Knowledge, practice and perception towards the informed consent process among physicians and patients in General Surgical Departments at Cairo University Hospitals

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Abstract

Although the informed consent process is considered a standard procedure for informing patients about their plan of care, benefits, risks and alternatives of treatment in developed countries; it often fails to meet its goal in many developing countries. **Goal:** to improve the quality of the informed consent process in general surgical departments at the Faculty of Medicine, Cairo University Hospitals. **Specific objectives:** evaluating the differences in knowledge, practice and perception between physicians and patients and setting recommendations to improve this process. **Subjects and methods:** A cross-sectional study was conducted on a total of 172 physicians and 216 elective adult patients who completed a voluntary multiple-choice questionnaire. **Results:** A significantly higher percent of physicians as compared to patients (73.8% vs. 27.3%, P< 0.001) reported being fully acquainted with the informed consent process. Nearly half of the physicians (49.4%) reported that they informed patients about their medical condition in details, while 38.9% of patients reported that they have been informed about their medical condition in details (P<0.001). A significantly higher percent of physicians as compared to patients reported that they explained to their patients the possible complications of their planned treatment in details (50% vs. 18.5%, P<0.001). Professors had a significantly higher (P<0.001) practice score compared to lecturers and residents regarding nearly all items about obtaining the surgical consent form. **Conclusion:** Significant differences were found between physicians and patients regarding their knowledge, practice and perception of the informed consent process which highlight the need for establishing better communication channels. Providing educational programs to patients and junior physicians is mandatory to fill the knowledge gaps and improve the quality of this process.

Key words: Informed consent-medical condition-communication channels-educational programs
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Introduction

Informed consent in clinical settings is now considered as the cornerstone of medical practice [1, 2, 3] as it could markedly affect the quality of care through improving the physician-patient communication and thereby, reducing adverse outcomes [4]. The implementation of the informed consent process differs markedly in-between countries and among different medical specialties [5, 6]. Although, it is considered as a standard procedure in developed countries for providing the patients with information about diagnostic and treatment procedures, benefits, risks and alternatives of treatment [7,8], it often fails to meet its goal in many developing countries [1].

Surgery is one of the medical specialties that involves invasive procedures and

requires complex decisions and a more precise informed consent due to higher frequencies of associated risks [6]. Despite that obtaining the patients' signature on the surgical consent form is necessary to start treatment, signing the consent form does not reflect the patients' comprehensive and proper understanding of the forthcoming treatment procedures [9]. The surgical informed consent should not be a passive and one-way process in which a medical decision is left mainly to the physician, but an interactive one which involves a competent patient, a clearly communicating physician, and transfer of focused, clear and understandable information about the planned surgical intervention [10, 11].

Although physicians have expressed a positive attitude towards patients' participation in the decision-making process in various studies, [12, 13] many patients still do not receive complete or desired information about their plan of care [14]. Patients often feel helpless and vulnerable and it is a well-known fact that their awareness of legal and ethical issues related to the consent process is often limited [15].

In Egypt, the validity of the informed consent process in medical practice is still challenged by many factors like educational level and socioeconomic status of patients together with other legal and cultural factors. To the researchers' best knowledge, few studies have been performed to address this process in medical practice [16, 17] especially in a teaching hospital where patients are poorly educated and suffer from a poor socioeconomic status. Hence, the rationale of this study was to improve the quality of the informed consent process in general surgical departments at the Faculty of Medicine, Cairo University Hospitals through evaluating the differences in knowledge, practice and perception of the informed consent process between physicians and patients and setting recommendations to improve this process.

Subjects & Methods

Study design, Period and Setting:

A cross-sectional design was used to assess the differences between physicians and patients regarding their knowledge, practice and perception towards the informed consent process. This study was conducted within a period of 4 months from January till April 2014 in all general surgical units at the Faculty of Medicine, Cairo University Hospitals.

Sampling and study population:

The study sample included a total of 172 physicians [72 junior (i.e. residents) and 100 senior (i.e. lecturers, assistant professors and professors)] performing invasive surgical procedures in the general surgical units at the Faculty of Medicine, Cairo University. All residents working in the 12 surgical units were included in the study, while, a convenient sample of senior physicians was taken from all senior staff members of the surgical units. Convenient sampling technique is easy, time-saving and readily collected with the population on hand and so it was used for senior physicians because they had a particular schedule to attend

and were not always accessible on the working days of data collection, unlike residents who were available all the time in the departments.

A total of 216 elective adult patients who were scheduled for invasive procedures in the surgical departments were included in the study (18 patients from each of the 12 departments). A convenient sample was also used for inclusion of patients who were accessible on the working days of data collection.

Study tools and data collection technique:

Pre-tested self-administered physician and patient questionnaires were designed from previously used and validated questionnaires by other researchers [18, 19]. The physician questionnaires were developed in English, while the patient questionnaires, in Arabic. Most of the questions in both the physician and patient questionnaires were similar; however, they were modified to be directed to either the physicians or the patients. The questionnaire included close–ended multiple choice questions divided into three sections as follows: the first one included demographic data and qualification of physicians (whether they were residents, lecturers, or professors), the second one covered some aspects of knowledge (eight questions) of both physicians and patients towards the informed consent process e.g.: knowledge about the informed consent process in clinical practice; legal regulations of the process in Cairo University Hospitals and if patients receive a copy of the signed consent form; who should give the consent form to the patients to be signed and where; the way of choosing the treatment method and signing the consent form; and if patient have received sufficient information to decide their treatment. The third section included nine questions regarding physicians' practices before and during obtaining the consent form and relevant perceptions of the patients towards those practices e.g. informing patients' about their rights, medical condition, possible risks and alternatives of treatment, possible sequale of treatment refusal, the average duration of hospitalization; replying the patients' questions; the average duration that physicians spent with their patients to explain all the necessary information; and the surrogate person to ask for consent if the patient was not able to decide. The physicians were asked to complete the questionnaires and return them back to the researcher after 20 minutes, whereas, patients had undergone a structured interview with the researchers who read the questions for them and then recorded the answers.

Statistical analysis:

After data collection, all completed questionnaires were revised for completeness and logical consistency. Pre-coded data was entered into the Statistical Package of Social Science (SPSS), version 21 to be statistically analyzed. Data were presented as frequencies and percentages in a tabulated format. The total knowledge score was computed (total of 8 questions) where correct responses were given a score of 1 and incorrect or

don't know scored 0. Similarly, the total practice score was computed for physicians (total of 9 questions).

Differences between categorical variables in each group were identified with the Chi-square test. Independent t-test was used for measuring differences between quantitative variables (mean knowledge score for both physicians and patients and mean practice score for physicians), while the ANOVA test was used for statistical comparisons of mean knowledge and practice scores of different groups of physicians followed by the Bonferroni method for post-hoc adjustment. All statistical tests were considered statistically significant at P< 0.05.

Ethical considerations:

Approval of the study protocol was obtained from the Ethical Committee at the Faculty of Medicine, Cairo University. Informed consent was obtained directly from each patient or his/her legal representative before enrolment and after explanation of the study objectives. All procedures for data collection were treated with confidentiality according to Helsinki declarations of biomedical ethics [20]. Once the study has been completed, all interview records, paper copies and notes containing any identifiable information were destroyed.

Results:

Out of a total of 240 questionnaires sent to physicians, 185 were returned (77.1% response rate) and 172 (71.7%) were fully completed and included in the analysis. All the physicians who returned the fully completed questionnaires were males, their median age was 43 years (range 27-60 years) and their median years of experience was 19 (range 3-35 years).

The median age of patients was 41 years (range 18-65 years). Fifty nine percent (59%) of patients were males. More than half of the patients (61%) were illiterate, while only 29% had received primary and secondary education.

Both physicians and patients were asked a few questions about knowledge and practice of the informed consent process to clinical procedures in Cairo University Hospitals (Table 1). A significantly higher percent of physicians as compared to patients (73.8% vs. 27.3%, P< 0.001) reported being fully acquainted with the informed consent process. A total of 160 physicians (93%) reported that they completely or partially inform patients about their rights, whereas only 54 patients (25%) mentioned the same (P< 0.001). A significantly higher percent of physicians correctly knew that the process of obtaining the informed consent is regulated by law in Cairo University Hospitals (46.5% vs. 33.8%, P= 0.009) and that the hospital regulations do not allow the patients to receive a copy of the signed consent form (83.7% vs. 76.9%, P< 0.001). About 89% and 75% of physicians and patients, respectively, thought that obtaining the signed consent form is the physicians' task. Nearly 10% of patients thought that the department clerk is responsible for this task, while only 1.8 % of physicians provided the same answer. These differences were statistically significant at P< 0.001.

Physicians' practices and patients' perceptions regarding their medical condition and plan of treatment were illustrated in Table 2. A significantly higher percent of physicians (49.4% vs. 38.9%, P< 0.001) reported that they explain to the patients their medical condition and plan of treatment in details, meanwhile, more patients reported that they were provided only with the necessary information about their medical condition to make a decision on consent (25.9% vs. 15.1%, P< 0.001). Much more patients than physicians mentioned that their questions were only partially answered (37% vs. 7%, P< 0.001). Half of the physicians (50%) reported that they inform their patients about the possible complications of the planned treatment in details, while 65.7% of patients mentioned being not informed at all (P<0.001). Similarly, a significantly higher percent (P< 0.001) of physicians reported explaining to their patients the alternative lines of treatment (89.5% vs. 16.7%) and the possible sequale of treatment refusal in details (50% vs. 26.9%). Most of the patients (92.6%) reported that they depend on their clinicians for choosing the treatment method compared to 84.3% of physicians who gave the same answer (P=0.007). A significantly higher percent of patients perceived that they were not informed about their length of hospital stay (81.5% vs. 18.6%, P< 0.001).

A comparison between physicians' and patients' responses regarding the procedure of obtaining the informed consent was shown in Table 3. Three quarters of physicians (75%) reported spending about five to fifteen minutes with their patients to explain the necessary information before signing the consent form, whereas 43.5% of patients reported spending only less than five minutes with their physicians (P< 0.001). A significantly higher percent of physicians mentioned that the surgical consent form should be signed in the surgical department (83.7% vs. 60.2%, P<0.001). More than half of patients (56.5%) thought that they received only the most necessary information to decide their treatment compared to 32.6% of physicians who provided the same answer (P<0.001). A significantly higher percent of patients reported signing the surgical consent form independently (54.6% vs. 25.6%, P<0.001). However, 66.3% of physicians reported that their patients signed the consent form after consulting the family, compared to 7.4% only of patients who gave the same answer (P<0.001). In case that the patients were not able to choose their treatment method, 66.2% of them would leave the decision to their treating physician, however, 93% of physicians reported that in that condition, they would ask for consent from the patients' family (P<0.001).

Physicians had a significantly (P=0.012) higher total knowledge score (mean= 4.395 ± 1.167) when compared to patients (mean= 4.148±1.433). Similarly, practice score among physicians was significantly (P<0.001) higher when compared to patients' perceptions towards that practice, with a mean of 5.657 ± 2.220 and 2.287± 1.828 for physicians and patients, respectively.

A comparison between physicians' practices regarding the informed consent process was illustrated in Table 4. A significant discrepancy was noticed between all groups of physicians. Professors had a significantly higher (P<0.001) practice score when compared to lecturers and residents regarding nearly all items related to obtaining the surgical consent form.

Table 5 shows the total knowledge and practice scores for different groups of physicians according to their professional experience. No significant difference was observed between professors, lecturers and residents regarding their knowledge of the informed consent process. However, professors had the highest practice score (mean= 7.132 ± 1.984) that was significantly different from both scores of lecturers (mean= 5.437 ± 1.933) and residents (lowest mean score= 4.361 ± 1.647) that also differed between each other (P< 0.001).

Discussion:

Obtaining the informed consent from patients before surgery represents the practical application of an interactive physician-patient relationship and respect for patients' autonomy [21, 22]. It is to be mentioned that the informed consent process is not just a form to be signed, but a process which entails respect for patients through provision of a thoughtful consent to facilitate their voluntary decision regarding the planned treatment procedures [23].The current study found significant differences between physicians and patients in general surgical departments at Cairo University Hospitals regarding their knowledge, practice and perception towards the informed consent process. The total physicians' knowledge score was significantly higher than that of the patients' (P=0.012). This could be attributed to lack of knowledge sharing between physicians and patients due to work overload and lack of physicians' awareness about their obligation to provide their patients with information about the informed consent. Moreover, poor educational level of patients may limit their ability to understand the information given by their physicians. Accordingly, consent forms for different procedures need to be developed to ensure the patients' proper understanding and to promote the interaction between physicians and patients.

In the current study, more physicians than patients correctly knew that the informed consent process was regulated by law in Cairo University Hospitals (P=0.009) and that the patients are not allowed to receive a copy of the signed consent form (P<0.001). In contrast, Jukic et al. found that a significantly higher percent of physicians (P<0.001) incorrectly knew that patients receive a copy of the signed informed consent [18]. A signed consent form should be obtained by the patient's physician after discussing all the required information [24] and other practices should be avoided as they will be contradictory to the code of medical ethics [25]. In this study, a significantly higher percent of physicians (P<0.001) thought that they should be responsible for obtaining the

signed informed consent from their patients. However, in another study conducted in South Croatia to evaluate the differences in knowledge and attitudes of physicians and patients regarding the informed consent process, the majority of the of physicians were prone to delegate such process to other members of medical stuff like their colleagues, nurses or administrative personnel [18].

The informed consent process must ensure that the patients receive the required information about their medical condition, the benefits and risks of the intended treatment and its alternatives [26, 27, 28, 29]. It's worth mentioning that patients' understanding of the information provided in the consent form is a prerequisite for obtaining a valid informed consent, otherwise it will be only symbolic [30]. However, in developing countries like Egypt, where literacy levels are low; knowledge and perception asymmetry usually exists between physicians and patients [31].

In the current study, a significant disagreement was noticed between the study groups regarding the amount of information given or received about the patients' medical condition as well as the possible risks and alternatives of the forthcoming treatment procedures ($P<0.001$). More physicians reported giving this information to their patients in details, whereas, more patients reported being provided only with the necessary information or not provided at all. This discrepancy could be attributed to limited understanding by the patients; physicians' overestimation of delivering the information to their patients; as well as lack of a clear and understandable way for delivering the information. Therefore, a plain and clear language should be used by physicians according to the cognitive abilities and education of patients [14]. Similarly, in other studies, patients reported receiving only limited information about their medical condition and the planned therapeutic procedures [5, 18]. Moreover, in a study conducted by Jamjoon et al. (2010), patients expected to receive more detailed information about the risks, complications and alternatives of treatment [32]. In contrast, Corfield (2006) found that patients often do not prefer to be fully informed of the possible risks and complications of the forthcoming surgical procedure [33]. Beresford and colleagues suggest that providing information to some patients about risks and complications causes unnecessary anxiety and that the standard of disclosure of information to reasonable patients should not be applied to them [34]. In the current study, about half of the physicians reported explaining to their patients the possible sequale of treatment refusal in details. Similar findings were reported by Jukic et al. (2011) [18]. A significantly higher percent of physicians in the present study mentioned that they inform their patients about the duration of their hospital stay. However, Jukic et al. (2011) found an agreement between physicians and patients about this issue [16].

In the present study, a significant discrepancy was observed between the responses of physicians and patients to

all questions comparing the physicians practices' for obtaining the consent form and the patients' perceptions towards those practices (P<0.001). Three quarters of physicians (75%) in this study reported spending about 5 to 15 minutes with their patients talking about the surgical procedure and consent form compared to 18.5% of patients who provided the same answer (P<0.001). Similarly, in another study, most of the physicians reported spending about 10 minutes talking to their patients [19].

Although more than half of the patients (56.5%) mentioned that they did not receive sufficient information to decide their own treatment, 66.2% of them were still willing to trust their physicians and leave the final medical decision for them. Similar findings were reported by Levinson and colleagues (2005) who found that nearly all patients (96%) preferred to be offered choices about their treatment and their opinions to be considered, while half of them (52%) preferred to leave the final decisions to their patients [35]. Moreover, 44% of patients did not want to participate in the decision making process [35]. Nowadays, a significant amount of health information is available to the general public due to the widespread internet access [36]. However, the inability of patients to understand this information due to poor education and decision conflicts have made them more likely than ever to depend on their doctors for decision making[37].

The current study revealed that a higher professional experience was associated with a better practice of obtaining the surgical consent form where professors had a significantly higher practice score than lecturers and residents (P< 0.001). The junior doctors particularly residents are usually the front line health care providers in developing as well as developed countries, however, they are not well educated or trained about the process of surgical informed consent [8]. Therefore, they are more prone to be mistaken by not providing information about the possible complications or alternatives of treatment and mostly providing information only on the benefits of certain surgical procedures [38, 39, 40]. Poor performance of residents in the process of surgical informed consent may be attributed to lack of practical experience and deficient training in the area of doctor-patient communication [41, 42, 43].

Conclusion:

The current study found significant differences between physicians and patients in general surgical departments at Cairo University Hospitals regarding knowledge, practice and perception of the informed consent process. Many physicians reported giving detailed information to their patients about their medical condition and the planned treatment procedures, while most patients reported receiving only limited or insufficient information. These findings reflect that the process of obtaining the surgical consent in Cairo University Hospitals is just a formal procedure, rather than a real interaction between physicians and patients. Higher professional experience was significantly associated with better

practice of obtaining the informed consent.

Recommendations:

There is a need for upgrading the informed consent process in general surgical departments by establishing better communication channels between physicians and patients. Moreover, providing educational programs to patients and junior physicians is mandatory to fill the knowledge gaps and thus improving the quality of this process at Cairo University Hospitals.

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Table (1): Knowledge and practice of the study group regarding the informed consent process to clinical procedures

Variable	Physicians		Patients		*P*-value*
	No. (n=172)	**Percent** (100%)	**No.** (n=216)	**Percent** (100%)	
Do you have enough knowledge about the informed consent process?					
- Yes	127	73.8	59	27.3	
- Partially	45	26.2	64	29.6	<0.001
- No	0	0	93	43.1	
Do you inform patients about their rights? / Were you informed about your rights?					
- Yes	100	58.1	28	13.0	
- Partly	60	34.9	26	12.0	<0.001
- No	12	7.0	162	75.0	
Are there any legal regulations concerning the informed consent process in Cairo University Hospitals?					
- Yes	80	46.5	73	33.8	
- No	48	27.9	58	26.9	0.009
- I don't know	44	25.6	85	39.3	
Do the hospital regulations permit giving the patients a copy of the signed consent form?					
- Yes	20	11.6	12	5.5	
- No	144	83.7	166	76.9	<0.001
- I don't know	8	4.7	38	17.6	
Who should give the informed consent form to the patients to be signed?					
- Doctor	153	88.9	162	75.0	
- Nurse	16	9.3	32	14.8	<0.001
- Department clerk	3	1.8	22	10.2	

***** Chi-square test

Table (2): Practice and perceptions of the study group regarding the patients' medical condition and plan of treatment

Variable	Physicians		Patients		*P*-value*
	No. (n=172)	Percent (100%)	No. (n=216)	Percent (100%)	
Do you explain to patients their medical condition and plan of treatment?/Was your medical condition explained to you?					
- In details	85	49.4	84	38.9	
- Briefly	61	35.5	46	21.3	
- Partially (as much as needed to make a decision on consent)	26	15.1	56	25.9	<0.001
- No	0	0	30	13.9	
Do you reply the patients' enquiries? / Were your enquiries replied by the doctor?					
- In details	84	48.8	92	42.6	
- Briefly	76	44.2	44	20.4	<0.001
- Partially	12	7.0	80	37.0	
Do you explain to patients the possible risks and complications of their planned treatment? / Were the possible risks of treatment explained to you?	86	50.0	40	18.5	
- In details	58	33.7	24	11.1	
- Briefly	28	16.3	10	4.6	<0.001
- Partially (only on most common risks and complications)	0	0	142	65.7	
- No					
On what basis do the patients/you usually choose their/your treatment method?					
- Based on clinicians' suggestions	145	84.3	200	92.6	
- Based on relatives' suggestions	25	14.5	8	3.7	0.007
- I don't know	2	1.2	8	3.7	
Do you explain to patients the alternative lines of treatment? Were the alternative lines of treatment explained to you?					
- Yes	154	89.5	36	16.7	<0.001
- No	18	10.5	180	83.3	
Do you explain to patients the possible sequale of treatment refusal?/were the sequale of treatment refusal explained to you?					
- In details	86	50.0	58	26.9	
- Briefly	80	46.5	26	12.0	<0.001
- No	6	3.5	132	61.1	
Do you tell your patients the average duration of their hospital stay? Were you informed about the average duration of your hospital stay?					
- Yes	140	77.8	40	18.5	<0.001
- No	32	18.6	176	81.5	

***** Chi-square test

Table (3): Physicians' and patients' experiences regarding the process of obtaining the surgical consent form

Variable	Physicians		Patients		*P*-value*
	No. (n=172)	Percent (100%)	No. (n=216)	Percent (100%)	
What is the average duration do/did you spend with the patients/doctor to explain/understand all the necessary information before signing the surgical consent form?					
- < 5 minutes	21	12.2	94	43.5	
- 5 - < 15 minutes	129	75.0	40	18.5	<0.001
- 15- 30 minutes	22	12.8	82	38.0	
Where should the surgical consent form be signed?	144	83.7	130	60.2	
- In the surgical department	6	3.5	11	5.1	<0.001
- In the operating room	22	12.8	75	34.7	
- I don't know					
Have your patients/you received all the necessary information to decide their/your treatment?	102	59.3	42	19.4	
- Yes	56	32.6	122	56.5	<0.001
- Only the most necessary	14	8.1	52	24.1	
- No					
How did your patients sign the surgical consent form? How did you sign the surgical consent form?					
- Independently	44	25.6	118	54.6	
- After consulting the family	114	66.3	16	7.4	<0.001
- After being convinced by me/ the treating surgeon to sign	14	8.1	82	38.0	
Who would you ask for consent if your patient/you were not able to choose the treatment method?	160	93.0	53	24.5	
- Patients' family/my family	0	0	20	9.3	<0.001
- The assigned nurse	12	7.0	143	66.2	
- My colleagues/ treating surgeon					

***** Chi-square test

Table (4): A comparison between physicians' practices towards the informed consent process

Variable	Professors		Lecturers		Residents		*P*-value
	No. (n=68)	Percent (100%)	No. (n=32)	Percent (100%)	No. (n=72)	Percent (100%)	
Informing patients about their rights:							
- In details	52	76.5	24	75	24	33.3	
- Partially	12	17.6	8	25	40	55.6	<0.001
- No	4	5.9	0	0	8	11.1	
Explaining to your patients their medical condition:							
- In details	53	78.0	6	18.8	26	36.1	
- Briefly	3	4.4	18	56.2	40	55.6	<0.001
- Partially	12	17.6	8	25	6	8.3	
Replying to your patients' questions:							
- In details	57	83.8	14	43.7	13	18.1	
- Briefly	8	11.8	14	43.7	54	75.0	<0.001
- Partially	3	4.4	4	12.6	5	6.9	
Explaining to your patients the possible risks of their planned treatment:							
- In details	46	67.7	10	31.2	30	41.7	
- Briefly	20	29.4	18	56.2	20	27.8	<0.001
- Partially	2	2.9	4	12.6	22	30.5	
Explaining to your patients the alternative lines of treatment:							
- Yes	66	97.1	29	90.6	59	81.9	<0.001
- No	2	2.9	3	9.4	13	18.1	
Explaining to your patients the possible sequale of treatment refusal:							
- In details	47	69.1	6	18.7	33	45.8	
- Briefly	20	29.4	24	75.0	36	50	<0.001
- No	1	1.5	2	6.3	3	4.2	
Informing your patients about their length of hospital stay:							
- Yes	63	92.6	24	75	53	73.6	<0.001
- No	5	7.4	8	25	19	26.4	

***** Chi-square test

Table (5): Total knowledge and practice scores of physicians

Variables	Professors (mean ± SD)	Lecturers (mean ± SD)	Residents (mean ± SD)	*P*-value*	*Post-hoc analysis*
- Knowledge score	4.529 ± 1.152	4.468 ± 1.367	4.236 ± 1.081	0.309	N.S.
- Practice score	7.132 ± 1.984	5.437 ± 1.933	4.361 ± 1.647	<0.001	A-B A-C B-C

*Annova test
N.S.: not significant

A-B: Significant mean difference between professors and lecturers scores
A-C: Significant mean difference between professors and residents scores
B-C: Significant mean difference between lecturers and residents scores