ORIGINAL RESEARCH

Assessing informed consent in surgical patients at Queen Elizabeth Central Hospital in Blantyre, Malawi: a cross-sectional study

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Abstract

Introduction

Informed consent is critical to medical practice, and a clearly outlined process that results in signing the consent form may improve the validity of the given consent. There is a paucity of studies in Malawi that have assessed the informed consent process in surgical patients.

Aim: To assess the informed consent process for patients undergoing surgery at QECH in Malawi.

Methods

A cross-sectional quantitative descriptive study was conducted among postoperative patients in the adult surgical wards at QECH through face-to-face interviews. The calculated sample size was 235. A consecutive sampling technique was used. Those below 18 years and those who didn't or couldn't consent were excluded. Data was entered and analyzed in Microsoft Excel 2016 and IBM SPSS 25.0. The level of significance was considered as $P<0.05$.

Results

A total of 222 patients were interviewed. The age range was 21 to 75 years, with a median of 38.5. Two hundred and twelve (95%) patients signed a consent form before surgery, and 21 (9%) knew the content of the form. Most patients, 100 (47%) had a primary school education, and 156 (70%) could read and write. Those with secondary or tertiary education were more likely to want to ask a question given the opportunity (OR 2.82, p= 0.0012), but there was no significant difference in the likelihood of being given time to ask questions between the two groups who had primary and no formal education vs those who had secondary and tertiary education (OR 1.4, p=0.3367)

Conclusion

This study highlights the necessity of employing effective communication strategies during the consent process for surgical procedures and the need to tailor the consent form to the patient's education level.

Keywords: Informed consent and surgery, Informed consent and literacy, Patient comprehension and informed consent, Patient perspectives of informed consent, Informed consent and clinical practice

Introduction

Although professionalism and the moral code should guide the practice of medicine, the informed consent process protects the patient's right to know what is happening to them and gives them a say in the treatment modality they will receive[1]. The presence of a clearly outlined process that will result in the signing of the consent form may improve the validity of the given consent. However, the presence of the signed form is not evidence of valid consent[2]. Poor informed consent results in low patient satisfaction, compromised treatment adherence, and litigation against medical practitioners[3]. Obtaining informed consent is vital to person-centred care and is crucial to patient safety[4].

There are challenges to obtaining informed consent where literacy levels are low, and this is because consent is considered to be 'informed' when given by a person or participant who understands the purpose and the nature of the research or proposed treatment and what is required of themselves as participants, in addition to the potential benefits and risks resulting from the study or surgery[5]. In Malawi, literacy and consent are compounded by the need for clear guidelines on who must take the consent, when and where this must be done, and who must sign the form. Data from UNESCO shows that 65.75% of those aged 15 and above in Malawi can read and write and that the literacy rate is 73% for men and 59% for women[6]. In situations where literacy levels are low, the medical personnel may take a more traditional paternalistic approach, assuming to have the patient's best interests. However, all patients must be presumed as desiring to be well-informed about any procedure or examination which may be performed on their bodies. If the opposite is true, then action must be taken according to the patient's wishes, which must be well documented in the patient's notes[7].

The informed consent form currently in use at Queen Elizabeth Central Hospital (QECH) has been observed to need to be improved in some of the fields mentioned above. The entire form takes up one-quarter of an A4 page. It is simply a statement that the patient has given consent for a doctor to perform any operations on his/her body that the doctor may consider necessary and for administering any anaesthetic for this purpose. The form does not reflect the process leading to the signing or person-centred care.

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It reflects clinicians obtaining the evidence of consent to document a legal and ethical obligation. Additional necessary procedures apply only to emergent and unexpected procedures and not procedures that are already highly likely to be performed[6], and this needs to be reflected in the current form. It has been observed that the contents of the consent form are only sometimes translated to the patients just before they sign, which raises questions about whether the patients are genuinely cognizant. Therefore, this study aimed to assess the informed consent process for patients undergoing surgery at QECH in Malawi.

Methods

QECH is the largest hospital in Malawi, with 1,200 beds. It is a referral centre mainly for the southern region of Malawi, which has a population of 7 million. It has a surgical unit that includes general, pediatric, ear, nose and throat, plastic, orthopaedic, ophthalmologic, and neurosurgery. Except for pediatric surgery, all other named departments use a generic form for informed consent. A different consent form exists for those undergoing gastroscopy and colonoscopy procedures, and it's available in the local language. The generic consent form which is used is only available in English. Similar studies have yet to be done in the region to help estimate the sample size.

Inclusion and Exclusion criteria

All Postoperative surgical patients above 18 who were admitted to the adult surgical wards and had consented to participate in the study were included. All adult postoperative adult surgical patients who did not consent to taking part in the study were excluded.

Research setting and participants

QECH performs 601 surgeries per month. Based on this number, we used the Cochran formula8 and calculated a sample size of 235. A consecutive sampling method was used to include as many participants as possible during the study period. A total of 222 patients consented to respond to the questionnaire. Data was collected throughout the week, both within and outside working hours.

Face-to-face interviews were conducted using questionnaires that were available in English and Chichewa translations. These questionnaires were available in hard copy and as a google form. A translator was used to translate the questionnaire, and the research team reviewed the translated document and agreed on the content. Patients were asked whether or not they signed a consent form before surgery, who signed it, where they signed it, whether they understood the content of the form, and whether they knew the diagnosis that necessitated the operation, the type of anaesthesia that was used, the name or description of their surgeon, whether they were allowed to ask questions before signing the consent form, whether they felt it was helpful to know the details of the procedure and whether they could have asked questions had the opportunity arisen. Files were also checked for the presence of a consent form, and the details were entered into the questionnaire.

The Procedure of Data Collection

Two research assistants assisted with data collection. One research assistant was an intern medical officer, and the other was a nurse technician. Both were bilingual. They were oriented on obtaining consent, filling out the questionnaire, following up with participants and transferring data from the questionnaires that were in hard copy into Google Forms, where they were automatically compiled into an Excel sheet. The questionnaire collected questions on the patient's demographic details, what they remembered about being informed of before surgery and what they would have liked to have been informed about before their surgery. The questionnaire was available in hard copy, and the patient was given the choice to self-administer the questionnaire or to be interviewed. All participants were assigned a numeric identifier. After data collection, the consent form was detached from the questionnaire to maintain participant anonymity.

The Procedure of Data Analysis

Data was analyzed on a personal computer, entered directly into Microsoft Excel 2016 version, and analyzed using the same software and IBM SPSS statistics 25.0. Descriptive statistics such as proportions, frequency, mean, and range were used. Odds ratio calculations were used to measure associations between specific exposures and outcomes. The level of significance was considered as $P<0.05$. All percentages were rounded to the nearest whole numbers. Tally charts were made to analyze data collected on opinion-related questions to develop common themes.

Ethical Issues

Approval was sought and given by the College of Medicine Research and Ethics Committee (COMREC), ethics approval number P.12/18/2485. Data was entered using unique numeric identifiers to ensure privacy, and hard-copy questionnaires were stored in a cabinet accessible only to the researcher. They were destroyed two months after the completion of the data collection. The Excel sheet containing all the de-identified data was saved, password-protected, and accessible only to the research team.

Results

Patient Demographics

A total of 233 patients were approached to be interviewed; 11(0.05%) did not consent and were excluded, and 222 consented were interviewed, giving a response rate of 95.3%. The age range was 21 to 75 years, with a median age of 38.5 (IQR = 22). There were 93 (48%) males and 102 (52%) females, and 27 (12%) patients had missing data on gender. One hundred and thirty-eight (62%) of these patients had undergone elective surgical procedures, and 84 (38%) had undergone emergency surgical procedures.

One hundred (47%) had a primary school education, 72 (34%) had a secondary school education, 17(8%) had a tertiary education, and 33(15%) had no formal education. A total of 156 (70%) reported that they could read and write, and 61(27%) could neither read nor write. Of the patients who had a tertiary level of education, 8 (47%) knew the content of the consent form, 11(65%) signed the form themselves and 5 (29%) had the opportunity to ask questions compared to 3(4.1%), 56 (77%), and 8 (11%) of those who had Secondary school level of education and 9 (9%), 63 (63%) and 14 (14%) of those who had a primary school level of education respectively (Table 1).

Patient Knowledge About Elements of Consent

Two hundred and twelve (95%) signed the consent form for surgery and knew the indication of their operation. One hundred thirty-eight (62%) signed the form themselves, 170 (77%) understood why they had to sign a consent form

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Table 1: Patient Demographics

Patient Baseline Characteristics (N=222)		Number	%
Age	Median (IQR)	38.5	22
Sex	Male	92	41
	Female	102	46
	Missing	27	12
Level of Education	Primary	100	45
	Secondary	72	32
	Tertiary	17	7,7
	No formal Education	22	10
Literacy	Able to read	1	0,45
	Able to write	2	0,9
	Able to read and write	156	70
	unable to read or write	60	27
	No response	3	1,35

Table 2: patient knowledge about elements of consent (n=222)

	Yes (%)	NO (%)
Number that had signed a consent form	212 (95)	10 (5)
How many signed the form themselves	139 (63)	73(37)
How many understood why they signed	171(77)	51(23)
How many knew the content of the form they signed	21 (10)	201(90)
How many knew what anesthesia would be used for their surgery	88(40)	134(60)
How many knew why they were operated	212(95)	10(5)
How many knew their surgeon by name or description	54(24)	168(76)
How many had the opportunity for questions before signing	29(13)	193(87)
How many felt it would have been useful to know the things asked above	203(91)	19(0.9)
How many would have asked questions if they were given the opportunity	52(23)	170(77)

before surgery, and 4 (1.9%) knew the content of the consent form they signed. Fifty-four (24%) knew their surgeon by name or description, and 28 (13%) had an opportunity to ask questions. Two hundred and three (91%) felt it would have been nice to have been able to ask questions, and 54 (24%) would have asked their doctor a question about the proposed procedure had they been given the opportunity. There was no statistically significant difference between the two genders and being allowed to ask a question. Nine patients (4%) responded "yes" to all questions about whether they recalled being told about the nature of the surgery, the anaesthesia

Table 3: Questions patients would have asked about their surgery

What question they would have asked	Frequency (1%)
Nature of the procedure	18 (34)
Possible outcomes of the procedure	14 (26)
Risks of the procedure	9 (17.3)
Complications of the procedure	6 (11)
Whether the procedure is curative	4 (7.6)
The anesthesia to be used	3(6)
Prevention of the condition that necessitated surgery	2 (4)

to be used, the risks, benefits, alternatives, and the result of no operation (Table 2). Of the 73 patients who did not sign their consent forms themselves, 36 (43%) underwent emergency procedures, and 37 (44%) had undergone elective procedures. Ten patients (5%) did not sign a consent form (Table 2). Of the ten who did not sign a consent form at all, 3 (30%) underwent emergency procedures, and the rest underwent elective surgeries.

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Of the 54 (24%) patients who indicated that they would have asked a question if allowed, 21(40%) were male, and there was no statistically significant difference between the two genders and willingness to ask a question given the opportunity (OR 0.6095, p = 0.1296). The following is what they would have wanted to ask about: 16 (30%) would have asked about the nature of the procedure, 14 (26%) would have asked about the expected outcomes of the procedure, 9 (17.3%) would have asked about the risks, 6 (11%) would have asked about complications, 4 (7.6%) would have asked if the procedure was curative, 3 (6%) the anaesthetic to be used and 2 (4%) how to prevent the condition that necessitated the operation (Table 3).

Opportunity to Ask Questions

Of the 89 (40%) that had a secondary and tertiary education, 48 (54%) had undergone elective surgeries, 14 (16%) felt that they had the opportunity to ask questions, and only 32 (36%) would have asked a question given the opportunity. Of the 133 (60%) who had primary or no formal education, only 22 (16%) would have asked questions if given the opportunity, and 15 (11%) felt they had been given room for questions. Those with primary or no formal education were less likely to have a chance to ask a question compared to those with secondary and tertiary education. Those with primary and no formal education were also less likely to have asked a question given the opportunity to ask. Those with a secondary or tertiary education were more likely to want to ask a question if given the opportunity (OR 2.82, p= 0.0012), but there was no significant difference in the likelihood of being given an opportunity for questions between the two groups who had primary and no formal education vs those who had secondary and tertiary education (OR 1.4, p=0.3367) (Figure 1).

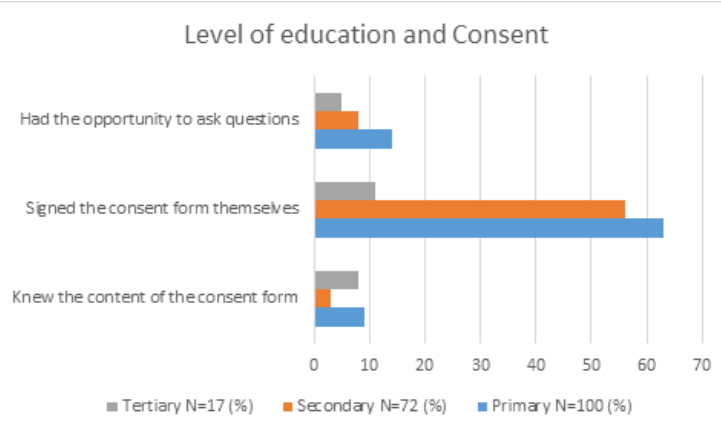

Figure 1: Level of Education and Consent

Where the consent form is signed

Consent was most frequently signed by 208 (98%) in the ward and 4 (1.9%) signed in the casualty department. All 4 (1.9%) patients who signed consent forms in the casualty department had emergency operations.

When consent is signed

Consent was taken on the day of surgery, in most cases 129 (58%), followed by 75 (33.7%) the night before surgery. Sixty-eight (57%) of those whose written consent was taken on the same day of surgery had undergone elective surgeries. There was no significant difference in the timing of written consent for those who underwent elective procedures and those who underwent emergency procedures (OR 0.6, p=0.102) (Figure 1)

What patients remembered being told before surgery

One hundred seventy-six (79%) respondents reported having been told about the nature of the procedure; this was followed by the benefits of the procedure 73 (33%), the result of no operation 44 (20%), risks of operation 34 (15%), and alternatives of the operation 16 (7%).

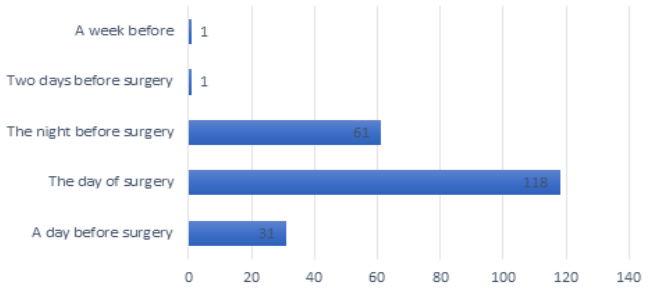

Figure 2: Timing of Written Consent

Discussion

Informed consent is a critical step in making patients and their families aware of the probable repercussions of the varied surgical treatment options presented to them by their surgeons and their associates. This study aimed to explore whether patients read and signed the consent form and their perceptions of the adequacy of the information they received from their surgeons.

Our findings reveal that most patients have a primary school education level and signed a consent form before surgery. Although a significant proportion signed the form themselves, only some know its contents. Most patients understand the need to sign a consent form and the reason for their operation. Few of these patients had the opportunity to ask questions, and even fewer indicated that they would have asked any questions if allowed. Most patients thought having occasion to enquire about the proposed surgical therapy was necessary.

A competent adult must be made aware of proposed treatments and their alternatives before the treatment is undertaken and the body violated. The doctor must ensure the patient knows the material risks and variant treatments. In this study, most patients remembered being told of the nature of the surgery, but few remembered the benefits, the result of no operation, the risks, and alternative therapies. Similar trends were observed in South Africa, where doctors most frequently informed patients of their diagnosis, followed by benefits, risks of proposed treatments, and alternatives[9]. A similar study done in Ethiopia[10] found that patients were most frequently aware of the indication of their surgery. Most participants knew the benefits and understood the consequences of refusing the planned surgery. Less than half the study population was informed about alternatives. A study in Nigeria also found that patients most frequently recalled being informed of their diagnosis and recalled the nature of the proposed procedure[10].

The numbers in our study and those of Ethiopia[10] and Nigeria[11] that were informed of the critical elements (risks, benefits, and alternatives) of the consenting process are pretty low compared to studies done in Pakistan[12] and Greece[13]. These findings align with those of other authors who found that surgeons primarily focus on providing information about the diagnosis and proposed surgical procedure[14,15]. The low numbers in our setting may be due to the high patient-to-surgeon ratio and, therefore, little

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time to spend on in-depth discussions. This is a question that could be further interrogated by qualitative research. On the other hand, some studies have demonstrated that patients are best informed immediately after signing the consent form. After that, recall of information deteriorates[16], and this poor recall of consent information was congruently demonstrated in a study of healthy participants[17]. It was also found that most of the patients admitted to not reading the consent form before signing it as they felt that they would still have the operation whether they read it or not[18]. In this study, the majority did not know the content of the form they signed despite over three-quarters of the population having had some formal education. This was not explored to understand whether it was due to the language in which the form was written or a lack of interest on the patient's part. We did not further explore why others did not sign the form themselves, which is an area for further study.

A study done in a research setting in Botswana found that patient education level could influence patient understanding of the consent. They found that the higher the education level, the better the comprehension. They also found that those who took the quiz in English were more likely to pass than those who took the quiz that had been translated into the native language[19]. This element was not explored to compare understanding between patients who use the consent in English and those in Chichewa.

Those who had a secondary school education were more likely to want to ask a question than those who had a primary school level of education or no formal education at all. This may suggest that the doctor must take greater initiative to inform those with a lower education level and that the consent form be tailored to someone with a primary education level. Our data collection tool was not designed to capture whether the patient had only started the level of education they stated to have had or whether they had completed it. We were also unable to distinguish whether the patients could read and write in Chichewa or English alone or both, and these are areas for further examination.

Consent was taken on the day of surgery for most patients. This timing is not in keeping with the best practices of (elective) surgery as it puts the patient under duress due to awareness of all the preparations made and may feel pressured into signing8. It is an expected finding for patients undergoing emergent procedures to have their consent taken on the very day of surgery. However, there was no significant difference between the timing of written consent in the two groups (electives vs emergency). More than half of the patients who did not sign a consent form before surgery were patients who underwent elective surgery, and this was an unexpected finding.

Studies done in Mali[20], Nigeria[21], Uganda[22], and South Africa[23] in the clinical research setting have reported patients as having problems comprehending the informed consent process. Most of these studies have recommended more education for patients, researchers, and health-care practitioners about biomedical ethics, and some have suggested that the quality of the informed consent forms be improved by simplifying the language to enhance understanding[9]. Other communication strategies, such as patient comprehension assessment, information sheets and printed brochures, videos or multimedia, extended discussions, and decisional aids, could be adopted for a meaningful consenting procedure[24]. In Malawi, biomedical ethics is part of undergraduate and postgraduate medical training. Still, more needs to be done to help and assess patients' understanding of their autonomy in the clinical setting. The study by Chima et al[8] incorporated clinicians, nurses, patients, and the informed consent form and included other departments (obstetrics and pediatric surgery) to allow for comparison. This study was limited to the adult surgical department, so the findings may not be extrapolated to other settings.

Limitations and Strengths

This kind of study, which includes the patient's perspective and expectations and considers the consent form being used, has not been done in Malawi.

However, this study has some limitations. We could not reach our sample size, and our findings may not represent all clinical settings. The sampling technique used was a non-probability sampling type, and attempts were made to include as many participants as possible to overcome this limitation and make the findings more representative.

The questions on the level of education and literacy were unrefined in terms of whether it is the level of education the patient had completed or started and whether the patient could read in Chichewa or English only or both.

Data on the age of patients was missing in 27 of the patients who were interviewed, and we could not recollect the data. This may have resulted in biased estimates of patient demographics.

The data collected from postoperative patients relied on the respondents' self-reporting and memory; this cannot be verified. There might have been under-reporting or over-reporting, which could have led to recall bias.

The data collection excluded patients who were in ICU and so could not be extrapolated to more severe situations. This study is quantitative, and the lack of a qualitative aspect limited our ability to explore some themes in greater depth.

Conclusions

This study highlights the need to adopt better communication strategies to ensure that patients are adequately informed of the risks, benefits, and alternatives for various surgeries they will undergo. The language should be simplified, the consent form should be tailored to the patient's education level, and extended discussions should be allowed to ensure patient comprehension.

Further multicenter research is required to incorporate the consent form involved and the perspectives of nurses and doctors on the informed consent process and patient satisfaction with the information given at the time of consent and to compare practice within the country. Staff should be trained to communicate effectively with patients to ensure a satisfactory informed consent process.

Authors Contributions

Lucy Kaomba was responsible for project concept, design, data collection tool development, data collection, analysis, and manuscript writing. Wakisa Mulwafu for manuscript editing, and data presentation. Both authors approved the final manuscript.

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Conflict of Interest

The authors have no competing interests to declare.

Patient Consent for Publication

All patients interviewed in this study signed a consent form, including consent to publish the research findings.

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