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International Journal for Quality in Health Care, 2015, 27(1), 46–51
doi: 10.1093/intqhc/mzu093
Advance Access Publication Date: 10 December 2014
Article

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Article

Quality and extent of informed consent for invasive procedures: a pilot study at the institutional level in Turkey

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Accepted 31 October 2014

Abstract

Objective: To assess the quality of informed consent for patients undergoing invasive procedures and to reveal patient preferences for being informed about the potential risks of treatment and alternatives to treatment.

Design: This study was planned as a pilot study. Hospitalized patients' perceptions and expectations about the informed-consent process were explored in a general surgery department. The prepared questionnaire was completed by patients via interview.

Setting: Inpatient services of the general surgery department of a large academic hospital in Istanbul, Turkey.

Participants: The study population consisted of hospitalized patients in a general surgery department who underwent invasive procedures in March 2013.

Main outcome measures: Recognition of consent forms by the patients, rate of patients' recall of risks, rate of patients who were willing to be involved in decision making, and rate of patients who were satisfied with the whole decision-making process were measured.

Results: All patients signed consent forms. Most patients did not properly read the consent form since they trusted their physician. Potential exposure to risk seemed to be important for patient expectations.

Conclusions: Paternalism seemed to dominate our clinical setting. The informed-consent process was definitely a separate issue from signing the consent forms. We conclude that the informed-consent process should be modified to be more functional and appropriate to human psychology. We suggest that education is necessary for informed consent to promote better quality and safety in health care.

Key words: informed consent, general surgery, quality of health care, Turkey, ethics

Introduction

'Every human being of adult years in sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without consent is liable in damages.' This famous statement by Justice Cardozo regarding the Schloendorff case in 1914 had the strongest impact on the doctrine of informed consent (IC) [1, 2]. However, IC is an older idea that dates back to ancient Greece. In his book *Epidemics I*, Hippocrates wrote that the patient had to be informed and give consent in order to cooperate with the physician to combat the disease [3].

IC currently refers to independent decision-making that depends on information that the patient receives about any medical intervention to which he/she will be exposed [4–7]. Complete disclosure requires information about the diagnosis, the current disease stage, the purpose of the proposed treatment, the risks and benefits of the treatment, alternative treatments and the course of the disease without treatment [7–10].

IC derives from both legal and ethical doctrines. The Turkish legal system encompasses an integrated body of legislation on IC. In Turkey, the Patients' Rights Regulation, issued in 1998 (and revised in 2014) by the Ministry of Health, requires that patients are informed and provide their consent for medical treatments. Seventeen of a total 50 articles in the Patients' Rights Regulation address topics related to informing patients and obtaining their consent. In the surgery departments of health-care institutions in Turkey, it is mandatory that patients sign informed consent forms. The European Biomedical Convention, Turkish Constitution and Turkish Criminal Law also require consent by the individual for any medical intervention.

IC is crucially important, especially for invasive surgical interventions, which carry potential risks at various levels, uncertainties and complications [3]. Although IC is a meaningful term in principle, it is debatable whether IC achieves its goals in practice [11, 12]. Clinical application of IC is culture dependent; field studies in different cultures are important for identifying relevant cultural parameters and for formulating the best form of implementation for better-quality health care worldwide [3, 4]. To our knowledge, no studies have questioned the quality and extent of the IC process in hospitalized surgery patients in Turkey. Our goal was therefore to identify how consent forms and the IC process are experienced by surgery patients, and to evaluate the quality and extent of IC.

Methods

Survey procedure

This pilot study was planned with a biostatistician. Patients answered a questionnaire via interview 24–48 h before surgery; this time interval was defined based on our observations in our setting in February 2013. The questionnaire was completed via interview in order to clarify any points that patients did not understand, with interviews lasting 10–20 min. Additional unique or complementary patient comments were recorded as notes in the interview booklet. Some issues were discussed with hospital staff after the interviews were completed.

The questionnaire validated by Dr Brezis [10] was modified (Table 1). The first part of the questionnaire addressed patient demographics, level of education and diagnosis. Questions 1, 7–13, 15, 16 and 18 in our questionnaire (Table 1) are the same as in the original questionnaire [10], but with different numbers. Questions 2–6 were added to our questionnaire because the written consent forms in our clinic differ from the explanatory process of IC (applied at different times and by different staff). Questions 6, 7, 9, 12 and 14 in the original questionnaire were either omitted or modified. Question 7 was not recognized by our participants and was therefore omitted (To what degree did you feel involved in the decision on the present treatment?). The 12th question was not relevant to our patient groups and was therefore omitted (Are you on a private medical service?).

Question 6 in the original questionnaire (To what degree did you want to be involved in the decision about your treatment?) was modified in February 2013 after preliminary observations in our setting to: 'Who do you think should make the final decision about your treatment?' Question 14 (Were you asked to repeat the explanation?) was modified (Were you asked whether you understood the explanation?) because it was never applied in our setting as originally written. Question 9 (How long before the treatment did you get the explanations?) was removed in order to eliminate the risk of confusing the patients because signing written forms and obtaining an explanation were two different processes realized at different times and conducted by different staff members.

This study was approved by the Internal Review Board of Istanbul University, Cerrahpaşa Medical School, Istanbul, Turkey, on 5 February 2013, no: A-11.

Setting

We surveyed hospitalized patients in the Department of General Surgery in a large academic hospital in Istanbul; the hospital's patient profile is a good representative of diverse social layers of the population. It is located in the most populous city of Turkey (Istanbul), and patients from various regions of the country are admitted for treatment [13].

Study participants

The study population consisted of 179 hospitalized patients in a general surgery department who underwent invasive procedures in March 2013. After the inclusion criteria (willingness to participate, appropriate time for interview and competency) were met, the patients provided IC to participate in the study and they were enrolled. Only the participants were allowed to answer the questions; comments from family members were not taken into consideration.

Data analysis

Data were evaluated with descriptive statistics. Normality was assessed with the Shapiro–Wilk test. Since the data were not normally distributed, the Mann–Whitney *U*-test was used to evaluate sex and age. Other data were assessed with the χ^2 test (some questions were not answered by all the patients and data assessment was made on the presence rate of answers), and statistical significance was accepted at $P < 0.05$; when $P < 0.05$, significance was re-evaluated by calculating the contingency coefficient (CC), if necessary.

Results

All participants for whom demographic and education data were obtained (Table 2) completed the questionnaire via interview (Table 1). All participants provided IC for their surgery and recalled signing the consent form. Most participants (98%) did not receive a copy of the form. Fifty-one percent of participants did not remember who brought the form to them to sign, but implied that he/she was definitely not their physician or nurse.

Sixty-three percent of participants were accompanied by family members when they signed the form; 68% of participants did not consult with others before signing it. Seventy-seven percent of participants

Table 1 Modified questionnaire administered to study participants

PART I

Name:
Age:
Gender: female/male
Resident in: Istanbul/outside Istanbul
Marital status: married/unmarried/divorced or widowed
Education level: illiterate, literate or elementary school/high school, prelicense, license, bachelor's degree or PhD
Diagnosis/treatment:

PART II

1. Have you signed an informed consent form? Yes/no
2. Who brought the form to you and asked you to sign it? Clinic doctor/clinic nurse/other hospital staff/I do not remember
3. Did you receive a copy of the consent form? Yes/no
4. Did you read the consent form before signing it? Yes/no/partially
5. Why did you not read the consent form?
    1. I did not have the chance to read it.
    2. I did not think that it was necessary, as I trust my doctor.
    3. The form was too long for me to read.
    4. I was not told to read it.
    5. I am indecisive.
    6. I am familiar with its content.
    7. It was unnecessary. I am going to have the operation.
    8. I read the form.
6. Were you accompanied by your spouse/relative/friend when you signed the consent form? Yes/no
7. Did you have enough time to think, seek advice and consult others before signing the form? Yes/no/I did not think it was necessary
8. To what degree was the information you received about your procedure sufficient, clear and detailed?
    1. It was sufficient, clear and detailed.
    2. It was only partially sufficient, clear and detailed.
    3. It was not sufficient, clear and detailed.
    4. I received no explanation.
    5. I am not sure.
9. Did you receive an explanation of the treatment risks? Yes/no/I do not remember/there were no explanations
10. Would you have wanted more explanation of these risks? Yes/no/I am not sure
11. Did you receive an explanation about alternative options for this treatment? For example were you told that the procedure was not necessary and that there were other forms of therapy available? Yes/no/I do not remember
12. From whom did you receive most of the explanations? Clinic doctor/clinic nurse/other hospital staff/I did not receive any explanations
13. To what degree did you feel comfortable asking questions? A lot/a little/not at all
14. Who do you think should make the final decision about the treatment? Clinic doctor/patient/clinic doctor and patient together
15. Would you have wanted to be more involved in the treatment decision? Yes/no/I do not know
16. To what degree are you satisfied with the process of deciding on the treatment (not the treatment itself)? Very satisfied/satisfied/somewhat satisfied/not so satisfied/not satisfied at all/no opinion
17. Were you asked whether you understood the explanation? Yes/no/I do not remember/I did not receive any explanation
18. Could you repeat the explanation now? Yes/no/somewhat I did not receive any explanation

Table 2 Participant demographics

Demographics	Mean ± SD	Range					
Age in years	50 ± 13	18–83					
Sex, residence, marital status	Male, *N* (%)	Female, *N* (%)	Istanbul, *N* (%)	Outside of Istanbul, *N* (%)	Married, *N* (%)	Single, *N* (%)	Widowed or divorced, *N* (%)
	80 (45)	99 (55)	143 (80)	36 (20)	135 (75)	31 (17)	13 (7)
Education	Illiterate, *N* (%)	Literate only, *N* (%)	Elementary school, *N* (%)	College, *N* (%)	Higher education, *N* (%)		
	13 (7)	9 (5)	91 (52)	28 (16)	35 (20)		

did not read the form before signing, and only 10% recalled reading it completely. Of the 138 participants who did not read the form, 55% stated that the reason for this behaviour was their trust in their physician ($P < 0.001$, CC = 0.7459). This trust was described as, 'He would know what to do in the surgery anyway.' Eleven percent of participants stated that they were not told to read the consent form in detail.

As a seperate issue from the consent form, verbal explanations about the procedure by the physician were described as 'clear and detailed enough' by 72% of participants, but 15% did not recall receiving any explanations.

Of the 120 patients who did not recall receiving information about risks, 78% stated that they did not remember receiving information about treatment alternatives ($P < 0.001$, CC = 0.555).

Sixty-nine percent of participants did not recall receiving any information about treatment risks, and 53% of participants desired more information about risk. Interestingly, of the 91 patients who said that they wished for more information about risk, 81% (74 patients out of 91) stated that they did not receive any information about risk ($P < 0.001$). Furthermore, 62% of the 120 patients who did not recall receiving any information about risk stated that they desired more information about risk. We were interested to note that 67% of the 52 patients who recalled receiving information about risk reported that they did not want any more information about risk ($P < 0.001$, Table 3).

Overall satisfaction with the decision-making process was rated as 'very satisfied' by 27% of patients, 'satisfied' by 48%, 'somewhat satisfied' by 19% and 'not satisfied at all' by 6%. Satisfaction level was related to some degree with recall risk information. Forty-two percent of 52 patients who recalled receiving information about risks were 'very satisfied', while only 22% of 120 patients who did not recall receiving risk information were 'very satisfied' about the decision-making process ($P < 0.001$).

Eighty-six percent of participants reported that they felt very comfortable when asking questions of their physician. Sixty-six percent of patients favoured sharing the treatment decision with their physician, while 30% wished the physician to make the decision for them; only 3% preferred to make an autonomous decision. The vast majority of patients (79%) received most explanations from their physician, and 82% of the 138 patients who obtained explanations from their physician reported that they did not want to be more involved in the decision-making process ($P < 0.001$). Forty-four percent of participants did not remember being asked whether they understood the explanations; 58% recalled being asked to repeat the explanation, which they did successfully, while 14% repeated it only partially.

The majority of the procedures in the surveyed general surgery department were elective procedures with varying levels of potential risk. We divided patients into three categories (high risk, medium risk, low risk) based on their diagnosis (Table 4). Approximately 75% of high-risk and low-risk patients reported that most explanations were provided by the physician and that they did not want to be more involved in the decision-making process.

On the other hand, of the 41 patients who recalled receiving risk information, 80% were high risk and only 20% were low risk. Of the 69 patients, who wished for more information about risk, 68% were high risk and only 32% were low risk. Of the 32 patients who were 'very satisfied', 78% were high risk and the other 22% were low risk. Of the 64 patients who were 'satisfied' 72% were high risk and 28% were low risk (Table 5). No consistent or statistically significant relationship was found between the replies of patients and education level and demographics.

Discussion

Here, we tested the hypotheses that the IC process manifests mostly as a legal consent form, in our institution at least, and that paternalism still dominates the clinical setting.

Our study was conducted in a single surgery department, in contrast with other studies [10, 12]. Our strategy enabled a clear comparison between the obligatory signing of consent forms and an explanatory IC process that is more flexible according to physician's preference and patients'needs. Risk information was compared within similar groups of patients undergoing elective surgeries but exposed to various potential risks. The large academic hospital that served as the study site provides health care to patients from various geographic regions and social layers of Turkey [13]. Based on our preliminary observations, we determined that it was most appropriate to administer the survey 24–48 h before surgery; the most appropriate interval may differ between settings [10, 12]. Here, this period was neither before the IC process was complete, nor was it so close to the surgery that the patients could not change their decisions based on the information provided to them during IC. This strategy enabled us to establish a common ground for comparing the information recalled by the patient.

Our results are consistent with previous findings [10] that signed forms document but cannot replace an ongoing IC process; the vast majority of our patients signed the forms, but 69 and 78% of them did not recall risk information or information about treatment alternatives, respectively. Most patients (86%) stated that they felt comfortable when questioning their physician, but they did not discuss risks and alternatives, which could be interpreted as reflecting physician paternalism as well as patient trust in the physician. When physician paternalism is dominant and patients are not aware of their rights, cultural barriers should not diminish the quality of IC [12].

Results referring to explanations as 'clear and detailed' are consistent with previous reports [10, 11] that information provided to the patient

Table 3 Distribution of patients who did not recall information on risk versus patients who wished for more information on risk ($P < 0.001$)

Do you recall receiving risk information?	Would you have desired more risk information?		Total, *N*
	Yes, *N* (%)	No, *N* (%)	
Yes	17 (33)	35 (67)	52
No	74 (62)	46 (38)	120
Total	91 (53)	81 (47)	172

Table 4 Diseases categorized roughly according to risk assessment

Risk	Diseases	*N*	%
High risk	Pancreatic carcinoma, colon carcinoma, hepatocellular carcinoma, total radical mastectomy (cancer), adrenal mass, morbid obesity, neck masses, oesophageal carcinoma, whipple etc.	96	53.6
Medium risk	Toxic multi-nodular goitre, papillary carcinoma of the thyroid, gall stones, closure of ileostomy, polyposis coli etc.	40	22.3
Low risk	Excision of small lesions with local anaesthesia, lipoma, simple inguinal hernia, abscess drainage etc.	37	20.7
Total		173	96.6
Missing			
System		6	3.4
Total		179	100.0

Table 5 Recall of risk explanation, wish for more risk information and satisfaction with the decision-making process (high-risk versus low-risk patients)

High-risk and low-risk patients	High risk, *N* (%)	Low risk, *N* (%)	*P*-value*
Patients recalled receiving risk information	32 (80)	9 (20)	<0.001
Patients desired more risk information	44 (68)	25 (32)	<0.001
Patients were 'very satisfied'	25 (78)	7 (22)	<0.001
Patients were 'satisfied'	46 (72)	18 (28)	<0.001

*P-value: high-risk patients versus low-risk patients.

Figure 1 A scene of role-playing the IC process as a physician, nurse, patient, and patient companion. Preclinic introductory education of lectures of 'medical practice and skills' was implemented in 2007 in our medical school. Coordinator of 'Informed Consent' lecture which was one of them, was Prof. Dogan who first implemented those lectures in early years of medical education, to start to teach the skills and knowledge and continue through the vertical line of medical education (1st–6th classes and in post-gratuate education), required for a better implementation of informed consent for a better quality and safety in health care.

(such as duration of hospital stay, pain after surgery, expected time to recover etc.) overshadowed deficiencies in information about potential risks (immediate death, permanent loss of a body function etc.), expected benefits and relevant alternative treatments [3–5, 10, 11]. It may be difficult for patients to recognize these deficiencies.

Our discussion with hospital staff revealed that they mostly recognize IC as legal forms for risk avoidance. Physicians usually preferred to talk about serious risks with patient family members rather than with the patients themselves. 'Therapeutic privilege' was presented as a reason for witholding information in the belief that disclosure would lead to patient harm or suffering [2, 8, 14–16]. Nonetheless, our study was limited by our inability to measure the extent to which the physician tried to provide adequate information and offered choices.

In our setting, 79% of participants received most explanations from the physician, and 82% did not want to be more involved in the decision-making process ($P < 0.001$, CC = 0.71). On the other hand, 68% of participants stated that the treatment decision should jointly belong to the patient and physician; 30% reported that the decision should belong only to the physician and only 3% required an autonomous decision. These observations indicate that patients favoured shared decisions, although paternalism dominated the setting. Recent studies emphasized that IC may enable shared and well-considered decisions, lowering patient anxiety [17] and increasing the acceptance of surgery benefits and limitations by both patients and physicians [18]. Other studies emphasized that IC is incomplete [19], that information should be adjusted to education level [20] and that procedures definitely need to be explained to patients to be ethically permissible [21]. When we stratified patients by risk (Table 4), 75% of patients in each group stated that they did not want to be more involved in the decision-making process.

In the present investigation, 44% of participants had not been asked whether they understood the information provided to them. Fifty-eight percent of patients were able to repeat the explanations when asked, and patients who were asked whether they understood the information were more successful at recalling it ($P < 0.001$, CC = 0.828). Encouraging patients to restate information in their own words may play a key role in patients taking an active role in the process.

After our survey, nearly 60% of the patients requested their files and re-read the consent forms. We suspect that these patients wished to understand the content of the form, but we were unable to ask the patients their opinions after the procedures.

Previously, no consistent association was detected among patients' recall of risk explanation, wish for more risk information and preferred mode of decision; this previous investigation was performed in various clinical settings but with a limited population [10, 12] (no detailed literature was found on communication of risks and alternatives). The present study revealed that patients who could not recall information of risks and alternatives were interested in obtaining this information, or vice versa ($P < 0.001$, Table 3).

However, recalling risk information and the desire for more risk information were significantly higher in high-risk patients than in low-risk patients (Table 5).

High-risk patients who recalled receiving risk information and stated that they did not want more risk information were 'very satisfied' with the decision-making process. Therefore, should risk perception be considered a driving force for the IC process even when physician paternalism dominates the setting? Does the importance of IC extend beyond legal protection?

Physician paternalism may sometimes contradict patient preferences as revealed in our investigation. Physicians'defense mechanisms or belief that patients may suffer from risk information should be separated from the patients' struggle to cope with risk. To our knowledge, no specific results have been reported for settings dominated by physician paternalism [10, 17, 22, 23]. Patients may be saddened by their disease, but this does not necessarily diminish their struggle when information is appropriately shared. However, how to communicate with patients is a separate issue from determining what information to provide.

The validated questionnaire [10] used in the current study has been used in different cultures [10, 12] such as Israel (2008) and Saudi Arabia (2012). Our results were similar and the new findings regarding informing patients about the risk relevant to their health are likely to improve the IC process and quality in health care [10–12, 17–20, 24]. In addition, the replication of studies under new conditions increases the external generalizability of the findings and the validity of the underlying theory [25] in checking and applying quality improvement efforts across countries and cultures. The predictive validity of questionnaires and similar studies of patient safety and health-care quality outcomes could be established in future prospective studies. If the results concerning IC are confirmed in different cultural contexts, high reliability organizations in health care might develop strategies for improvement of quality.

More consideration is required to make the IC process functional for problem-solving and decision-making. Information becomes crucially important when it could affect patient decisions. Our medical school has taught introductory knowledge of IC in preclinic classes since 2007, and health-quality commissions have been operating since then. Lectures for staff and faculty also take place in postgraduate education and 'educators' education' (Fig. 1). Feedback has been very positive and is still being assessed. The Patient Rights Regulation as revised in May 2014 requires new 'Patients' Rights Commissions' and 'Patient Communication Units' in health-care institutions.

From our preliminary findings, IC may constitute an essential need of human psychology that could be focused on each patient and setting. Education and supportive material such as written brochures and videos may be important for the IC process, but assessment and management by the administration is crucial. Clinical ethics committees could also be very supportive of institutional education programmes and instrumental in deciding policy about IC. A detailed institutional policy on 'how to inform', especially for high-risk patients, may serve as a starting point for increasing quality and safety in health care.

Acknowledgements

We thank Ahmet V. Dogan, M.Sc. (social scientist), for reviewing the paper.

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