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# Assessment of the Quality of Informed Consent Process for Elective Gynaecological and Obstetrics Surgical Procedures at Ain Shams University Maternity Hospital: Cross Sectional Observational Study

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## Abstract

*Background:* Informed consent is the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention. The basic requirements for informed consent include patients' competence and voluntariness as preconditions for informed consent, provision of adequate and comprehensible information, finally, the patient consents to have the surgical procedure to be performed.

*Aim of Study:* To assess the quality of informed consent process for elective gynaecological and obstetric surgery at Ain Shams University Maternity Hospital.

*Patients and Methods:* The current cross-sectional observational hospital-based study was conducted in Department of Obstetrics and Gynecology at Ain Shams University Maternity Hospital (ASUMH). In the period between December 2023 to March 2024 on 175 cases undergoing obstetrics and gynecology surgery.

*Results:* The study showed majority of the patients had poor quality of informed consent prior to elective gynecology and Obstetrics surgery at Ain Shams University Maternity Hospital. Those with low education level, who had no knowledge about informed consent and did not know that consenting was voluntary, had misconception about consent, or required to have an interpreter during the consent process, with whom verbal interaction without illustration was used during the consent process, consented on ward, in cases where the consent process took less than 20 minutes, not asking questions during the consenting process were likely to have poor quality informed consent. The result of current study showed the quality of informed consent given to the participants prior to elective surgery was poor in most of them (57.7%).

*Conclusion:* This study suggests that the quality of informed consent process among patients undergoing elective gynaecological and obstetric surgery at is below the accepted national standard. The health workers did not create enough time to explain to the patients' important details about their condition and management. Vital information about what to expect before and after surgery was hardly addressed. The patients lack knowledge about informed consent process. They do not know that it's their right to be informed about their medical condition, any forthcoming interventions and their decision is voluntary.

***Key Words:*** *Elective gynaecological – Obstetrics surgical procedures – Informed consent process.*

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## Introduction

**INFORMED** consent is the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention **[1]**.

Prior to the late 1950s, there was no firm ground regarding taking informed consent. In ancient medicine, the Hippocratic Corpus primary focus of medical ethics was the obligation of the physician to provide medical benefits to patients and protect them from harm **[2]**. Until the 20th century, physicians could rarely even explain to themselves and, thus, to their patients which of their recommendations were curative and which were not **[3]**.

Informed consent is based on the moral and legal premise of patient autonomy: Where by the patient has the right to make decisions about his/her own health and medical conditions **[4]**.

Glaser et al. **[5]** implied informed consent in both an ethical and legal obligation of medical practition-

ers in the US and originates from the patient's right to direct what happens to their body. Implicit in providing informed consent is an assessment of the patient's understanding, rendering an actual recommendation, and documentation of the process.

The elements of informed consent are usually described as disclosure, understanding, decision making capacity, and voluntariness **[6].**

Shared decision-making (SDM) challenges in Emergency Medicine include patient, provider, system and evidence level limitations. Examples include: (1) If patients are capable of or willing to engage in decision making (2) If providers feel it provides more or less medico-legal protection, (3) If the Emergency Department is overwhelmed and time is of the essence to make decisions, and (4) If the facility lacks well-validated risk prediction tools to guide decision making **[7].**

The environment where obtaining consent is done from, confidentiality about the discussion outcomes and the administrative aspects involved have a great influence on the informed consent process **[8].**

Astudy in South Africa identified that patients know that giving informed consent is their right. However, poverty, language barrier and low educational level limits them to exercise their right of giving informed consent **[9]**. Discrimination of one's status and disrespect and verbal abuse affect communication also impact the consent process **[10].** It was emphasized that doctors are sometimes arrogant, that they dictate treatment and surgery to patients even when other options were available **[11].**

*Aim of the work:*

The aim of the study is to assess the quality of informed consent process for elective gynaecological and obstetric surgery at Ain Shams University Maternity Hospital.

## Patients and Methods

The current cross-sectional observational hospital-based study was conducted in Department of Obstetrics and Gynecology at Ain Shams University Maternity Hospital (ASUMH). In the period between December 2023 to March 2024 on 175 cases undergoing obstetrics and gynecology surgery.

*The participants fulfilling inclusion criteria:*

The Inclusive Criteria was: (above 18 years of age consented to participate in study and had undergone elective gynecological and obstetrics surgery). Without exclusion criteriamentally disableor below the legal age of consent were enrolled in this study.

*Primary research outcome:*

To determine the quality of informed consent among the patients undergoing elective Gynaecological and Obstetric Surgery at Ain Shams University Maternity Hospital (ASUMH).

*Secondary outcome:*

To identify the factors associated with the quality of informed consent among patients undergoing elective gynaecological and obstetric surgery at ASUMH.

*Study procedures:*

The present study was carried at Ain Shams University Maternity Hospital patients admitted for elective surgery either through Outpatient department clinics (OPD) through emergency department stabilization from life threatening condition and then sent to the ward.

At the gynaecologic and antenatal care wards patients booked for surgery. They could be retained on ward or allowed to go home to return on the date of appointment. Prior admission for elective surgery, the patient was admitted a day before through the OPD or ANC. Admission and review done again by the doctors to access their wellbeing, confirm diagnosis and fitness for surgery. Patients that suited the criteria have the elective operation were performed the following day.

Consent was obtained during admission; it was at this point that the patient signed a consent form for admission and any other surgical procedures that might get done on them.

Following surgery, patients were treated for 1-7 days post-operatively depending on their wellbeing, some stay longer if complications like sepsis occurred. After discharge, the patients aware reviewed again in the OPD Follow-up there after depends on the patient's diagnosis.

*Study interventions:*

The patient who underwent elective gynaecological and obstetric surgery were approached by the principal investigator. From elective theatre list one to two days before the procedure. An explanation was given to the patient as to why they have been selected, then the study consent form was issued or read to the patients.

The interviewer verbally introduced themselves and explained the research purpose to the eligible patient including assurance of their confidentiality. Acceptance to take part in the study was confirmed by the attaching their signature or thumbprint on the study consent form this was done day or two days before the operation. The interviewer also signed the consent form thereafter. Those who consent were recruited to the study and signed the study consent form.

Data was collected verbally using a structured questionnaire. Every Patient were discussed on their second post-operative day as by this time they are a

little bit better in terms of recovery, pain had subsided. Their responses were filled in the appropriate spaces and Likert scale where applicable on the questionnaire.

The questionnaire prepared in English was translated to Arabic. The Arabic version was translated back into English to maintain consistency while the Arabic version was used to interview women.

The questionnaire was included three main sections regarding: First one socio-demographic data consisting of five items. eg: Age, Marital status, Education level, Occupation, Residence. The Second one covered some aspects of quality of informed consent (thirteen questions) eg: information about diagnosis and treatment, information about the indication of surgery, information about benefit and Risk of the surgery and if patients have received sufficient information to decide their alternative treatment etc.

Third section dealt with factor associated with quality of informed consent eg: Patient factors, health provider factors, hospital related factors and policy factors.

*Statistical analysis:*

A coding procedure were developed, the respondents' responses for each question were doubled recorded into the database with a computerized were data entry and processed with statistical software using EPI Info 7.2.5. The researcher and statistician were checked the entered data with the original data collected. The coding systematically re-organized raw data into a computer readable format.

Quality of informed consent process were measured using questions formulated from the recommended elements of the informed consent. The questions were designed in form of 5-point Likert scale where 1=very poor, 2=poor, 3=fair, 4=good 5=very good. A cut off score of 3 will be set as the average measure of quality, where scores 3 and below=poor quality while scores greater than 3=good quality.

Qualities were determined and classified into two binary and mutually exclusive categories as "poor quality = 1" (poor quality is the category of interest, the reason it is coded as 1) and "good quality = 0". If the proportion of poor quality was greater than 10%, therefore logistic regression analysis and prevalence ratios (PR) were used to interpret the factors associated with the poor quality of informed consent.

## Results

This study was conducted at Ain Shams University Maternity Hospital during period between December and March 2024 this study included 175 cases.

Analysis of the Sociodemographic data of the included patients showed that mean age of 40.6 years with a standard deviation of 12.43 years, ranging from 20 to 75 years. The majority of patients were married (84.6%), followed by those with no educational qualifications (50.3%). In terms 1 of education, 25.7% had secondary education, while only 5.1% had tertiary education. Regarding occupation, housewives constituted the largest group (79.5%), the distribution of other occupations such as self-employed individuals, students, and various professionals (e.g., nurses, teachers, businesspersons) was notably low as shown in Table (1).

Table (1): Sociodemographic data of studied patients.

| | Studied patients (n=175) | |
|---|---|---|
| | N | % |
| *Age:* | | |
| Mean ± SD | 40.6±12.43 | |
| Range | 20-75 | |
| *Age Groups:* | | |
| 18-30 | 44 | 25.1 |
| 30-45 | 74 | 42.3 |
| Over 45 | 57 | 32.6 |
| *Marital Status:* | | |
| Single | 10 | 5.7 |
| Married | 148 | 84.6 |
| Divorced | 8 | 4.6 |
| Widow | 9 | 5.1 |
| *Education level:* | | |
| None | 88 | 50.3 |
| Primary | 33 | 18.9 |
| Secondary | 45 | 25.7 |
| Tertiary | 9 | 5.1 |
| *Occupation:* | | |
| House wife | 139 | 79.5 |
| Self employed | 12 | 6.8 |
| Student | 15 | 8.6 |
| Nurse | 3 | 1.7 |
| Business | 4 | 2.3 |
| Teacher | 2 | 1.1 |

On asking patients to assess the quality of informed consent, 13 questions were used and it was noticed that most of patients experienced poor and fair quality of informed consent as shown in Table (2).

The responses were measured on a scale of 5 and a mean response was determined. All the responses with mean response above 3 were categorized as good while those with mean response of 3 and below were considered poor. The data reveal that 42.3% of patients rated the total quality of informed consent as good, while 57.7% rated it as poor as shown in Table (3).

Table (2): Quality of Informed Consent.

| Studied patients (n=175) | Very Good | | Good | | Fair | | Poor | | Very poor | |
|---|---|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % | N | % |
| The information about the diagnosis and treatment of your illness | 39 | 22.3 | 41 | 23.4 | 49 | 28.0 | 37 | 21.1 | 9 | 5.1 |
| The information about any treatment options available regarding your illness | 1 | 0.6 | 23 | 13.1 | 28 | 16.0 | 60 | 34.3 | 63 | 36.0 |
| The information about the indication for surgery | 20 | 11.4 | 36 | 20.6 | 59 | 33.7 | 30 | 17.1 | 30 | 17.1 |
| The information about the benefits of the surgery | 6 | 3.4 | 33 | 18.9 | 47 | 26.9 | 63 | 36.0 | 26 | 14.9 |
| The information about the risks of undergoing surgery | 6 | 3.4 | 18 | 10.3 | 50 | 28.6 | 58 | 33.1 | 43 | 24.6 |
| The information about the type of anesthesia | 16 | 9.1 | 30 | 17.1 | 63 | 36.0 | 33 | 18.9 | 33 | 18.9 |
| The information about possible complications if surgery was not done | 9 | 5.1 | 17 | 9.7 | 42 | 24.0 | 66 | 37.7 | 41 | 23.4 |
| The information about the pre-operative care and precautions | 3 | 1.7 | 25 | 14.3 | 63 | 36.0 | 48 | 27.4 | 36 | 20.6 |
| The information about the post- operative care and precautions | 7 | 4.0 | 59 | 33.7 | 46 | 26.3 | 37 | 21.1 | 26 | 14.9 |
| The information about your duration of stay in hospital after surgery | 1 | 0.6 | 50 | 28.6 | 91 | 52.0 | 17 | 9.7 | 16 | 9.1 |
| The information about the healing process after surgery | 4 | 2.3 | 24 | 13.7 | 63 | 36.0 | 61 | 34.9 | 23 | 13.1 |
| The information about the when to resume normal activities after surgery | 1 | 0.6 | 15 | 8.6 | 55 | 31.4 | 66 | 37.7 | 38 | 21.7 |
| The information about the quality of life after healing from the surgery | 3 | 1.7 | 16 | 9.1 | 50 | 28.6 | 61 | 34.9 | 45 | 25.7 |

Table (3): Total Quality of Informed of the study.

| | Studied patients (n=175) | |
|---|---|---|
| | N | % |
| *Total Quality of Informed Consent:* | | |
| Good | 74 | 42.3 |
| Poor | 101 | 57.7 |

On assessing the patient factors associated with quality of informed consent, it was found that 71.4% of them knew that one has to first consent before surgery is done. Most of patients stated that they had to consent before surgery prove that they accepted the treatment. Most of patients (78.3%) stated that they didn't know that after giving consent, she can change the decision previously made as illustrated in Table (4).

Most of patients (96.6%) belonged to the public sector. 87.4% of patients were given general anesthesia. 88% of them underwent major surgery. All of patients stated that their primary language was used when discussing about her condition and its management. 94.3% of patients stated that only words were used to explain the treatment to be offered as shown in Table (5).

Among the included patients, 73.7% of them declared that the informed consent given during admission in the clinic, 83.4% of them stated that conversation with the clinician last Resident doctor obtained the informed consent and 65.7% reported that conversation with the clinician lasted for 10-15 minutes as shown in Table (6).

Table (4): Factors associated with quality of informed consent.

| | Studied patients (n=175) | |
|---|---|---|
| | N | % |
| *Did you know that one has to first consent before surgery is done?:* | | |
| Yes | 125 | 71.4 |
| No | 50 | 28.6 |
| *Why does one have consent before surgery?:* | | |
| It's just a hospital policy | 3 | 1.7 |
| To prove that I have accepted the treatment | 140 | 80.0 |
| To protect the hospital from litigation if any problem arises | 6 | 3.4 |
| To protect my personal right | 21 | 12.0 |
| I don't know | 5 | 2.9 |
| *After giving consent, can one change the decision previously made?:* | | |
| Yes | 11 | 6.3 |
| No | 137 | 78.3 |
| I don't know | 27 | 15.4 |

Table (5): Health provider factors associated with guality of informed consent.

| | Studied patients (n=175) | |
|---|---|---|
| | N | % |
| *Category of patient:* | | |
| Private | 6 | 3.4 |
| Public | 169 | 96.6 |
| *Type of Anesthesia given:* | | |
| GA | 153 | 87.4 |
| SA | 22 | 12.6 |
| *Type of surgery undergone:* | | |
| Major | 154 | 88.0 |
| Minor | 21 | 12.0 |
| *Which language was used when discussing about your condition and its management:* | | |
| My primary language (mother tongue) | 175 | 100 |
| English | 0 | 0 |
| An interpreter | 0 | 0 |
| *Which of the following methods was used to explain the treatment to be offered?:* | | |
| Only words | 165 | 94.3 |
| Diagrams | 10 | 5.7 |
| Pictures | 0 | 0 |
| *Which of the following methods was used to explain the treatment to be offered?:* | | |
| Friendly and empathetic | 107 | 61.1 |
| Was tough, I feared to express my self | 2 | 1.1 |
| Was arrogant | 11 | 6.3 |
| I was too anxious after knowing the diagnosis | 4 | 2.3 |
| I just had to accept for the sake of saving my life | 45 | 25.7 |
| Used medical jargons, I didn't understand | 1 | 0.6 |
| My family/ spouse/ friends influenced my decision, not me | 5 | 2.9 |
| *Did the experience above have any influence on your decision to consent?:* | | |
| Yes | 25 | 14.3 |
| No | 116 | 66.3 |
| I don't know | 34 | 19.4 |

Table (6): Hospital related factors associated with quality of informed consent.

| | Studied patients (n=175) | |
|---|---|---|
| | N | % |
| *Where was the informed consent given?:* | | |
| During admission in the clinic | 129 | 73.7 |
| On ward | 46 | 26.3 |
| Immediately before going to theatre | 0 | 0 |
| In theatre | 0 | 0 |
| *What was the profession of the person who obtained the informed consent?:* | | |
| Obstetrician-gynecologist | 0 | 0 |
| Resident doctor | 146 | 83.4 |
| Intern doctor | 1 | 0.6 |
| Nurse-midwife | 0 | 0 |
| Did not know | 28 | 16.0 |
| *How long did this conversation with the clinician last?:* | | |
| <5 minutes | 4 | 2.3 |
| 10-15 minutes | 115 | 65.7 |
| >20 minutes | 56 | 32.0 |

Table (7): Comparison of Quality of Informed Consent among Group A and Group B according to Demographic Data.

| | Group A (n=74) | | Group B (n=101) | | Test value | *p*-value |
|---|---|---|---|---|---|---|
| | N | % | N | % | | |
| *Age:* | | | | | | |
| Mean ± SD | 38.9±11.58 | | 41.9±12.9 | | *t*=1.601 | 0.112 |
| Range | 21-75 | | 20-61 | | | |
| *Marital Status:* | | | | | | |
| Single | 1 | 1.3 | 9 | 8.9 | $X^2$=1.530 | 0.675 |
| Married | 67 | 90.5 | 81 | 80.3 | | |
| Divorced | 3 | 4.1 | 5 | 4.9 | | |
| Widow | 3 | 4.1 | 6 | 5.9 | | |
| *Education level:* | | | | | | |
| None | 39 | 52.7 | 49 | 48.6 | $X^2$=4.621 | 0.032 |
| Primary | 10 | 13.5 | 23 | 22.8 | | |
| Secondary | 20 | 27.0 | 25 | 24.7 | | |
| Tertiary | 5 | 6.8 | 4 | 3.9 | | |
| *Occupation:* | | | | | | |
| House wife | 62 | 83.8 | 77 | 77.3 | $X^2$=6.494 | 0.370 |
| Self employed | 4 | 5.3 | 8 | 7.9 | | |
| Student | 6 | 8.1 | 9 | 8.9 | | |
| Nurse | 0 | 0 | 3 | 2.9 | | |
| Business | 1 | 1.4 | 3 | 2.9 | | |
| Teacher | 1 | 1.4 | 1 | 0.1 | | |

Using: *t*-Independent Sample *t*-test for Mean ± SD.
$X^2$ = Chi-Square test.
*p*-value >0.05 is insignificant.
*p*-value <0.05 is significant.
*p*-value <0.01 is highly significant.

Table (8): Comparison of Quality of Informed Consent among Group A and Group B according.

| | Group A (n=74) | | Group B (n=101) | | Test value | *p*-value |
|---|---|---|---|---|---|---|
| | N | % | N | % | | |
| *Where was the informed consent given?:* | | | | | | |
| During admission in the clinic | 43 | 58.1 | 86 | 85.1 | $X^2$=3.615 | 0.048 |
| On ward | 31 | 41.9 | 15 | 14.9 | | |
| Immediately before going to theatre | 0 | 0 | 0 | 0 | | |
| In theatre | 0 | 0 | 0 | 0 | | |
| *What was the profession of the person who obtained the informed consent?:* | | | | | | |
| Obstetrician-gynecologist | 0 | 0 | 0 | 0 | $X^2$=1.277 | 0.528 |
| Resident doctor | 58 | 78.4 | 88 | 87.1 | | |
| Intern doctor | 0 | 0 | 1 | 0.1 | | |
| Nurse-midwife | 0 | 0 | 0 | 0 | | |
| Did not know | 16 | 21.6 | 12 | 11.9 | | |
| *How long did this conversation with the clinician last?:* | | | | | | |
| <5 minutes | 3 | 4.1 | 1 | 0.1 | $X^2$=1.101 | 0.777 |
| 10 -15 minutes | 42 | 56.8 | 73 | 72.3 | | |
| >20 minutes | 29 | 39.2 | 27 | 34.6 | | |
| *Category of patient:* | | | | | | |
| Private | 3 | 4.1 | 3 | 3.0 | $X^2$=0.074 | 0.785 |
| Public | 71 | 95.9 | 98 | 97.0 | | |
| *Type of Anesthesia given:* | | | | | | |
| GA | 61 | 82.4 | 92 | 91.1 | $X^2$=0.137 | 0.712 |
| SA | 13 | 17.6 | 9 | 8.9 | | |
| *Type of surgery undergone:* | | | | | | |
| Major | 59 | 79.7 | 95 | 94.1 | $X^2$=2.459 | 0.117 |
| Minor | 15 | 20.3 | 6 | 5.9 | | |
| *Which language was used when discussing about your condition and its management:* | | | | | | |
| My primary language (mother tongue) | 74 | 100 | 101 | 100 | – | – |
| English | 0 | 0 | 0 | 0 | | |
| An interpreter | 0 | 0 | 0 | 0 | | |
| *Which of the following methods was used to explain the treatment to be offered?:* | | | | | | |
| Only words | 67 | 90.5 | 98 | 97.0 | $X^2$=0.912 | 0.340 |
| Diagrams | 7 | 9.5 | 3 | 3.0 | | |
| Pictures | 0 | 0 | 0 | 0 | | |
| *Which of the following methods was used to explain the treatment to be offered?:* | | | | | | |
| Friendly and empathetic | 34 | 45.9 | 73 | 72.3 | $X^2$=9.710 | 0.137 |
| Was tough, I feared to express my self | 0 | 0 | 2 | 1.9 | | |
| Was arrogant | 9 | 12.2 | 2 | 1.9 | | |
| I was too anxious after knowing the diagnosis | 3 | 4.1 | 1 | 0.1 | | |
| I just had to o accept for the sake of saving my life | 26 | 35.1 | 19 | 18.8 | | |
| Used medical jargons, I didn't understand | 0 | 0 | 1 | 0.1 | | |
| My family/spouse/friends influenced my decision, not me | 2 | 2.7 | 3 | 1.9 | | |
| *Did the experience above have any influence on your decision to consent?:* | | | | | | |
| Yes | 15 | 20.3 | 10 | 9.9 | $X^2$=1.101 | 0.777 |
| No | 37 | 50.0 | 79 | 78.2 | | |
| I don't know | 22 | 29.7 | 12 | 11.9 | | |

Using: $X^2$ = Chi-Square test. *p*-value >0.05 is insignificant. *p*-value <0.05 is significant. *p*-value <0.01 is highly significant.

For the Secondary outcome we will divide the study group into 2 groups according to the quality of informed consent.

- Group A: 74 Patients who had good quality of informed consent.
- Group B: 101 Patients who had poor quality of informed consent.

Comparison of Quality of Informed Consent among Group A and Group B according to Demographic Data the mean ages of Group A (38.9 years) and Group B (41.9 years) were statistically different ($t$=1.601, $p$-value=0.112), although the difference was not significant. In terms of marital status, there were no significant differences between the groups ($\chi 2$=1.779, $p$-value=0.620). However, notable differences were observed in education level ($\chi 2$=4.621, $p$-value=0.032) and occupation ($\chi 2$=6.494, $p$-value=0.010) as shown in Table (7).

Group A had a higher proportion of individuals with tertiary education compared to Group B (3.9% vs. 6.8%), and Group A also had more individuals with no occupation (83.8% vs. 77.3%). These differences suggest that education level and occupation may influence the quality of informed consent. Notably, statistical significance was reached in education level, indicating that individuals with higher education might perceive and engage differently in the informed consent process compared to those with lower education levels. This underscores the importance of considering demographic factors in healthcare communication and decision-making processes.

Significant differences were observed in where the informed consent was given, with a higher percentage of Group B patients (85.1%) receiving consent on the ward compared to Group A (58.1%) ($\chi 2$=3.615, $p$-value=0.048). However, significant differences were found in the profession of the person obtaining consent, duration of the conversation with clinicians, category of patient (private vs. public), type of anesthesia given, type of surgery undergone, methods used to explain treatment, or the influence of the experience on the decision to consent. Notably, a large proportion of patients in both groups had their consent obtained by resident doctors, and most conversations lasted between 10 to 15 minutes. Additionally, both groups predominantly received explanations using only words. Although differences in where consent was obtained were observed, other clinical factors did not significantly influence the quality of informed consent between Group A and Group B as shown in Table (8).

## Discussion

Informed consent is the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention.

The basic requirements for informed consent include patients' competence and voluntariness as preconditions for informed consent, provision of adequate and comprehensible information, finally, the patient consents to have the surgical procedure to be performed.

The principle of self-determination recognizes patient autonomy and independence to make own decisions without coercion, providing educational programs to patients is mandatory to fill knowledge gaps and improve the quality of the informed consent process.

Informed consent is aimed to protect patients from unwanted medical intervention, safe guard patients' rights to autonomy and self-determination.

The main aim of this study was to determine the quality of informed consent among the patients undergoing elective gynaecological and obstetric surgery at ASUMH.

The Secondary aims were to identify the factors associated with the quality of informed consent among patients undergoing elective gynaecological and obstetric surgery at ASUMH.

The current cross-sectional observational hospital-based study was conducted in Departement of Obstetrics and Gynecology at Ains Shams University Maternity Hospital (ASUMH). To assess the quality of informed consent process for elective gynaecological and obstetric surgery In the period between December 2023 to March 2024.

Patients above 18 years of age who consented to participate in study and had undergone elective gynaecological and obstetric surgery were enrolled our study.

Patients who did not have the mental capacity to understand and discuss finally provide informed consent process or below the legal age of consent were excluded from our study.

The study showed majority of the patients had poor quality of informed consent prior to elective Gynecology and Obstetrics Surgery at ASUMH. Those with low education level, who had no knowledge about informed consent and did not know that consenting was voluntary, had misconception about consent, or required to have an interpreter during the consent process, with whom verbal interaction without illustration was used during the consent process, consented on ward, in cases where the consent process took less than 20 minutes, not asking questions during the consenting process were likely to have poor quality informed consent.

The population of study was 175 cases who underwent elective gynaecological and obstetric surgery The majority of patients were married (84.6%), followed by those with no educational qualifications (50.3%). mean age of 40.6±12.43 years More than fiftty percent (57.7%) of the participants had poor quality of informed consent prior to the elective gynaecological/obstetric surgery were enrolled in our study.

Compared article in Teshome and colleagues the finding was 40% of the mean age of studied cases was 28.2 SD ± (7.9) with range (25-29), Nearly a quarter (22.6%) had no formal education, while 20.9% have attended only primary school. Nearly all (92.2%) of the women involved in this study were married and more than half (53%) were housewives [12].

The result of current study showed the quality of informed consent given to the participants prior to elective surgery was poor in most of them (57.7%). This is comparable to the findings by Jukic [13] where only 29 patient (11%) of patients reported being informed about their medical condition and forthcoming clinical procedures in detail and 186 patient (70.2%) reported to have received only basic information [13]. Although it is difficulty that obtaining informed consent involves mutual sharing of information between the clinician and the patient as disclosure of required information greatly determines the quality of informed consent [14].

The present study showed factor associated with poor quality of informed consent were participants with lower education level 50.3% of them were not educated,18.9% had primary education, 25.7% of them received secondary education 5.1 received tertiary education and 2% of them received university education.

Similar study done in Rwanda 5% of the participants had a high level of knowledge, 12% moderate, and the rest 83% had a low level of knowledge towards informed consent [15]. Patients level of understanding on surgical informed consent was significantly associated with educationl level [16].

The present study showed that the patients had misconceptions about giving informed consent which is a hindrance to quality informed consent. 80% of them believed that giving an informed consent was just to prove that they had accepted the treatment while 12% to protect my personal right thought and only 6% knew that is to protect the hospital from ligation if any problem arises.

According to the similar study the finding from Hawassa 178 patients (77.4%) was believed to accepted treatment, where 186 patients (80.6%) was accept to protect my personal right 149(64.8) was believed to protect hospital from ligation if any problem arises [12].

Also the results of the current study showed that the guality of informed consent 71.4% of them knew that one has to first consent before surgery most of patient 78.3% stated they did not know that after giving consent, she can change previously made.

The finding is comparable where 46% of patients from UK believed that the primary purpose of an Informed Consent was to protect the hospital from litigation [17].

Previous studies found an association between the patients' socio-demographic characteristics and the informed consent process. For instance, Poverty, language barrier and low educational level limits patients to exercise their right of giving informed consent [18]. It is believed that the pre-surgery anxiety increases when too much information is provided [19]. Many individuals sign the consent form without being fully aware of what they are signing [20]. Therefore, these factors affect the information disclosure, comprehension, recall ability, voluntariness to make decisions for their quality of care.

The presented study showed that the consenting process for the health care providers spend 10-15 minutes was 115 patients (65.7%) and >20 minutes was 56 patients (32%) and 4 patients about (3.2%) spent less than 5 minutes.

According to research by jahan and his colleagues from 2014, Health-care providers who spend more time (10-15 minutes) on the consenting process were more likely to practice adequate consent than those who spent less than 5 minutes. The extra time spent for consenting allows more discussion and interaction between patient-healthcare providers and adequate time to adress patient issues [21].

Work experience was positively associated with adequate practice of informed consent. Respondents who had more than 10 years of work experience were more likely to practice adequate informed consent than those who had less than or equal to years' work experience. This finding is consistent with a study from Italy [22].

The current study results showed for the patient method used to explain treatment was only words 165 patient 94.3%, diagram 10 patients 5.7% and no patient with pictures.

Verbal discussion alone without pictorial illustration when explaining the treatment to be offered was associated with poor quality informed consent. Comparable findings from a study by Moseley et al. [23] demonstrated that use of visual aids beyond just verbal presentation improved the patient ability to remember facts and risks associated with the surgery [23]. A study finding emphasized that patient retention of information can be improved by 50% if supplemental written information is provided [24].

According to the result of the current study (61%) had a friendly and empathetic communication with their health workers during the process of consenting which is a promoter of quality informed consent. It is consistent with reports from Nigeria and Uganda that the attitude of the health worker determines the effectiveness of informed consent **[25]**. It is further stressed that good communication between the clinician and patient is the basis of a good process of informed consent. It's reflected by the patients' ability to recall the information they were provided with **[26].**

The result of the current study showed the patients not asking questions about their diagnosis and treatment is associated with poor quality of informed consent. Majority of the 38 patients (21.7%) were not given the opportunity to ask any questions.

Similar study from Pakistan showed 230 patients (66.6%) were not given the chance to ask questions Ashraf et al. **[27].** Another study from India reported that disclosing too much information of the potential side-effects may scare the patient away from a life-saving or life-enhancing surgery therefore, the patients do not ask questions **[28].**

Also, the results of the current study showed that the patient not reading the consent form is associated with poor quality of informed consent. The assumption is that having the opportunity to read through the consent form may prompt the patient to ask for clarification for what they are signing for which then can improve informed consent. However, majority of the patients (49.1%) were not given the opportunity to read what they were consenting for. Comparable studies from South Africa reported that patients hardly read the consent form because it was only available only in English which they could not understand **[29].**

*Conclusion:*

This study suggests that the quality of informed consent process among patients undergoing elective gynaecological and obstetric surgery at is below the accepted national standard.

The health workers did not create enough time to explain to the patients' important details about their condition and management. Vital information about what to expect before and after surgery was hardly addressed.

The patients lack knowledge about informed consent process. They do not know that it's their right to be informed about their medical condition, any forthcoming interventions and their decision is voluntary.

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# تقييم جودة أخذ الموافقة المستنيره قبل اجراء العمليات الجراحية الاختياريه لامراض النساء والتوليد بمستشفيات جامعة عين شمس

الخلفية: يُعد الإقرار بالموافقة المستنيرة عملية يقوم فيها مقدم الرعاية الصحية بتثقيف المريض حول المخاطر والفوائد والبدائل لإجراء أو تدخل معين. يجب أن يكون المريض مؤهلاً لاتخاذ قرار طوعي بشأن ما إذا كان سيخضع للإجراء أو التدخل أم لا. تشمل المتطلبات الأساسية للموافقة المستنيرة كفاءة المرضى والتطوعية كشرطين مسبقين، وتقديم معلومات كافية ومفهومة، وأخيراً موافقة المريض على إجراء الجراحة.

الهدف: تقييم جودة عملية الموافقة المستنيرة للجراحة النسائية والتوليدية الاختيارية فى مستشفى عين شمس الجامعى للولادة.

الطرق: أُجريت هذه الدراسة المستعرضة القائمة على الملاحظة فى قسم أمراض النساء والتوليد فى مستشفى عين شمس الجامعى للولادة خلال الفترة من ديسمبر ٢٠٢٣ إلى مارس ٢٠٢٤ على ١٧٥ حالة خضعت لجراحات التوليد وأمراض النساء.

النتائج: أظهرت الدراسة أن غالبية المرضى كان لديهم جودة ضعيفة من الموافقة المستنيرة قبل الجراحات النسائية والتوليدية الاختيارية فى مستشفى عين شمس الجامعى للولادة. كان من المحتمل أن يكون لدى أولئك الذين لديهم مستوى تعليمى منخفض، أو لم يكن لديهم معرفة بالموافقة المستنيرة، أو لم يعلموا أن الموافقة طوعية، أو لديهم مفهوم خاطئ عن الموافقة، أو كانوا بحاجة إلى مترجم أثناء عملية الموافقة، حيث تم استخدام التفاعل اللفظى بدون توضيح أثناء عملية الموافقة، أو تمت الموافقة فى القسم، أو فى الحالات التى استغرقت فيها عملية الموافقة أقل من ٢٠ دقيقة، أو لم يسألوا أسئلة أثناء عملية الموافقة، موافقة مستنيرة ذات جودة ضعيفة. أظهرت نتائج الدراسة الحالية أن جودة الموافقة المستنيرة المقدمة للمشاركين قبل الجراحة الاختيارية كانت ضعيفة لدى معظمهم (٥٧,٧٪).

الاستنتاج: تشير هذه الدراسة إلى أن جودة عملية الموافقة المستنيرة بين المرضى الذين يخضعون للجراحة النسائية والتوليدية الاختيارية أقل من المعايير الوطنية المقبولة. لم يخصص العاملون الصحيون وقتًا كافيًا لشرح التفاصيل المهمة للمريض حول حالته وإدارته. نادراً ما تم التطرق إلى المعلومات الحيوية حول ما يمكن توقعه قبل الجراحة وبعدها. يفتقر المرضى إلى المعرفة بعملية الموافقة المستنيرة، ولا يعلمون أنه من حقهم أن يتم إعلامهم بحالتهم الطبية وأى تدخلات قادمة وأن قرارهم طوعى.