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Improving surgical informed consent in obstetric and gynaecologic surgeries in a teaching hospital in Ethiopia: A before and after study

Million Teshome,[1] Zenebe Wolde,[1] Abel Gedefaw,[1] Anteneh Asefa[2,3]

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[1]Department of Obstetrics and Gynecology, School of Medicine, College of Medicine and Health Sciences, Hawassa University, Hawassa, Ethiopia
[2]School of Public Health, College of Medicine and Health Sciences, Hawassa University, Hawassa, Ethiopia
[3]Nossal Institute for Global Health, School of Population and Global Health, University of Melbourne, Melbourne, Australia

Correspondence to
Anteneh Asefa;
antex98@yahoo.com

ABSTRACT

Objectives Even though surgical informed consent (SIC) has marked benefits, in many settings the information is not provided appropriately. In Ethiopia, minimal attention is given to SIC. This study assesses whether an intervention designed to improve SIC in obstetric and gynaecologic surgeries is associated with receipt of SIC components.

Design Pre-intervention and post-intervention surveys were conducted at Hawassa University Comprehensive Specialized Hospital among women who underwent obstetric or gynaecologic surgeries. The intervention consisted of a 3-day training on standard counselling for surgical procedures offered to health professionals. A total of 457 women were surveyed (230 pre-intervention, 227 post-intervention). An adjusted Poisson regression analysis was used to identify the association between the intervention and the number of SIC components received.

Results The majority of participants were 25–34 years of age in both the pre-intervention and post-intervention groups (p=0.66). 45.7% of the pre-intervention and 51.5% of the post-intervention survey participants underwent elective surgery (p=0.21). Additionally, 70.4% of pre-intervention survey participants received counselling immediately before surgery, compared with 62.4% of post-intervention participants (p<0.001). 5.7% of pre-intervention and 6.6% of post-intervention participants reported the belief that SIC consists entirely of signing on a piece of paper (p=0.66). After controlling for effects of potential confounders, the number of SIC components reported by post-intervention survey participants was 16% higher than what is received by pre-intervention ones (adjusted coefficient=1.16 (1.06–1.28)). Having elective versus emergency surgery was not associated with the number of components received by participants in either group (adjusted coefficient=0.98 (0.88–1.09)).

Conclusion Training on the delivery of standard SIC is associated with receipt of a higher number of standard counselling components. However, there is a need to evaluate whether a one-time intervention leads to sustained improvement. A system-wide study of factors that promote SIC is required.

Strengths and limitations of this study

- ► Surveying women right after their discharge minimised recall bias.
- ► Counting attributes instead of categorising helped to assess small changes.
- ► The lack of comparison/control groups posed a limitation in estimating the attribution of the intervened implementation.
- ► The evidence generated by this study may not be generalised to non-teaching hospitals.

INTRODUCTION

Surgical informed consent (SIC) has received much attention in current medical practice. The process of SIC is dependent on good client and health worker communication leading up to all surgical procedures. Appropriate SIC is defined as a client's right to receive adequate and pertinent information that allows the client to fully understand the proposed surgery, including possible benefits and complications.[1 2] When SIC is obtained after adequate delivery of information to a mentally competent client, the probability that the client accepts the surgery with due consideration of the inherent complications is very high.[3] Such transfer of information results in client satisfaction, which in turn promotes a positive image of the healthcare system, minimised malpractice claims and economisation of healthcare system resources, especially time and money.[4–7]

Even though SIC has marked benefits, in many settings the information is not provided in an acceptable manner. Among the factors that contribute to a substandard SIC are insufficient informational content laden with difficult medical jargon that could not be understood by clients.[3 8] A well-written consent sheet should contain information on the surgical indication/s, planned procedure/s and partakers of the surgery and their respective roles. It should also contain information on the type of anaesthesia to be used, dangers of not having the surgery, possible

anticipated complications and availability of alternative treatment options.[9 10]

Inadequate time is a primary barrier to achieving standard SIC. Clients often rush into surgery before discussing the issue with family and friends. Previous studies have found that clients undergoing elective surgeries—which afford them enough time to make informed decisions—achieve a better understanding of proposed treatments compared with clients undergoing emergency surgeries, where there is little or no time for lengthy discussion.[11–13] Some elderly or illiterate clients experience challenges understanding the information provided in SIC process.[14] Language barriers and low health literacy level of clients or the community also deter the proper transfer of information for SIC. To overcome these barriers, translators should always be available in healthcare settings and the information sheet for consent should be prepared at the equivalent of a sixth grade language level. Alternative delivery options like videos and interactive audiovisuals can also be used to improve clients' understanding.[15–19]

It is always recommended that the surgeon performing the procedure should counsel the client before the surgery. The counsellor should discuss what is going to be performed and the anticipated complications, even if they are minor and rare, and allow the client adequate time to ask questions. The counsellor should also discuss the reasons why the proposed treatment plan is preferred compared with other options, if any exist. If the surgeon is unable, other appropriately trained staff can provide counselling. However, most studies have shown that this role is often delegated to junior doctors and nurses who have little or no training in counselling.[3 12 20]

Current medical philosophy is shifting from physician-centred, paternalistic care to a participatory, client-centred approach. This helps to ensure that SIC is properly performed and that clients' autonomy and the right to information is respected.[3 4 13]

In Ethiopia, where modern medicine is in its infancy, too little attention is given to SIC. This may have an impact on clients' acceptance and adherence to health workers' recommendations and their satisfaction with surgical procedures. This study was conceptualised based on the authors' personal experiences of substandard SIC in the study hospital and other similar settings in Ethiopia. Prior to this investigation, there have been no studies of the status or implementation of SIC in gynaecologic and obstetric surgical procedures in this setting. A limited collection of studies from the African continent reveals that SIC is provided to clients in a highly compromised manner, which includes performing surgeries immediately after obtaining clients' signatures and without delivering any information regarding the surgical procedure to be performed.[2] This is contrary to international recommendations, which SIC is one of the pillars of high-quality care.[21 22] This is affirmed by recent Ethiopian health reform guidelines. This study was undertaken to evaluate the status of SIC and the effectiveness of a newly introduced standardised surgical consent sheet and procedures.

MATERIALS AND METHODS

Study setting

This study was conducted at Hawassa University Comprehensive Specialized Hospital, a teaching hospital ranked in the top tier of the three-tier Ethiopian healthcare system. The hospital has a bed capacity of 400 and renders tertiary care services to a catchment population from the Southern Nations Nationalities and Peoples Region and other neighbouring catchments of the Oromia region. At the time of the study, the Department of Obstetrics and Gynecology employed 8 obstetrician-gynaecologists, 12 resident physicians, 39 midwives and 20 ward nurses. Between 20 and 25 practising medical interns rotate through the department at a time. The hospital has three operation theatres for obstetric and gynaecologic surgeries. An average of about 4000 deliveries (childbirths) takes place in the hospital each year, of which 30%–35% are delivered by caesarean section.

Study design

A before and after (pre–post) study without a comparison group was conducted to measure differences in the receipt of SIC components reported by clients who underwent obstetric or gynaecologic surgeries. Pre-intervention data collection involved exit interviews with women who received obstetric or gynaecologic surgeries in November and December of 2016. Women were surveyed on discharge and immediately before exit from the study hospital. Post-intervention data were collected using an identical approach in March and April of 2017. In order to prevent contamination, nothing except survey of women was conducted during the pre-intervention phase.

Intervention design

This study involved a four-component quality improvement intervention (introduction of a standard SIC form, preparation of a wall poster, training of health professionals, and delivery of post-training support to health professionals). First, a standard SIC delivery form (online supplementary file 1) and wall posters were prepared in the hospital's working language (Amharic), based on the recommendations of England's Royal College of Surgeons.[22] This was in contrast to the previous informed consent form, which only states that 'the client is going to have a surgery and the hospital and health workers are not responsible for anything that goes wrong' (online supplementary file 2). The new SIC delivery form includes information on: possible actions that will be taken if unanticipated complications occur during the surgery; potential risks of the surgery; any alternative medical procedures that exist; the type of anaesthesia to be used and authorisation for the surgeon to perform the surgery, administer blood or blood products, and

take photographs for education purpose. A training manual introducing the new SIC form and standard SIC components was prepared to orient health professionals who were assigned to the labour unit and obstetrics and gynaecologic wards of the study hospital. The manual was organised in three sections: medical ethics, informed consent and counselling methods. In February 2017, a two-day training was delivered in three rounds to the target audiences, which included 18 nurses, 30 midwives, 24 medical interns, 12 residents and 6 obstetricians-gynaecologists. A team of study investigators (two obstetricians-gynaecologists and one public health expert) who are qualified trainers in women-friendly and respectful care facilitated the training sessions. During the last days of the training sessions, a practical visit was held in the study hospital and standard SIC was delivered to actual clients using the new SIC form. The wall posters were posted in the wards on the completion of the training. Finally, post-intervention support (on-the-job mentorship and support) was provided in February 2017 by the investigators who conducted the training. The aim of the post-intervention support was to draw lessons from implementation, identify any challenges that service providers faced in delivering the standard SIC and make necessary adaptations.

Study participants

Participants in this study were women who underwent elective or emergency obstetric or gynaecological surgeries during the preintervention and postintervention survey periods. To prevent information contamination between repeated surgeries undergone by the same person, respondents who had more than one surgery during the study period were excluded. Careful screening excluded women who participated in the preintervention survey from the postintervention survey.

Sample size and sampling

The appropriate sample size for this study was estimated through a double proportion formula using OpenEpi software with the following assumptions: confidence level of 95%; an anticipated 46% of clients who report having had counselling on their condition before giving consent (taken from a study conducted in Ugandan teaching hospital)[18]; an anticipated 61.5% of clients who will report receipt of counselling on their condition in the current context (incremental improvement by 34%); a potential non-response rate of 10% and statistical power of 80%. Accordingly, the minimum total required sample size was calculated to be 380. Eventually, 457 women (230 in the pre-intervention sample and 227 in the post-intervention sample) were involved in the study. Eligible women were enrolled and surveyed continuously until the required sample size was achieved. All participants gave written informed consent prior to exit interviews.

Variables

Recommendations of the Royal College of Surgeons were used to develop 13 standard indicators used to assess the components of SIC received by the study participants. As displayed in table 1, all 13 questions have two mutually exclusive options: 'yes' or 'no'. The outcome of interest was the number of the 13 standard SIC components displayed in table 1 received by respondents. The primary independent variable was the timing of the SIC process, that is, whether participants belonged to the pre-intervention or post-intervention group. Other independent variables included: sociodemographic factors, schedule of surgery (elective or emergency), type of anaesthesia, referral status, timing of counselling and profession of the counsellor.

Data collection and processing

The data collection instrument used in this study was originally prepared in English and later translated into Amharic language. Translation and back translation were performed by two different experts to ensure consistency between the original and translated versions of the questionnaire. Female nurse professionals conducted both pre-intervention and post-intervention surveys. Women were approached to participate in the study on the decision of discharge. However, exit interviews were conducted after women finished all discharge processes, in a dedicated room that ensured privacy.

The data collectors and their supervisor received two days training on the data collection tool and techniques of conducting effective surveys before the pre-intervention survey. The survey instrument was pretested on the second day of training and feedback was generated to better organise the questionnaire. Before the start of the post-intervention training, a one-day refresher training was provided for the data collectors and supervisor. Collected data were checked on a daily basis by the supervisor and the principal investigator to correct minor mistakes, and questionnaires with gross defects were discarded.

Data were entered and analysed using SPSS V.20 for Windows. To determine the outcome variable (the number of SIC components received), SIC components marked as 'yes' were counted, resulting in a count value ranging from 0 to 13 for every participant. Descriptive statistics like percentages and frequency distributions compiled in tables and figures. A test for normality of distribution was performed to decide on the types of numerical summary measures to describe continuous variables; means and SD were used to describe variables with normal distribution. A Poisson (log-linear) model was used to assess whether there was an association between the independent and the dependent variables. A one sample independent Kolmogorov-Smirnov test confirmed that the dependent variable (counts of SIC standards received) followed a Poisson distribution (p=0.353). The goodness of fit of the independent variable was also found to be acceptable to continue the analysis (deviance=0.7). Furthermore, the omnibus

Table 1 Essential components of surgical informed consent received by respondents, Hawassa, 2016/2017

Essential components of surgical informed consent	Pre-intervention; n (%)			Post-intervention; n (%)			P value
	Yes	No	Do not remember	Yes	No	Do not remember	
Respondent/respondent's family was requested for an informed consent	229 (99.6)	1 (0.4)	–	227 (100.0)	–	–	0.72
Respondent/respondent's family signed on an informed consent form	229 (99.6)	1 (0.4)	–	226 (99.6)	1 (0.4)	–	0.36
Respondent was informed why the surgery will be performed (indication of surgery)	200 (87.0)	30 (13.0)	–	212 (93.4)	15 (6.6)	–	0.21
Respondent was informed the expected time the surgery will take	33 (14.3)	194 (84.3)	3 (1.3)	44 (19.6)	178 (79.1)	3 (1.3)	0.33
Respondent was informed about presence/absence of alternative treatment option/s	56 (24.3)	170 (73.9)	4 (1.7)	98 (43.2)	126 (55.5)	3 (1.3)	<0.001
Respondent was informed about type of anaesthesia to be used	26 (11.3)	203 (88.3)	1 (0.4)	102 (44.3)	122 (53.7)	3 (1.3)	<0.001
Respondent was given counselling aids which assist in decision-making	3 (1.3)	227 (98.7)	–	5 (2.2)	218 (97.3)	1 (0.4)	0.45
Respondent was informed about potential complication/s which may arise	27 (11.7)	201 (87.4)	2 (0.9)	64 (28.2)	160 (70.5)	3 (1.3)	<0.001
Respondent was informed about consequences of refusing the proposed surgery	111 (48.3)	115 (50.0)	4 (1.7)	144 (63.4)	80 (35.2)	3 (1.3)	0.005
There was a favourable environment to say 'no' to the proposed surgery	15 (6.6)	214 (93.4)	–	13 (15.7)	214 (94.3)	–	0.71
Respondent was given adequate time for decision to sign on the informed consent form	67 (30.9)	150 (69.1)	–	119 (53.1)	105 (46.9)	–	<0.001
Respondent was given an opportunity to ask question	48 (61.5)	30 (38.5)	–	46 (88.5)	6 (11.5)	–	<0.001
Respondent given opportunity to choose from anaesthesia options	14 (6.1)	216 (93.9)	–	24 (10.6)	292 (89.4)	–	0.08

test revealed that the model including independent variables was statistically different from the intercept-only model (χ^2=86, p<0.001). A crude Poisson regression analysis was conducted to assess the difference in receipt of SIC components between participants of the pre-intervention and post-intervention surveys. Additionally, an adjusted Poisson regression analysis was conducted to control for the effects of potential confounders, including sociodemographic variables. Age and monthly income were the only continuous sociodemographic variables included as covariates. In the multivariate analysis, all the aforementioned independent variables were taken as factors. The adjusted exponentiated Poisson regression coefficients (β) with their respective 95% CIs were reported to indicate which independent variables were associated with the dependent variable.

Patient involvement

This study involved only women who had obstetric or gynaecologic surgeries. These women were not involved in developing the research questions, outcome measures, study design or recruitment procedures. The findings of this study will not be directly disseminated to study participants.

RESULTS

Sociodemographic characteristics

A majority of the participants were between 25 and 34 years of age in both the pre-intervention and post-intervention

groups (p=0.66). The mean±SD was calculated to be 28.2±7.9 and 27.3±6.8 years of age in the pre-intervention and post-intervention groups, respectively (table 2). The educational level, marital status, religion, ethnicity and occupation of respondents did not differ between participants of the two groups. With regard to religion, 90 (39.1%) and 80 (35.2%) respondents in the pre-intervention and post-intervention groups were protestant Christians, respectively. A majority of respondents in the two groups were married. Additionally, 122 (53%) and 108 (47.6%) respondents in the pre-intervention and post-intervention groups were housewives, respectively. A higher proportion of respondents in the post-intervention group had a regular monthly income, compared with those in the pre-intervention group (85% vs 72.8%, respectively); p<0.001 (table 2). However, the mean±SD of the monthly income of respondents of the two groups did not show a significant difference (p=0.48) (table 2).

Respondents' service-related characteristics

Close to one-third (29.6%) of the pre-intervention respondents presented directly to the hospital while the remainder (70.4%) visited the hospital upon referral from other health facilities. A slightly higher proportion (34.5%) of the post-intervention participants came directly to the hospital (p=0.26). A majority of the participants both in the pre-intervention and post-intervention groups did not know the profession of the person who provided their counselling session (table 3). As to the schedule of respondents' surgeries, 105 (45.7%) pre-intervention and 117 (51.5%) post-intervention survey participants had an elective surgery, respectively (p=0.21). A roughly equal proportion of participants in both groups received spinal anaesthesia—181 (78.7%) in the pre-intervention group and 185 (80.6%) in the post-intervention group. A significant difference was observed between participants of the groups regarding the timing of counselling for SIC. One hundred and fifty-two (70.4%) pre-intervention survey participants received counselling immediately before their surgery while 141 (62.4%) post-intervention participants experienced so (p<0.001) (table 3). Meanwhile, 26 (12%) pre-intervention and 36 (15.9%) post-intervention participants received counselling on the day before their date of surgery.

SIC components received

Compared with the pre-intervention group, a higher proportion of women in the post-intervention group reported having received all 13 standard SIC components. However, only six of the informed consent components were delivered to a significantly different proportion of participants in pre-intervention versus post-intervention groups. The greatest difference was observed regarding the component that assessed whether participants were informed about the type of anaesthesia to be used during their surgery (11.3% in the pre-intervention group and 44.3% in the post-intervention group; p<0.001) (table 1). Significant differences were also found between the two groups with regard to receipt of the following consent components: informed of the presence or absence of alternative treatment options; provided with decision making aids; informed about potential complications that could arise; informed about the consequences of refusing the planned surgery; given adequate time for decision before signing on the consent sheet and given an opportunity to ask question (table 1).

Perceptions and misconceptions on SIC

About four-fifths (80.9%) of participants in the pre-intervention group believed that SIC was a legal requirement to undergo a surgery while 96.5% of the post-intervention participants believed so (p<0.001) (table 4). No difference was observed between the two groups of participants regarding the perception that SIC was important for oneself (77.4% in the pre-intervention and 83.2% in the post-intervention group; p=0.12). Additionally, 5.7% and 6.6% of pre-intervention and post-intervention participants reported that SIC was no more than a signature on a piece of paper, respectively (p=0.66). Pertaining to the purpose of informed consent, 149 (64.8%) of pre-intervention participants believe that consent is primarily sought to protect hospitals and health professionals (66.8% in the post-intervention group; p=0.65). Furthermore, 34 (14.8%) of the pre-intervention group and 24 (11.1%) post-intervention group participants believed that providing consent revoked their right to compensation (p=0.25) (table 4).

Factors associated with receipt of the components of SIC

In the bivariate analysis, the intervention, schedule of surgery, type of anaesthesia used, referral status of respondents, profession of SIC counsellor, and timing of counselling were identified to be associated with the number of SIC components received by the respondents. The intervention was the only variable proven to be associated with the number of SIC components received by respondents in the multivariate analysis, which adjusted the aforementioned variables for one another and for sociodemographic variables (age, monthly income, educational level, occupation, marital status, religion and ethnicity). As displayed in table 5, the SIC components received by the post-intervention survey participants was 16% higher (adjusted coefficient=1.16 (1.06–1.28)). The schedule of surgery, dichotomised as either elective or emergency, showed no statistically significant association with the number of components received by the pre-intervention and post-intervention survey participants (adjusted coefficient=0.98 (0.88–1.09)) (table 5).

DISCUSSION

The current study is the first of its kind in Ethiopia to quantitatively assess the effects of institutionalising a new SIC process, measured in terms of the number of standard SIC components received by women who underwent obstetric or gynaecologic surgeries before and after

Table 2 Sociodemographic and economic characteristics of respondents, Hawassa, 2016/2017

Variables	Pre-intervention n (%)	Post-intervention n (%)	P value
Age in completed year			0.66
15–24	66 (28.8)	66 (29.1)	
25–34	125 (54.6)	134 (59.0)	
35–44	26 (11.4)	20 (8.8)	
45–54	7 (3.1)	4 (1.8)	
55 and above	5 (2.2)	3 (1.3)	
Total	229 (100.0)	227 (100.0)	
Mean±SD	28.2±7.9	27.3±6.8	
Educational level			0.93
No formal education	52 (22.6)	44 (19.4)	
Some primary education	48 (20.9)	53 (23.3)	
Completed grade 8	18 (7.8)	22 (9.7)	
Some secondary education	25 (10.9)	25 (11.0)	
Completed grade 12	23 (10.0)	22 (9.7)	
College and above	32 (16.4)	61 (26.9)	
Total	230 (100.0)	227 (100.0)	
Marital status			0.76
Single	7 (3.0)	5 (2.2)	
Married	212 (92.2)	215 (94.7)	
Separated	5 (2.2)	2 (0.9)	
Divorced	1 (0.4)	1 (0.4)	
Widowed	5 (2.2)	4 (1.8)	
Total	230 (100.0)	227 (100.0)	
Religion			0.89
Christian Orthodox	61 (26.5)	64 (28.2)	
Christian Protestant	90 (39.1)	80 (35.2)	
Muslim	74 (32.2)	79 (34.8)	
Others	5 (2.2)	3 (1.3)	
Total	230 (100.0)	227 (100.0)	
Ethnicity			0.40
Sidama	43 (18.7)	35 (15.4)	
Oromo	85 (37.0)	85 (37.4)	
Amhara	28 (12.2)	41 (18.1)	
Gurage	29 (12.6)	24 (10.6)	
Wolayita	20 (8.7)	21 (9.3)	
Others	25 (10.9)	21 (9.3)	
Total	230 (100.0)	227 (100.0)	
Occupation			0.71
Housewife	122 (53.0)	108 (47.6)	
Private employee	13 (5.7)	24 (10.6)	
Government employee	38 (16.5)	16 (7.0)	
Private business	39 (17.0)	38 (16.7)	
Farmer	16 (7.0)	38 (16.7)	
Others	2 (0.9)	3 (1.3)	
Total	230 (100.0)	227 (100.0)	
Respondent has regular monthly income*			
Yes	166 (72.8)	192 (85.0)	<0.001

Continued

Table 2 Continued

Variables	Pre-intervention n (%)	Post-intervention n (%)	P value
<Br845	17 (10.2)	24 (12.6)	0.48
≥Br845	149 (89.8)	166 (87.4)	
Mean±SD	Br3690.7±Br4343.6	Br3215.9±Br2963.7	
No	62 (27.2)	26 (11.5)	
Total	228 (100.0)	218 (100.0)	

*US$1=Br23.5 during the study period, on average.

the intervention. Non-consented care is one among the seven categories of the mistreatment women face during facility-based childbirth.[23] Thus, the scope of this study extends to the mistreatment of women during childbirth in health facilities—a phenomenon which in turn contributes to the unacceptable proportion of deliveries outside of health facilities in Ethiopia. This study also challenges the idea that informed consent for clinical treatment is theoretical rather than systematic and difficult to put into practice in different contexts.[1]

Women who had surgeries after the institutionalisation of the new SIC process were found to receive more SIC components than their counterparts by 16% after controlling for the effects of potential confounders. However, such a measure used by the current study only grasps the quantitative changes and misses those aspects of client-centred care that can only be described qualitatively.[24] The current study design does not allow us to evaluate changes in clients' clinical outcomes due to the current intervention because structure-level and supply-level (inputs) factors also play a significant role in outcomes of clinical care.[25] Importantly, the aforementioned results were obtained after a one-time intervention. More robust changes might be expected if the interventions were repetitive.

An integrated literature review also highlights that repetitive interventions have higher positive outcomes in terms of healthcare providers' skill and clinical practice behaviours.[26] Additionally, according to a mixed-methods study on healthcare innovations, involving middle-level managers can improve staff commitment to new implementations, increasing their effectiveness.[27] With this in mind, we recommend future implementation studies to engage middle-level managers as change agents.

In the current study, 70.4% and 62.4% of pre-intervention and post-intervention survey participants received

Table 3 Service-related characteristics of respondents 2016/2017

Variables		Pre-intervention n (%)	Post-intervention n (%)	P value
Referred from other health facility	Yes	162 (70.4)	148 (65.5)	0.26
	No	68 (29.6)	78 (34.5)	
	Total	230 (100.0)	226 (100.0)	
Profession of the person who gave counselling	Obstetrician-gynaecologist	32 (14.8)	36 (16.0)	0.06
	Resident physician	59 (27.3)	64 (28.4)	
	Nurse-midwife	46 (21.3)	25 (11.1)	
	Did not know	79 (36.6)	100 (44.4)	
	Total	216 (100.0)	225 (100.0)	
Schedule of obstetric/ gynaecologic surgery performed	Elective	105 (45.7)	117 (51.5)	0.21
	Emergency	125 (54.3)	110 (48.5)	
	Total	230 (100.0)	227 (100.0)	
Type of anaesthesia received	General	49 (21.3)	44 (194)	0.61
	Spinal	181 (78.7)	183 (80.6)	
	Total	230 (100.0)	227 (100.0)	
Timing of counselling for informed consent	The day before date of surgery	26 (12.0)	36 (15.9)	<0.001
	On the day of surgery	19 (8.8)	45 (19.9)	
	Immediately before surgery	152 (70.4)	141 (62.4)	
	On the operation table	19 (8.8)	4 (1.8)	
	Total	216 (100.0)	226 (100.0)	

Table 4 Respondents' perceptions and misconceptions on surgical informed consent, Hawassa, 2016/2017

Essential components of surgical informed consent	Pre-intervention; n (%)		Post-intervention; n (%)		P value
	Yes	No	Yes	No	
Surgical informed consent is a legal requirement to undergo a surgery	186 (80.9)	44 (19.1)	218 (96.5)	8 (3.5)	<0.001
Surgical informed consent is important for myself	178 (77.4)	52 (22.6)	188 (83.2)	38 (16.8)	0.12
Surgical informed consent is just signing on a piece of paper	13 (5.7)	217 (94.3)	15 (6.6)	211 (93.4)	0.66
Surgical informed consent is used just to protect hospitals and health professionals	149 (64.8)	81 (35.2)	151 (66.8)	75 (33.2)	0.65
By providing a surgical informed consent, there would be loss of right to compensation	34 (14.8)	196 (85.2)	24 (11.1)	192 (88.9)	0.25
The surgical informed consent delivery process needs improvement	114 (49.6)	116 (50.4)	38 (16.7)	189 (83.3)	<0.001

counselling immediately before their surgery, respectively (p<0.001), highlighting a gap in service providers' knowledge about when to seek an informed consent. However, it is not possible to conclude that only improving service providers' knowledge leads to adherence to the recommended guidelines, as other overriding factors such as provider attitudes, lack of adequate motivation and space constraints in health facilities can deter adoption of new guidelines.[28] It should be noted that from the clients' perspective, a study from a Ugandan university teaching hospital revealed that some women wish to have detailed information provided to them after their surgery, which is contradictory to clinical and ethical recommendations regarding informed consent.[18]

Although there was no significant difference in the level of misconception about SIC between the pre-intervention

Table 5 Factors associated with receipt of components of surgical informed consent, Hawassa, 2016/2017

Explanatory variables		Exponentiated regression coefficient, β (crude)	95% CI	P value	Exponentiated regression coefficient, β (adjusted)*	95% CI	P value
Group	Pre-intervention	Ref.			Ref.		0.002
	Post-intervention	1.27	(1.17 to 1.38)	<0.001	1.16	(1.06 to 1.28)	
Schedule of surgery	Elective	Ref.			Ref.		0.72
	Emergency	0.88	(0.81 to 0.95)	0.02	0.98	(0.88 to 1.09)	
Type of anaesthesia	General	Ref.			Ref.		0.96
	Spinal	1.06	(0.96 to 1.17)	0.28	1.00	(0.89 to 1.14)	
Referred from other health facility	Yes	Ref.			Ref.		0.76
	No	1.22	(1.12 to 1.32)	<0.001	1.02	(0.92 to 1.13)	
Counselling received from	Obstetrician-gynaecologist	Ref.			Ref.		
	Resident physician	0.83	(0.74 to 0.94)	0.03	0.92	(0.80 to 1.06)	0.26
	Nurse-midwife	0.88	(0.47 to 1.55)	0.61	0.95	(0.81 to 1.12)	0.56
	Did not know	0.71	(0.63 to 0.80)	<0.001	0.88	(0.48 to 1.64)	0.69
Timing of counselling	The day before date of surgery	Ref.			Ref.		0.92
	On the day of surgery	0.98	(0.85 to 1.13)	0.80	0.99	(0.83 to 1.18)	
	Immediately before surgery	0.83	(0.74 to 0.93)	0.001	0.95	(0.82 to 1.10)	0.5
	On the operation table	0.53	(0.42 to 0.68)	<0.001	0.72	(0.5 to 1.05)	0.08

*Adjusted for each other and sociodemographic variables.

and post-intervention groups, these findings are comparable to those from a cross-sectional study from India.[29] In that study, 75% of participants reported that SIC is a legal requirement. In the present study, 80.9% of pre-intervention and 96.5% of post-intervention participants reported the same. Innovative tactics like making the SIC information sheet attractive, adjusting the delivery of information to the client's ability to comprehend and use of computer-based demonstrations are reported to be effective in reducing misconceptions among clients.[10]

A mixed-methods landscape analysis of innovative maternal and newborn health services revealed that an intervention in one health system component is affected by other system components, thereby challenging sustainability.[30] Therefore, a system-wide approach should be considered in future innovations that aim to improve SIC process.

This study analysed the difference in the number of SIC components received by women before and after the introduction of a new SIC procedure. Surveying women immediately after their discharge from the hospital minimised problems recalling what was offered during counselling for surgical procedures. A strength of the study is the use of Poisson regression for the count data instead of categorising the counts using cut-off point for the sake of logistic regression. However, the lack of comparison/control groups and the use of a between-subject (rather than within subjects) design posed limitations in estimating the isolated effects of the intervention. Future studies could improve on this design by inquiring further about women's expectations that were not met during the SIC counselling. Additionally, as contexts vary between teaching and non-teaching hospitals, the evidence generated by this study may not be generalisable to non-teaching hospitals. Therefore, it is recommended that future studies should include control groups and deploy a mixed-methods approach that includes analysis of client-centred care experiences to achieve a more nuanced understanding of the changes that results from an intervention to improve SIC delivery. We believe that this study adds to existing knowledge about SIC delivery processes and approaches to improve them, especially in low-resource settings.

CONCLUSIONS

The institutionalisation of a standard SIC delivery approach is associated with receipt of a higher number of standard counselling components. However, the improvement may not endure without sustained intervention. Therefore, there is a need for a continuous survey of care recipients to track the durability of the current intervention. The findings of the study also justify the need for wider exploration of the deterrents that challenge adherence to innovative practices. Furthermore, a system-wide study of the factors that promote informed consent in all aspects of clinical care is required.

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Contributors MT conceived the study; MT, ZW and AA designed and conceptualised the study; MT, ZW and AA trained data collectors and supervised data collection; AA analysed the data; MT, ZW, AA and AG drafted the manuscript. All authors have read and approved the final manuscript.

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REFERENCES

1. Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. *CMAJ* 2012;184:533–40.
2. Lawal YZ, Garba ES, Ogirima MO, *et al*. The doctrine of informed consent in surgical practice. *Ann Afr Med* 2011;10:1–5.
3. Messer NG. Professional-patient relationships and informed consent. *Postgrad Med J* 2004;80:277–83.
4. Agre P, McKee K, Gargon N, *et al*. Patient satisfaction with an informed consent process. *Cancer Pract* 1997;5:162–7.
5. Hölzel LP, Kriston L, Härter M. Patient preference for involvement, experienced involvement, decisional conflict, and satisfaction with physician: a structural equation model test. *BMC Health Serv Res* 2013;13:231.
6. Wamisho BL, Abeje M, Feleke Y, *et al*. Analysis of medical malpractice clams and measures proposed by the health professionals ethics federal committee of Ethiopia: review of the three years proceedings. *Ethiop Med J* 2015;53:1–6.
7. Will JF. A brief historical and theoretical perspective on patient autonomy and medical decision making: part II: The autonomy model. *Chest* 2011;139:1491–7.
8. San Norberto EM, Gómez-Alonso D, Trigueros JM, *et al*. [Readability of surgical informed consent in Spain]. *Cir Esp* 2014;92:201–7.
9. Falagas ME, Korbila IP, Giannopoulou KP, *et al*. Informed consent: how much and what do patients understand? *Am J Surg* 2009;198:420–35.
10. Leclercq WK, Keulers BJ, Scheltinga MR, *et al*. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. *World J Surg* 2010;34:1406–15.
11. Akkad A, Jackson C, Kenyon S, *et al*. Informed consent for elective and emergency surgery: questionnaire study. *BJOG* 2004;111:1133–8.
12. Anderson OA, Wearne IM. Informed consent for elective surgery-what is best practice? *J R Soc Med* 2007;100:97–100.
13. Hallock JL, Rios R, Handa VL. Patient satisfaction and informed consent for surgery. *Am J Obstet Gynecol* 2017;217:181.e1–7.
14. Yek JL, Lee AK, Tan JA, *et al*. Defining reasonable patient standard and preference for shared decision making among patients undergoing anaesthesia in Singapore. *BMC Med Ethics* 2017;18:6.
15. Bossert S, Kahrass H, Heinemeyer U, *et al*. Participatory improvement of a template for informed consent documents in

biobank research - study results and methodological reflections. *BMC Med Ethics* 2017;18:78.
16. Leclercq WK, Keulers BJ, Houterman S, *et al*. A survey of the current practice of the informed consent process in general surgery in the Netherlands. *Patient Saf Surg* 2013;7:4.
17. Lin YK, Chen CW, Lee WC, *et al*. Development and pilot testing of an informed consent video for patients with limb trauma prior to debridement surgery using a modified Delphi technique. *BMC Med Ethics* 2017;18:67.
18. Ochieng J, Buwembo W, Munabi I, *et al*. Informed consent in clinical practice: patients' experiences and perspectives following surgery. *BMC Res Notes* 2015;8:765.
19. ACOG Committee on Ethics. ACOG Committee Opinion No. 439: Informed consent. *Obstet Gynecol* 2009;114:401–8.
20. Ochieng J, Ibingira C, Buwembo W, *et al*. Informed consent practices for surgical care at university teaching hospitals: a case in a low resource setting. *BMC Med Ethics* 2014;15:40.
21. Royal College of Obstetricians and Gynaecologists. *Obtaining valid consent. clinical governance advice*. London, United Kingdom: Royal College of Obstetricians and Gynaecologists, 2015.
22. The Royal College of Surgeons of England. *Consent: supported decision making. a guide to good practice*. London, United Kingdom: The Royal College of Surgeons, 2016.
23. Bohren MA, Vogel JP, Hunter EC, *et al*. The mistreatment of women during childbirth in health facilities globally: a mixed-methods systematic review. *PLoS Med* 2015;12:e1001847.
24. Pope C, van Royen P, Baker R. Qualitative methods in research on healthcare quality. *Qual Saf Health Care* 2002;11:148–52.
25. Gardner G, Gardner A, O'Connell J. Using the Donabedian framework to examine the quality and safety of nursing service innovation. *J Clin Nurs* 2014;23:145–55.
26. Bluestone J, Johnson P, Fullerton J, *et al*. Effective in-service training design and delivery: evidence from an integrative literature review. *Hum Resour Health* 2013;11:51.
27. Birken SA, Lee SY, Weiner BJ, *et al*. Improving the effectiveness of health care innovation implementation: middle managers as change agents. *Med Care Res Rev* 2013;70:29–45.
28. Spallek H, Song M, Polk DE, *et al*. Barriers to implementing evidence-based clinical guidelines: a survey of early adopters. *J Evid Based Dent Pract* 2010;10:195–206.
29. Rajesh DR AS, Chopra M, *et al*. Patients' awareness attitude,understanding and perception towards legal nature of informed consent. *J Indian Acad Forensic Med* 2013;35:40–3.
30. Lunze K, Higgins-Steele A, Simen-Kapeu A, *et al*. Innovative approaches for improving maternal and newborn health-A landscape analysis. *BMC Pregnancy Childbirth* 2015;15:337.