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Knowledge and Practices of Obtaining Informed Consent for Medical Procedures among Specialist Physicians: Questionnaire Study in 6 Croatian Hospitals

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Aim To assess physicians' knowledge and practices for obtaining patients' informed consent to medical procedures.

Methods An anonymous and voluntary survey of knowledge and practices for obtaining informed consent was conducted among 470 physicians (63% response rate) working in 6 hospitals: 93 specialists in anesthesiology, 166 in internal medicine, and 211 in surgery.

Results Only 54% physicians were acquainted with the fact that the procedure for obtaining consent was regulated by the law. Internists and surgeons were better informed than anesthesiologists ($P=0.024$). More than a half of respondents (66%) were familiar with the fact that a law on patient rights was passed in Croatia; there were no differences among different specialties ($P=0.638$). Only 38% of the physicians were fully informed about the procedure of obtaining consent. Internists and surgeons provided detailed information to the patient in 33% of the cases and anesthesiologists in 16% of the cases ($P<0.050$). Internists reported spending more time on informing the patient than anesthesiologists and surgeons ($P<0.001$). There were no differences in knowledge and practices for obtaining informed consent between physicians working in university and those working in community hospitals ($P\geq0.05$ for all questions).

Conclusion Physicians in Croatia have no formal education on informed consent and implement the informed consent process in a rather formal manner, regardless of the type of hospital or medical specialty. Systemic approach at education and training at the national level is needed to improve the informed consent process.

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Informed consent is a professional ethics issue emanating from the fiduciary responsibility of the physician to the patient. It is an integral component of the physician's fiduciary responsibility. In many countries informed consent for medical procedures is a standard procedure (1-9) for providing the patients with the information on diagnostic and treatment procedures, risks, complications, and alternative treatment options in non-emergency cases (5,9,10), thereby considerably improving the communication between physician and patient. A signed form is the evidence that their conversation led to a mutual understanding. However, the implementation of the informed consent process differs among countries because informing the patient and requiring the consent are still not regarded as a legal obligation of the physician (6).

In the clinical setting, the term "informed consent" was developed in the USA in 1957. It was further developed in the Declaration of Helsinki in 1964, which established worldwide ethical principles for medical research involving human participants. In its current, 2008 version (11), the article 24 states: "In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed." (citation, paragraph 24). The Belmont Report from 1979 outlined the guidelines for the protection of human participants of research.

In Croatia, the requirement to obtain treatment consent was first legally introduced in 1997 (12) and the Act on The Protection of Patent's Rights was passed in 2004 (13). The regulations proscribe that patients are entitled to get full information on their health condition, including medical assessment of the results and outcomes of a certain diagnostic or therapeutic procedure and recommended examinations and procedures, and to know the dates when they are to get that information. The patients should be informed on the possible advantages of performing or not performing the procedures recommended and risks involved, and possible alternatives for the procedures. Thereafter, they have the right to make a decision to accept or reject the outlined treatment. The information should be clearly explained having in mind the patients' age, education, and mental abilities. A signed form is just evidence that a conversation between physician and patient led to that mutual understanding.

Physicians' knowledge and attitudes toward informed consent considerably differ in various countries and among different medical specialists (14-17). We conducted this study to compare knowledge and practices for obtaining informed consent for medical procedures between 3 groups of specialists. We compared the specialists in anesthesiology, internal medicine and related medical specialties, and in surgery, who obtain informed consent for medical procedures on a daily basis.

PARTICIPANTS AND METHODS

Sample

The study was conducted from February to July 2006 in 6 hospitals: University Hospital Split, General Hospital Zadar, General Hospital Dubrovnik, General Hospital of the Šibenik-Knin County, General Hospital Varaždin, and University Hospital Osijek. The authors were either employed in these hospitals or had contacts there, which made it easier to conduct the survey. The sample included all the hospitals in the 4 counties on the Adriatic coast south of Zadar (Zadar, Šibenik, Split, and Dubrovnik) and 2 hospitals in the north of the country (Varaždin in Varaždinska County and Osijek in Osijek-Baranja County). Two of these hospitals (Split and Osijek) are teaching and research hospitals of the respective universities.

The questionnaire was distributed by the authors to all physicians working in a particular hospital. The number of questionnaires prepared was determined according to the list of employees of each hospital department or ward (total 750 physicians). The physicians present at the time of the survey filled out the questionnaire on their own and returned the completed form to the author who was in charge of the local survey. Participation in the study was voluntary and anonymous. We received approval from the Ethics Committee of the Split University Hospital Centre.

Questionnaire

The questionnaire consisted of 33 questions (13 questions on knowledge and 20 on the use of informed consent for medical procedures; web extra material). It was checked for clarity and consistency in a pilot study including 60 physicians. After pilot testing, several questions were rephrased to improve clarity. The questions were formulated according to the guidelines for obtaining patients' consent (5,10).

The questionnaire also contained a list of procedures for which patients' written consent is required in the USA (10), and the respondents were asked to indicate which procedures needed informed consent in Croatia.

Statistical analysis

For the statistical analysis of the data we used Statistica 8.0 software package (StatSoft, Inc.,Tulsa, OK, USA). Differences between categorical variables were estimated by χ^2 test. Statistical values were considered significant at $P<0.05$.

RESULTS

Out of total of 750 questionnaires sent to individual hospitals, 470 were returned (63% response rate): 93 out of 150 (62%) for anesthesiologists, 166 out of 300 (55%) for internists, and 211 out of 300 (70%) for surgeons ($P<0.001$ for surgeons vs internists).

There were 298 male and 172 female respondents (173 from Split, 121 from Osijek, 46 from Zadar, 41 from Dubrovnik, 35 from Šibenik, and 54 from Varaždin). The average age of physicians was 46.7 ± 8.9 years and average number of their years of practice was 20.1 ± 9.1. There was no significant difference in age ($P=0.298$) and years of practice ($P=0.254$) between anesthesiologists, internists, and surgical specialists. There were also no differences in demographic characteristics of the respondents working in university hospitals (n = 294, 62.5%) and those working in community hospitals (n = 176, 37.5%).

Most of the respondents were specialists, with only 20 (4%) physicians in residency training. There were 93 specialists or

TABLE 1. Opinions of medical specialists (n = 470) about the need for mandatory written patient consent for procedures

Procedures for which written consent is required*	No. (%) of positive answers from specialists in				
	total (n = 470)	anesthesia (n = 93)	surgery (n = 211)	internal medicine (n = 166)	P‡
Anesthesia†	416 (89)	92 (99)	181 (86)	143 (86)	0.002
Surgical procedure†	411 (87)	87 (94)	193 (92)	131 (79)	0.001
Heart catheterization	400 (85)	86 (93)	175 (83)	139 (84)	0.08
Tooth extraction	246 (52)	47 (51)	117 (56)	82 (49)	0.469
Thoracotomy	403 (86)	84 (90)	190 (90)	129 (78)	0.001
Ultrasound therapy	267 (57)	48 (52)	130 (62)	89 (54)	0.157
Hemodialysis	306 (65)	60 (65)	135 (64)	111 (67)	0.836
Peritoneal dialysis	313 (67)	63 (68)	135 (64)	115 (69)	0.538
Blood transfusion†	360 (77)	75 (81)	159 (75)	126 (76)	0.584
Laser therapy	282 (60)	53 (57)	146 (69)	83 (50)	0.001
Lumbar puncture	354 (75)	68 (73)	167 (79)	119 (71)	0.214
Cardioversion	315 (67)	67 (72)	123 (58)	125 (75)	0.001
Chemotherapy	366 (78)	71 (76)	176 (83)	119 (72)	0.022
Endoscopic procedures	295 (63)	54 (58)	148 (70)	93 (56)	0.01
Sterilization (reproductive)	398 (85)	78 (84)	187 (89)	133 (80)	0.073
Implantation of heart electrostimulators	380 (81)	74 (80)	172 (82)	134 (81)	0.922
Biopsy (under short anesthesia)	366 (78)	67 (72)	177 (84)	122 (74)	0.017
Radiological tests with contrast	330 (70)	72 (77)	139 (66)	119 (72)	0.111
Implantation of a central venous catheter	320 (68)	69 (74)	134 (64)	117 (71)	0.131
HIV testing	278 (59)	49 (53)	140 (66)	89 (54)	0.017
Tracheotomy	369 (79)	75 (81)	175 (83)	119 (72)	0.026

*All procedures need written patient consent in the USA (10).
†Procedures explicitly mentioned as examples of procedures needing written patient consent in the Croatian law (11).
‡χ^2 test.

TABLE 2. Knowledge of medical specialists about legal regulation of patients' informed consent for medical procedures

Questions	No. (%) of specialists from the field of				
	total (n = 470)	anesthesia (n = 93)	surgery (n = 211)	internal medicine (n = 166)	*P**
Is the procedure of obtaining informed consent for treatment regulated by law?					
yes	252 (54)	37 (40)	120 (57)	95 (57)	0.023
no	34 (7)	8 (9)	19 (9)	7 (4)	
I don't know	184 (39)	48 (51)	72 (34)	64 (39)	
Do you know what the sanctions are if a physician withholds the right of information to the patient?					
no	382 (81)	88 (95)	164 (78)	130 (78)	<0.001
yes	88 (19)	5 (5)	47 (22)	36 (22)	
In your opinion, who should educate the patient on the issues of providing consent for treatment?					
physician	362 (77)	80 (86)	165 (78)	117 (70)	0.005
nurse	108 (23)	13 (14)	46 (22)	49 (30)	
In your opinion, who should give the form for informed consent for treatment to the patients to be signed?					
physician	303 (64)	78 (84)	125 (59)	100 (60)	0.001
nurse	89 (19)	4 (4)	48 (23)	37 (22)	
department clerk	57 (12)	6 (7)	28 (13)	23 (14)	
I don't know	21 (5)	5 (5)	10 (5)	6 (4)	
In your opinion, is it justified to talk about the cost of treatment when the patient is treated in a public hospital?					
yes	271(58)	47 (50)	127 (60)	97 (58)	0.004
no	107 (23)	33 (36)	35 (17)	39 (24)	
it is not important	92 (19)	13 (14)	49 (23)	30 (18)	

*χ^2 test.

residents in anesthesiology, 166 in medicine (76 in internal medicine, 40 in pediatrics, 15 in neurology, 21 in psychiatry, and 14 in infectious disease medicine) and 211 in surgery (28 in gynecology, 92 in surgery, 28 in ophthalmology, 8 in urology, 15 in orthopedics, and 40 in ear and nose surgery).

When asked to indicate which procedures required informed consent in Croatia (Table 1), most respondents listed anesthesia (89%) and surgical procedures (87%). Fewer respondents (77%) mentioned blood transfusion, which is explicitly stated in the Croatian law. Only 52% considered that tooth extraction needed informed consent, 57% mentioned ultrasound therapy, and 59% HIV testing. We found a difference in the knowledge on procedures requiring consent between anesthesiologists, internists, and surgical specialists (Table 1).

Only about a half of the respondents knew that the procedure of obtaining informed consent was prescribed by the law (Table 2). In comparison with surgeons and internists, more anesthesiologists claimed to be familiar with the sanctions for withholding the information from a patient (Table 2). Regardless of their specialty, most respondents (80%) thought that informing the patient about the informed consent process was the physician's task. Most anesthesiologists (84%) thought that the physician should be the person responsible for giving the form to the patient, whereas 60% of the internists and 59% of the surgeons thought that this should be done by someone else. More than a half of the respondents (58%) considered that it was legitimate to discuss the costs of the treatment when the patient was being treated in a state-owned institution.

More than a half of the respondents reported that they provided only the information they considered necessary for the patient to make the decision on consent (Table 3). About 60% of the respondents thought they answered patients' questions in a clear and concise manner. More surgeons than other specialists thought they answered patients' questions in more detail. In cases when the patient is not able to reach the decision on the treatment or is tem-

porarily prevented from doing so, most of the respondents would address the family and relatives, whereas a smaller fraction (15%) would consult their colleagues or reach a decision on their own (5%). There were no differences between specialists in regard to this question (P > 0.05 for all comparisons).

Most of the respondents (74%) would agree with the patient's wish to perform the procedure in another hospital and 21% of them would help the patient in that intention. As much as 87% of internists and surgeons reported that patients accepted the method of treatment they recommended, compared with 67% of anesthesiologists.

TABLE 3. Comparison of the estimates of anesthesiologists (n = 93), surgeons (n = 211), and internists (n = 166) regarding the level of informing the patients on their health condition when obtaining the consent for medical procedures

	No. (%) of specialist in the field of				
Questions	total (n = 470)	anesthesia (n = 93)	surgery (n = 211)	internal medicine (n = 166)	*P**
I inform patients about their medical condition and treatment procedures:					
in detail	136 (29)	15 (16)	67 (32)	54 (33)	0.007
as much as I think is necessary	268 (57)	57 (61)	116 (55)	95 (57)	
only as much as is needed for the patient to make a decision	66 (14)	21 (23)	28 (13)	17 (10)	
I answer patient's questions:					
in detail	127 (27)	6 (6)	78 (37)	43 (26)	<0.001
clearly and briefly	281 (60)	74 (80)	121 (57)	86 (52)	
by providing only the most necessary information	62 (13)	13 (14)	12 (6)	37 (22)	
Patients usually chooses the treatment method:					
suggested by me	392 (83)	62 (67)	184 (87)	146 (88)	<0.001
suggested by his friends	14 (3)	6 (6)	7 (3)	1 (1)	
I don't know	64 (14)	25 (27)	20 (10)	19 (11)	
How long does your conversation with the patient last?					
<5 min	72 (15)	20 (22)	39 (19)	13 (8)	<0.001
10 min	283 (60)	56 (60)	146 (69)	81 (49)	
15 min	103 (22)	17 (18)	23 (11)	63 (38)	
>30 min	12 (3)	0 (0)	3 (1)	9 (5)	
Do you inform your patient about possible consequences if he or she refuses the treatment?					
I explain in details what can be expected	223 (47)	23 (25)	104 (49)	96 (58)	<0.001
I briefly explain what can be expected	241 (52)	69 (74)	104 (49)	68 (41)	
I advise the patient to ask another physician for second opinion	6 (1)	1 (1)	3 (2)	2 (1)	
Do patients receive a copy of signed consent form?					
yes	62 (13)	9 (10)	22 (10)	31 (19)	<0.001
no	306 (65)	75 (80)	132 (63)	99 (59)	
I don't know	102 (22)	9 (10)	57 (27)	36 (22)	
How often do you use the informed consent for treatment form?					
on a daily basis	249 (53)	65 (70)	122 (58)	62 (37)	0.001
a few times a week	114 (24)	16 (17)	58 (27)	40 (24)	
a few times a month	54 (12)	8 (9)	21 (10)	25 (15)	
a few times a year	53 (11)	4 (4)	10 (5)	39 (24)	
How does your patient give consent for the treatment?					
independently, without anyone's help	398 (84)	84 (90)	195 (92)	119 (72)	<0.001
after consulting the family	51 (11)	8 (9)	14 (7)	29 (17)	
after special coercive talk by the physician	21 (5)	1 (1)	2 (1)	18 (11)	
Do you inform patients about the length of their hospital stay?					
yes	375 (80)	28 (30)	196 (93)	151 (91)	<0.001
no	95 (20)	65 (70)	15 (7)	15 (9)	

*χ^2 test.

Most of the respondents (60%) reported that they spent about 10 minutes with the patient talking about the procedure and consent form. More internists than anesthesiologists and surgeons reported that they spent about 15 minutes talking with the patient (Table 3). About 74% of surgeons and internists reported that they always informed patients on the advantages and disadvantages of treatment, compared with 49% of anesthesiologists ($P < 0.001$). If the patient refused the recommended treatment, most internists and surgeons would describe the consequences of such a decision in detail, whereas anesthesiologists would mostly describe them briefly ($P < 0.001$).

The majority of respondents from all 3 fields of medicine (63%) did not know the duration of validity of an individual signed informed consent form. As much as 70% of anesthesiologists reported that they asked for patient's consent on a daily basis, compared with 37% internists and 58% surgeons (Table 3, $P < 0.001$). A high percentage (90%) of anesthesiologists and surgeons thought that the patients decided to give the consent for treatment on their own, whereas internists attributed major importance to the influence of the environment (17%) (Table 3). More than 90% of surgeons and internists and only 30% anesthesiologists informed the patients about the length of their stay in hospital ($P < 0.001$).

There were no major differences in the responses between the physicians working in teaching and those working in community hospitals ($P > 0.05$ for all comparisons).

DISCUSSION

Our study on the knowledge on informed consent for medical procedures of physicians from 6 Croatian hospitals demonstrated that this process was rather formal and inadequate when it came to fulfilling legal and professional requirements. Although some of the respondents worked in university hospitals where clinical trials are a part of everyday work and teaching activities, we found no differences between their knowledge and practice of obtaining informed consent and those of their colleagues from non-academic hospital settings.

Limitations of the study are its survey design and the fact that it did not study the extent to which the physicians were actually informed about the informed consent and its legal regulation and did not measure the implementation of informed consent in practice. However, the response rate of 63% and inclusion of 6 hospitals increase the external validity of the study results.

In the USA, UK, and Canada, physicians are thoroughly trained on the procedure of obtaining informed consent, primarily due to the possibility that patients make damages claims in case of complications (5). In these countries, it is well defined by law which procedures require patient's written consent (10). This is not the case in Croatia, where only anesthesia, surgical procedures, and blood transfusion are given as examples (12,13). Only 54% of the physicians included in our study were acquainted with the fact that the informed consent process for each specific procedure or treatment is regulated by the law and that the Law on Patient's Rights was passed in Croatia. The physicians were not even familiar with the sanctions that might be imposed on them in case they withheld information from the patient. Due to the nature of their role in preoperative preparation of a patient, anesthesiologists were best informed on this matter.

In Croatia, there are no general recommendations determining which procedures require the patient's written consent and there is no systematic training in this field (14). The law also does not define a common form for consent, but mandates individual health care institutions to develop their own forms. The Ordinance on the Consent Form was adopted in 2008 and it states (18): "The contents of the information regarding each recommended diagnostic, i.e. therapeutic procedure which is enclosed to the Consent form is decided upon by the health care institution with a previously obtained opinion of the competent chambers and the consent of the Agency for Quality and Accreditation in Health Care."

Nevertheless, the Act and Ordinance do not specify the behavior of the physicians and patients or the diagnostic or treatment procedures which require consent. The form was created but no protocol was adopted to specify the amount and type of information the patient should get, the person responsible for giving the form to the patient, and the time when the form is to be signed. Moreover, it is not specified for which procedures the protocol is to be applied. Rather, the procedure of obtaining consent was prescribed only in general terms and the implementation was left to the physician's own knowledge and conscience. This leads to large variations in the structure of the form and the extent of information provided to the patients (M. Jukić, unpublished results).

A possible confusion among patients arises especially because of the reports that patients do not have sufficient understanding of the intervention procedure and the po-

tentially related risks and complications (19,20). This may be especially important when medical interventions are a part of clinical research (20). Since informed consent differs for medical procedures and for research, we investigated only informed consent for medical procedures.

The fact that a large percentage of physicians in Croatia was not familiar with the fact that the signed consent is not given back to the patients indicates that the procedure of obtaining the consent is currently just a formal procedure, rather than a real interaction between the physician and patient. Although both physicians and nurses may administer the informed consent form and the information regarding the informed consent, education of patients is a physician's responsibility – it is not a piece of paper. Informing the patient and getting consent is a process that should be provided by a physician (21).

To ensure that information was presented to patients, special informed consent forms listing the treatment procedures and potential complications connected with the treatment are currently used (22,23).Written information, audio-visual recordings, or both do not necessarily provide better information for the patient and cannot replace conversation with the physician (24-26). This process helps that at least some patients reach a decision. It therefore must result from exchange of information, understanding, deliberation, and balancing of alternatives between physicians and patients.

It is important how a physician formulates the information presented to the patient, as it has been shown that patients often do not recollect all information provided by a physician (8), and the physicians often estimate that patients do not understand the obtained information on the health condition and possibilities of treatment (19). Nevertheless, the majority of physicians respect patients' autonomy and their decisions and requires the consent of relatives when the patient is not capable of reaching a decision (27). However there are still many physicians who have a paternalistic attitude toward their patients, as demonstrated by our finding that 83% of physicians thought that patients would consent to the method recommended by the physician (28).

Due to the nature of their work, which requires obtaining the consent for treatment procedures more frequently than other colleagues, anesthesiologists know more about procedures and informed consent but provide less detailed information to the patient. On the other hand, internal medicine specialists perform diagnostic procedures that last longer, which gives the patient an opportunity to obtain more detailed information and ask questions. This is supported by our finding that internists spend more time talking to the patient in comparison with specialists in surgery or anesthesiology. The length of time spent in talking to the patients in our study is similar to the length of surgeon's conversation with the patient reported in a study from the USA (29).

Our study indicates a serious problem in legal protection of patient's rights in Croatia and calls for systematic nation-wide training for physicians and other health workers in this field. It has been shown that greater theoretical knowledge and more experience in conducting interviews might contribute that informed consent process is aimed more at informing the patients than only at obtaining their consent (30). Following the experience of countries with established systems of patient information (31-33), professional associations in Croatia should prepare guidelines for physicians on the process of informing patients and obtaining consent for treatment. Creating uniform requirements at the national level may increase the quality of health care provided to the patients, and the legal security for both patients and their physicians. Since informed consent process is an ethical duty, emphasis should not be on filling in the forms but rather on communication between the physician and patient and on the individual human values, principles, and standards.

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