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Assessment

The quality of informed consent in Croatia—a cross-sectional study and instrument development

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ABSTRACT

Objective: To examine the informed consent process implementation and quality in Croatia using a specially developed instrument.
Methods: A cross-sectional questionnaire study was conducted in 300 patients (response rate 73%) from six hospitals in Croatia, along with psychometric evaluation of the questionnaire.
Results: Signing the informed consent form was a formality for 64% of patients, 54% of patients did not give their written consent, and in 39% of cases physicians made treatment decisions by themselves. The overall informed consent process score was 4.06 ± 0.60 (of 5.00). Physician–patient relationship score was 4.61 ± 0.57, Verbal information 3.99 ± 0.98, Decision making 3.94 ± 0.75, and Written information 3.60 ± 1.42. The overall Cronbach's alpha coefficient was 0.890. Significant correlations were found in relation to Physician–patient relationship and education levels (OR = 0.43, 95% CI = 0.18–0.99, $p = 0.048$), and Verbal information and duration of health problems (OR = 1.83, 95% CI = 1.02–3.25, $p = 0.041$).
Conclusion: The developed questionnaire is reliable and valid. The informed consent process quality in Croatia was reasonably high, although insufficient and inadequate written materials represent a weak spot that require enhancement.
Practice implications: The study contributes to the development of suitable measuring instrument for assessment of the informed consent process quality in clinical practice. The questionnaire could be of use in the hospital accreditation process.

1. Introduction

The practice of obtaining informed consent is well-accepted in everyday clinical practice and clinical trials although it often fails to achieve its purpose. Despite the fact that patients have actually not received all the relevant information regarding management of their health, they often think they are sufficiently well informed [1]. Furthermore, the level of patient comprehension is often not satisfactory and they cannot fully recall information provided [2–4]. Physicians should be involved in the informed consent process [5], however it has been confirmed that although physicians explicitly support the patient's right to autonomous choice, they pay little attention to it in everyday clinical practice [6,7]. Physicians often make decisions without discussing the treatment details with patients [8]. Additionally, they often tend to overestimate the patient's understanding of the care plan, which may affect the informed consent process [9]. It is evident that the quality of the informed consent process depends on a variety of factors, where it seems that a high quality of informed consent is sometimes difficult to achieve and even more difficult to quantify.

Achieving good-quality informed consent can prove to be even more challenging in countries still in transition, such as Croatia [10]. Studies show that there is often a discrepancy between the legislation and the actual position of patients, who, despite enacted laws, are not always in the focus of healthcare delivery [11,12]. According to the Croatian legislation, the Act on the Protection of Patients' Right, informed consent is defined as the right to co-decide, including the right to be fully informed and the right to accept or refuse a particular diagnostic or therapeutic

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procedure [13]. The patient has the right to all information regarding his or her health condition, planned medical procedures, and all the risks and complications of refusing and accepting them [13]. To ensure complete comprehension of planned medical treatment, the information provided must be understandable, in a form adjusted to the patient's age, education and mental abilities [13]. Only after having received and fully understood all the information should patients express their acceptance or refusal of a medical procedure by signing the consent form [13]. According to the Croatian legislation informed consent is required for all diagnostic and therapeutic procedures [13] without distinguishing ordinariness, invasiveness and the procedure risk level.

The process of accreditation of Croatian hospitals has, as one of its components, the monitoring of the quality of the informed consent procedures in hospitals [14]. However, this process is in its beginning phases and little is known about the actual data collected from different hospitals, if they exist at all. Therefore, we decided to embark on an in-depth evaluation of the informed consent process in Croatian hospitals. The aim of this study was to examine the implementation and quality of the informed consent process in clinical practice in Croatia. We also wanted to determine whether there were differences on the informed consent process between different hospitals, and if certain socio-demographic and clinical variables could predict the quality of the informed consent process. Moreover, for our study we developed an instrument that may be of use in refinement to the process of accreditation, especially the part that deals with the quality of the informed consent procedure. To the best of our knowledge, apart from in Slovakia [15], the issue of informed consent has not been systematically studied in hospitals in the transition countries of Central and South-eastern Europe. We hope that our research can shed light on many issues important for countries in transition, using Croatia as a model.

2. Methods

2.1. Sample

The survey was conducted with a sample of 300 patients from six hospitals in Croatia, using an independently created questionnaire. The hospitals were randomly selected based on the national list of hospitals, taking into account the geographical distribution of Croatia into 6 geographical statistical regions, taking one hospital from each region. The hospitals were divided to two groups. Three of the six hospitals were university, highly specialised teaching hospitals on the tertiary health-care level, where the most complex medical procedures and scientific research are performed, involving different subspecialties and highly differentiated and sophisticated equipment. The other 3 hospitals were general regional hospitals on the secondary health-care level that provide in-patient care and consultation for primary care. In each hospital we selected 5 departments using a computer program for randomisation. Prior to randomization paediatric departments, psychiatric departments, and intensive care units were excluded. The participants for the study were patients who spent more than two days in hospital for a variety of diagnostic and/or therapeutic procedures, and who voluntarily agreed to fill in the questionnaire anonymously before being discharged from the hospital. Patients without the capacity to consent were excluded from the study.

2.2. Instrument

The authors developed the questionnaire on the basis of the instrument used in the preliminary studies [16,17], previous research on the informed consent process in clinical practice [3,15,18], and the current legislation [13]. The authors had performed two preliminary studies [16,17]. Through 11 questions in the first study the authors examined the experience and knowledge of the general population about informed consent on a nationally representative sample [17]. The second study was conducted in 5 tertiary level hospitals in the City of Zagreb, with a questionnaire containing 32 items dealing with patients' rights, 20 of which dealt with Physician–patient communication and the informed consent process, 6 with the Physician–patient relationship, and 6 with other patients' rights, such as the right to privacy and confidentiality [16]. To assess informed consent as a unified concept we extracted the questions about the informed consent process from previous questionnaires and included additional questions (e.g. dealing with Written information). The first part of the questionnaire contained 41 statements related to the informed consent process including: disclosure of information, Decision-making and the Physician–patient relationship. We used a 5-point Likert scale with the following ratings: 1 (strongly disagree), 2 (partially disagree), 3 (neither agree nor disagree), 4 (partially agree) and 5 (strongly agree). Bias agreement was avoided by varying the direction of the statements. The second part of the questionnaire contained items dealing with socio-demographic data and questions about who informed patients and where, and who gave consent forms to them. Prior to the research, pilot testing was conducted on 30 subjects to verify the user-friendliness of the questionnaire.

2.3. Data collection

Data was collected by the interviewers. The interviewers were physicians who were not involved in healthcare delivery in the selected departments in each hospital, except in the one fifth of cases. The questionnaire was conducted in the remaining one fifth of cases by physicians involved in the respective patients' care, because the authors needed help in conducting the questionnaire from colleagues employed in the selected hospitals, due to wide distribution of hospitals throughout Croatia and the extensive scope of work. They paid visits to each of the selected departments and, in consultation with a departmental doctor or nurse, learned which patients were to be discharged. If the patients met the inclusion criteria, the interviewer approached them, providing a thorough explanation of the research, offering participation in the study and handing them the questionnaire. If the patient refused to fill out the questionnaire, the interviewer would offer the questionnaire to the following eligible patient, repeating the process, until the required number of 10 completed questionnaires per department, that is a total of 50 questionnaires per hospital, was collected.

2.4. Statistical analysis

Descriptive analysis of the socio-demographic data was performed with a sample of 300 respondents. To achieve unidirectional positive orientation of all the answers on the Likert scale, several statements (statements 3, 7, 18, 20, 24, 26, 30, 31, 34, 37, 38, 39, 40, 41) were recoded prior to any further analysis. The frequencies were calculated for all 41 questionnaire statements. Factor analysis on the data was also performed, along with descriptive analysis. Initially, exploratory factor analysis was conducted to reduce the number of variables using principal component factor analysis, Kaiser's rule, Cattell's scree plot and Varimax rotation. Based on the proportion variance explained, we excluded the following statements from further processing: 3, 14, 17, 20, 21 and 30. Statement number 13 was also omitted from further analysis because of the high percentage (9.7%) of no response. Performing exploratory factor analysis was insufficient,