provide supporting tool to their patients. This was much lower when compared to the study done in the Netherlands which reported that almost all of the physicians (97%) provided leaflets. In addition 37% of the consultants and 24% of the residents used websites to fulfill the information needs of their patients (20). Major factor for this might be the fact that lack of administrative support for obtaining SIC and absence of a proper policy and regulations to guide the preparation and utilization of this sorts of supporting tools. In our survey, more than half (57.1%) of respondents stated that they do not know about SIC policies or there are no policies in place that support the practice of informed consent. Furthermore majority (84.5%) replied that they have no administrative support available. Furthermore, the most of health-care users are uneducated, making technology or a computer-based interface less likely to be utilized.

Strength and limitation of the study

Our study assessed the current overall practice level of informed consenting process among physicians in a tertiary care hospital which mostly involved trainees. There are no studies on the title under study in our country that involve physicians from tertiary care hospitals. Although a 36% response rate is comparable to results obtained from other studies (20), the busy schedule of the trainees and consultants may have negatively influenced this response rate. Since it is self-reported, there may be recall bias and an exaggerated informed consent practice level connected to social desirability bias.

Conclusion and Recommendation

Two-third of the physicians practiced adequate informed consent. Experience above five years and training on informed consent process had a statistically significant positive association with high knowledge of informed consent practice where as being married and higher knowledge had a statistically significant positive association with the informed consent practice.

In conclusion, the practice of informed consent process is suboptimal. Therefore, Physicians require further training aimed at enhancing their knowledge and abilities in informed consent process. The SIC process can ideally be improved using modern tools like leaflets, websites, soft wares, and information personnel. The quality, thoroughness, and legal validity of a SIC process will all be enhanced by proper structuring of the process. This in turn will improve satisfaction of patients, safety, and the avoidance of serious malpractice claims. Finally, more research must be conducted that will help create a standard SIC that can be successfully used in everyday use.

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Annex Information Sheet and questionnaire

Research Title: Informed consent practice and factors affecting the process for surgical procedures among Physicians in a Tertiary Care Hospital, Addis Ababa, Ethiopia.

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Part III: Knowledge related Questions

S.no	Variable	Response
301	Do you know the elements informed consent process?	1. Yes 2. No 3. I don't know
302	If yes to Q. No. 301 which of the following do you know?	
302a	Assessment of preconditions like patient competence and voluntariness	1. Yes 2. No
302b	Provision of information to patients	1. Yes 2. No
302c	Recording of consent	1. Yes 2. No
303	Do you know all the contents of informed consent	1. Yes 2. No
304	For which type of surgical procedure the SIC should be sought?	1. For all procedures 2. For elective ones

		3. For emergency 4. Critical cases only
305	Patient of what age do you think is able to give a valid SIC?	1. All ages 2. Patients aged above 14 3. Depending on the individual's intelligence 4. Depending on clinical judgment of maturity
306	Who should obtain the SIC?	1. The operating surgeon himself 2. The junior doctor on duty 3. Staff nurse on duty 4. Other
307	From whom do you obtain the SIC?	1. The patient 2. The attendant 3. The husband 4. The father 5. Other person
308	Which time do you obtain the SIC?	1. On the admission counter

		2. In the ward 3. In the operating theatre 4. The night before surgery 5. Other
309	What is the best way to ensure that the patient understood the information?	1. Repeat back 2. Asking if everything was understood 3. Asking if there are any questions 4. judged on the basis of one's own intuition

Part IV: Attitude related Questions

S. no	Variable	Response
401	Informed consent is not just about signature of the patients and health care providers.	1. Strongly agree 2. Agree 3. Neutral 4. Disagree 5. Strongly disagree
402	Informed consent signifies shared decision making	1. Strongly agree

		2. Agree 3. Neutral 4. Disagree 5. Strongly disagree
403	Decision making about proposed treatment/procedure does not belongs only to health care provider.	1. Strongly agree 2. Agree 3. Neutral 4. Disagree 5. Strongly disagree
404	All risks need to be explained to the patient	1. Strongly agree 2. Agree 3. Neutral 4. Disagree 5. Strongly disagree
406	It is important to repeat the explanation if the patient demands it.	1. Strongly agree 2. Agree 3. Neutral 4. Disagree 5. Strongly disagree
407	The duty of obtaining informed consent is belongs to health care provider who is doing the procedure	1. Strongly agree 2. Agree 3. Neutral

		4. Disagree 5. Strongly disagree
408	Informed consent Improve the patient's compliance with medical care	1. Strongly agree 2. Agree 3. Neutral 4. Disagree 5. Strongly disagree
409	Informed consent process that starts as soon as the doctor meets the patient and should continue after the operation	1. Strongly agree 2. Agree 3. Neutral 4. Disagree 5. Strongly disagree

Part V: Practice of informed consent related Questionnaire

S. no	Variable	Response		
		Never	Sometimes	Always
401	I obtain informed consent from patients for major surgical procedures			
402	I inform the patients why the surgery will be performed			
403	I explain the benefit of the procedure to the patient			
404	I explain the risks or potential complication/s related to the procedure to the patient			
405	I inform the patients about presence/absence of alternative treatment option/s to surgery			
406	I inform the patients about type of anesthesia to be used			

407	I provide supporting tools like leaflets, websites, soft wares, information personnel for patient's education and guidance			
408	I provide an opportunity to ask questions to the patients			
409	I assess the competence of my patients to give consent to treatment/procedure			
410	I check that my patients understand the explanations I provided to them			