



An audit of the knowledge and attitudes of doctors towards Surgical Informed Consent (SIC)



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Abstract

Background: The Surgical Informed Consent (SIC) is a comprehensive process that establishes an information-based agreement between the patient and his doctor to undertake a clearly outlined medical or surgical intervention. It is neither a casual formality nor a casually signed piece of paper. The present study was designed to audit the current knowledge and attitudes of doctors towards SIC at a tertiary care teaching hospital in Pakistan.

Methods: This cross-sectional qualitative investigation was conducted under the auspices of the Department of Medical Education (DME), Pakistan Institute of Medical Sciences (PIMS), Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU), Islamabad over three months period. A 19-item questionnaire was employed for data collection. The participants were selected at random from the list of the surgeons maintained in the hospital and approached face-to-face with the help of a team of junior doctors detailed for questionnaire distribution among them. The target was to cover over 50% of these doctors by convenience sampling.

Results: Out of 231 respondents, there were 32 seniors while 199 junior doctors, constituting a ratio of 1:6.22. The respondents variably responded to the questions regarding various attributes of the process of SIC. Overall, the junior doctors performed poorer compared to the seniors.

Conclusion: The knowledge and attitudes of our doctors particularly the junior ones, towards the SIC are less than ideal. This results in their failure to avail this golden opportunity of doctor-patient communication to guide their patients through a solidly informative and legally valid SIC. They are often unaware of the essential preconditions of the SIC; provide incomplete information to their patients; and quite often do not ensure direct involvement of their patients in the process. Additionally they lack an understanding of using interactive computer-based programs as well as the concept of nocebo effect of informed consent.

Keywords: Surgical Informed Consent (SIC), Consent, Nocebo Effect of Informed Consent, Surgery

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Citation: Ashraf B, Tasnim N, Saaiq M, Zaman KU. An audit of the knowledge and attitudes of doctors towards Surgical Informed Consent (SIC). *Int J Health Policy Manag* 2014; 3: 315–321. doi: 10.15171/ijhpm.2014.109

Article History:

Received: 22 July 2014

Accepted: 26 October 2014

ePublished: 27 October 2014

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Key Messages

Implications for policy makers

- Given the considerable deficiencies in the knowledge and attitudes of doctors regarding Surgical Informed Consent (SIC), there is a need for creating awareness among them about the negative impact of these deficiencies on the overall well-being of their patients.
- A structured SIC template should be developed for the institution and be enforced on the operating surgeons to document the process of SIC before embarking on any surgeries.
- There is a need for formal training sessions and workshops for surgical residents and house officers to improve their knowledge and skills regarding SIC. The specialists and faculty should also have similar capacity building sessions as part of their Continued Professional Development (CPD).
- There is a need to introduce more advanced technologies such as computer-based interactive programs to enhance the quality of the SIC process.

Implications for public

Awareness of the patients regarding adequacy of Surgical Informed Consent (SIC) is imperative to improve the SIC process, which, in turn, will enhance the patient satisfaction and reduce their misunderstandings with surgical staff.

Introduction

The Surgical Informed Consent (SIC) is a comprehensive process that involves a competent patient, a clearly communicating doctor, and transfer of focused information about the planned surgical procedure. The basic components of SIC thus include preconditions, information,

and voluntary willingness. The preconditions for a valid SIC include the patient's competence and voluntariness for the procedure in question. The information provided must be adequate and comprehensible (1–3).

The information provided should particularly include medical facts about the patient's condition, details of the

proposed procedures, the potential risks and benefits of the procedure and the alternatives to the proposed procedure including the natural course of non-treatment. All this information must be disclosed by the operating surgeon himself to the patient to help him arrive at informed decision-making about his treatment. A well-defined care plan incorporating the surgeon's advice should be discussed and it must be ensured that the patient understands all this information (3–6).

The objective of the present study was to audit the current knowledge and attitudes of surgical doctors towards the SIC at a tertiary care teaching hospital in a Pakistan.

Methods

This cross-sectional study was carried out by the Department of Medical Education (DME), Pakistan Institute of Medical Sciences (PIMS), Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU), Islamabad over three months period (from January 01, 2014 to March 31, 2014).

PIMS is the tertiary care teaching dispensation affiliated with the SZABMU and is one of the country's leading medical institutions, attracting doctors from all parts of the country (Pakistan) as well as abroad, to pursue various postgraduate residency programs.

Study participants

The study population included the junior surgical doctors (i.e. house-officers and postgraduate residents) and senior surgeons (i.e. surgical specialists and surgical faculty members) working in various surgical disciplines of PIMS. The surgical specialties included general surgery, orthopedics surgery, plastic surgery, burns surgery, neurosurgery, obstetrics and gynecology, eye surgery, maxillofacial surgery, otorhinolaryngology, hepatobiliary surgery, urology, and cardiovascular surgery. The participants were selected at random from the list of the surgeons in the hospital and approached face-to-face, with the help of a team of junior doctors detailed for questionnaire distribution among them. The target was to cover over 50% of these doctors by convenience sampling. The questionnaire was completed anonymously.

Study questionnaire

A self-administered questionnaire was employed for the study. The aim was to cover all fundamental aspects of the knowledge and relevant attitudes that surround the process of SIC and hence generate a representative data that could serve as a valid outcome variable. The questionnaire was prepared by consulting previously used and validated questionnaires employed by other researchers (3,5–8).

We employed a series of questions to cover the fundamental aspects of knowledge and relevant attitudes of doctors that impact the consent process. Pretesting of the questionnaire was performed on a limited number ($n=15$) of surgeons and subsequent language modifications and amendments were done in light of their suggestions. The final refined version of the questionnaire contained the following nineteen items (summarized in Tables 1 and 2).

The questionnaire entailed the age cut off of 14 years as it is the officially accepted cut off point to distinguish children from adults in our hospital as well as elsewhere in other hospitals in our country. The law does not strictly define the age cut off as far as the SIC is concerned, hence is left to the discretion of individual healthcare institutions.

Statistical analysis

The data were analyzed through SPSS 17 (SPSS Inc., Chicago, IL, USA). The nominal variables were reported as frequency and percentages. The numerical data were reported as Mean \pm SD. The responses to the questions were recorded and descriptive statistics (i.e. frequency and percentages) were employed to calculate the various qualitative variables under study.

Results

Response rate

In the target population of 300 surgical doctors contacted, 231 doctors returned the questionnaires duly answered in all respects, constituting a response rate of 77%. The non-respondents were excluded from further analyses.

Demographic features of the included doctors

Overall there were 134 males (58%) and 97 female respondents (42%). Among them, there were 32 seniors while 199 junior doctors, constituting a ratio of 1:6.22 respectively. The junior doctors ranged in age from 22–35 years with a mean age of 26.60 ± 3.77 years whereas the senior doctors were aged 36–59 years with mean age of 44.96 ± 9.68 years. There were 113 males among the junior doctors while the remainder 86 were females. Among the senior doctors there were 21 males and 11 females.

The breakdown of the respondents with respect to their surgical disciplines includes obstetrics and gynecology ($n=46$), general surgery ($n=39$), orthopedics surgery ($n=33$), urology ($n=26$), otorhinolaryngology ($n=23$), neurosurgery ($n=18$), maxillofacial surgery ($n=15$), plastic surgery ($n=9$), eye surgery ($n=9$), hepatobiliary surgery ($n=8$), and cardiovascular surgery ($n=4$) and burns surgery ($n=1$). There were no significant differences between responses to the questions with respect to the surgical disciplines of the respondents.

Responses to the questions regarding knowledge and current hospital practices of the process of SIC are shown in Tables 1 and 2 respectively.

The participants variably responded to the questions regarding various attributes of the process of SIC. Overall, the junior doctors performed poorer compared to the seniors. Instead of the SIC being obtained by the operating surgeon himself, majority of the respondents delegated its responsibility to the staff nurse or junior doctors. Instead of directly involving the patient and obtaining the SIC from patient himself/herself, more responses were observed in favor of obtaining it from the attendants or husbands. The night before surgery was stated as the most frequently employed time for obtaining the SIC. There was neither any formal standard used to ensure the competence of the person from whom the SIC was

Table 1. Responses to the questions regarding knowledge of the key aspects of the SIC (n= 231)

	Junior doctors (n= 199)	Senior doctors (n= 32)
For which type of surgical procedure the SIC should be sought?		
All procedures	39 (19.59%)	27 (84.37%)
Elective ones	43 (21.60%)	-
Emergency cases only	117 (58.79%)	2 (6.25%)
Critical cases only	-	3 (9.37%)
Others	-	-
Patient of what age do you think is able to give a valid SIC?		
All ages	127 (63.81%)	-
Patients aged above 14	56 (28.14%)	26 (81.25%)
Depending on the individual's intelligence	3 (1.50%)	5 (15.62%)
Depending on clinical judgment of maturity	6 (3.01%)	1 (3.12%)
Others	7 (3.51%)	-
Do you inform your patient on the following?		
The diagnosis and indication of operation	163 (81.90%)	32 (100%)
The surgical procedure	93 (46.73%)	32 (100%)
Likely complications	3 (1.50%)	13 (40.62%)
Alternative treatment options	1 (0.50%)	4 (12.50%)
Others	-	-
Are the following items required in the SIC (elements of consent)		
Evaluation of competence	-	2 (6.25%)
Patient education	-	1 (0.50%)
Recording of consent	113 (56.78%)	25 (78.12%)
Patients' signature	139 (69.84%)	21 (65.62%)
Surgeons' signature	4 (2.01%)	-
Others	-	-
Are you aware of the NEIC?		
Yes	-	-
No	199 (100%)	32 (100%)
Others	-	-
Do you think the process of SIC has any impact on the well-being of you patients?		
Yes	-	-
No	199 (100%)	32 (100%)
Others	-	-
Did you ever receive any formal training on the process of SIC?		
Yes	-	-
No	199 (100%)	32 (100%)
Others	-	-

SIC= Surgical Informed Consent; NEIC= Nocebo Effect of Informed Consent

obtained, nor was any regular use of structured proforma. There was serious deficiency regarding communication of the likely complications as well as the available alternative treatment options. Also it was often not ensured if the patient understood the information. Although all the respondents endorsed that the process of SIC had impact on the well-being of their patients, none of them had ever received any formal training on the process of SIC (Tables 1 and 2).

Discussion

The present study is the first of its kind at our institute and it looked at the process of SIC in a doctors' perspective. Our study identified considerable deficiencies in the current knowledge and attitudes of our doctors toward this very

crucial area of doctor-patient communication. Surprisingly certain studies from institutions in the western countries such as the USA, Europe, Netherlands and New Zealand have also reported a lack of doctors' knowledge regarding the process of SIC (1,3,7-10). Less than ideal level of working knowledge and attitudes regarding SIC on part of our doctors indicates a case for their focused education regarding SIC. Enhancing their education in this regard will certainly address the deficiencies identified by our study (11,12).

In our study, the overall knowledge and attitudes the doctors did not conform to the established norms of SIC, with the junior doctors performing even poorer than specialists and the faculty. The junior doctors particularly the residents are usually the front line healthcare providers in developing as

Table 2. Responses to the questions regarding current practices and attitudes towards SIC (n= 231)

	Junior doctors (n= 199)	Senior doctors (n= 32)
Who obtains the SIC?		
The operating surgeon himself	3 (1.50%)	2 (6.25%)
The junior doctor on duty	53 (26.63%)	14 (43.75%)
Staff nurse on duty	143 (71.85%)	16 (50%)
Others	-	-
From whom do you obtain the SIC?		
The patient	8 (4.02%)	7 (21.87%)
The attendants	151 (75.87%)	25 (78.12%)
The husband	23 (11.55%)	-
The father	17 (8.54%)	-
Any other person	-	-
Others	-	-
Which time do you obtain the SIC?		
On the admission counter	1 (0.50%)	2 (6.25%)
In the ward	5 (2.51%)	9 (28.12%)
In the operating theatre	20 (10.05%)	-
The night before surgery	173 (86.93%)	21 (65.62%)
Others	-	-
How do you check the if the patient is competent to obtain SIC?		
Use own clinical judgment	10 (28.14%)	6 (18.75%)
Use structured questionnaire	-	-
Not using any standard	183 (91.95%)	26 (81.25%)
Others	-	-
What do you do if the next of kin is not available to obtain SIC?		
Do not proceed to surgery	-	-
Give consent on behalf of the patient	181 (90.95%)	28 (87.50%)
Inform the hospital administration	18 (9.04%)	4 (12.50%)
Others	-	-
Do you use any structured proforma for obtaining SIC?		
Yes	-	-
No	199 (100%)	32 (100%)
Others	-	-
How do you ensure that the patient understood the information?		
Repeat back	-	1 (3.12%)
Do not ensure	183 (91.95%)	31 (96.87%)
Others	-	-
Do you have an institutional standard on complication rates?		
Yes	-	-
No	199 (100%)	32 (100%)
Others	-	-
Which complication percentage do you use to inform your patient in the process of SIC?		
Rates from published literature	-	25 (78.12%)
Rates from own department	-	-
Personal rates	-	-
None of these	181 (90.95%)	-
Others	-	-
Do you use any check prior to starting the surgical procedure if the SIC is correctly completed?		
Yes	-	-
No	173 (86.93%)	29 (90.62%)
Others	-	-
Which of the following supporting tools do you use for patient's education and guidance?		
Leaflets	-	-
Websites/software	-	-
Movies	-	-
Information personnel	-	-
None of these	193 (96.98%)	32 (100%)
Others	-	-
Are you interested in using software for SIC?		
Yes	-	-
No	173 (86.93%)	27 (84.37%)
Others	-	-

SIC= Surgical Informed Consent

well as developed countries, however they are often not well versed with the process of SIC, and hence err by not giving information about the potential complications of the planned procedures or alternative treatments and mostly provide only information on the benefits of particular surgical interventions (13–15). Lack of practical experience as well as deficient training on part of the residents in the critical area of doctor-patient communication are the possible explanations for their poor performance in the process of SIC (7,9,16–20). Our findings of the study constitute a compelling evidence for educating residents in this particular area of doctor-patient communication in future.

In our study majority (84.37%) of the senior doctors admitted that SIC was necessary for all surgical procedures, however only 19.59% among the juniors felt it essential for all procedures.

In response to the question as to how do you satisfy the needs of SIC when no next of kin is available in emergency situations, majority answered that they obtained the consent on their own. Certainly the hospital administration has a role to play in such situations, and we need to devise a mechanism so that doctors do not face frustration for tasks beyond their scope and capacity as surgeons.

In our study majority of the doctors said that the SIC should be sought and documented on the night prior to the planned surgery. Majority of doctors expressed that staff nurse has to obtain the consent. It cannot be over-emphasized that a valid SIC should only be obtained by the operating surgeon who is going to operate upon the patient. Also it is equally important to understand that the SIC is a continuous process that starts as soon as the doctor meets the patient and should continue after the operation to facilitate the patient's understanding of the procedure, benefits, anticipated risks of the operation and the post operative follow up period.

In our study majority of the doctors endorsed that the SIC should be obtained from either the attendants or husbands. This unethical trend of not directly involving the patients in the process of informed decision-making should be discouraged. Also the local custom of employing husbands as surrogates but not the vice versa in the process of SIC needs rectification by encouraging women empowerment.

In our study none of the doctors neither used computers in the process of SIC nor showed any inclination/interest in using the relevant software for this purpose in future. Indeed computers and other similar supporting tools have the potential to make the process easier for the doctors and better comprehensible for the patients. Such tools can further strengthen the doctor-patient trust. An integrated interactive computer program may be developed for case specific SIC. This will enhance recapitulation of the facts on part of the patients as well as save precious time of the surgeons. The additional gains with the use of computer programs for SIC would include better structure, improved quality, diminished consultation time and stimulated patient commitment. The time and effort saved for busy surgeons can better be used for answering specific queries and concerns of the patient in brief consultation sessions with the patients (1,21,22).

In our study majority of doctors admitted that they did

not employ any structured proforma for the SIC. Since it is a crucial part of patient care, it needs to be standardized to conform to the accepted norms of the process. It will surely improve its quality, completeness, patient satisfaction, safety, and legal solidity (1,23–25). Structured SIC form has been successfully implemented in the daily practice of doctors in other countries (15).

As is evident from our study, our doctors under-estimate the information needs of their patients. Several published studies have also identified the fact that surgeons often underestimate the information needs of their surgical patients (26–28). Given the findings of our study, it will be logical to undertake further studies to explore why the younger generation of doctors are doing a worse job compared with their seniors. Is this a case of a lack of ethical training at undergraduate medical school or overt paternalism or simply a lack of practical experience? These issues whether educational or cultural will need to be addressed accordingly.

In our study none of the doctors knew the concept of Nocebo Effect of Informed Consent (NEIC). Nocebo phenomenon is the negative analogue of placebo phenomenon. In fact the SIC is an ethical responsibility of the doctors, however they should be prudent enough to strike a balance between what information is necessary and what information is going to further harm their already jeopardized patients. So while discussing negative outcomes with the patients they should wisely tailor their communication accordingly to avoid the undesirable NEIC (29–31).

We wanted to have more robust comparison of the findings of our study with similar published literature from particularly the other developing countries in our neighborhoods, however we could not find any quality publications from these countries. In glaring contrast to this situation, the majority of studies published from the developed countries are more focused on patients' perspectives of the process of SIC, with a recent growing trend towards the use of multimedia in the process and their impact on the patient's understanding of the content of SIC (32–39).

Strengths, limitations and future directions

Our study has some strengths as well as presents some limitations. It is the first institutional study which has attempted to objectively evaluate the process of SIC in the doctors' perspective and hence establish a baseline evidence-base of their knowledge and attitudes towards this crucial component of doctor-patient communication. The suboptimal level of knowledge and attitudes of particularly the junior doctors identified by the present study should motivate their formal training and capacity-building at both undergraduate level as well as during their postgraduate residency including internship period. Additionally a number of measures on both institutional and national level are needed to address the attitudinal and cultural barriers which serve as potential hindrances to the successful implementation of the desired changes.

The limitations of the study include: Firstly, the study was a qualitative one rather than being a detailed quantitative analysis of the various complex factors that impact the

knowledge and attitudes of doctors towards SIC in the context of the developing economy of Pakistan with its recognized limitations of the healthcare system. Secondly, response bias by the participants could not be completely eliminated as the questionnaire employed remained somewhat instructive on its own because of the close ended questions. Thirdly, the study was based on a single institution's data, and its findings cannot be generalized to the rest of the hospitals in Pakistan. We suggest future studies to confirm our findings and improve upon our limitations.

Conclusion

The knowledge and attitudes of our doctors particularly the junior ones, towards the SIC are less than ideal. This results in their failure to avail this golden opportunity of doctor-patient communication to guide their patients through a solidly informative and legally valid SIC. They are often unaware of the essential preconditions of the SIC; provide incomplete information to their patients; and quite often do not ensure direct involvement of their patients in the process. Additionally they lack an understanding of using interactive computer-based programs as well as the concept of nocebo effect of informed consent.

Acknowledgements

We are grateful to the following doctors for helping us in collecting data from the participants: Dr. Saad Siddiqui, Dr. Shahzad Ahmad, and Dr. Muhammad Salman Zaib.

Ethical issues

Informed consent was taken from the participants for inclusion in the study. The study was conducted in accordance with the Declaration of Helsinki of 1975, as revised in 1983 and anonymity of the participants was ensured.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KUZ and NT conceived and designed the study. MS and BA performed the literature search and wrote the first draft of the manuscript. All authors participated in the data acquisition, analysis, and interpretation. All authors critically reviewed, refined, and approved the final version of the manuscript.

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