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Short Communication

Are Patients Willing to Be Informed on the Risks and Complications Associated with the Proposed Therapy? A Survey on Informed Consent

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Abstract

Introduction: Informed consent is essential to the patient-physician relationship. The paternalistic old-time approach used by physicians to achieve the optimal management is changing today; detailed medical information must be disclosed to the patients regarding their health problem.

Aim: The aim of this study was to highlight the value of informed consent in the context of medical practice as well as to emphasize its importance through the prism of human rights.

Materials and methods: A patient survey was conducted in two public and one private hospitals in Greece. Eighty-three inpatients from the Surgical Departments of Democritus University Hospital of Alexandroupolis (DUHA), Laikon University Hospital of Athens (LUHA) and a private hospital were included in the study. A questionnaire regarding patients' attitude towards informed consent was distributed to patients prior to surgery.

Results: The majority of the patients (63.86% in DUHA, 59.38% in LUHA, and 78.95% in the private hospital) opted for full disclosure regarding the course and development of their condition.

Conclusion: Patients want to be informed about their treatment options and possible complications so that they can make decisions about their treatment after a comprehensive and understandable discussion.

Keywords

informed consent, patient survey, risk, surgical intervention

INTRODUCTION

Nowadays, fundamental ethical and philosophical aspects are involved in patients' management portrayed through the establishment of the informed consent (IC). IC is an ethical concept by which the physician discloses appropriate information to a patient so that the patient may make a voluntary choice to accept or refuse treatment.[1] According to Merriam-Webster, IC is "consent to surgery by a patient, or to participation in a medical experiment by a subject after achieving an understanding of what is involved".[2] The context of IC can take many different forms, for different treatment interventions ranging from active request by a patient of a particular treatment to passive acceptance.

Three fundamental criteria are needed for IC, i.e., the patient's competency, adequacy and not coercing. Patients must have the capacity to understand and assess the provided information, to communicate their choices as well as to understand the consequences of their decision. The physician's role is to provide adequate information with the minimum being the diagnosis and to give a clear explanation about the medical procedure with its risks, benefits, and alternatives, along with their benefits and risks.

Independently of the types of the procedures performed (i.e., biopsy, endoscopy, etc.) to major interventions (i.e., laparoscopic cholecystectomy, colorectal surgery, partial hepatectomy, etc.) ascertaining the patient's approval through the IC is imperative.[3] The development of the IC term may lead to conflicts between doctors and patients, but the final outcome should be the collaboration that will ascertain the fine balance between the physician acting on the patient's best medical interest while respecting his human rights.[4-6]

Enormous steps towards optimization have been reported from the ancient times to the Amsterdam declaration. In ancient Greece, patient's perception and opinion was considered undesirable during medical interventions.[7] The physician's responsibility was to inspire confidence in patients, while disclosing complications may create problems in the physician-patient trustful relationship.[4] During the medieval period, interaction among the patient and the physician was encouraged in order to establish trust.

The Amsterdam Declaration is the first collective and organized attempt within the EU which ensures the patient's right to IC. Several articles are included in the declaration, highlighting the principles under which the physician-patient relationship should be established and also the circumstances under which IC may not be required.

Many studies present the necessity of IC.[9-15] In the 18th and 19th centuries, the concept of assault originated from English common law and established new legislative procedures, e.g., surgeons should obtain patient's authorization prior to operation.[6] In the 20th century, medical decision-making methods that encompassed patient-centric characteristics were opted for, and IC could be provided voluntarily by patients.[16]

There is no doubt that medical ethics exert a substantial impact on medical practice. IC, constituting an expression of medical ethics, should weigh patient and physician requirements and needs. Despite the physicians' attempts to delineate medical interventions, patients and also legal representatives lack the scientific background to fully comprehend the disclosed information, and therefore, possible complications may arise.[6]

It is widely acceptable for patients to provide authorization in the form of 'signature' prior to surgery. However, according to Jones et al.[17] "this is not just a signed form". The role of physicians in engaging patients to complete an IC form requires more than clinical skills. Interestingly, despite the large number of studies published on the role of physicians, less data is available on the patient's attitude toward IC, its completion, and their respective understanding of the document that has been provided to them for approval.

AIM

This is a preliminary study in two public and one private hospitals. The aim was to highlight the value of IC in the context of medical practice as well as to emphasize its importance in order to get the best therapeutic result for the patient and develop a trustful relationship between patient and physician which would promote a better medical outcome.

MATERIALS AND METHODS

A questionnaire regarding patients' attitudes towards IC prior to surgery was designed **(Table 1)**. The questionnaire was distributed to inpatients from Surgical Departments of two public hospitals, Democritus University Hospital, Alexandroupolis (DUHA) and Laikon University Hospital of Athens (LUHA), and one private hospital.

Inclusion criteria were Greek speaking inpatients in the three hospitals. Patients with mental and psychological instability were excluded, as well as alcohol users or patients who demonstrated any negative psychiatric symptom. Eighty-three eligible subjects met the inclusion criteria of our study and agreed to complete the developed questionnaire.

Variables

Age, gender, marital status, education level, occupational status of the inpatients, type of surgery as well as the patient's medical history were selected as independent variables. The patient's general perception of the questions posed by the applied questionnaire was determined as dependent variable in our study.

Table 1. Questionnaire on patients' attitudes towards content of the IC form to be completed prior to surgery

Question	Would you prefer the IC document that you have to sign prior to being subjected to a surgical procedure to list in detail the following: Complications, risks, possible development, information on mortality/morbidity, consent for retrospective use of serum and tissue postoperatively?
Answer A	Yes, because this way I can know the course and potential development of my condition
Answer B	No, because I do not have the knowledge in order to understand medical terms and consent
Answer C	I am not certain. I am worried that requesting all these details might lead to negatively affecting my treatment.
Answer D	No, because the prospect of a potential unpleasant development is upsetting
Participants	83

Ethical considerations

The study was conducted following all the fundamental ethical principles. Particularly, full confidentiality and anonymity of the participants were ensured and the data obtained were used only for the purposes of this study. The study questionnaire was approved by the Scientific Committee of Democritus University Hospital, Alexandroupolis (781/03-09-2019), which allowed the collection of data, while also ensuring that participants signed a written consent form enabling recruitment and ensuring participation in the study.

Statistical analysis

The data were statistically analyzed using Bayes factor (BF). The Bayes factor quantifies the evidence in favour of one statistical model compared to another. Mathematically, it is defined as the ratio of two marginal likelihoods: the likelihood of the data under the null hypothesis (H0) and the likelihood of the data under the alternative hypothesis (H1). When BF is between 1 and 3, the strength of the evidence in favour of H1 is weak and barely worth mentioning. If BF is between 3 and 20, the evidence for H1 is positive (substantial). When BF is between 20 and 150, there is strong evidence for H1, and when it is >150 there is very strong (decisive) evidence for H1. Of course, when BF<1, the evidence supports H0.[18]

RESULTS

Eighty-three inpatients (n=83), aged between 18-79 years, from the Surgical Departments, agreed to participate. Sixty-four participants (n=64) replied from the two public hospitals, and nineteen participants (n=19) from the private hospital.

Table 2 presents the number of responses both for all participants and divided into public and private hospitals. A strong prevalence of answer A is observed in both patient groups; however, the prevalence of answer A is statistically higher among participants of public surgical departments, respectively 46% vs. 18% of total answers (**Table 2)**. Patients are keen on ensuring they are aware of the risk factors and potential complications and outcomes of the therapeutic approach.

The results presented in **Table 3** indicate a strong prevalence of answer A in all cases, as well as lack of significant change of opinion between participants from surgical departments of private and public hospitals (**Table 3**: Public Private Difference Bayes Factor).

As shown in **Table 3**, the combined Bayes Factor computed for the answers received from public and private surgical departments of hospitals is 31.488, which means that the hypothesis is strongly supported by the data. The Bayes Factor achieved for the answers provided in the surgical departments of public hospitals is 22.0 (38/64) meaning that the hypothesis is strongly supported by the data. The answer provided by the surgical department from the private hospital achieved a Bayes factor of 23.2 (15/19), which indicates that this hypothesis is strongly supported by the data. This translates into very strong support for answer A. By comparing the answers between both patient groups, it is concluded that there is no difference in the distribution of answers between public and private surgical inpatients because the Bayes factor (**Table 3**: Public Private Difference Bayes Factor) used to distinguish between public and private surgical departments is 0.1.

Table 2. Number of responses received on each option of the questionnaire's responses by patient group

Responses	A	B	C	D
Mixed group participants from Surgical Departments of Public and Private Surgical Departments	53	13	13	4
Participants from Surgical Departments of Public Hospitals	38	11	11	4
Participants from the Surgical Department of Private Hospital	15	2	2	0

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Table 3. Questionnaire variables and their respective values

Parameter	Explanation	Value
Maximum total answers	Answer which received most selections (participants from both public and private hospitals)	A
Maximum total count	Number of selections and percentage of prevailing answer compared to total answers (participants from both public and private hospitals)	53 out of 83 – 63.855%
Total difference from united sample utilizing the Bayes factor calculation	Bayes factor (BF) which indicates that there is strong evidence for the specific answer in relation to the even distribution (participants from both public and private hospitals)	31.488
Maximum public answers	Answer which received most selections (participants from public hospitals)	A
Maximum public count	Number of selections and percentage of prevailing answer compared to total answers (participants from public hospitals)	38 out of 64 – 59.375%
Public difference from united sample utilizing the Bayes factor calculation	Bayes factor (BF) which indicates that there is strong evidence for the specific answer in relation to the even distribution (participants from public hospitals)	22
Maximum private answers	Answer which received most selections (participants from private hospitals)	A
Maximum private count	Number of selections and percentage of prevailing answer compared to total answers (participants from private hospitals)	15 out of 19 – 78.947%
Private difference from united sample utilizing the Bayes factor calculation	Bayes factor (BF) which indicates that there is strong evidence for the specific answer in relation to the even distribution (participants from private hospitals)	23.2
Public private difference Bayes factor	Bayes factor for the difference of distribution of answers between participants from private and public hospitals.	0.1

DISCUSSION

To the best of our knowledge, this is the first study conducted in Greece whose main principle is the modern physician-patient interaction, aiming to highlight the need of developing an IC form which, on one hand, would respect the patient and his rights, and on the other hand, would legally ensure the physician. This is a preliminary study in two public and one private hospitals in Greece which will be expanded in the future as a prospective study that would include additional questions and more public and private hospitals.

Based on the results of the questionnaire, patients want to be informed about their treatment options, and possible complications and risks entailed in the therapeutic intervention, so that they can make decisions about their treatment after a detailed update by their physician. Patients also opt for all respective information to be included in the IC form, so that they can defend and claim their absolute right to autonomy.

There is extensive literature on human rights in relation to clinical research, clinical trials, and placebo use which sets out rules on patient participation and protection. In such cases, the patient must be informed about the study, the risks and the anticipated results, and has also the right to withdraw from the study at any instant. Patient rights are defined, among others, by the Helsinki and the Tokyo Declaration, and the World Medical Association.[19,20] In the present study, however, we refer to the great need to protect the patient, not only when participating in clinical research, but also when undergoing any treatment such as surgery, emphasizing that he must know everything about the treatment and the possible complications.

Following the paternalistic approach to managing patients during the last century, the concept of IC has been unravelled based on moral and legal rules.[21,22] In the new era, physicians with patient support should develop a complete IC form which will give all possible information about the complications and the proposed treatment.[23]

A transition from the concept of simple consent to the IC has been described throughout the decades.[24] Simple consent was introduced as a straightforward tool to acquire patient's approval. It constituted a simple question concerning the treatment method that the patient was required to answer with a yes or no, in order to determine if an agreement was established and the surgeon could proceed with performing the operation.[3]

The driving force for the evolution of consent originated from patient's dissatisfaction and frustration that provoked subsequent complaints in regard to the outcome of the operation. Due to the lack of thorough explanation of

the medical procedure or omissions in interpretation of the anticipated consequences following intervention, patients were prone to complain about the outcome.[25] Despite the complaints and the financial cost entailed in compensation claims by patients, the analysis of medical complications provides certain advantages. Not only does it establish a strong relationship between patients and their physicians, but it further improves the credibility of physicians by allowing them to relieve patients' psychological distress and burdens.

Another important component and ethical point of disclosure adequacy is the shared decision-making process (DMP), in which clinicians may collaborate to support patients during evidence-based, informed and consistent medical decisions.[26] The author of the Georgetown bioethics model envisages the five regional elements IC consists of: the surgeon discloses important information, recommends the plan and promotes understanding in order for patients to conclude on approving the plan and authorize the surgeon.[27] At the same time, decision could improve the effectiveness of DMP, since they assist patients to make informed medical decisions based on their personal values and preferences.[25]

From the bioethical perspective, the role of both physicians and patients and its interpretation in an IC has been investigated. Legally, the role of physicians is considered more essential. It is crucial for patients to understand that a prerequisite to exercising autonomy rights is to comprehend procedure details and risks enclosed by physicians. Adjustments to patients' needs and unique characteristics should be made in order to ensure transparency and full disclosure.

Discrepancies amongst legislation in various countries further highlight the various perspectives on the role of IC. According to the German legislation, certain medical procedures, especially in cases of non-therapeutic drugs, require extended information about risks or complications. These risks or complications should have an estimated minimal statistical probability and a detailed status. In Greece, failing to disclose medical complications results in 9 cases of violation of legal consent, which is a *stricto sensu* medical error. In Anglo-American law, physician responsibilities in providing information are distinguished between hypothetical and established consequences.

Interestingly, in English courts, providing inadequate information to the patient is interpreted as a failure by the patient's side to comply. Thus, physicians may not face severe consequences nor be convicted in such cases. This attitude by the English courts has been criticized since the best interests of the patients are neglected.[28] On the contrary, in Greek courts, along with other European courts, the degree of responsibility of the doctor in failing to inform the patient does not affect the legal consequences.[23] As a result, the doctor shall compensate the patient with the same amount for damages as in the case of negligence or fraudulence.

Prior to the IC era, patient's autonomy was devalued in numerous ways. Since then, physician attitudes have been challenged and modified accordingly as dictated by the societal and legal norms. There have been many interpretations of the "meaning" of IC, with the legal definition of IC still being vague, due to the uncertainty related to risk disclosure under legal, ethical and clinical consideration. As it was described in the current study, a detailed IC from patients is required. Additionally, patients should be able to comprehend all the information provided by physicians, concerning their treatment. It is proven that undisclosed risks associated with medical procedures on one hand may jeopardize the physician-patient relationship, and on the other hand they may be interpreted as a violation of patient rights.

CONCLUSIONS

Patients want and must understand the severity of the medical problem before accepting or refusing the recommended therapy. Physicians must inform the patient meticulously in order to have a written approval, while at the same time strengthening the patient-physician relationship. If there is no signed consent by the patient, physicians are not allowed to perform any medical intervention, except for certain cases which are justified by law.

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Готовы ли пациенты узнавать о рисках и осложнениях, связанных с предлагаемой терапией? Обзор информированного согласия

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Резюме

Введение: Информированное согласие необходимо для взаимоотношений пациента и врача. Старомодный покровительственный подход, используемый врачами для достижения оптимального контроля над заболеванием, в наши дни меняется. Пациентам должна предоставляться подробная медицинская информация, касающаяся их проблем со здоровьем.

Цель: Цель этого исследования заключалась в том, чтобы подчеркнуть важность информированного согласия в контексте медицинской практики, а также подчеркнуть его важность через призму прав человека.

Материалы и методы: Исследование проводилось среди пациентов двух государственных и одной частной больниц в Греции. В исследование были включены 83 пациента из хирургического отделения Демокритской университетской больницы Александруполиса (ДУБА), Университетской больницы Лайкон в Афинах (УБЛА) и частной больницы. Пациентам был предложен вопросник об их отношении к информированному согласию до операции.

Результаты: Большинство пациентов (63.86% в ДУБА, 59.38% в УБЛА и 78.95% в частной больнице) выбрали полную информацию о течении и развитии своего состояния.

Заключение: Пациенты хотят быть проинформированными о вариантах лечения и возможных осложнениях, чтобы они могли принять решение о своём лечении после подробного и понятного обсуждения.

Ключевые слова

информированное согласие, опрос пациентов, риск, хирургическое вмешательство