Original paper

Sensitive elements in the patient's giving consent to a Health Service

Newralgiczne elementy w procesie wyrażania przez pacjenta zgody na świadczenie zdrowotne

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Słowa kluczowe: pacjent, pouczenie terapeutyczne, świadoma zgoda pacjenta, formularz świadomej zgody.

Abstract

Introduction: The study rolled out in the hospitals in 2019, which covered both informed consent forms to high risk procedures, as well as surveys on the patients' knowledge on their right to give an informed consent to treatment, has provided vital information on the key elements required to legally proceed in the process of making therapeutic decisions.
Aim of the research: The survey asked the respondents about their command of the rules to give consent to a high-risk medical surgery or procedure.
Material and methods: A scientific study was rolled out in 2 hospitals in the Świętokrzyskie voivodeship and was aimed to assess informed consent forms to medical procedures (surgical or high-risk ones). Concomitantly, data on the patients' state of knowledge on their right to make an autonomous, informed decision to undergo a specific medical procedure, preceded by doctor-patient communication, were gathered in a research tool, a survey developed by its authors.
Results and conclusions: The study has shown that in the process of giving consent to treatment carrying high risk for the patient, the very elements of the tool, i.e. the informed consent form, used to receive this type of declaration in writing (as required by the Polish legislature), and equally their content and how this information is conveyed to the patient, are of pivotal importance in giving legally effective consent to a medical procedure.

Streszczenie

Wprowadzenie: Przeprowadzone w szpitalach w 2019 roku badania, które objęły zarówno formularze świadomej zgody na zabiegi o podwyższonym ryzyku, jak i ankiety na temat poziomu wiedzy chorych w przedmiocie prawa do wyrażenia świadomej i poinformowanej zgody na leczenie dostarczyły istotnych informacji w zakresie kluczowych elementów wymaganych do zgodnego z prawem procedowania w procesie podejmowania decyzji terapeutycznych.
Cel pracy: W ankiecie na temat znajomości zasad udzielania zgody na wykonanie zabiegu indagowano respondentów na temat ich znajomości zasad dotyczących wyrażania zgody na operację lub zabieg o podwyższonym ryzyku. Ustalano także, czy pacjenci są świadomi istnienia dla personelu medycznego prawnych konsekwencji na wypadek niewłaściwego procedowania w procesie wyrażania zgody oraz jakie czynniki stanowią dla nich kluczowy element decyzyjny w tym procesie.
Materiał i metody: W dwóch szpitalach województwa świętokrzyskiego przeprowadzono badanie naukowe obejmujące ocenę formularzy świadomej zgody na zabiegi medyczne operacyjne lub o podwyższonym ryzyku dla pacjenta. Równolegle w jednym z dwóch wskazanych szpitali, wieloprofilowym, pośród losowo wybranych pacjentów oczekujących na tego rodzaju procedurę medyczną zebrano na podstawie narzędzia badawczego – autorskiej ankiety – dane na temat poziomu wiedzy chorych co do prawa do podjęcia autonomicznej, świadomej i poprzedzonej wymaganym pouczeniem terapeutycznym decyzji o poddaniu się procedurze medycznej.
Wyniki i wnioski: Przeprowadzane badania wykazały, że w procesie wyrażania zgody na stwarzające dla pacjenta podwyższone ryzyko leczenie zarówno same elementy narzędzia, jakim jest formularz świadomej zgody, wykorzystywany do odbioru tego rodzaju oświadczenia na piśmie, czego wymaga w polskim prawie ustawodawca, jak i w równym stopniu ich treść oraz sposób przekazania pacjentowi tych informacji mają kluczowe znaczenie dla udzielenia prawnie skutecznej zgody na procedurę medyczną.

Introduction

A legally effective patient's consent to a medical procedure, i.e. consent sanctioning a doctor's activity, is one which illustrates the patient's own, informed, free, and voluntary decision. Any of these pertinent elements being absent gives rise to a non-consent-based medical procedure, which meets the criteria for an offence against Article 192 (1) of the Penal Code [1]. One of the conditions for consent to be effective is that it is preceded by specific, intelligible, and comprehensive doctor-patient communication. It is for the patient, in giving their consent, to understand what kind of treatment they are being offered and to compare alternative methods, and to opt for the one they consider best. With respect to surgical or high-risk procedures, the legislature requires written consent, which makes the medical staff use forms in the process that contain information on the medical offer to the patient. Because legally effective consent must be informed, whether the proposed treatment method is legitimate depends on both the content of the form (which should contain the elements the legislature requires) and how well its components are understood, which is the patient's degree of awareness while giving the consent.

Aim of the research

The aim of the conducted research was an in-depth exploration of the issue of consent to health services from the recipient of the consent (the doctor) and the patient providing the consent. Consent for a medical procedure is a part of the process in which the recipient and the patient participate, and it is a critical element of sanctioning the agreed upon medical intervention. During this process, the patient entrusts the doctor with their health and life. The legal effectiveness of the consent depends on the level of understanding of the character and the matter of the consent provided by both parties of the therapeutic relationship.

Material and methods

Between June and July 2019, a scientific study was rolled out in 2 hospitals in the Świętokrzyskie voivodeship, aimed at assessing informed consent forms for medical procedures (surgical or high risk). Concomitantly, data on the patients' state of knowledge on their right to make an autonomous, informed decision to undergo a specific medical procedure, preceded by doctor-patient communication, were gathered in a research tool – a survey developed by its authors. The data came from random patients awaiting such procedures in one out of 2 hospitals (one multi-profile and one oncological hospital). With prior approval from the relevant Bioethics Commission, the study provided vital information on the key elements necessary to lawfully proceed with the medical decision-making. Informed consent-related documentation relevant for the pertinent hospitals (multi-profile and oncological) was analysed in the part concerning the assessment of compliance with the law. The consent covered such procedures as: central venous cannulation, subcutaneous mastectomy with simultaneous reconstruction with a prosthesis/expander, excision of the head of the pancreas with duodenum, opening of the abdominal cavity, or X-ray examination with oral or rectal administration of a contrast agent. The above-mentioned activities were combined with the assessment of the knowledge of the patients accepted at the multi-profile hospital to undergo high-risk treatment, who awaited a pre-scheduled surgery at the hospitals' wards, on the legal requirements of the institution of the consent and certain motives of the patients in deciding to undergo a specific medical procedure.

Analysis

The survey asked the respondents about their command of the rules to give consent to a high-risk medical surgery or procedure. They were asked whether the communication came from the doctor to perform the specific procedure and whether the said communication was exhaustive, comprehensible, and important from the perspective of giving, or not, such a consent. It was also discerned whether the patients were aware of the legal effects the medical staff would face if they proceeded inadequately in the process of giving consent, and what factors were the key elements for them in the process. A total of 128 patients were incorporated in the study. The respondents were 57 years old on average. The respondents were female (59) and male (65) – 4 persons did not provide their gender, and they came from various hospital wards, in particular from ophthalmology (49), orthopaedics (14), and surgery (14). Most of them declared to have completed vocational (37) or high-school education (32).

The majority of respondents (91.4%) declared they knew the rules of giving consent to a high-risk medical procedure. Merely 10 persons (7.8% of the sample) did not confirm having received any doctor-patient communication. When asked if the communication was intelligible, 50 respondents (39% of the sample) denied, and every fifth (21%) defined the communication as vital in the process of giving consent. At the same time, fewer than every fifth survey participant (19.5%) declared their consent to a specific procedure had been conditional on the content of the preceding communication. A total of 58.6% of the respondents declared they knew the legal effects the medical staff might face. When it comes to the motives behind the decision to undergo a particular procedure, it was, most of the time, a desire to be operated on by a particular doctor (62.5%) or at a given healthcare entity (28.9%).

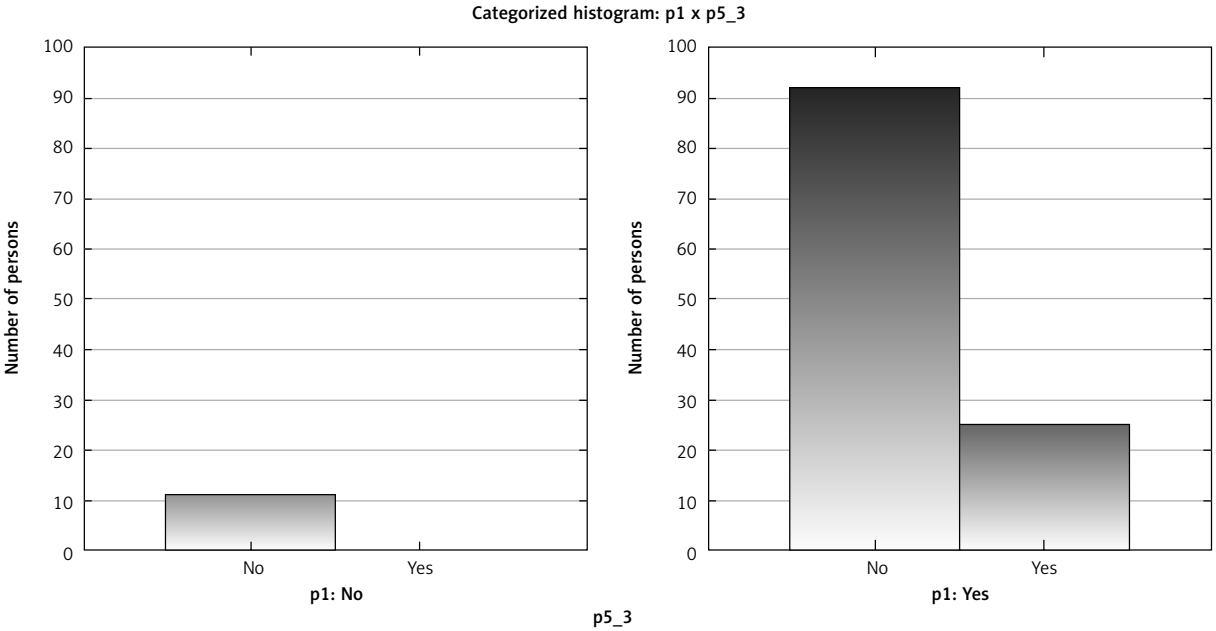

Figure 1. The relationship between declared command of the rules of giving consent to the health service and the content of doctor-patient communication

The analyses showed no significant relationship between command of the rules of giving consent to a medical procedure and the role that the doctor-patient communication plays for the patient. This is because none of the persons who denied knowing the rules of giving consent to high-risk treatment made such a consent conditional on the content of the communication. There is only low correlation evident between a declared command of the rules of consent for the procedure and making it conditional on the content of the communication. Nevertheless, only a minority (21.37%) of the persons claiming to be knowledgeable about the rules made their consent to surgery conditional on the content of doctor-patient communication (Figure 1).

A total of 150 documents from 3 healthcare entities were incorporated into a parallel study on whether the forms of informed consent to a medical surgery or a high-risk procedure comply with relevant laws. In accordance with relevant provisions, doctor-patient communication should include intelligible information on the patient's health condition, the diagnosis, on the proposed and feasible diagnostic and treatment methods, foreseeable consequences they entail if used or abandoned, treatment outcome, and prospects. The quality of the forms in question was analysed to ascertain whether they comply with normative requirements as for their content. Almost all the documents (148 out of 150) provided insight into the diagnostic methods proposed to the patients. At the same time, however, information on alternative treatment methods was provided by one-third only. The vast majority, 116 out of 150 forms, included information on diagnosis, but almost none (148) had an element on the patient's medical condition. In 143 forms, the doctors showed the anticipated consequences of the medical procedures that the patient was to embrace. At the same time, 99 forms ignored the foreseeable consequences of abandoning the procedures. An overwhelming majority of forms did not include data on treatment outcome (127 out of 150) and prospects (97 out of 150).

The survey showed that only one-fifth of the respondents declared that doctor-patient communication played an important role in their decision-making process. More than half of the respondents stated that the decision to undergo a certain procedure was based on who was to perform it, which confirms the important role of the doctor in the therapeutic process and the special nature of the trust-based relationship between the doctor and the patient. The pertinent forms of consent to a medical procedure were found non-compliant with the legislature's requirements. Above all, they missed out on intelligible information on the patient's condition, the former being crucial in the process of giving consent to a risky medical intervention. Furthermore, the lack of information on alternative diagnostic methods did not allow the patient to make a decision on a specific treatment method. Almost two-thirds of the forms failed to mention the risk of abandoning the proposed medical procedure, with this risk appearing to be as important as the risk of performing the procedure. Most of the documents did not include data on the prospects and expected outcome of treatment, which was also what the legislature required.

In the absence of a legal definition of surgery and high-risk procedures, a relatively objective approach should be adapted in identifying the categories. It should, however, include certain subjective medical determinants relating to a particular patient. A surgical procedure may be characterised as a procedure performed inside an operating theatre as construed by the Appendix to the Ordinance of the Minister of Health of 26 March 2019 on Detailed Requirements on the Facilities and Equipment at a Healthcare Entity (codified text in Journal of Laws [Dz. U.] of 2022, item 402), but a high-risk procedure can be any procedure performed on a patient with numerous comorbid conditions. Legal authors claim that the border line between regular and high-risk procedures is blurred and the degree of risk attributable to a given procedure can only be determined case-by-case [2, 3].

Discussion

A condition for informed consent to be deemed given by a patient should be that it is based on doctor-patient communication. Coming prior to the patient's approving of specific treatment, the communication will allow the patient to comprehend all the elements intrinsic to the decision, and thus make it an informed decision. Doctor-patient communication has an informative function in that it attributes an "informed" status to the consent. At the same time, it contributes to the patient being aware of the nature of the consent while giving it, which satisfies the 2 key conditions for the consent. If the patient's consent to treatment is not preceded by adequate communication, the doctor acts illegally and exposes themselves to liability, even if they perform the treatment *lege artis* [4].

The legislature places certain requirements on the doctor-patient communication, the fulfilment of which is necessary for its legal scope. Absence of any of the elements from the statutory scope of doctor-patient communication precludes obtaining comprehensive information, which consequently invalidates the "informed" value of the consent. However, it is in the doctor-patient communication that the greatest risk of ineffectively informing the patient may be inherent, and it may render the decision on the proposed treatment uninformed. As such, of pivotal importance is not only the content of the document that the patient signs before accepting the risky treatment, but also how it was drafted, i.e. whether it is intelligible (as required) and thus tailored to the recipients and their possible limitations or qualities.

Given the special nature of the trust-based relationship between the doctor and the patient, consent to perform a specific medical procedure should be given in relation to a specific doctor. The literature shows that a doctor cannot engage in communication with an arbitrary patient with whom they have no medical relationship, just as a patient cannot expect to be given reliable information by a casual doctor [5]. The study that involved a group of 128 patients shows that the doctor who performs the procedure is important in deciding whether to undergo it. However, it is definitely more difficult in practice to organise the communication for a specific doctor to be able to accompany the patient in the decision-making process, to set aside adequate time well in advance of the planned procedure, and to match individual elements and the course of this process with the qualities of a specific patient.

Another critical stage of the consent process is the process of understanding all the elements of the communication: this process implies the patient's ability to make an informed decision and express their intention. The literature cites studies that show that verbal and brief information is more effective than written and elaborate information [6]. This may show that patients find it difficult to assimilate the individual pieces of information that make up the doctor-patient communication, especially in the circumstances of the consent, when the decision-making deadline is not always sufficient. It may also be difficult to convey, legally and effectively, the information identified in the study as easier for the patient while striking a balance between scarce information and its comprehensive character, or while using oral information whenever the written form is required by law. While the absence of written consent for a high-risk procedure does not render it invalid, it does make it necessary to prove by other means of evidence that it was given, which can entail numerous difficulties.

A study shows that a significant proportion of the informed consent forms for a high-risk procedure used in the hospitals involved in the study did not include information on the possible consequences of the patient abandoning a specific medical procedure. In turn, other studies show that, in the patients' view, the most important aspects of informed consent include the main risks of the medical procedure and the above consequences [7]. The analysis of the informed consent forms also revealed that almost none of them contained the instruction on alternative methods of treatment. Concomitantly, according to the studies, such information seems to be of particular importance for a doctor who intends to perform a specific procedure in exchange for another one, and they want to win the patient's approval for that exchange [7].

Doctor-patient communication is problematic both with respect to its content and the degree of its intelligibility. In fact, it has been shown that patients remember on average less than 40% of what they have been told, while those who have been told more will remember more but recall less of what has been said [8]. The patient's personal characteristics are also of tremendous importance for the effectiveness of comprehending the doctor-patient communication. This is because older people manifest a much

poorer understanding of the consent information [9]. The forms themselves prove somewhat less difficult for patients to understand than medical journals, but considerably more difficult than the popular press, and understanding some passages describing treatments, procedures, and risks requires higher education or greater reading skills [10].

The patient's consent must be informed, which implies that the patient accepts the intelligible risks inherent in the procedure. A mere authorisation of a specific procedure given without previously providing the patient with intelligible and exhaustive information cannot be considered legally effective. This, in turn, results in the doctor's act being regarded as unlawful [11]. It applies also to denying consent to a medically grounded procedure or to the discontinuation of treatment, in which case it is the doctor's duty to provide comprehensive information on the health consequences brought about by such a denial or by late implementation of medical instructions [12]. To be able to give informed consent, a patient must be informed of an alternative method of treatment or diagnostics. This is because, if such methods are available, it will be up to the patient to opt for one of them [13], although it is not necessary to inform the patient about any possible consequences of such a procedure, but only on the foreseeable, typical, and probable ones [14].

Signing the forms is not tantamount to giving informed consent. Informed consent is a process, and it requires a debate that will eventually make the patient understand the options they have at hand, as well as the risks and opportunities inherent in alternative solutions [15]. The institution of informed consent aims to engage patients in decision-making (much as patients often claim that decision-making is a doctor's task) [16]. The consent process should underlie fiduciary relationship between the patient and doctor, for which it is fundamental that the partner understands and accepts the degree of autonomy in the decision-making process [17].

Medical procedure informed consent forms used in the process of expressing approval for risky treatments should be designed to include all legally required elements. At the same time, however, they should also be understood by the specific recipient, and the process of obtaining consent through them should be viewed as an educational tool and not as a means of evading responsibility [18]. Mere conversations with the doctor to subsequently perform the procedure are not equivalent to informing the patient about the procedure [19]. A blanket statement giving consent to a proposed course of treatment without being provided all the information (including on the planned treatment and risks) should be considered as culpable, due to a failure to exercise due diligence that should be expected of a doctor [20]. In this respect, information on the risks of not undertaking a medical procedure is the "mirror image" of information on the risks of undertaking the same. It must therefore have identical features and be equally reliable and intelligible [21].

Conclusions

The study has shown that in the process of giving consent to treatment carrying high risk for the patient, the very elements of the tool, i.e. the informed consent form, used to receive this type of declaration in writing (as required by the Polish legislature), and equally their content and how this information is conveyed to the patient, are of pivotal importance in giving legally effective consent to a medical procedure.

The methodological difficulties in examining the volitional element of the process of providing consent by patients led to limitations in using typical instruments available for empirical research of this matter. It is possible to expand the research methods with a more detailed focus on the decision-making process of the patients providing consent within the realm of the therapeutic relationship between the patient and the doctor, using interdisciplinary tools from other fields of scientific disciplines, including imaging techniques, such as fMRI or psychological measurements.

Following the analyses in question, it was found that the documents the patients sign when giving their consent to a specific procedure might not contain all the elements that the legislature requires content-wise. Hence, the documents not only fail to meet the condition of exhaustiveness but also may entail giving consent without awareness of its consequences if a patient agrees to be treated in a specific manner, either not knowing there are other methods or not being informed about the risk of denying the consent, but only about possible complications. For the legitimacy of any medical intervention, it is necessary that the legally required elements of consent and certain awareness be included in the patient's decision to give their consent in consultation with the doctor.

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Ethical approval

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Conflict of interest

The authors declare no conflict of interest.

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