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PRACTICE AND FACTORS AFFECTING INFORMED CONSENT PROCESS AMONG HEALTH CARE WORKERS FOR MAJOR SURGICAL PROCEDURES AT GURAGE ZONE HOSPITALS, SOUTH ETHIOPIA, 2022

Bitew Tefera Zewudie[1*], ,Shegaw Geze[2],Yibeltal Mesfin[2,] Haimanot Abebe[1], Zebene Mekonnen[1],Shegaw Tesfa[1], Bogale Chekole[1] [1],Agerie Aynalem[1] Tadele lankrew[3],Yihenew Sewale[4] , Muche Argaw[2], Tadesse Sahle[1], Daniel Tsega[2]

[1]Department of Nursing, College of medicine and health science, Wolkite University, Wolkite, Ethiopia

[2]Department of Midwifery, College of medicine and health science, Wolkite University, Wolkite, Ethiopia

[3]Department of Nursing, College of medicine and health science, Wolaita Sodo University, Wolaita, Ethiopia

[4]Department of Nursing, College of medicine and health science, Debre Birhan University, Debre Birhan, Ethiopia

*corresponding author: Department of Nursing, College of Medicine and Health Sciences, Wolkite University, Wolkite, Ethiopia, bitewtefera1@gmail.com (BTZ)

Abstract

Objective: - This study aimed to assess the informed consent practice process and associated factors among healthcare workers for major surgical procedures at Gurage zone hospitals, in 2022.

Methods and Materials: Institution-based cross-sectional study was employed

Settings: This study was conducted in Gurage zone hospitals.

Participants: - All healthcare workers who have been working in Gurage Zone hospitals of surgical, operation rooms, and obstetrics /gynecology wards had exposure to patients who had undergone surgery during the study period

Outcome:- the primary outcome of the study was practice of informed consent practice

Result:- From a total of 457 sample size, 448 study participants were involved in this study with a response rate of 98%. The mean (±SD) age of the study participants was 29.16 (±4.06) years. The mean score of study participants towards the surgical informed consenting process was 19.5, and 260 (58%, 95 % CI: 53.7, 62.5) of them had good practice in the surgical informed consenting process. In multivariable logistic analysis model factors such as favorable attitude towards informed consent 2.4(1.556, 3.596), work experience participants 4.9 (2.8, 8.7), adequate knowledge of informed consent 2.5(1.6, 3.9) and communication challenge 1.6 (1.07, 2.50) were independently associated with the practice of informed consenting process at a p-value of <0.05.

Conclusion:- More than half of health care providers had good practice towards the surgical informed consenting process. The practice of informed consent is low and it is better to work on healthcare providers' in-service training, knowledge, and attitude toward informed consent.

Keywords:- informed consent, practice, health care provider, Gurage zone, Ethiopia.

Strengths and limitations of the study

We used multi-center study setting which is crucial for conclusion for the study area

We used validated tool to assess the practice of informed consent

Since the study design is cross-sectional cause and effect relationship cannot be established.

Self-reporting bias might affect the outcome of the study since some respondents may not report what they practice.

INTRODUCTION

Informed consent is a core concept in the process of communication between a patient and health- care provider[1]. Surgical informed consent (SIC) is not only putting a signature on a piece of paper but is an ongoing process that begins in initial contact with the patient and continues through surgery and postoperative care[2, 3]. It is an established ethical and legal requirement for surgical treatment with paramount importance to protect both the patient and health care providers from unnecessary accusations[3, 4]. It is the health care professional's obligation of disclosing information to the patient to undergo a specific medical intervention which is fundamental to the proper care and treatment of patients[5].

Putting a signature on the informed consent form does not by itself constitute informed consent; it is the whole complex process of gaining information, deciding, and consenting[2, 5]. According to the Canadian Medical Association, informed consent is the primary paradigm for protecting patients' rights and guiding ethical practice[6]. Surgical informed consent is vital for acknowledging patients' autonomy and self-determination as well as for promoting shared

decision-making by shifting the care from physician-centered to patient-centered[2]. The updated World Medical Association Declaration stated that the consent process should respect the patient's right to refuse or agree to any diagnostic procedures or treatments[7].

The information given is the most determinant factor for decision-making in the consenting process[2]. The reason for surgery, the proposed type of surgery, the risks and benefits of the proposed surgery, alternative treatments, and the benefits of refusing therapy should be incorporated into the consenting process[2, 4]. A legal and ethical context of informed consent requires five key elements to establish validity which, include competence, voluntariness, information disclosure, understanding of information disclosed, and authorization or consent to the medical procedure [8].

The informed consent process is the corner of shared decision-making, legal requirement, and ethical obligations for all surgical procedures if it is properly practiced[9]. Despite this fact, it is inconsistently practiced and rarely achieves the theoretical ideal. Without a basic understanding of the nature of the procedure, risks, benefits, and treatment alternatives, the patient cannot meaningfully participate in decision-making. Therefore, to provide safe, quality, patient-centered health care it is important to emphasize the proper informed consenting process[10].

Studies conducted in different countries of the globe (the United Kingdom, Pakistan, and the Netherlands) showed that the practice of surgical informed consent among healthcare providers didn't meet the minimum standard when they perform informed consent with their patients[11-13]. A study done in Iran showed that only 12.6% of nurses give sufficient information to their patients to assure suitable practice of informed consent[14].

Studies conducted in the African region showed that the practice of proper informed consenting practice is poor. For instance, in studies done in Uganda and Egypt, only 50% of surgeons obtain informed consent with adequate information before major surgical procedures[15, 16]. Similarly, 65.7% of the clients reported that they are not being informed about their procedure and instead simply ordered to put their signature on the informed consent sheet[15]. A study which was conducted in bale zone hospitals showed that only 50% of healthcare professionals practice the proper informed consenting process[17].

Previous studies in different countries of the world mainly focus on informed consent from patient perspectives and showed that there is a gap in the informed consenting process. However, factors affecting the informed consenting process are not yet addressed. There is also scarce information on the practice and factors affecting the informed consent process from a healthcare perspective in the study area and even in Ethiopia. Therefore, this study aimed to assess the informed consent practice process and associated factors among healthcare workers for major surgical procedures at Gurage zone hospitals, in Ethiopia.

Methods

Study Setting and Study Design

This study was conducted in public hospitals of the Gurage zone, South Ethiopia. The Gurage zone is one of the 11 administrative zones and four special woredas in the southern nation nationality people region (SNNPR). Wolkite town is the capital city of the Gurage zone. It is found 153 km southwest of Addis Ababa, the capital city of Ethiopia. According to the Ethiopian national census of 2007, it has 1,279,646 total populations. There are six hospitals (five public

and one non-governmental) serving the catchment population in the zone. An Institution-based cross-sectional study was employed

Participants

The source populations were all healthcare workers (nurses, midwives, GPs, surgeons, gynecologists), anesthetists) working at Gurage Zone hospitals. All healthcare workers who have been working in Gurage Zone hospitals of surgical, operation rooms, and obstetrics /gynecology wards had exposure to patients who had undergone surgery during the study period were study populations.

Inclusion and Exclusion Criteria

All healthcare workers (nurses, midwives, doctors, and anesthetists) who worked for at least 6 months in the hospital were included. Healthcare workers who were on annual leave, sick leave, or training were excluded from the study. Those who have not been working in surgical, labor, emergency, obstetrics, and gynecology ward and operating room in the last 6 months were excluded.

Sample Size Determination and Sampling Procedures

Sample Size Calculation

The minimum required sample size for the first objective was calculated by using single population proportion formula, assuming the prevalence of informed consent practice as 50.1 based on a study conducted in South Eastern Ethiopia[17], 5% margin of error at 95% CI as follows;

$$n=\frac{(Z\ \alpha / 2)^2\ P\ (1-p)}{d^2}$$

n = Sample size

p = Proportion =0.501

d = Margin of error =0.05

q = 1-p = 0.499

Z = 1.96 at a 95% Confidence Interval (CI)

$n= (1.96)^2X\ 0.501\ X\ 0.499/\ (0.05)^2= 0.960/(0.05)^2 \sim 384$

By adding 10% for possible non-response rate the total sample becomes **423.**

Sampling procedure

There were a total of six hospitals in Gurage Zone, namely; Wolkite University Comprehensive Specialized Hospital, Butajira General Hospital, Gunchirie Primary Hospital, Agena Primary hospital, Buie Primary Hospital, and Atat lord Maryam Primary Hospital. There were a total of 457 healthcare providers involved in the informed consent process in the last six months in Gurage zone hospitals. Since the total population (457) was small enough to apply the sampling technique, all(457) were included in this study.

Measurement of variables

- Thirteen structured Likert-type questions with options of "never", "sometimes" and "always" which scored 1, 2, and 3, respectively will be used to assess the practice of informed consent, and the total score for practice was dichotomized into good and poor practice using the mean score as the cut-off point.
- **Good practice:** A score greater or equal to the mean score for the practice questions.
- **Poor practice:** A score below the mean score for the practice questions
- **Adequate knowledge:-** A score greater or equal to the mean score for the knowledge questions

- **Inadequate knowledge:-** A score below the mean score for the knowledge questions
- **Favorable attitude:-** A score greater or equal to the mean score for the attitude-related questions
- **Unfavorable attitude:-** A score below the mean score for the attitude-related questions

Covariates

- Socio-demographic characteristics like (age, sex, educational profession, and communication barrier).
- Organizational factors (lack of standard consent form, in-service training, time constraint, availability of interpreter), workload, working unit
- Healthcare worker-related factors (knowledge, attitude), work-experience

Data Collection tool and Procedure

Data were collected by using a pretested structured questionnaire developed after the review of different kinds of literature. The questionnaire contains five parts; socio-demographic characteristics, organizational related, knowledge part, attitude section, and informed consent practice assessment-related items. Data were collected by six BSc nurses and two supervisors after one day of training by the principal investigator. Data were gathered using a self-administered structured questionnaire.

Data Quality Control

A pre-test was done on 5% of the samples. The one-day training was given by the principal investigator to the data collectors and supervisors before data collection. The training was focused on understanding the meaning of each question, obtaining consent, keeping the confidentiality of the information they gathered, and quality of data collection. Emphasis was given on the significance and the appropriate meanings of each question as well as how to

explain to the participants in an understandable manner if required. On top of this, supervisors were following data collectors and the investigator was also checking for the collected data clarity and completeness.

Data management and Analysis

Before data entry, questionnaires were checked for completeness and clarity. Cleaned and coded data were entered using Epidata 3.1 and exported to SPSS windows version 25 for analysis. Percentage and Frequency were calculated. The findings of the study were presented by using tables, graphs, Charts, and Narration. The bivariate analysis was used primarily to check which variables have an association with the dependent variable individually. The goodness of fit was tested by the Hosmer-Lemeshow statistic which is greater than 0.05. All variables with $P \leq 0.25$ in the bivariate analysis were included in the final model of multivariate analysis to control all possible confounders. The multi-co-linearity test was carried out to see the correlation between independent variables by using standard error and Co linearity statistics (VIF >10 and standard error >2 were considered suggestive of the existence of multi-co-linearity). The degree of association between independent and dependent variables was assessed using an adjusted odds ratio with a 95% confidence interval. Finally, the variables that have a p-value of <0.05 were considered statistically significant.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

RESULTS

From a total of 457 sample sizes, 448 study participants were involved in this study with a response rate of 98%.

Socio-demographic characteristics of the study participants

The mean (±SD) age of the study participants was 29.16 (±4.06) years. More than half of 241 (53.8%) of the study participants were male health professionals. Regarding the marital status of respondents, half 228 (50.9%) of them were married marital status. Nearly three-fourths 327 (73%) of the study participant's professional experience was greater than or equal to five years. Regarding the specialty of respondents more than half 249 (55.6 %) of them were nurses (216 (48.2 %) BSc and 33 (7.4%) clinical nurses) and one-quarter of the participants were midwifery **(Table 1)**.

Table 1: Sociodemographic related factors of the informed consenting process for major surgical procedures among Gurage zone hospitals health care providers, Southern Ethiopia. (n=448)

Variables	Category	Frequency(n)	Percent (%)
Sex	Female	207	46.2%
	Male	241	53.8%
Age	21-25 years	81	18.1%
	26-30 years	227	50.7%
	31-35 years	76	17.0%
	>=35 years	64	14.3%
Marital status	Single	211	47.1%
	Married	228	50.9%
	Divorced	9	2.0%
Work experience	< 5years	121	27.0%

	>= 5 years	327	73.0%
Types of profession	Nurse	249	55.6%
	Midwifery	112	25%
	Anesthesia	20	4.4%
	Physician	67	15%
Communication	No	230	51.3%
challenge	Yes	218	48.7%

Organizational related factors

Among the participants, nearly one-third of them were working at surgical 146(32.6%) and operation room 162(36.2%). Regarding the number of patients cared for per day, more than forty percent196 (43.8%) of study participants were given to care for about 6-10 patients per day. More than half of 238 (53.1%) study participants reported that there is administrative support. Of the study participants, two-thirds 300 (67%) of them had no training regarding the surgical informed consenting process. The majority of study participants 369 (82.4%) reported that the informed consent form contents are not adequate and standard in their setup. Nearly three-fourth329 (73.4%) of study participants reported that they had specific policies or regulations of informed consent in their institution (**Table 2**).

Table 2:-Organizational related factors of the informed consenting process for major surgical procedures among Gurage zone hospitals health care providers, Southern Ethiopia. (n=448)

Variables	Category	Frequency(n	Percent (%)
Working unit	Surgical ward	146	32.6%
	Delivery ward	63	14%
	Gynecology ward	49	11%
	Operation room	162	36.2%

	Surgical emergency	28	6.2%
The average number of patient care per day	< =5 years	149	33.3%
	6- 10 years	196	43.8%
	>10 years	103	23.0%
Time spent on the surgical consenting process	< 5 minutes	81	18.1%
	5-10 minutes	202	45.1%
	11-20 minutes	121	27.0%
	21- 30 minutes	44	9.8%
The informed consent form contents are adequate and standard	No	369	82.4%
	Yes	79	17.6%
Administrative support available	No	210	46.9%
	Yes	238	53.1%
Training on the process of informed consent	No	300	67.0%
	Yes	148	33.0%

Knowledge, attitude, and practice of respondents

The mean score of study participants' knowledge was 14, and more than half of 252 (56.3%) of study participants had adequate knowledge of the surgical informed consenting process. Regarding the attitude of respondents, the mean score of attitude was 37, and more than half of 230 (51.3%) participants had a favorable attitude towards the surgical informed consenting process. The mean score of study participants towards the surgical informed consenting process was 19.5, and 260 (58%, 95 % CI: 53.7, 62.5) of them had good practice in the surgical informed consenting process **(Figure 1).**

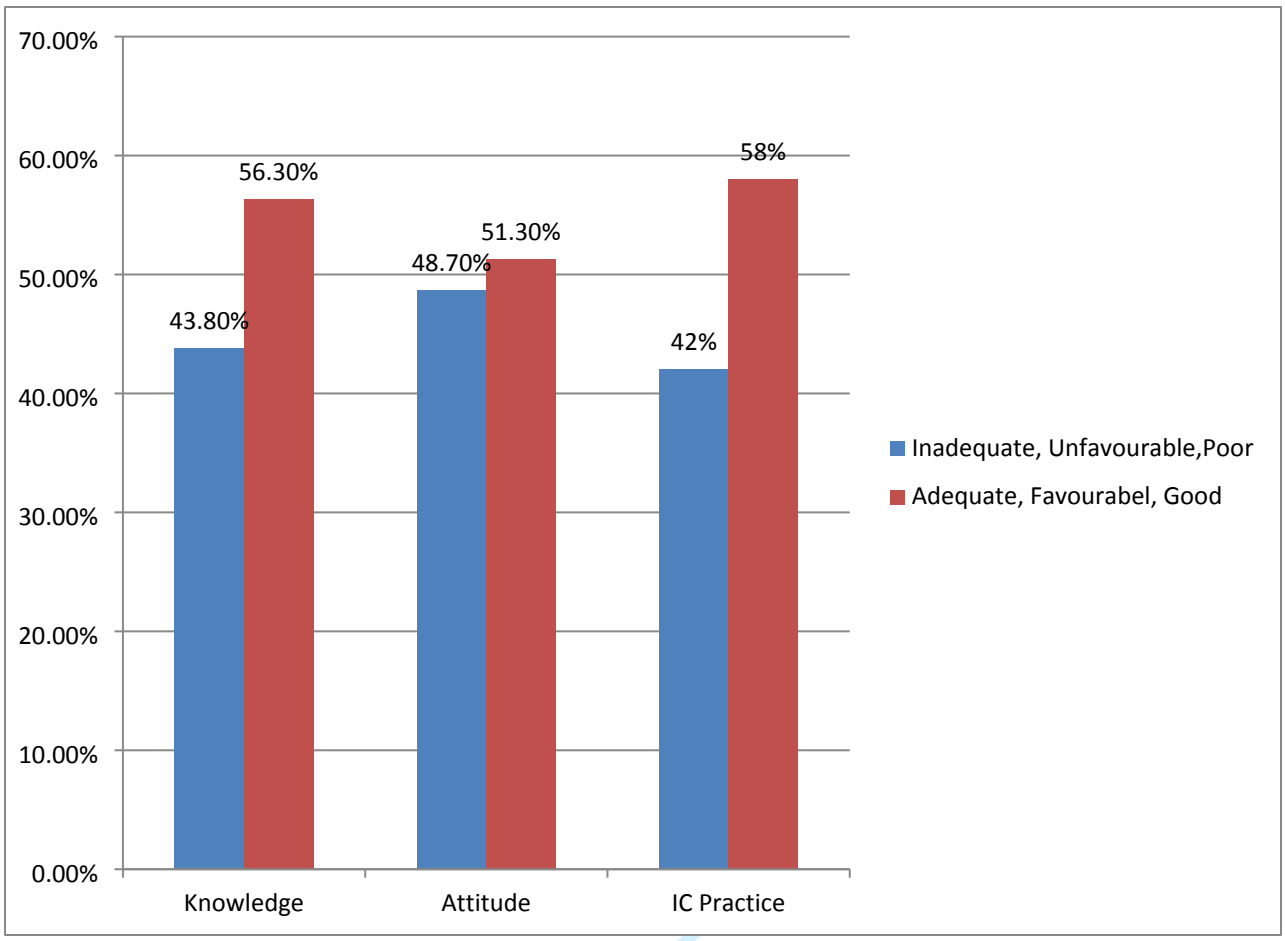

Figure 1:-knowledge, attitude, and practice of informed consenting process for major surgical procedure among Gurage zone hospitals health care providers, Southern Ethiopia. (n=448)

Factors associated with the surgical informed consenting practice

In this study variables such as working experience, knowledge of informed consent, attitude towards informed consent, communication barrier, training on informed consent, and content of informed consent were factors significantly associated with informed consenting practice in the bivariable logistic analysis model. In the multivariable logistic analysis model factors such as attitude towards informed consent, work experience of participants, knowledge of informed consent, and communication barrier were independently associated with the practice of the informed consenting process at a p-value of <0.05.

In our study participants who had >= 5 years of working experience were 4.9 (2.8,8.7) times more likely to practice the surgical informed consenting process properly compared with the respondent who had < 5 years of experience. The odds of performing informed consenting practice properly were 2.5(1.6, 3.9) times in health care providers having adequate knowledge compared with their counterparts. Similarly, those study participants who had a favorable attitude towards the informed consenting process were 2.4(1.556, 3.596) times more likely to practice informed consent properly. Lastly, healthcare providers who didn't face a communication challenge in the consenting process were 1.6 (1.07, 2.50) times more likely to practice the informed consenting process compared with their counterparts **(Table 3)**.

Table 3:-Multivariable Logistic regression analysis for factors associated with the informed consenting practice for major surgical procedures among Gurage zone hospital health care providers, Southern Ethiopia. (n=448)

Variables	**Category**	**IC Practice**		**95% confidence interval**		**P-value**
		Poor	Good	COR	AOR	
Working experience	< 5 years	20	101	1	1	
	>=5 years	168	159	5.336 (3.152, 9.033)	**4.912(2.779,8.682)**	0.000*
Knowledge of informed consent	Inadequate	60	136	1	1	
	Adequate	128	124	2.340 (1.582, 3.461)	**2.539 (1.632, 3.95)**	0.000*
Attitude on informed consent	Unfavorable	68	150	1	1	
	Favorable	120	110	2.406 (1.636, 3.540)	**2.365 (1.556, 3.596)**	0.000*
Training on	No	118	182	1	1.544 (0.966, 2.468)	

informed consent	Yes	70	78	1.384 (0.930, 2.059)		0.069
Communication barrier	No	112	118	1.773 (1.213, 2.593)	**1.635(1.068, 2.504)**	0. 024*
	Yes	76	142	1	1	
Adequate content of consent form	No	148	221	1	1	
	Yes	40	39	1.532 (0.940, 2.494)	1.105 (0.638,1.913)	0.721

IC:- Informed consent, **COR**:- Crude Odds Ratio, **AOR**:- Adjusted Odds Ratio

highly significant variable, * significant variable, **1:- constant

Discussion

The practical application of an interactive healthcare provider-patient relationship and respect for the patient's autonomy is assured by obtaining surgical informed consent from patients before the procedure[18, 19]. In our study, surgical informed consent process practice and factors associated with it were assessed. The finding of the study revealed that about 58% (95 % CI: 53.7, 62.5) of healthcare providers had good practice towards the surgical informed consenting process. Our study finding is higher than the study conducted in Turkey 32.6%[13], Uganda at 48.8%[16], southeastern Ethiopia at 50.1%[17], and in another study in Ethiopia 32.7%[20]. The possible explanation could be a difference in sample size(small sample size in Uganda and turkey), study setting, and study participants(only nurse professionals were involved in turkey) as well as operation national definition used to categorize as good and poor practice.

The finding of the study was lower than the study conducted in Italy 71%[21]. The possible justification could be study participant differences, study setting differences, as well as the

socioeconomic difference between studies. A study conducted in Italy incorporates only nurse professionals whereas we included all health care providers, and our study included five different hospitals to select study participants which may vary in patient flow, health care providers-patient ratio as well as difference in hospital setup compared with a study done in Italy.

Our study findings showed that healthcare providers who had greater than or equal to five years of experience were 5 times more likely to practice surgical informed consent compared with their working experience is less than five years. The finding is congruent with a study done in Italy[21], the democratic republic of congo[22], and southeastern Ethiopia[17]. It is a fact that experience has the advantage to get in-service training related to the informed consenting process and practicing informed consent properly. Experience has also an effect to have good relationships and communication between patients, as a result, they can easily exercise informed consenting practice.

Healthcare providers who had good knowledge regarding surgical consent were 2.5 times more likely to practice surgical informed consent than those who had inadequate knowledge. This finding is consistent with the study done in Pakistan [23], the Cape Coast Metropolis of Ghana[24], and southeastern Ethiopia [17]. Having a basic understanding of the surgical informed consenting process aids to integrate the component of consent and practicing it effectively. It is also a fact that having a basic understanding of the components of informed consent, the implementation of the informed consenting process will become optimal and properly practiced[25]. Similarly, healthcare providers with favorable attitude were 2.4 times more likely to practice surgical informed consent compared with their counterparts. The finding is supported by studies done in Pakistan[23], southeastern Ethiopia[17], and cross-sectional studies in Ethiopia health facilities[20]. Having a favorable attitude is fundamental and enhances

motivation to practice surgical informed consent as well as other procedures in the health care setup. The other possible justification might be the attitudes of healthcare personnel influence what they do, and those who have a positive attitude are more positive to perform activities positively[26].

In this study, healthcare providers who didn't face communication barriers with patients were 1.6 times more likely to practice surgical informed consent compared with those who face communication barriers with their clients. The possible explanation might be taking informed consent from patients across language barriers can be very difficult, and is often a source of major frustration both for patients and for healthcare providers[27, 28]. Studies suggested that language barriers and the absence of trained interpreters for effective communication have a negative impact on the process of informed consent as a result hinders the quality of patient care[29]. Another previous study in South Africa revealed that the absence of appropriately trained interpreters is a major barrier to the surgical informed consenting process for health care providers[8, 30].

Conclusions

More than half of healthcare providers had good practice towards the surgical informed consenting process. The finding of this study showed that the practice of informed consent is low. In this study participants who had >= 5 years of working experience, healthcare providers having adequate knowledge, participants who had a favorable attitude towards the informed consenting process, and healthcare providers who didn't face a communication challenge in the consenting process were factors independently associated with the surgical informed consenting practice. It is better to work on health care providers' in-service training, knowledge as well as

attitude towards informed consent. For future researchers, we recommended considering a multidimensional approach that includes observations as well as interviews with healthcare providers at different levels across the country.

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A Competing Interests Statement

The authors declared there is no conflict of interest concerning the research, authorship, and publication of this article

Ethical approval and informed consent

The study was approved by the Institutional Ethical Review Committee Board of Wolkite University with reference number (Ref no. RCSUIL024/14). Permission to conduct the study was also obtained from Gurage zone hospital administrators. Written informed consent was obtained from all subjects before the study. The study was also conducted following the Helsinki Declaration of Research involving human subjects.

Consent for publication

Not applicable.

Availability of data and materials

The data set used or analyzed during this study is available from the corresponding author on reasonable request.

Authors' contribution

Bitew Tefera Zewudie: Conceptualization; Investigation; Supervision; Resource; validation; writing original draft; writing-review and editing

Shegaw Geze: Conceptualization; Supervision; Resource; validation; writing original draft; writing-review and editing

Bogale Checkole: Conceptualization; Investigation; Resource; validation; writing original draft; writing-review and editing

Tadele Lankrew: Conceptualization; Data curation; Formal analysis; Investigation; Resource; Writing the original draft

Muche Argaw Eniyew: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Yibeltal Mesfin: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Daniel Tsega: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Tadese sahle: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Yihenew Sewale : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Haimanot Abebe : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Shegaw Geze : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Agere Aynalem : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Zebene Mekonnen: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

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PRACTICE AND FACTORS AFFECTING INFORMED CONSENT AMONG HEALTH CARE WORKERS FOR MAJOR SURGICAL PROCEDURES AT GURAGE ZONE HOSPITALS, SOUTH ETHIOPIA, 2022. FACILITY-BASED CROSS-SECTIONAL STUDY.

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PRACTICE AND FACTORS AFFECTING INFORMED CONSENT AMONG HEALTH CARE WORKERS FOR MAJOR SURGICAL PROCEDURES AT GURAGE ZONE HOSPITALS, SOUTH ETHIOPIA, 2022. FACILITY-BASED CROSS-SECTIONAL STUDY.

Bitew Tefera Zewudie[1*], ,Shegaw Geze[2],Yibeltal Mesfin[2,] Haimanot Abebe[1], Zebene Mekonnen[1],Shegaw Tesfa[1], Bogale Chekole[1] [1],Agerie Aynalem[1] Tadele lankrew[3],Yihenew Sewale[4] , Muche Argaw[2], Tadesse Sahle[1], Daniel Tsega[2]

[1]Department of Nursing, College of medicine and health science, Wolkite University, Wolkite, Ethiopia

[2]Department of Midwifery, College of medicine and health science, Wolkite University, Wolkite, Ethiopia

[3]Department of Nursing, College of medicine and health science, Wolaita Sodo University, Wolaita, Ethiopia

[4]Department of Nursing, College of medicine and health science, Debre Birhan University, Debre Birhan, Ethiopia

*corresponding author: Department of Nursing, College of Medicine and Health Sciences, Wolkite University, Wolkite, Ethiopia, bitewtefera1@gmail.com (BTZ)

Abstract

Objective: - This study aimed to assess the informed consent practice process and associated factors among healthcare workers for major surgical procedures at Gurage zone hospitals, in 2022.

Methods and Materials: Institution-based cross-sectional study was employed

Settings: This study was conducted in Gurage zone hospitals.

Participants: - All healthcare workers who have been working in Gurage Zone hospitals of surgical, operation rooms, and obstetrics /gynecology wards had exposure to patients who had undergone surgery during the study period

Outcome: - The primary outcome of the study was the practice of informed consent practice among health care workers in gurage zone hospitals

Result: - A total of 448 study participants were involved in this study giving a response rate of 98%. The mean (±SD) age of the study participants was 29.16 (±4.06) years. The mean score of study participants towards the surgical informed consent was 19.5, and 260 (58%, 95 % CI: 53.7, 62.5) of them had good practice in the surgical informed consent. In multivariable logistic analysis model, factors like favorable attitude towards informed consent 2.4(1.556, 3.596), work experience participants 4.9 (2.8, 8.7), adequate knowledge of informed consent 2.5(1.6, 3.9) and communication challenge 1.6 (1.07, 2.50) were independently associated with the practice of informed consent at a p-value of <0.05.

Conclusion: - More than half of health care providers had good practice towards the surgical informed consenting process. The practice of informed consent is low and it is better to work on healthcare providers' in-service training, knowledge, and attitude toward informed consent.

Keywords: - informed consent, practice, health care provider, Gurage zone, Ethiopia.

Strengths and limitations of the study

- We used multi-center study setting which is crucial for conclusion for the study area
- We used validated tool to assess the practice of informed consent
- Since the study design is cross-sectional cause and effect relationship cannot be established.
- Self-reporting bias might affect the outcome of the study since some respondents may not report what they practice.

INTRODUCTION

Informed consent is a core concept in the process of communication between a patient and health-care provider[1]. Surgical informed consent (SIC) is not only putting a signature on a piece of paper but is an ongoing process that begins in initial contact with the patient and continues through surgery and postoperative care[2, 3]. It is an established ethical and legal requirement for surgical treatment with paramount importance to protect both the patient and health care providers from unnecessary accusations[3, 4]. It is the health care professional's obligation of disclosing information to the patient to undergo a specific medical intervention which is fundamental to the proper care and treatment of patients[5].

Putting a signature on the informed consent form does not by itself constitute informed consent; it is the whole complex process of gaining information, deciding, and consenting[2, 5]. According to the Canadian Medical Association, informed consent is the primary paradigm for protecting patients' rights and guiding ethical practice[6]. Surgical informed consent is vital for acknowledging patients' autonomy and self-determination as well as for promoting shared decision-making by shifting the care from physician-centered to patient-centered[2]. The updated

World Medical Association Declaration stated that the consent process should respect the patient's right to refuse or agree to any diagnostic procedures or treatments[7].

The information given is the most determinant factor for decision-making in the consenting process[2]. The reason for surgery, the proposed type of surgery, the risks and benefits of the proposed surgery, alternative treatments, and the benefits of refusing therapy should be incorporated into the consent [2, 4]. A legal and ethical context of informed consent requires five key elements to establish validity which, include competence, voluntariness, information disclosure, understanding of information disclosed, and authorization or consent to the medical procedure [8].

The informed consent is the corner of shared decision-making, legal requirement, and ethical obligations for all surgical procedures if it is properly practiced[9]. Despite this fact, it is inconsistently practiced and rarely achieves the theoretical ideal. Without a basic understanding of the nature of the procedure, risks, benefits, and treatment alternatives, the patient cannot meaningfully participate in decision-making. Therefore, to provide safe, quality, patient-centered health care it is important to emphasize the proper informed consenting process[10].

Studies conducted in different countries of the globe (the United Kingdom, Pakistan, and the Netherlands) showed that the practice of surgical informed consent among healthcare providers didn't meet the minimum standard when they perform informed consent with their patients[11-13]. A study done in Iran showed that only 12.6% of nurses give sufficient information to their patients to assure suitable practice of informed consent[14].

Studies conducted in the African region showed that the practice of proper informed consenting practice is poor. For instance, in studies done in Uganda and Egypt, only 50% of surgeons obtain

informed consent with adequate information before major surgical procedures[15, 16]. Similarly, 65.7% of the clients reported that they are not being informed about their procedure and instead simply ordered to put their signature on the informed consent sheet[15]. A study which was conducted in bale zone hospitals showed that only 50% of healthcare professionals practice the proper informed consenting process[17].

Previous studies in different countries of the world mainly focus on informed consent from patient perspectives and showed that there is a gap in the informed consenting process. However, factors affecting the informed consenting process are not yet addressed. There is also scarce information on the practice and factors affecting the informed consent process from a healthcare perspective in the study area and even in Ethiopia. Therefore, this study aimed to assess the informed consent practice process and associated factors among healthcare workers for major surgical procedures at Gurage zone hospitals, in Ethiopia.

Methods

Study Setting and Study Design

This study was conducted in public hospitals of the Gurage zone, South Ethiopia. The Gurage zone is one of the 11 administrative zones and four special woredas in the southern nation nationality people region (SNNPR). Wolkite town is the capital city of the Gurage zone. It is found 153 km southwest of Addis Ababa, the capital city of Ethiopia. According to the Ethiopian national census of 2007, it has 1,279,646 total populations. There are six hospitals (five public and one non-governmental) serving the catchment population in the zone. An Institution-based cross-sectional study was employed

Participants

The source populations were all healthcare workers (nurses, midwives, GPs, surgeons, gynecologists), anesthetists) working at Gurage Zone hospitals. All healthcare workers who have been working in Gurage Zone hospitals of surgical, operation rooms, and obstetrics /gynecology wards had exposure to patients who had undergone surgery during the study period were study populations.

Inclusion and Exclusion Criteria

All healthcare workers (nurses, midwives, doctors, and anesthetists) who worked for at least 6 months in the hospital were included. Healthcare workers who were on annual leave, sick leave, or training were excluded from the study. Those who have not been working in surgical, labor, emergency, obstetrics, and gynecology ward and operating room in the last 6 months were excluded.

Goals of study

- ✓ To assess the practice of informed consent among health-care workers for major surgical procedures of Gurage zone hospitals, 2022.
- ✓ To identify factors affecting informed consent practice among health-care workers for major surgical procedures of Gurage zone hospitals, 2022.

Sample Size Determination and Sampling Procedures

Sample Size Calculation

The minimum required sample size was calculated by using single population proportion formula, assuming the prevalence of informed consent practice as 50.1 based on a study conducted in South Eastern Ethiopia[17], 5% margin of error at 95% CI as follows;

$$n=\frac{(Z\ \alpha / 2)^2\ P\ (1-p)}{d^2}$$

n = Sample size

p = Proportion =0.501

d = Margin of error =0.05

q = 1-p = 0.499

Z = 1.96 at a 95% Confidence Interval (CI)

$n= (1.96)^2X\ 0.501\ X\ 0.499/\ (0.05)^2= 0.960/(0.05)^2 \sim 384$

By adding 10% for possible non-response rate the total sample becomes **423.**

Sampling procedure

There were six hospitals in Gurage Zone: Wolkite University Comprehensive Specialized Hospital, Butajira General Hospital, Gunchirie Primary Hospital, Agena Primary hospital, Buie Primary Hospital, and Atat lord Maryam Primary Hospital. There were 457 healthcare providers involved in the informed consent in the last six months in Gurage zone hospitals. Since the total population (457) was small enough to apply the sampling technique, all (457) were included in this study.

Measurement of variables

- Thirteen structured Likert-type questions with options of "never", "sometimes" and "always" which scored 1, 2, and 3, respectively will be used to assess the practice of informed consent, and the total score for practice was dichotomized into good and poor practice using the mean score as the cut-off point.
- **Good practice:** A score greater or equal to the mean score for the practice questions.
- **Poor practice:** A score below the mean score for the practice questions
- **Adequate knowledge:-** A score greater or equal to the mean score for the knowledge questions

- **Inadequate knowledge:-** A score below the mean score for the knowledge questions
- **Favorable attitude:-** A score greater or equal to the mean score for the attitude-related questions
- **Unfavorable attitude:-** A score below the mean score for the attitude-related questions

Covariates

- Socio-demographic characteristics like (age, sex, educational profession, and communication barrier).
- Organizational factors (lack of standard consent form, in-service training, time constraint, availability of interpreter), workload, working unit
- Healthcare worker-related factors (knowledge, attitude), work-experience

Data Collection tool and Procedure

Data were collected by using a pretested structured questionnaire developed after the review of different kinds of literature. The questionnaire contains five parts; socio-demographic characteristics, organizational related, knowledge part, attitude section, and informed consent practice assessment-related items. Data were collected by six BSc nurses and two supervisors after one day of training by the principal investigator. Data were gathered using a self-administered structured questionnaire.

Data Quality Control

A pre-test was done on 5% of the samples. The one-day training was given by the principal investigator to the data collectors and supervisors before data collection. The training was focused on understanding the meaning of each question, obtaining consent, keeping the confidentiality of the information they gathered, and quality of data collection. Emphasis was given on the significance and the appropriate meanings of each question as well as how to explain to the

participants in an understandable manner if required. On top of this, supervisors were following data collectors and the investigator was also checking for the collected data clarity and completeness. The double data entry method was used by two data clerks, and the consistencies of the entered data were cross-checked by comparing the two separately entered data.

Data management and Analysis

Before data entry, questionnaires were checked for completeness and clarity. Cleaned and coded data were entered using Epidata 3.1 and exported to SPSS windows version 25 for analysis. Percentage and Frequency were calculated. The findings of the study were presented by using tables, graphs, Charts, and Narration. The bivariate analysis was used primarily to check which variables have an association with the dependent variable individually. The goodness of fit was tested by the Hosmer-Lemeshow statistic which is greater than 0.05. All variables with $P \leq 0.25$ in the bivariate analysis were included in the final model of multivariate analysis to control all possible confounders. The multi-co-linearity test was carried out to see the correlation between independent variables by using standard error and Co linearity statistics (VIF >10 and standard error >2 were considered suggestive of the existence of multi-co-linearity). The degree of association between independent and dependent variables was assessed using an adjusted odds ratio with a 95% confidence interval. Finally, the variables that have a p-value of <0.05 were considered statistically significant.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

RESULTS

From a total of 457 sample sizes, 448 study participants were involved in this study with a response rate of 98%.

Socio-demographic characteristics of the study participants

The mean (±SD) age of the study participants was 29.16 (±4.06) years. More than half of 241 (53.8%) of the study participants were male health professionals. Regarding the marital status of respondents, half 228 (50.9%) of them were married marital status. Nearly three-fourths 327 (73%) of the study participant's professional experience was greater than or equal to five years. Regarding the specialty of respondents more than half 249 (55.6 %) of them were nurses (216 (48.2 %) BSc and 33 (7.4%) clinical nurses) and one-quarter of the participants were midwifery **(Table 1)**.

Table 1: Sociodemographic related factors of the informed consenting process for major surgical procedures among Gurage zone hospitals health care providers, Southern Ethiopia. (n=448)

Variables	Category	Frequency(n)	Percent (%)
Sex	Female	207	46.2%
	Male	241	53.8%
Age	21-25 years	81	18.1%
	26-30 years	227	50.7%
	31-35 years	76	17.0%
	>=35 years	64	14.3%
Marital status	Single	211	47.1%
	Married	228	50.9%
	Divorced	9	2.0%
Work experience	< 5years	121	27.0%

	>= 5 years	327	73.0%
Types of profession	Nurse	249	55.6%
	Midwifery	112	25%
	Anesthesia	20	4.4%
	Physician	67	15%
Communication	No	230	51.3%
challenge	Yes	218	48.7%

Organizational related factors

Among the participants, nearly one-third of them were working at surgical 146(32.6%) and operation room 162(36.2%). Regarding the number of patients cared for per day, more than forty percent196 (43.8%) of study participants were given to care for about 6-10 patients per day. More than half of 238 (53.1%) study participants reported that there is administrative support. Of the study participants, two-thirds 300 (67%) of them had no training regarding the surgical informed consenting process. The majority of study participants 369 (82.4%) reported that the informed consent form contents are not adequate and standard in their setup. Nearly three-fourth329 (73.4%) of study participants reported that they had specific policies or regulations of informed consent in their institution (**Table 2**).

Table 2:-Organizational related factors of the informed consenting process for major surgical procedures among Gurage zone hospitals health care providers, Southern Ethiopia. (n=448)

Variables	Category	Frequency(n	Percent (%)
Working unit	Surgical ward	146	32.6%
	Delivery ward	63	14%
	Gynecology ward	49	11%
	Operation room	162	36.2%

	Surgical emergency	28	6.2%
The average number of patient care per day	< =5 years	149	33.3%
	6- 10 years	196	43.8%
	>10 years	103	23.0%
Time spent on the surgical consenting process	< 5 minutes	81	18.1%
	5-10 minutes	202	45.1%
	11-20 minutes	121	27.0%
	21- 30 minutes	44	9.8%
The informed consent form contents are adequate and standard	No	369	82.4%
	Yes	79	17.6%
Administrative support available	No	210	46.9%
	Yes	238	53.1%
Training on the process of informed consent	No	300	67.0%
	Yes	148	33.0%

Knowledge, attitude, and practice of respondents

The mean score of study participants' knowledge was 14, and more than half of 252 (56.3%) of study participants had adequate knowledge of the surgical informed consenting process. Regarding the attitude of respondents, the mean score of attitude was 37, and more than half of 230 (51.3%) participants had a favorable attitude towards the surgical informed consenting process. The mean score of study participants towards the surgical informed consenting process was 19.5, and 260 (58%, 95 % CI: 53.7, 62.5) of them had good practice in the surgical informed consenting process

Figure 1:-knowledge, attitude, and practice of informed consenting process for major surgical procedure among Gurage zone hospitals health care providers, Southern Ethiopia. (n=448)

Factors associated with the surgical informed consenting practice

In this study variables such as working experience, knowledge of informed consent, attitude towards informed consent, communication barrier, training on informed consent, and content of informed consent were factors significantly associated with informed consenting practice in the bivariable logistic analysis model. In the multivariable logistic analysis model factors such as attitude towards informed consent, work experience of participants, knowledge of informed consent, and communication barrier were independently associated with the practice of the informed consenting process at a p-value of <0.05.

In our study participants who had >= 5 years of working experience were 4.9 (2.8,8.7) times more likely to practice the surgical informed consenting process properly compared with the respondent who had < 5 years of experience. The odds of performing informed consenting practice properly were 2.5(1.6, 3.9) times in health care providers having adequate knowledge compared with their counterparts. Similarly, those study participants who had a favorable attitude towards the informed consenting process were 2.4(1.556, 3.596) times more likely to practice informed consent properly. Lastly, healthcare providers who didn't face a communication challenge in the consenting process were 1.6 (1.07, 2.50) times more likely to practice the informed consenting process compared with their counterparts **(Table 3)**.

Table 3:-Multivariable Logistic regression analysis for factors associated with the informed consenting practice for major surgical procedures among Gurage zone hospital health care providers, Southern Ethiopia. (n=448)

IC:- Informed consent, **COR**:- Crude Odds Ratio, **AOR**:- Adjusted Odds Ratio

Variables	**Category**	**IC Practice**		**95% confidence interval**		**P-value**
		Poor	Good	COR	AOR	
Working experience	< 5 years	20	101	1	1	
	>=5 years	168	159	5.336 (3.152, 9.033)	**4.912(2.779,8.682)**	0.000*
Knowledge of informed consent	Inadequate	60	136	1	1	
	Adequate	128	124	2.340 (1.582, 3.461)	**2.539 (1.632, 3.95)**	0.000*
Attitude on informed consent	Unfavorable	68	150	1	1	
	Favorable	120	110	2.406 (1.636, 3.540)	**2.365 (1.556, 3.596)**	0.000*
Training on informed consent	No	118	182	1	1.544 (0.966, 2.468)	
	Yes	70	78	1.384 (0.930, 2.059)		0.069
Communication barrier	No	112	118	1.773 (1.213, 2.593)	**1.635(1.068, 2.504)**	0. 024*
	Yes	76	142	1	1	
Adequate content of consent form	No	148	221	1	1	
	Yes	40	39	1.532 (0.940, 2.494)	1.105 (0.638,1.913)	0.721

highly significant variable, * significant variable, **1:- constant

Discussion

The practical application of an interactive healthcare provider-patient relationship and respect for the patient's autonomy is assured by obtaining surgical informed consent from patients before the procedure[18, 19]. In our study, surgical informed consent process practice and factors associated with it were assessed. The finding of the study revealed that about 58% (95 % CI: 53.7, 62.5) of healthcare providers had good practice towards the surgical informed consenting process. Our study finding is higher than the study conducted in Turkey 32.6%[13], Uganda at 48.8%[16], southeastern Ethiopia at 50.1%[17], and in another study in Ethiopia 32.7%[20]. The possible explanation could be a difference in sample size(small sample size in Uganda and turkey), study setting, and study participants(only nurse professionals were involved in turkey) as well as operation national definition used to categorize as good and poor practice.

The finding of the study was lower than the study conducted in Italy 71%[21]. The possible justification could be study participant differences, study setting differences, as well as the socioeconomic difference between studies. A study conducted in Italy incorporates only nurse professionals whereas we included all health care providers, and our study included five different hospitals to select study participants which may vary in patient flow, health care providers- patient ratio as well as difference in hospital setup compared with a study done in Italy.

Our study findings showed that healthcare providers who had greater than or equal to five years of experience were 5 times more likely to practice surgical informed consent compared with their working experience is less than five years. The finding is congruent with a study done in Italy[21], the democratic republic of congo[22], and southeastern Ethiopia[17]. It is a fact that experience has the advantage to get in-service training related to the informed consenting process and

practicing informed consent properly. Experience has also an effect to have good relationships and communication between patients, as a result, they can easily exercise informed consenting practice.

Healthcare providers who had good knowledge regarding surgical consent were 2.5 times more likely to practice surgical informed consent than those who had inadequate knowledge. This finding is consistent with the study done in Pakistan [23], the Cape Coast Metropolis of Ghana[24], and southeastern Ethiopia [17]. Having a basic understanding of the surgical informed consenting process aids to integrate the component of consent and practicing it effectively. It is also a fact that having a basic understanding of the components of informed consent, the implementation of the informed consenting process will become optimal and properly practiced[25]. Similarly, healthcare providers with favorable attitude were 2.4 times more likely to practice surgical informed consent compared with their counterparts. The finding is supported by studies done in Pakistan[23], southeastern Ethiopia[17], and cross-sectional studies in Ethiopia health facilities[20]. Having a favorable attitude is fundamental and enhances motivation to practice surgical informed consent as well as other procedures in the health care setup. The other possible justification might be the attitudes of healthcare personnel influence what they do, and those who have a positive attitude are more positive to perform activities positively[26].

In this study, healthcare providers who didn't face communication barriers with patients were 1.6 times more likely to practice surgical informed consent compared with those who face communication barriers with their clients. The possible explanation might be taking informed consent from patients across language barriers can be very difficult, and is often a source of major frustration both for patients and for healthcare providers[27, 28]. Studies suggested that language barriers and the absence of trained interpreters for effective communication have a negative impact

on the process of informed consent as a result hinders the quality of patient care[29]. Another previous study in South Africa revealed that the absence of appropriately trained interpreters is a major barrier to the surgical informed consenting process for health care providers[8, 30].

As a limitation, our study design is a facility-based cross-sectional study, cause-and-effect relationship cannot be established. Our study uses paper-based questionnaire, self-reporting bias might affect the outcome of the study since some respondents may not report what they practice.

Conclusions

More than half of healthcare providers had good practice (answered above the mean) towards the surgical informed consenting process. The finding of this study showed that the practice of informed consent is low. In this study participants who had >= 5 years of working experience, healthcare providers having adequate knowledge, participants who had a favorable attitude towards the informed consenting process, and healthcare providers who didn't face a communication challenge in the consenting process were factors independently associated with the surgical informed consenting practice. It is better to work on health care providers' knowledge related with informed consent, communication challenges as well as attitude towards informed consent. For future researchers, we recommended considering a multidimensional approach that includes observations as well as interviews with healthcare providers at different levels across the country. We also recommend that researchers to use triangulations (to add qualitative aspect). Future researchers are also recommended to conduct longitudinal research to confirm a definitive cause-and-effect relationship between the practice of informed consent and the independent variables.

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A Competing Interests Statement

The authors declared there is no conflict of interest concerning the research, authorship, and publication of this article

Ethical approval and informed consent

The study was approved by the Institutional Ethical Review Committee Board of Wolkite University with reference number (Ref no. RCSUIL024/14). Permission to conduct the study was also obtained from Gurage zone hospital administrators. Written informed consent was obtained from all subjects before the study. The study was also conducted following the Helsinki Declaration of Research involving human subjects.

Consent for publication

Not applicable.

Availability of data and materials

The data set used or analyzed during this study is available from the corresponding author on reasonable request.

Authors' contribution

Bitew Tefera Zewudie: Conceptualization; Investigation; Supervision; Resource; validation; writing original draft; writing-review and editing

Shegaw Geze: Conceptualization; Supervision; Resource; validation; writing original draft; writing-review and editing

Bogale Checkole: Conceptualization; Investigation; Resource; validation; writing original draft; writing-review and editing

Tadele Lankrew: Conceptualization; Data curation; Formal analysis; Investigation; Resource; Writing the original draft

Muche Argaw Eniyew: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Yibeltal Mesfin: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Daniel Tsega: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Tadese sahle: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Yihenew Sewale : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Haimanot Abebe : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Shegaw Geze : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Agere Aynalem : Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

Zebene Mekonnen: Conceptualization; Formal analysis; Investigation; Methodology; Writing-review and editing

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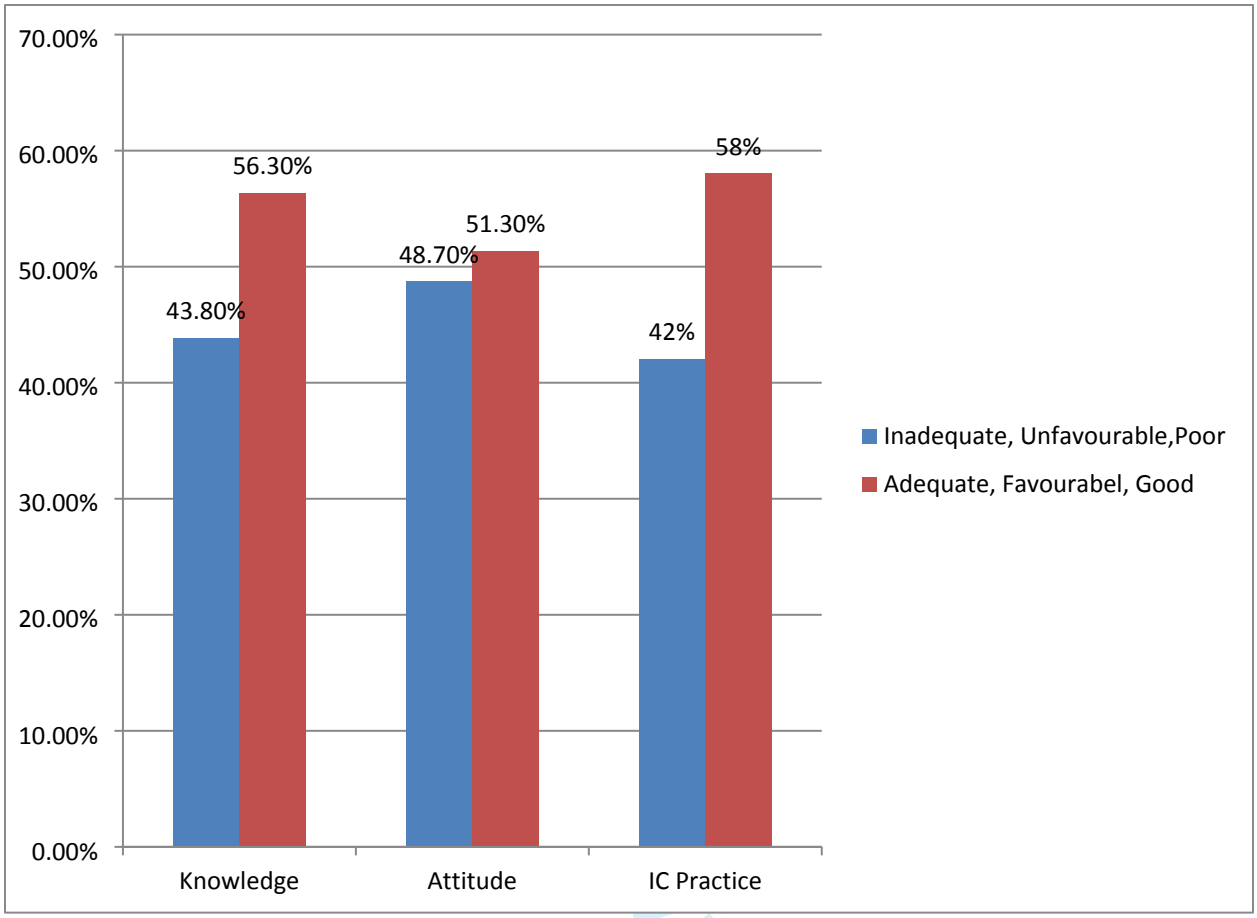

Figure 1:-knowledge, attitude, and practice of informed consenting process for major surgical procedure among Gurage zone hospitals health care providers, Southern Ethiopia. (n=448)