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Physicians overestimate patient's knowledge of the process of informed consent: a cross-sectional study

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ABSTRACT

Aim To evaluate the differences in the knowledge and attitudes of physicians and patients regarding the informed consent process.

Methods After institutional approval was obtained cohorts of 269 physicians and 265 patients completed a voluntary multiple-choice questionnaire on the informed consent process.

Results Most of the responses between physicians and patients were significantly different. A total of 77 physicians (30.7%) reported that they personally informed patients about their medical condition and forthcoming clinical procedures in detail and 138 (55%) informed patients as much as necessary. Only 29 patients (11%) reported being informed in detail, and 186 (70.2%) reported that they received only basic information ($P<0.001$). Although 132 physicians (52.6%) reported that their patients received sufficient information to be able to decide on their treatment, only 31 patient (11.7%) reported the same ($P<0.001$). Half of the doctors (126, 50.2%) reported that they informed their patients in detail on the possible consequences of treatment refusal whereas 23 patients (8.7%) were given such information.

Conclusion There is a great discrepancy between physicians and patients concerning both understanding and knowledge of the informed consent process. The physicians have evaluated their practice of giving information and obtaining informed consent to be more detailed than their patients. The results of this study reflect the need for better communication between doctors and patients as well as physician and patient education programs on the process of informed consent.

Key words: patient rights, informed consent; preanesthetic visit; invasive procedures; health education, consumer health education.

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INTRODUCTION

The informed consent process involves communication between a physician and a patient. It should not be a passive and unilateral procedure in which a medical decision is left to the discretion of the physician, but an interactive process whereby patient's preferences regarding medical decisions are considered (1-5). Without official patient consent and essential communication with their physician, the principles of informed consent and patients' rights would not be honoured with regard to diagnostic and treatment procedures, potential risks and complications and possible treatment alternatives concerning medical procedures (2). The completion of a consent form is only one part of the informed consent process, which also consists of discussions between patients and physicians regarding any proposed medical procedures (3,4). A patient's signature on an informed consent form is necessary to initiate the treatment procedures, however, signing the consent form does not confirm a patient's complete and correct understanding of the issues surrounding a medical procedure (1).

Over the past three to four decades, medical ethicists have argued that patients should have a role in medical decision making (1). Due to efforts by professional medical organisations and lawmakers, patients now more consistently receive information concerning diagnostic and therapeutic procedures, risks, complications, and alternative methods of treatment (2, 4, 5). Even though the informed consent process has now been in use for a number of years, many patients still do not receive complete or desired information (2).

In numerous studies, physicians have expressed a consistently positive attitude toward patient participation in the decision-making process (3,4). Despite this, however, patients' understanding of their plan of care often remains limited (5). This insufficient knowledge may impair their ability to make important decisions regarding their hospital treatment (5).

The aim of this study was to determine the differences in knowledge between physicians and patients regarding the informed consent process for invasive procedures and to compare their personal perception on the range of information given and obtained during the informed consent process.

METHODS

Study sample

After obtaining institutional review board approval from the Ethics Committee in the Split University Hospital Centre from April to June 2006 the survey was conducted among physicians performing invasive procedures at four hospitals in south Croatia, including Split University Hospital Centre, Zadar General Hospital, Dubrovnik General Hospital, and Sibenik General Hospital. Patients who were scheduled for invasive procedures in general anaesthesia were interviewed at the same time. Prior to study inclusion, all participants were informed about the purpose of the study and that participation was voluntary and anonymous.

Data collection

A self-administered questionnaire containing 33 multiple-choice questions was given to 475 physicians performing invasive procedures in general anaesthesia in the departments of anaesthesiology, surgery, gynaecology, urology, orthopaedics, ophthalmology, otorhinolaryngology and internal medicine at the four hospitals. The physicians were asked to complete the questionnaire and return it within two months to the anaesthesiologist in charge of collecting completed questionnaires at each hospital.

Three hundred consecutive elective adult patients undergoing invasive procedures at the Split University Hospital Centre during the study period were also asked to participate in the study during preanesthetic visit before invasive procedures. Of the 300 eligible patients, 265 (88.3%) agreed to a structured interview with an anaesthesiologist who read the questions aloud and recorded their answers. There were 145 patients interviewed at the Department of Surgery, 43 at the Department of Ophthalmology, 32 at the Department of Gynaecology, 18 at the Department of Urology, 19 at the Department of Orthopaedics, and eight patients at the Department of Otorhinolaryngology.

Questionnaires

We developed physician and patient multiple-choice questionnaires containing questions related to the informed consent process, i.e. provision of information to patients, respecting patient

autonomy, knowledge of regulations and assessment of patient competence. The questionnaires were previously pilot-tested among 50 subjects and revised to create the final versions. After the pilot testing the physicians were given a questionnaire consisting of 33 multiple-choice questions (6). Finally, 18 questions appropriate for both physicians and patients were extracted, tested, and thereafter compared.

Most of the questions on the physician and patient questionnaires were similar; however, the questions were rephrased to ask about experiences specific to either physicians or patients. For example, we asked physicians: "Where did your patient sign the treatment consent form?" This question was rephrased for patients as: "Where did you sign the treatment consent form?"

Patients were given instructions to refer to the informed consent for procedure they are currently prepared for, whereas physicians were asked to refer to their last obtained informed consent process.

Statistical analysis

Data were presented as frequencies and percentages in a tabulated format. Differences between categorical variables in each group were identified with the chi-square test and considered significant at $P < 0.05$. The statistical analysis was performed with Statistica 8.0 software package (StatSoft Inc., Tulsa, OK, USA).

RESULTS

Of 269 returned questionnaires (response rate 56.6%), 251 (52.8%) were fully completed and included in the analysis. Among the clinicians who returned the fully completed questionnaire, 165 (65.7%) were men and 86 (34.3%) were women; 239 (95.2%) were specialists and 12 (4.8%) were residents. The median age of clinicians was 46 years (range 28-65 years) and their median years of practice was 20 (range 3-39 years).

Knowledge and practices regarding the informed consent process

Table 1 presents a comparison of knowledge and practices regarding the informed consent process of physicians and patients. Less than half of physicians 109 (43.4%) reported being fully acquainted with the informed consent process, whereas 142 (54.6%) reported having partial or no knowledge.

Most patients (186; 70.2%) reported having partial knowledge of the informed consent process. Overall physicians' knowledge about the process of obtaining informed consent was significantly more than patients' knowledge ($p < 0.001$).

A total of 100 physicians reported that they completely or partially informed their patients about their rights although only 40 patients reported that they felt that they were fully informed about their rights ($p < 0.001$). Over half of both physicians and patients (129 vs. 145) did not know that the informed consent process was regulated by law in the Republic of Croatia. Two-thirds of physicians and patients (166 vs. 181) knew that a patient does not receive a copy of the informed consent form, but 30 physicians and only six patients incorrectly thought that patients receive a copy ($p < 0.001$). A large majority of patients (248; 93.6%) considered that a clinician should obtain informed consent and 156 physicians (62.2%) provided the same answer. Although 145 physicians reported that discussing the cost of treatment was justified 217 patients reported that discussing treatment costs was either unjustified or unimportant ($p < 0.001$).

Table 1. Comparison between the responses of physicians and patients to questions about knowledge and practice of obtaining patient informed consent to clinical procedures

| Multiple-choice question | No. of respondents (%) | | p* |
|---|------------------------|------------------|--------|
| | Physicians (n=251) | Patients (n=265) | |
| 1. Are you familiar with the informed consent process? | | | |
| Completely | 109 (43.4) | 66 (24.9) | <0.001 |
| Partly | 121 (48.2) | 186 (70.2) | |
| No | 21 (8.4) | 13 (4.9) | |
| 2. Do you inform patients about their rights? / Are you informed about your patient rights? | | | |
| in detail | 100 (39.8) | 40 (15.1) | <0.001 |
| partly | 124 (49.4) | 160 (60.4) | |
| no | 27 (10.8) | 64 (24.2) | |
| 3. Is the informed consent process legally regulated? | | | |
| yes | 101 (40.2) | 99 (37.4) | 0.750 |
| no | 21 (8.4) | 21 (7.9) | |
| I don't know. | 129 (51.4) | 145 (54.7) | |
| 4. Do patients receive a copy of signed consent form? | | | |
| yes | 30 (12.0) | 6 (2.3) | <0.001 |
| no | 166 (66.1) | 181 (68.3) | |
| I don't know. | 55 (21.9) | 78 (29.4) | |
| 5. In your opinion, who should ask the patient to sign an informed consent form? | | | |
| physician | 156 (62.2) | 248 (93.6) | <0.001 |
| nurse | 54 (21.5) | 6 (2.3) | |
| ward clerk | 29 (11.6) | 1 (0.4) | |
| I don't know. | 12 (4.8) | 10 (3.8) | |
| 6. In your opinion, is it justified to talk about the cost of treatment when the patient is treated at a public hospital? | | | |
| yes | 145 (57.8) | 48 (18.1) | <0.001 |
| no | 56 (22.3) | 91 (34.3) | |
| It is not important. | 50 (19.9) | 126 (47.6) | |

*Chi-square test.

Patients' knowledge about medical condition and medical procedures

Physician and patient perceptions regarding patients' knowledge about their medical condition and forthcoming medical procedures are illustrated in Table 2.

Table 2. Patients' knowledge concerning their medical condition and forthcoming treatment procedures

| Multiple-choice question/ statement | No. of respondents (%) | | P* |
|---|------------------------|----------------------|--------|
| | Physicians (n=251) | Patients (n= 265) | |
| 1. I inform patients about their medical condition and treatment procedures / I was informed about my condition | | | |
| in detail | 77 (30.7) | 29 (10.9) | <0.001 |
| as much as necessary | 138 (55.0) | 186 (70.2) | |
| only as much as needed (for a patient) to make a decision | 36 (14.3) | 50 (18.9) | |
| 2. I answered patient's questions / Clinician answered my questions | | | |
| in detail | 63 (25.1) | 50 (18.9) | <0.001 |
| clearly and briefly | 174 (69.3) | 155 (58.5) | |
| by providing only the most necessary information | 14 (5.6) | 60 (22.6) | |
| 3. I provide/received information on risks and possible complications of treatment | | | |
| in detail | 66 (26.3) | 19 (7.2) | <0.001 |
| as much as necessary | 124 (49.4) | 115 (43.4) | |
| only on most common risks and complications. | 59 (23.5) | 85 (32.1) | |
| no (to avoid upsetting the patient) | 2 (0.8) | 44 (16.6) | |
| 4. Patients / I usually choose the treatment method | | | |
| suggested by a clinician | 200 (79.7) | 252 (95.1) | <0.001 |
| suggested by friends | 10 (4.0) | 3 (1.1) | |
| I don't know | 41 (16.3) | 10 (3.8) | |
| 5. I provide/received information on possible alternative methods of treatment | | | |
| on more than one method (if existing). | 190 (75.7) | 144 (54.3) | <0.001 |
| I do not talk about other methods in order not to confuse the patient. / No, clinician did not mention other methods. | 29 (11.6) | 93 (35.1) | |
| Patients themselves can find information / I myself found information. | 32 (12.7) | 28 (10.6) | |
| 6. How long does/did the conversation with the patient/clinician last? | | | |
| <5 minutes | 48 (19.1) | 42 (15.8) | <0.001 |
| 10 minutes | 137 (54.6) | 196 (74.0) | |
| 15 minutes | 58 (23.1) | 17 (6.4) | |
| >30 minutes | 8 (3.2) | 10 (3.8) | |
| 7. Do you inform patients about their length of hospital stay? /Were you informed about the length of your hospital stay? | | | |
| yes | 205 (81.7) | 211 (79.6) | <0.556 |
| no | 46 (18.3) | 54 (20.4) | |
| 8. Do you inform patients on possible consequences of treatment refusal? / Were you informed on the consequences if you refuse the treatment? | | | |
| in detail | 126 (50.2) | 23 (8.7) | <0.001 |
| briefly | 122 (48.6) | 171 (64.5) | |
| no | 0 (0) | 54 (20.4) | |
| I recommend/was recommended to ask for a second opinion | 3 (1.2) | 17 (6.4) | |

This table lists responses of physicians and patients to questions about their health status and scheduled treatment procedures; *Chi-square test.

A significant disagreement was observed in the answers to the questions on the amount of information that was given or obtained about patients medical condition, forthcoming clinical procedures and on the possible complications of forthcoming medical procedures ($p < 0.001$).

On the other hand, physicians underestimated their own role in the patient's decision making. Almost all patients (252; 95.1%) reported that they had chosen the treatment method suggested by clinician ($p < 0.001$). Physicians reported that they spent more time talking to their patients and that they provided information on the alternative treatment methods than patients reported (190 doctors vs. 144 patients, $p < 0.001$). Half of physicians (126) reported providing detailed explanations of the consequences of treatment refusal, whereas 171 patients (64.5%) reported being informed only briefly ($p < 0.001$). In the group of questions on the forthcoming treatment an agreement between doctors and patients was achieved only regarding the answers to the questions on the length of the hospital stay.

Experiences regarding the procedure of informed consent

As shown in the table 3, significant disagreement was registered between the answers from

Table 3. Comparison between responses of physicians and patients to questions about the procedure of obtaining informed consent to treatment

| Multiple-choice question | No. of respondents (%) | | P* |
|---|------------------------|----------------------|--------|
| | physicians (n=251) | patients (n= 265) | |
| 1. Where did your patient/you sign the treatment consent form? | | | |
| in a clinic | 97 (38.6) | 137 (51.7) | <0.001 |
| at a hospital reception desk | 35 (13.9) | 11 (4.2) | |
| in a patient room | 104 (41.4) | 103 (38.9) | |
| I don't know | 14 (5.6) | 14 (5.3) | |
| 2. In your opinion, do your patients receive sufficient information to be able to decide on their treatment? / Did you receive sufficient information to be able to decide on your treatment? | | | |
| yes, complete information | 132 (52.6) | 31 (11.7) | <0.001 |
| only the most necessary information | 113 (45.0) | 201 (75.8) | |
| not complete information | 6 (2.4) | 31 (11.7) | |
| 3. Your patients/you provided consent to treatment | | | |
| independently, without anyone's help | 213 (84.9) | 239 (90.2) | <0.001 |
| after consulting with the family | 26 (10.4) | 18 (6.8) | |
| after special persuasion by a clinician | 12 (4.8) | 8 (3.0) | |
| 4. If patients/you are not able to choose the treatment method, who would you ask for consent? | | | |
| (patient's) family | 246 (98.0) | 105 (39.6) | <0.001 |
| (patient's) friends | 1 (0.4) | 0 (0.0) | |
| colleagues /physician | 4 (1.6) | 160 (60.4) | |

*Chi-square test.

patients and physicians to all the questions comparing their experiences regarding the procedure of obtaining informed consent to treatment ($p < 0.001$). Disagreement was the most prominent in the question on the amount of the information presented to the patients before they had to make their decision on the forthcoming procedures. In the instance that patients were not able to make their own decision regarding treatment, most of them would leave the decision to physicians. On the contrary, physicians reported that, in such cases, they would routinely ask for consent from the patient's family.

DISCUSSION

Recently Dieterich have identified a number of issues including law, ethics, knowledge, information, structural health care problems and funding issues as major areas of importance within a particular physician-patient interaction (7). The results of our study have shown significant differences in the knowledge and perception of these points of interests defining patient-doctor interaction between two study groups. Physicians lacked awareness about their professional, legal, and ethical obligations to provide patients with information concerning their medical condition and forthcoming diagnostic and therapeutic procedures. Accordingly, most patients reported receiving only limited or incomplete information, or in some cases no information obtained at all, in both this and numerous other studies (8).

There was a limited amount of information that could be shared during the physician-patient consultation and this may occur because physicians often feel pressed for time. The majority of physicians in our study believed that patients received sufficient information to be able to make an informed decision on the recommended treatment. Patients expected to receive more detailed information, even though they were adequately informed about the risks, complications, and alternative methods of treatment (8,9). Other studies have shown that, after either two weeks or six months, patients do not seem to remember some information on the risks or alternative treatment methods (9). In addition, patients often do not wish to be fully informed of the risks and possible complications of the forthcoming surgery (10).

Although many patients felt that they were gi-

ven an insufficient amount of information, they still appreciate the input from medical staff. In situations where patients were unable to choose a treatment method and participate in the informed consent process, they were willing to trust their doctors with medical decisions. The most patients in our study reported providing their consent independently and agreeing on the treatment method suggested by their physicians. Levinson and co-workers in their population-based survey have obtained similar results to those observed in this study (11). They confirmed that nearly all respondents (96%) preferred to be offered choices and their opinions considered, but half of the respondents (52%) preferred to leave final decisions to their physicians. Furthermore, 44% of patients have preferred to rely on physicians for medical knowledge, and did not want to participate in the decision making process (11). In the era of widespread internet access, a significant amount of health information is now available to the general public, but the inability of patients to understand which information is useful have made them more likely than ever to trust their doctors (12, 13). In a recent survey, Hesse et al confirmed that patients performing their own internet research are more likely to want to talk with their doctors about the treatment methods and that the internet does not replace the role of doctors in patient's lives (12). Written information, video-recordings or web-based information might decrease decisional conflict and facilitate decision making, but are not substitutes for patient - physician communication (12-14). This is because during interpersonal discussion, decisions may vary depending on the nature of the procedure and the relevant comorbidities of the patient (15). A plain language should be used according to the cognitive abilities and education of the patient (1).

Our study has shown that patients in South Croatia want their doctors be more involved in the informed consent process. On the contrary more doctors are prone to delegate such procedures to other members of medical staff such as nurses or administrative personnel. Such a practice should be avoided as it is contrary to the code of medical ethics (4,16). Prior to obtaining consent, physicians should initiate a discussion about the diagnosis and treatment procedures, provide information concerning the potential risks and complications,

and review possible alternative methods of treatment. A signed consent form must be obtained by the patient's physician, otherwise the signature on the consent form is nearly symbolic, possessing little value and may be legally and ethically discarded.

In our study, patients did not find discussions regarding treatment costs justified or important before the treatment in public hospitals. As new treatment modalities are now available, and because patients and their families will be more engaged in the continuous treatments that may prolong after their discharge from hospital, this issue must be discussed before treatment has started. This is particularly important for therapies that are not paid by health insurance systems (16).

This survey has several limitations. Firstly, a question regarding the completed level of education of the patient was excluded from the questionnaire. We were therefore unable to assess how the educational level of the patient influenced their ability to understand the provided medical information during the consent process. Physicians believed that only half of their patients completely understood the information provided that was needed to decide on treatment. Under that circumstances patient's signature on the infor-

med consent form is legally and ethically questionable and consent should be obtained from family members.

Another limitation of this study is that we interviewed only surgical patients, whereas not all of the physicians who completed the self-administered questionnaire work in surgical specialties (17).

Taking into account the results of this survey, we believe that both physicians and patients would benefit from upgrading informed consent procedures. Accordingly, consent forms for different procedures need to be developed to ensure informed patient participation. Procedure specific protocols would promote dialogue to enable patients to make informed and autonomous choices and require physicians to inform patients about all aspects of specific procedures, be they routine or invasive (18,19).

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