

# IS THERE A NEED TO IMPROVE THE INFORMED CONSENT PROCEDURES IN CROATIA - A PILOT FIELD SURVEY ON A REPRESENTATIVE SAMPLE, A FOOD FOR THOUGHT?

*Luka Vučemilo\**, *Milan Milošević\*\**, *Sanja Babić-Bosanac\*\**,  
*Jadranka Mustajbegović\*\**, *Ana Borovečki\*\**

## **Abstract**

*Background: The informed consent, if obtained properly, can bring additional value to the physician-patient relationship and in many cases to the patients' safety. The previous research studies done in Croatia show the formality of the process of informed consent which often lacks quality and substance, as well as the poor knowledge of patients' rights. Therefore, the authors sought to elucidate the main issues related to the experience and assess the knowledge of general patient population about informed consent after several years of application of the Act on Protection of Patients' Rights.*

*Methods: A short survey was conducted using an independently created questionnaire on a nationally representative sample of 1023 adult subjects divided into two groups: those who had been or not in a hospital for treatment in the past five years.*

*Results: 60% of respondents had only partial knowledge of patients' rights. The level of knowledge about the informed consent was average but not in depth. 25% of respondents stated that they have received complete information during the informed consent procedure, and graded the level of the received information as high in nine percent of the cases. 15% of respondents could not remember whether they have signed or not an informed consent form.*

*Conclusion: Based on the results obtained in our research there is need for improvement of the informed consent procedures and for further research in the issues surrounding the practices of informed consent in Croatia especially in the areas of quality and comprehension of the information, as well as the physician-patient decision-making process and education of physicians and general public.*

**Keywords:** Informed consent, patients' rights, Croatia

Corresponding author : Luka Vučemilo - lukavucemilo@yahoo.com

\* Institute for Ear, Nose, Throat Disease and Head and Neck Surgery, University Hospital Merkur, Zagreb,

\*\* Croatia University of Zagreb, School of Medicine, School of public health "Andrija Štampar", Zagreb, Croatia

## **Introduction**

The informed consent (IC) is now an essential part of everyday practice in clinical settings. The medical and legal professions have defined the best practices and standards for obtaining the IC [1]. Moreover, the patient's involvement, and this clearly begins with adequate IC procedures, can in turn improve the patients' safety and quality of healthcare delivery [2].

From 1990's to 2004 the rights of patients in Croatia were regulated by several laws that defined general concept of the IC. However, none of these regulations were able to provide successful implementation of IC process for all patients during medical treatment in hospitals or at general practice offices. In 2004 the Act on the Protection of Patients' Rights has defined the IC as right to co-decide including right to be fully informed and right to accept or refuse a medical procedure [3]. This law requires the IC for all diagnostic and therapeutic procedures and their approval or refusal is confirmed by patient's signature on the consent form. However, the studies have shown that there is a discrepancy between the regulations and the actual position of patients within the healthcare system in Croatia [4-6]. One of the observed problems is the problem of implementation of the IC in the Croatian hospitals. The researches available on the subject of patients' rights and IC in Croatia indicate the formality of the process of IC in hospital setting and the poor knowledge of patients' rights among both patients and physicians [7-11]. For a high percentage of patients the IC was nothing more than signing a form [7]. Physicians are not

completely acquainted with patients' rights [5], they have no formal education about the IC and they conduct the process of informing patients in a very formal manner [8].

Another possible problem that highlights the discrepancies between regulation and actual position of the patient within the Croatian healthcare system is connected to physician-patient relationship. Although Croatian law defines relationship between physicians and patients as the model of shared decision-making [3] there is still a high prevalence of paternalistic traits in physician patient relationship. This can create a lot of issues since the relationship between a physician and a patient is a key factor in the optimal management of any medical procedure, and the success of a good of IC procedure depends on the strength and quality of the relationship between the physician and the patient and their communication [12]. Joint decision making by the physician and the patient creates a shift from a paternalistic relationship to a partnership and this is the basis today of inclusion of the patient in the decision-making process and a mark of a good quality healthcare provision. All above clearly presents a need for further investigation of the IC process in Croatia. That is why we have decided to undertake an analysis of the situation regarding knowledge and experience related to IC procedures.

So far, the studies done in Croatia concentrated mainly on the patients and practices in close physician-patient encounters in hospital settings dealing with decision-making procedures in surgical and gynaecological patients [7,9-11]. Although, these studies are valuable they do not present the

situation in general population. We feel that the experience of general population, examined through field survey on nationally representative sample, can give us the real picture of the Croatian situation, since this population differs from the previous research subjects. Our research also presents the first research done on a representative sample in a South-eastern European transitional country since previous research done in other studies, did not involve such a significant sample of general population nor our methodological approach. Additional impetus to our research was created by the process of accreditation of Croatian hospitals that is now underway where IC forms and procedures are becoming a part of accreditation standards and the quality insurance. We believe, that the highlights obtained by this research will help us later in focusing our further research in specific areas connected with the practice of the IC in Croatia.

### **Methods**

**Subjects and data collection:** The field survey with representative three-stage probabilistic sample was conducted in October 2011 in Croatia by an agency using self-administered questionnaire. The location of the survey, the starting points and the subjects within a household were selected by random selection. The surveyors were given starting points, that is, streets with a house number. In each household, the last birthday method was used as the criterion for selection of subjects (a person over 14 years of age who recently had a birthday was interviewed). The surveyors read the questions and recorded the subjects' answers. These

were voluntary and not rewarded, while the anonymity of the subjects was ensured.

**Questionnaire:** A short questionnaire was constructed in a focus group discussion. Doctors, psychologists, statisticians and epidemiologists took part in the creation of our questionnaire. For the testing of the IC process the questions were prepared in accordance with existing the Act on the Protection of Patients' Rights and its definition of the IC as right to co-decide that includes right to be full informed and right to accept or refuse medical procedure [3]. After testing the comprehension level of the questionnaire on 15 individuals with different profiles, the questions and answers were amended to make them clearer and to ensure unambiguous replies. The final questionnaire consisted of 11 questions in total divided in two parts.

When data was collected the respondents were classified into two groups based on the replies to the first question of the questionnaire: those who had been in hospital in the past five years and those who had not been. The first group of subjects had to reply to five questions. The questions dealt with the level of information that respondents received regarding patients' rights and regarding their health, illness, possible procedures and risks related to these procedures. They were also asked who made the decisions about the course of their treatment and whether they had to sign an IC form. The respondents who had not been in hospital were asked about the level of their knowledge regarding patients' rights and IC. They were also asked whether in their opinion a patient has to sign a consent form for

diagnostic and therapeutic procedures and whether one can refuse a procedure after signing an IC form. They also had to provide an answer whether they would give their consent if they had not been completely informed about illness, procedures, risks, complications and alternative methods. Demographical data (gender, age, educational level) was also collected (Table1).

The statistical analysis of the results obtained was performed using IBM SPSS Statistica, version 19.0.0.1 (www.spss.com). The differences between the category variables were tested using the  $\chi^2$  test with Yates correction. The statistical values were considered significant at  $p < 0.05$ . By including weights, the sample became nationally representative in terms of gender, age, education and regional representation. The pondering of our data enables it to be aligned with available official data of Croatian Bureau of Statistics.

## Results

Out of a total of 3329 persons who were contacted to participate in survey 1032 completed the questionnaire (response rate of 31%). The replies of nine minors were excluded. After including weights in the statistical analysis we got the following results. The average age of the subjects was  $42.0 \pm 14.5$  years. Women made 52.4% of the total sample. Of the total sample, 251 subjects or 25.3% (95% CI, 0.22 to 0.28) had been treated in hospital in the last five years. Their answers are presented in the Table 1 together with the answers of those respondents who were not treated in hospital in the last five years. There is a statistical significance between answers in the two groups when the same question "How far are you informed about your rights as a patient?" was asked ( $p < 0.001$ ). The demographic data about both groups is also presented in the Table1. The distribution of answers by gender and age is presented in Table 2.

Table 1. Experience and Knowledge of Subjects about the Informed Consent with Demographic Data per Groups

Questions		Answers	N (%)
Have you been in hospital in the past 5 years, that is have you stayed in hospital for more than one day on at least one occasion?		Yes	251 (25.3)
		No	740 (74.7)
Subjects' demographic data		Subjects who answered YES (%)	NO (%)
Gender	Male	112 (44.6)	360 (48.6)
	Female	139 (55.4)	380 (52.4)
Age	≤ 25	20 (8.0)	135 (18.3)
	26 – 45	48 (19.0)	310 (41.9)
	46 – 65	88 (34.9)	211 (28.5)
	≥ 66	96 (38.1)	84 (11.3)
Education	Elementary school	151 (60.0)	228 (30.8)
	High school	80 (31.7)	409 (55.3)
	Further education	8 (3.3)	34 (4.6)

Higher education

12 (4.9)

69 (9.3)

Questions	Answers	N (%)
<b>Questions answered by subjects who were in hospital</b>		
How far are you informed about your rights as a patient?	Completely	36 (14.3)
	Partially	157 (62.4)
	Not at all	58 (23.3)
How far were you informed about your health, illness, procedures and risks?	Completely	62 (25.0)
	Partially	167 (62.1)
	Not at all	22 (12.9)
The level of information you received from health workers	Low	63 (24.6)
	Average	156 (66.4)
	High	32 (8.9)
Did you need to sign a consent form for medical procedures?	Yes	90 (36.0)
	No	123 (49.0)
	I don't know/I don't remember	38 (14.9)
Who made decisions on your treatment?	The doctor alone	86 (34.2)
	You and the doctor together	143 (57.0)
	You independently	22 (8.7)
<b>Questions answered by subjects who were not in hospital</b>		
How far are you informed about your rights as a patient?	Completely	58 (7.8)
	Partially	446 (60.2)
	Not at all	237 (32.0)
Are you acquainted with the concept of informed consent or agreement for medical procedures?	Completely	69 (9.3)
	Partially	401 (54.2)
	Not at all	270 (36.5)
The patient expresses their consent for individual diagnostics or therapeutic procedures by signing a consent form?	Yes	343 (46.3)
	No	81 (11.0)
	I don't know	316 (42.7)
Is a patient able to refuse a procedure after he/she has signed consent?	Yes	360 (48.6)

Would you give consent for a procedure if you were not completely informed about the illness, procedure, risks, complications and alternative methods?

No	96 (13.0)
I don't know	284 (38.3)
Yes	99 (13.4)
No	495 (66.9)
I don't know	146 (19.7)

Table 2. The subjects' replies to the question about the informed consent by gender and age

	Gender		Age			
	M	F	≤25	26-45	46-65	≥66
<b>Level of information you received from health workers</b>						
<i>Low</i>	23 (23.2)	36 (25.9)	5 (23.8)	10 (21.3)	21 (23.9)	26 (27.1)
<i>Average</i>	67 (59.8)	100 (71.9)	13 (61.9)	27 (57.4)	60 (68.2)	68 (70.8)
<i>High</i>	19 (17.0)	3 (2.2)	3 (14.3)	10 (21.3)	7 (8.0)	2 (2.1)
p*	<0.001		0.016			
<b>How far were you informed about your health, illness, procedures and risks?</b>						
<i>Completely</i>	32 (28.6)	31 (22.3)	5 (25.0)	22 (46.8)	18 (20.7)	17 (17.9)
<i>Partially</i>	62 (55.4)	94 (67.6)	14 (70.0)	21 (44.7)	62 (71.3)	59 (62.1)
<i>Not at all</i>	18 (16.1)	14 (10.1)	1 (5.0)	4 (8.5)	7 (8.0)	19 (20.0)
p*	0.121		<0.001			
<b>Who made decisions on your treatment?</b>						
<i>Only the doctor</i>	39 (34.8)	47 (33.6)	10 (50.0)	21 (44.7)	26 (29.9)	28 (29.2)
<i>You and the doctor</i>	56 (50.0)	88 (62.9)	9 (45.0)	20 (42.6)	59 (67.8)	55 (57.3)
<i>You independently</i>	17(15.2)	5 (3.6)	1 (5.0)	6 (12.8)	2 (2.3)	13 (13.5)
p*	0.003		0.014			
<b>Are you acquainted with the term "informed consent"?</b>						
<i>Completely</i>	35 (9.7)	33 (8.7)	5 (3.7)	30 (9.6)	16 (7.6)	18 (21.7)
<i>Partially</i>	176 (48.9)	225 (59.2)	60 (44.1)	183 (58.8)	128 (60.7)	30 (36.1)
<i>Not at all</i>	149 (41.4)	122 (32.1)	71 (52.2)	98 (31.5)	67 (31.8)	35 (42.2)
p*	0.017		<0.001			
<b>Is a patient able to refuse a procedure after he/she has signed consent?</b>						
<i>Yes</i>	180 (50.0)	180 (47.4)	60 (44.4)	157 (50.6)	108 (51.2)	34 (41.0)

<i>No</i>	43 (11.9)	53 (13.9)	11 (8.1)	43 (13.9)	23 (10.9)	19 (22.9)
<i>I don't know</i>	137 (38.1)	147 (38.7)	64 (47.4)	110 (35.5)	80 (37.9)	30 (36.1)
p*	0.653		0.018			
Would you give consent for a procedure if you were not completely informed?						
<i>Yes</i>	43 (11.9)	57 (15.0)	16 (11.9)	30 (9.7)	29 (13.7)	24 (28.6)
<i>No</i>	243 (67.3)	53 (66.4)	89 (65.9)	232 (74.8)	138 (65.4)	36 (42.9)
<i>I don't know</i>	75 (20.8)	71 (18.6)	30 (22.2)	48 (15.5)	44 (20.9)	24 (28.6)
p*	0.420		<0.001			

\*  $\chi^2$  test

## Discussion

Although a number of campaigns for patients' rights promotion took place in Croatia and a number of NGOs are actively involved in spreading the word about patients' rights, our results show that insufficient level of information has reached the general population. In our research more than one quarter (30%) of all our subjects stated that they do not know their rights as patients and every tenth subject stated that they know their rights completely. These findings are similar to those of Jukic et al from 2006 [9].

The replies to the question, in our survey, about knowledge of the concept of IC, by the people who had not been in hospital, showed that a third (36%) were not acquainted with that concept and a little more than half (54%) were partially acquainted. Krizova et al, in their research in the Czech Republic attained similar results that almost one third of the population did not know the meaning of the term IC [13].

One worrying thing also noticed in

our study was that every seventh subject who had been hospitalized did not know or did not remember whether they had had to sign a consent form and that half of them did not sign any IC form, which is a prerequisite for entering a hospital service in Croatia and such forms are to be found in patients' charts. Furthermore, one quarter of the hospitalized subjects reported receiving a low level of information from health workers. These results indicate the formality of IC process and discrepancy between patients' rights in terms of legislation and reality [3-5,7,14,15].

Our results also show that in one third (34%) of cases the decision on the patient's treatment was made by the doctor alone. A possible explanation offers Talanga who states that an average Croatian patient, as a result of free medical care under socialism, harbours paternalistic expectations of the health system, in the way that a physician must fulfil his duty and help patient unconditionally [16]. A significant proportion of paternalism may also be explained by

the fact that specialized doctors are on average older and their training and some of their internship was undertaken at a time when a paternalistic relationship towards patients was predominant [10].

The most subjects who were not acquainted with the IC were found amongst those with a lower level of education, those with only elementary school, and the older subjects. These groups also included the highest proportion of those who would give consent although they were not completely informed about their illness, procedures and risks. This indicates that the IC process in Croatia should be adjusted so that the patient has full understanding, regardless of their level of education or age [12,17,18].

In our research men and younger subjects received a higher level of information than women and older subjects. Younger subjects and those who were more educated were more informed, and women and subjects aged between 46 and 65 years mostly made decisions on treatment together with their doctor. These results are in accordance with the assertion that when answering the questions on IC, men and youth and more educated subjects tended to have a more autonomous attitude, whereas women, the older and the less well-educated subjects showed a traditionally submissive attitude [13].

One of the limitations of the research was the response rate of 31% which was lower than the average response rate of 53% in the USA for face-to-face surveys [19]. Low response rate can be attributed to the fact that research was conducted as

face-to-face interviews in subjects' homes with no pre-arranged time for conducting interviews. Another possible explanation could be because of the topic of survey itself, where low response rate explains relevance of these issues for Croatian people and this could go in favor of paternalism in physician-patient relationship. We have tried to avoid possible selection bias by including weights in our sample thus making it nationally representative. In our research we did not ask subjects who had been in hospital about the type of information received, their understanding and recall of the information offered, which could possibly give a more detailed explanation for our results. Finally, our study aimed at only providing the cross-sectional view of the situation in Croatia, and after they have completed the survey, respondents were not additionally educated about their rights as patients. The study did not have for its aim education of the general public.

### **Conclusion**

Several key areas should be adequately addressed and researched if we were to improve the quality of IC procedures in Croatia. The first area is the area of the quantity and the quality of the information exchange that we will address, in future research, by looking at the readability and comprehension of the IC forms. The second key area is the decision-making process that still presents some paternalistic traits. Thirdly, it should be seen how one could improve the level of general knowledge of a population about patients' rights and IC procedures.

## References

- [1]. Goldfarb E, Fromson JA, Gorrindo T, Birnbaum RJ. Enhancing informed consent best practices: gaining patient, family and provider perspectives using reverse simulation. *J Med Ethics*. 2012;38(9):546–51.
- [2]. Davis RE, Sevdalis N, Jacklin R, Vincent CA. An examination of opportunities for the active patient in improving patient safety. *J Patient Saf*. 2012;8(1):36–43.
- [3]. Act on Protection of Patients' Rights. Official Gazette no. 169/2004.
- [4]. Babić-Bosanac S, Dzakula A. Patients' rights in the Republic of Croatia. *Eur J Health Law*. 2006;13(4):399–411.
- [5]. Babić-Bosanac S, Borovečki A, Fišter K. Patients' right in the Republic of Croatia – between the law and reality. *Med Glas (Zenica)*. 2008;5(1):37–43.
- [6]. Borovečki A, Babić-Bosanac S, ten Have H. The status of the implementation of the Act on the protection of patients' rights in Croatia - a pilot study. *Rev Rom Bioet*. 2010;8(3):136–48.
- [7]. Frković A, Zec Sambol S. Informed consent u opstetriciji [Informed consent in obstetrics]. *Synth Philos*. 2002;22:549–55. Croatian.
- [8]. Jukic M, Kvolik S, Kardum G, Kozina S, Tomic Juraga A. Knowledge and practises of obtaining informed consent for medical procedures among specialist physicians: questionnaire study in 6 Croatian hospitals. *Croat Med J*. 2009;50(6):567–74.
- [9]. Jukic M, Kozina S, Kardum G, Hogg R, Kvolik S. Physicians overestimate patient's knowledge of the process of informed consent: a cross-sectional study. *Med Glas (Zenica)*. 2011;8(1):39–45.
- [10]. Banic M, Kardum D, Plesko S, Petrovecki M, Urek M, Babic Z et al. Informed consent for gastrointestinal endoscopy: a view of endoscopists in Croatia. *Dig Dis*. 2008;26(1):66–70.
- [11]. Rušinić-Sunara Đ, Lugović G, Belicza B, Radovančević Lj, Liović J. [Responses given by patients and health workers in the Republic of Croatia to the Proposed Draft Act on the Rights, Obligations and Responsibilities of Patients – pilot research]. *Medix*. 2004;54/55:162–6. Croatian.
- [12]. Giampieri M. Communication and informed consent in elderly people. *Minerva Anesthesiol*. 2012;78(2):236–42.
- [13]. Krizova E, Simek J. Theory and practice of informed consent in the Czech Republic. *J Med Ethics*. 2007;33(5):273–7.
- [14]. Gazdek D. Informirani pristanak u liječenju ovisnosti o opijatima [Informed consent in opioid dependence treatment][dissertation]. [Zagreb], University of Zagreb; 2011. Croatian.
- [15]. Brezis M, Israel S, Weinstein-Birenshtock A, Pogoda P, Sharon A, Tauber R. Quality of informed consent for invasive procedures. *Int J Qual Health Care*. 2008;20(5):352–7.
- [16]. Talanga J. Odnos liječnika i pacijenta prema medicinskoj etici [The relationship of doctor and patient toward the medical ethics]. *Bogoslovska smotra*. 2006;76:47–59. Croatian.
- [17]. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *JAMA*. 2004;292(13):1593–601.
- [18]. Paillaud E, Ferrand E, Lejonc JL, Henry O, Bouillanne O, Montagne O. Medical information and surrogate designation: Results of a prospective study in elderly hospitalised patients. *Age Ageing*. 2007;36(3):274–9.
- [19]. Galešić M. Utjecaj dužine upitnika na anketni odaziv [Effect of questionnaire length on survey response rate]. *Društvena Istraživanja*. 2003;12:807–24. Croatian.