

Factors affecting the process of obtaining informed consent to surgery among patients and relatives in a developing country: results from Pakistan

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العوامل التي تؤثر على عملية الحصول على موافقة مسبقة على عملية جراحية لدى المرضى وأقاربهم في البلدان النامية: نتائج من باكستان
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الخلاصة: لقد بذلت جهود مؤخرًا في باكستان من أجل وضع دلائل إرشادية أخلاقية للبحوث والممارسة الطبية. وقد استكشفت هذه الدراسة التصورات عن عملية الحصول على موافقة مسبقة على عملية جراحية، والعوامل التي تؤثر على هذه العملية لدى مرضى داخليين وعائلاتهم في مستشفى للرعاية الثالثية في كراتشي. ففي دراسة مستعرضة أجريت عام 2010 أجابت عينة عشوائية مكونة من 400 مريض بالغ بعد الجراحة على استبيان منظم تم اختياره مسبقاً. فكان ما إجماليه 233 مريضاً (58.3%) قد وقعوا على استمارة الموافقة على الجراحة بأنفسهم، في حين وقع 167 من الأقارب (41.7%) نيابة عن المريض. وكانت العوامل المتصورة التي ارتبطت - بشكل ملحوظ - بعدم توقيع المرضى على استمارة الموافقة بأنفسهم: اللغة المستخدمة (OR المعدلة = 4.6)، والمصطلحات الطبية المستخدمة (OR المعدلة = 2.7)، وعدم كفاية الوقت المخصص (OR المعدلة = 3.8)، وأسباب ثقافية/تقليدية (OR المعدلة = 1.5)، والتعليم المنخفض (OR المعدلة = 2.4). وكان التوقيت غير المناسب لأخذ الموافقة، وعدم الإبلاغ/السؤال عن الموافقة عامليْن غير مهمَّين إحصائياً. فينبغي أن يكون ممارسو الرعاية الصحية على علم بالعوامل التي تؤثر في عملية الموافقة المسبقة، وأن يشجعوا المرضى على التوقيع على استمارة الموافقة بأنفسهم.

ABSTRACT Efforts have been made in Pakistan to create ethical guidelines for research and medical practice. This study explored the perceptions of and factors affecting the process of obtaining informed consent to surgery among inpatients and families at a tertiary-care hospital in Karachi. A random sample of 400 post-surgery adult patients answered a pre-tested, structured questionnaire. Overall, 233 patients (58.3%) had signed the surgery consent form themselves, while 167 relatives (41.7%) had signed on behalf of the patient. Perceived factors significantly associated with patients not signing the consent form themselves were: language used (adjusted OR = 4.6), medical terminology used (aOR = 2.7), insufficient time allocation (aOR = 3.8), cultural/traditional reasons (aOR = 1.5) and low education (aOR = 2.4). Inappropriate timing for taking consent and not being informed/asked about consent were not statistically significant factors. Health-care practitioners should encourage patients to sign the consent form themselves.

Facteurs influant sur le processus d'obtention d'un consentement éclairé pour une intervention chirurgicale chez des patients et des parents dans un pays en développement : résultats du Pakistan

RÉSUMÉ Des efforts récents ont été réalisés au Pakistan en vue de créer des lignes directrices pour l'éthique en recherche et pratique médicales. La présente étude a évalué les perceptions relatives au processus d'obtention d'un consentement éclairé pour une intervention chirurgicale et les facteurs d'influence chez des patients hospitalisés et leur famille dans un hôpital de soins tertiaires à Karachi. Un échantillon aléatoire de 400 patients adultes postopératoires a répondu à un questionnaire prétesté et structuré. Au total, 233 patients (58,3 %) avaient signé eux-mêmes le formulaire de consentement à une intervention chirurgicale, tandis que 167 parents (41,7 %) avaient signé pour le patient. Les facteurs perçus comme fortement associés aux patients qui n'avaient pas signé eux-mêmes le formulaire de consentement étaient les suivants : la langue utilisée (OR ajusté = 4,6), la terminologie médicale utilisée (OR ajusté = 2,7), l'insuffisance du temps alloué (OR ajusté = 3,8), des raisons culturelles/traditionnelles (OR ajusté = 1,5) et un faible niveau d'études (OR ajusté = 2,4). Un moment inopportun pour demander le consentement et l'absence d'information/d'interrogation à ce sujet n'étaient pas des facteurs statistiquement significatifs. Les professionnels de santé doivent encourager les patients à signer eux-mêmes le formulaire.

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Introduction

The most important goal of informed consent is that patients have an opportunity to be informed participants in decisions about their health care (1). It is generally accepted that complete informed consent includes a discussion of the following elements: the nature of the decision/procedure; reasonable alternatives to the proposed intervention; the relevant risks, benefits and uncertainties related to each alternative (2); assessment of the patient's understanding; and the patient's acceptance of the intervention. It originates from the legal and ethical right the patient has to direct what happens to his/her body and from the ethical duty of the physician to involve the patient in health-care decisions.

Informed consent recognizes not only patients' autonomy in decision-making but also their right to complete information. The informed consent process requires the physician to explain in sufficient detail the diagnostic, therapeutic and prognostic reasoning that leads to his/her expert decision on what is in the best interest of the patient (3). In most cases, it is clear whether or not patients are competent to make their own decisions (4). However, if patients are judged to be incapacitated /incompetent to make health care decisions, a surrogate decision-maker must speak for them (5).

Most developed countries have enshrined these concepts of informed consent, privacy and confidentiality in federal or state laws and codes of ethics. In Pakistan there have been some recent efforts to create ethical guidelines for research and medical practice. Significantly, the Pakistan Medical and Dental Council, the regulatory body of medical practitioners, has formulated a code of ethics for all doctors, although no concrete steps have been taken to ensure its application. At the same time, cultural values in Pakistan offer a challenge to the practice of medical

ethics in Pakistan (6). This is because crucial decisions are often made by family members or are left entirely up to the physician, and there seems to be a general acceptance of this practise among the public. Patients' awareness of their rights to informed consent and privacy is often low (7). Previous qualitative research has shown that many physicians do not think it is necessary to obtain a formal consent after providing the patients with thorough information (8,9). In view of these observations, this study was conducted to identify the perceptions of and factors affecting the process of obtaining informed consent to surgery among inpatients and families attending a tertiary care hospital in Karachi, Pakistan.

Methods

Study setting

This hospital-based, cross-sectional study was conducted between July and October 2010 in Aga Khan University Hospital, Karachi, Pakistan. Karachi is the largest city of Pakistan and is the capital city of Sind Province. The Aga Khan University is a 563-bed not-for-profit, private institution in Pakistan providing high-quality health care. The hospital has also been awarded the prestigious Joint Commission International accreditation and ISO 9001:2008 certification. The study patients were selected from the surgical ward of the hospital. This ward has 56 beds and provides comprehensive inpatient services for general surgery, urology, otolaryngology and head and neck surgery, ophthalmology, cardiothoracic and dental surgery.

Sample selection

Post-surgery patients, over the age of 18 years, admitted to the surgical ward and giving consent to participate were included in the study. Those patients who required special care, intensive care unit or coronary care unit admission were

excluded. The sample size was calculated using *Epi-Info*, version 6, and based on a prevalence of 50% with 5% error bound and 5% level of significance; the required sample size was estimated as at least 385 subjects.

The patients were selected through simple random sampling. The study statistician used computer-generated random numbers to identify patients from the daily list of patients requiring surgery. Patients were identified on the day of the surgery and were recruited and interviewed on the 2nd day of the surgery. Written informed consent for participation in this survey was obtained from each participant (verbally with thumb impression from those who could not read or write). The study was reviewed and approved by the ethics review committee of the Aga Khan University and Hospital.

Data collection

Data were collected while ensuring strict confidentiality for the participants. The patients were interviewed in an environment where their privacy could be ensured (attendants were asked to leave the area and ambulant patients were interviewed in a separate room adjacent to the ward). Two nursing graduates were trained for screening the eligible patients and administration of the questionnaire.

Questionnaire development

The questionnaire was formulated after an extensive literature search (*Medline*) and consensus by the study investigators, who are involved in the hospital quality management committee. The questionnaire comprised 3 sections: section A dealt with the descriptive characteristics of the study participants; section B consisted of 12 questions about the consent process and 9 questions about the important clauses of the surgical informed consent form; and section C was about the factors associated with not signing of the consent form by patients themselves, and future

recommendations. To enhance its comprehensibility the English version of the questionnaire was translated into the local Urdu language and was back-translated into English to check for consistency; any discrepancies found were removed. Pre-testing of the Urdu version was done on 5% of the sample size ($n = 25$). The final questionnaire was shared with experts in the field of family medicine and the quality control department to obtain their suggestions for improvement.

Data analysis

Statistical analysis was carried out using SPSS software, version 17. Proportions were reported for all the variables such as age, sex and occupation. Univariate and multivariate logistic regression was done to identify the perceived factors associated with the consent process. The results are reported in form of odds ratio (OR) and 95% confidence interval (CI). P -values < 0.05 were considered statistically significant throughout the study.

Results

A total of 490 eligible patients were approached, out of whom 400 consented to participate and were included in the final analysis, yielding a response rate of 81.6% (400/490). Missing information was handled through mean imputation.

Table 1 shows the sociodemographic characteristics of the study sample. Out of the total 400 participants a majority were males (53.5%). The median age was 37 years, range 14–78 years. Most of the participants were single, divorced or widowed (75.0%) and one-quarter were married. Less than half of the participants (42.8%) were in paid employment, while 7.8% were students and 4.0% were retired. Of the participants 41.8% had education to secondary level, 35.0% had education to intermediate level and above, while

Table 1 Sociodemographic characteristics of the study respondents ($n = 400$)

Variable	No.	%
Sex		
Male	214	53.5
Female	186	46.5
Age [median (IQR) years]	37 (14–78)	
Marital status		
Married	100	25.0
Single	300	75.0
Occupation		
Earning	171	42.8
Housewife	165	41.3
Retired	16	4.0
Student	31	7.8
Unemployed	17	4.3
Educational status		
Cannot read or write	37	9.3
Primary (1–5 years)	56	14.0
Secondary (6–10 years)	167	41.8
Intermediate and above (> 10 years)	140	35.0
Consent form signed by:		
Self	233	58.3
Parent	36	9.0
Spouse	56	14.0
Child	51	12.8
Sibling	24	6.0

IQR = interquartile range.

9.3% participants were unable to read or write.

Table 2 presents the perceptions of patients regarding the informed consent process. Although in most cases information about surgery was given in the clinic (70.0%), the consent for surgery was signed in the ward (76.8%) and 14.8% of respondents stated that consent was only signed in the operating theatre. Just over half of the respondents (57.3%) agreed that informed consent was important to obtain before any surgery. About one-third of the patients (32.9%) said they were influenced by family and friends to proceed to surgery.

In this study 233 (58.3%) of the patients signed the surgery consent form themselves, while for 167 (42.8%) of patients the form was signed on their behalf by a relative (spouse, parent,

sibling or child). There was no statistically significant difference in the proportion of males and females whose relatives signed on their behalf [data not shown].

Table 2 compares the perceptions of patients who signed for themselves and relatives who signed on their behalf regarding the informed consent process. When asked about the importance of obtaining consent before any surgery 63.8% of patients who signed the consent form themselves agree that consent before any surgery was important, whereas only 48.2% of the relatives signing agreed that it was important ($P < 0.01$). A majority of patients (84.3%) and relatives (79.6%) agreed that the consent form has a medico-legal meaning and wanted detailed information (86.5% and 78.4% respectively). Of

Table 2 Perceptions of patients and relatives who signed the surgery consent form regarding the informed consent process

Statement/ characteristics of consent	Total (n = 400)		Self-signed (n = 233)		Relative signed ^a (n = 167)		P-value
	No.	%	No.	%	No.	%	
Who explained the information							
Doctor	271	67.8	168	72.1	103	61.7	0.01
Resident	129	32.3	65	27.9	64	38.3	
Where information was given							
Operating theatre	32	8.0	14	6.0	18	10.8	0.04
Ward	88	22.0	45	19.3	43	25.7	
Clinic	280	70.0	174	74.7	106	63.5	
Where consent was taken							
Operating theatre	59	14.8	28	12.0	31	18.6	> 0.05
Ward	307	76.8	183	78.5	124	74.3	
Clinic	34	8.5	22	9.4	12	7.2	
Informed consent influenced your decision to proceed with surgery							
Yes	135	33.8	72	31.9	63	37.7	< 0.01
No	265	66.3	161	69.1	104	62.3	
Influenced by anyone to proceed with surgery							
No	67	17.0	40	17.7	27	16.2	0.04
Yes, family/friends	74	32.9	51	22.6	23	13.8	
Yes, doctor	252	64.1	135	59.7	117	70.1	
Informed consent is important before any surgery							
Yes	225	57.3	146	63.8	79	48.2	< 0.01
No	168	42.7	83	36.2	85	51.8	
Know about medico-legal significance of informed consent							
Yes	326	82.3	193	84.3	133	79.6	< 0.01
No	70	17.7	36	15.7	34	20.4	
Amount of information preferred							
Detailed	329	83.1	198	86.5	131	78.4	0.02
Limited	67	16.9	31	13.5	36	21.6	
Amount of information preferred if going for same surgery							
Detailed	303	77.1	164	71.6	139	84.8	< 0.01
Limited	90	22.9	65	28.4	25	15.2	
Received educational materials about pre- & post-operative management							
Yes	78	19.6	49	21.3	29	17.4	> 0.05
No	319	80.4	181	78.7	138	82.6	
Materials were helpful (n = 81)							
Yes	62	76.5	39	79.6	23	71.9	< 0.01
No	19	23.5	10	20.4	9	28.1	
Satisfied with information provided							
Yes	367	91.8	227	97.4	140	83.8	< 0.001
No	33	8.3	6	2.6	27	16.2	

^aRelatives: parent, spouse, sibling, other relative.

the patients who signed the consent form themselves 89.7% said they were given the opportunity to ask questions compared with 76.6% of relatives who signed for them. Many patients and relatives reported that they were not informed about the complications (51.1% and 56.9% respectively), length of stay in the hospital (21.2% and 16.8% respectively), alternatives to surgery (44.7% and 44.3% respectively) and type of anaesthesia (28.8% and 20.4% respectively). Few patients (21.3%) or relatives (17.4%) had received any educational materials regarding pre- and post-operative management and care/information guidance, but those who received them found the information very helpful (79.6% and 71.9% respectively). Almost all the patients signing for themselves (97.4%) were satisfied with the information they had been given, compared with 83.8% of relatives who were satisfied ($P < 0.001$).

Table 3 presents responses to the important clauses of the surgery informed consent form. All the patients who signed the consent form reported they were informed about the indications for surgery, whereas 7.8% of the relatives who signed the consent said they were not informed about the indications ($P < 0.001$). Of the patients 83.8% said that they were informed about possible complications if surgery were not done, compared with only 69.5% of the relatives ($P < 0.001$). Overall, in only 14.8% of cases were respondents informed about the alternatives to surgery and 59.8% were informed about the type of anaesthesia to be used in the surgery. Most of the patients who signed the consent form themselves (82.4%) were informed about the nature of the surgery as compared with only 59.9% of the relatives who signed on their behalf, whereas 89.3% versus 73.1% of the patients and relatives respectively were informed about the expected benefits of the surgery. Most of the

patients who signed for themselves (89.7%) were given the opportunity to ask questions whereas 76.6% of the relatives were given the opportunity.

Table 4 shows the univariate and multivariate regression analysis of the factors associated with not signing of the surgical consent form by patients themselves. When adjusted for other confounders in multivariate logistic regression analysis the statistically significant factors associated with patients not signing the consent form themselves were: language, medical terminology, insufficient time, culture/traditions and educational status. When there were language barriers the patient was 4.6 times more likely to not sign the form themselves, whereas when there were cultural barriers the patients were 1.5 times more likely to not sign the form. Those patients who had lower educational status were 2.4 times more likely not to sign the consent form themselves. Moreover, when inappropriate medical terminologies were used patients were 2.7 times more likely to not sign the consent form. If patients were given insufficient time to understand the contents of the consent form, they were 3.8 times more likely to not sign the consent form themselves. Factors that were not significant in the regression analysis were: inappropriate timing for taking consent and not being informed about or asked for consent.

Discussion

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and the physician that results in the patient's authorization or agreement to undergo a specific medical intervention (10). An important part of such a clinical, ethical judgement is the patient's capacity to participate in the informed consent process, which

includes understanding that one is being asked to authorize surgical management and understanding the nature of that surgery as well as its clinical benefits and risks.

Just over half of the patients (58.3%) signed the consent form themselves and for the rest consent was given by a relative. The literature supports our finding that signing consent forms by relatives and not only by patients is also common practice in other countries (11). In practice, surgeons and physicians in Pakistan prefer to fill out the consent form in the outpatient clinic where they can explain the procedure and ask the patients to sign the relevant forms (12). However, this may not allow adequate time for deliberation and reflection, as outlined by the United Kingdom General Medical Council guidelines (2). In our study, although a majority of patients (70.0%) had received information from the consultant in the outpatient clinic, in fact signature was taken on the ward for 76.8%, while 14.8% claimed that signature was taken in the operating theatre.

In clinical situations it is important to have informed consent to make important decisions; however consent practices vary in different institutions and countries. There is a lack of awareness about consent even among educated patients in Pakistan (13,14). Previous studies have also looked at the consent practices in surgery patients (15). In a study in Pakistan and the United Kingdom written consent was routinely obtained for surgical treatment by the staff (16). This practice has previously been pointed out in another study in Pakistan, in which only 29% patients signed their own consent (8).

A great majority of patients and relatives agreed that the consent form has a medico-legal meaning and wanted detailed information. Few patients (21.3%) or relatives (17.4%) had received any educational materials

Table 3 Attitudes of patients and relatives who signed the surgery consent form towards the important clauses of the consent form

Statement	Total (n = 400)		Self-signed (n = 233)		Relative signed ^a (n = 167)		P-value
	No.	%	No.	%	No.	%	
<i>Informed about nature of surgery</i>							
Yes	292	73.0	192	82.4	100	59.9	< 0.001
No	75	18.8	32	13.7	43	25.7	
Don't know	33	8.3	9	3.9	24	14.4	
<i>Informed about indications for surgery</i>							
Yes	383	95.8	233	100.0	150	89.8	< 0.001
No	13	3.3	0	0.0	13	7.8	
Don't know	4	1.0	0	0.0	4	2.4	
<i>Informed about possible complications of surgery</i>							
Yes	177	44.3	105	45.1	72	43.1	> 0.05
No	214	53.5	119	51.1	95	56.9	
Don't know	9	2.3	9	3.9	0	0.0	
<i>Informed about length of hospital stay after surgery</i>							
Yes	291	74.0	169	74.8	122	73.1	0.037
No	76	19.3	48	21.2	28	16.8	
Don't know	26	6.6	9	4.0	17	10.2	
<i>Informed about alternatives to surgery</i>							
Yes	58	14.8	35	15.5	23	13.8	> 0.05
No	175	44.5	101	44.7	74	44.3	
Don't know	160	40.7	90	39.8	70	41.9	
<i>Informed about possible complications if surgery was not done</i>							
Yes	306	77.9	192	83.8	114	69.5	< 0.001
No	58	14.8	27	11.8	31	18.9	
Don't know	29	7.4	10	4.4	19	11.6	
<i>Informed about expected benefits of surgery</i>							
Yes	330	82.5	208	89.3	122	73.1	< 0.001
No	27	6.8	9	3.9	18	10.8	
Don't know	43	10.8	16	6.9	27	16.2	
<i>Informed about type of anaesthesia</i>							
Yes	239	59.8	144	61.8	95	56.9	0.01
No	101	25.3	67	28.8	34	20.4	
Don't know	60	15.0	22	9.4	38	22.8	
<i>Given opportunity to ask questions</i>							
Yes	337	84.3	209	89.7	128	76.6	< 0.001
No	28	7.0	12	5.2	16	9.6	
Don't know	35	8.8	12	5.2	23	13.8	

^aRelatives: parent, spouse, sibling, other relative.

Table 4 Factors associated with patients not signing the surgery informed consent form for themselves (n = 400)

Variable	Self-signed		Relative signed		OR (95% CI)	AOR (95% CI)	P-value
	No.	%	No.	%			
Language factors							
No	33	44.6	41	55.4	1	1	
Yes	200	61.3	126	38.7	2.3 (1.6–3.3)	4.6 (1.9–5.2)	< 0.01
Better educational status^a							
Yes	177	57.7	130	42.3	1		
No	56	62.2	34	37.8	2.6 (1.8–3.9)	2.4 (1.8–5.0)	0.01
Insufficient time allocated							
No	41	45.1	50	54.9	1	1	
Yes	192	62.1	117	37.9	1.9 (1.4–2.6)	3.8 (2.8–4.7)	0.02
Medical terminology used							
No	59	56.7	45	43.3	1	1	
Yes	174	58.8	122	41.2	1.8 (1.3–2.5)	2.7 (1.1–6.7)	0.03
Cultural/traditional reasons							
No	133	71.5	53	28.5	1	1	
Yes	100	46.7	114	53.3	1.6 (1.2–2.3)	1.5 (1.1–3.5)	0.04
Inappropriate timing							
No	184	57.1	138	42.9	1		
Yes	49	62.8	29	37.2	1.3 (1.0–1.8)	–	–
Not informed/asked							
No	208	63.0	122	37.0	1		
Yes	25	35.7	45	64.3	1.2 (1.0–1.7)	–	–

^aYes: > 6 years of education.

OR = odds ratio; CI = confidence interval; AOR = adjusted odds ratio.

regarding pre- and post-operative management and care/information guidance. However, satisfaction with the information provided was high among both patients (97.4%) and relatives (83.8%).

Regarding perceptions and knowledge about the important clauses of informed consent for surgery there were significant differences between the patients and relatives. In the current study 82.4% of patients who signed the consent form themselves were informed about the nature of the surgery as compared with only 59.9% of the relatives who signed on the patient's behalf. Slightly higher proportions of patients and relatives reported that they were informed about the expected benefits of the surgery (89.3% versus 73.1% respectively). Not all the patients or relatives

were given the opportunity to ask questions. Other research has shown that knowledge regarding consent is deficient not only in patients, but also among health-care professionals, who are often unaware of some of the important aspect of consent (17). Many of our patients and relatives reported that they were not informed about the complications, length of stay in the hospital, alternatives to surgery and type of anaesthesia.

In this study the multiple regression analysis shows that the significant factors associated with not signing of the consent form by patient themselves were language problems, medical terms used during explanation, insufficient time allocated, cultural/traditional reasons and low educational status. The literature has shown before that a low level of literacy

influences patients' understanding about the information given regarding procedures (18). In Pakistan the high rates of illiteracy among the population obstructs patients' ability to read the informed consent forms. People with regional dialects sometimes do not understand either the national (Urdu) or official (English) languages, and this makes communication difficult (8). Another factor identified in the study was cultural/traditional reasons. In this part of the world women are commonly not given autonomy to take decisions. Usually a male or the head of the family takes important decisions and, since the consent form is seen as a legal document, it is mostly men who sign it on behalf of their wives. However, in this study there was no significant difference in the proportion of males and females

whose relatives signed on their behalf. This could be because the study private hospital mainly serves an urban population, who tend to be better educated (only 9.3% of our patients were illiterate) and therefore more likely to understand and acknowledge women's autonomy. It would be interesting to note the practice in government and rural hospitals, where patients may have lower literacy levels.

There is evidence that if the consent process is communicated properly patient satisfaction levels during and after surgery are higher (19,20). Taking consent at the appropriate time and in the correct manner can resolve many issues after surgery (21,22). This was evident from the results of our study, in which a majority of the patients (86.5%) and their relatives (78.4%) wanted to have detailed information about the surgery. Moreover, the patients (63.8%) and relatives (48.2%) who signed the consent form knew that obtaining consent before any surgery is important. Making patients' aware

about their right to informed consent and privacy is essential in health care (23). Previous qualitative research has shown that a significant number of physicians do not think it is necessary to obtain a proper consent and that signing a document is sufficient, but the literature has shown that shared decision-making and proper communication will lead to better outcomes in terms of patient satisfaction, smooth recovery from procedures and surgery as well as better compliance with doctors' advice (9, 24).

This study had some limitations. It was a quantitative study and the results could have been more meaningful if patients' perceptions had been assessed qualitatively to determine the subjective perceptions of the patients regarding the barriers faced during signing of the consent form. In addition, this study was conducted in a private hospital, so extrapolation of the results to government and semi-private hospitals should be done with caution as there could be differences in practices.

Conclusions

This study showed the perceptions of patients and their relatives to signing a surgery consent form. Health care practitioners need to be aware and knowledgeable about the various factors affecting informed consent in order to improve the informed consent process. In this study language was identified as the greatest barrier to informed consent. Therefore translation of the informed consent form into various regional languages and providing translators is recommended. Health-care practitioners also need to be aware of particular items in the consent form (such as medical terminology) that may be problematic and to ask potential subjects direct questions about their understanding of those items. Further comparative studies regarding the informed consent process should be carried out between government and private hospitals to improve the process.

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