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Use of Multimedia Technology in the Doctor-Patient Relationship for Obtaining Patient Informed Consent

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Patient informed consent for surgery or for high-risk methods of treatment or diagnosis means that unlawful breach of the patient's personal interests is avoided and the patient accepts the risk of surgery and takes the brunt of it. Patient awareness – their knowledge of the condition and circumstances of continued therapeutic procedure, including offered and available methods of treatment and their possible complications – constitutes a particular aspect of the informed-consent process.

The rapid development of technologies and methods of treatment may cause communication problems between the doctor and the patient regarding the scope and method of patient education prior to surgery. The use of multimedia technology (e.g., videos of surgical procedures, computer animation, and graphics), in addition to media used in preoperative patient education, may be a factor in improving the quality of the informed consent process. Studies conducted in clinical centers show that with use of multimedia technology, patients remember more of the information presented. The use of new technology also makes it possible to reduce the difference in the amount of information assimilated by patients with different levels of education. The use of media is a way to improve the quality of preoperative patient education and, at the same time, a step towards their further empowerment in the healing process.

MeSH Keywords: **Informed Consent • Multimedia • Physician-Patient Relations**

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Background

Issues related to patient consent for surgery or the use of high-risk methods of treatment and diagnosis are widely discussed in the Polish and international legal and medical literature. The development of legal and ethical standards can reduce the paternalism that may exist in the doctor-patient relationship, as well as increasing patient empowerment in the healing process, with particular emphasis on self-determination [1]. The form and the quality of consent for treatment (whether it is well explained and the patient is sufficiently informed) is a recurrent subject in judicial decisions. In addition, the patient consent process is reflected in medical records that are the basis for determining what information the patient received about possible consequences and complications of the undertaken therapeutic procedures. The documentation must also contain the patient's written consent and its scope.

Description of the State of Knowledge

The legal basis

Patient consent for treatment is one of the most important elements of medical law. In Poland, the obligation to obtain patient consent for examination or other health services follows from Art. 32 Par. 1 of the Act of 5 December 1996 on the Professions of Physician and Dentist, Journal of Laws of 2011, No. 277, item. 1634 and Art. 16 of the Act of 6 November 2008 on Patients' Rights and the Patients' Ombudsman, Journal of Laws of 2012, item 159. Patient consent for surgery or for the use of a high-risk method of treatment or diagnosis is a special case. Polish law governs the issue in Art. 34 of the Act on the Professions of Physician and Dentist and Art. 18 of the Act on Patients' Rights and the Patient Ombudsman. According to these provisions, consent for surgery needs to be made in writing, and the patient should receive specific information before giving consent. The scope of the information is defined in Art. 31 of the Medical Profession Act and Art. 9 of the Act on Patients' Rights and the Patient's Ombudsman. In accordance with Art. 31 Par. 1 of the Medical Profession Act, "The doctor is obliged to provide the patient or their statutory representative with reasonable information about his health, diagnosis, and proposed possible methods of diagnosis or treatment as well as with the foreseeable consequences of their use or withholding, the outcome of treatment and prognosis." Likewise, the scope of the information is defined in Art. 9 Par. 2 of the Act on Patients' Rights and the Patient Ombudsman. The established rules define the scope of the information and the manner in which the information is to be communicated; this should be done in an "understandable" way.

The requirement of obtaining free and informed patient consent is also set out in Art. 5 of the Convention on Human Rights and Biomedicine¹, opened for signature by the Council of Europe in Oviedo on 4 April 1997. This article also stipulates that prior to medical intervention, the person concerned needs to be provided with adequate information about the purpose and nature of the intervention, as well as its consequences and risks.

The need to obtain informed consent for treatment procedure is also contained in Art. 15 Par. 1 of the Code of Medical Ethics (CME). The obligation to respect the patient's conscious participation in the treatment process is included in Art. 13 Par. 1 of the Code of Medical Ethics. According to Art. 13 Par. 3 of the CME, the patient has the right to know the degree of potential risk of diagnostic procedures and treatment, the expected benefits associated with these treatments, and the possible application of other medical procedures. In accordance with Art. 13 Par. 2 of the CME, this information should be formulated in a manner understandable to the patient.

Patient consent for any medical procedure means that unlawful breach of the patient's personal interests is avoided and the patient accepts the risk of surgery and takes the brunt of it [2]. In its judgment of 28 August 1972 (II CR 196/72, OSN 5/1973, pos. 86), the Polish Supreme Court stated that "the patient who agrees to have surgery accepts the risks associated with the treatment (i.e., direct, typical and usual adverse effects on the possibility of which they should be instructed according to the circumstances. No instruction or instruction omitting some of the typical consequences of the operation shall render the consent void (...)." The judgment of the Court of Appeal in Warsaw of 10 January 2007 (VI ACa 753/06) states that "in the absence of proper instruction, it is the doctor who takes the risk of adverse effects." It is also necessary to emphasize that according to the Supreme Court's rulings, the burden of proving that the consent for surgery was obtained from the patient in a proper manner is the responsibility of the physician (II CK 303/04).

Patient awareness before deciding on further therapeutic intervention is a particular issue related to the patient-consent process. The level of knowledge about the patient's condition and circumstances relating to any further therapeutic procedure is contingent upon the actions of medical staff. The physician decides about the amount of information provided to the patient and its quality, which should correspond to the advancement of medical science.

The amount of and manner of delivering information is important, as the patient's lack of knowledge about the risks and

¹ Full title: Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine; adopted by the Committee of Ministers of the Council of Europe on 19 November 1996, entered into force on 01 December 1999. Poland signed the Convention but has not yet ratified it.

consequences of surgery renders their prior consent void (82 CC), and the application of medical error laws is not required (Art. 84 et seq. of the CC) [2]. Both in the absence of consent and its deficiency, surgical risk lies with the doctor, which may give rise to the liability for injury, regardless of whether they act in accordance with medical principles or not [3].

Obtaining Patient Consent – Studies on the Use of Multimedia Technology

With the rapid development of technology and methods of treatment, attention should be paid not only to the amount (scope) of information provided to the patient, but also to the way it is done. The related problem of communication between doctor and patient, which may affect the act of obtaining patient consent, has already been seen in medical units. Physicians look for ways to improve the process of obtaining consent for surgery and see the related benefits – improved image of health services and better protection against potential claims. Studies in this area are also a reflection of the tendency to further empower the patient, and they are particularly valuable because they indicate that physicians recognize the importance of the problems associated with the informed consent process. The literature describes studies on obtaining consent for surgery in different surgical specialties, especially those that deal with highly complex operations. It is worth noting that the studies analyze parameters that provide, for example, the number of possible intraoperative and postoperative complications remembered by patients, and it should be stressed that concerns about precisely these aspects of patient consent are often the subject of judicial decisions in the area of informed patient consent.

Based on recorded doctor-patient interviews, Braddock et al. report that in the case of consents to medical procedures (not just invasive treatments), only 9% of decisions met all the criteria of informed consent, while for more complicated procedures, this percentage was even lower [4].

In a study on laser corneal refractive surgery conducted by Guerin and O’Keeffe, 11 of the 102 analyzed patients could not name any of the 5 possible complications presented in the standard patient consent process. As many as 65% of patients used the Internet to obtain additional information about the planned surgery. The authors emphasize that written patient consent is not, in itself, a sufficient protection against the charge of its invalidity, and they note that the information provided in the process of obtaining consent must be understandable to the patient [5].

Research conducted in other centers shows that the use of new ways of presenting data on treatment significantly

increases patient understanding of the information. In a study by Wollinger et al., a group of patients who were presented an interactive multimedia presentation before agreeing to cataract surgery remembered more facts than the control group. The number of correct answers to a set of 19 questions was 15 and 12 for the test and control groups, respectively [6]. Shukla et al. come to a similar conclusion in their study in which a video was used to improve the amount of information assimilated by patients. The authors also emphasize that taking extra care to obtain patient consent is important for economic reasons because adequately informing patients may be a factor in reducing the risk of payment of any compensation [7]. Tompsett et al. demonstrate a positive impact on the level of patient awareness of videos shown before genitourinary system surgeries [8].

lhrig et al. reported that doctors positively evaluate the introduction of multimedia as an aid in preoperative patient education – all the physicians surveyed would prefer to use multimedia methods as an additional aid in conducting interviews with patients [9]. Patients also positively evaluate the possibility of using the media to obtain information prior to surgery. Ellett et al. reported that 76.1% of patients in the study group chose a medical interview enriched with multimedia presentation as the preferred method of receiving information before laparoscopic treatment of pelvic pain. Only 19.6% of patients indicated that a medical interview was a sufficient means of communication [10]. These kinds of studies are carried out to find better ways of informing patients and thus reduce the number of misunderstandings between doctors and patients.

The introduction of multimedia presentations to the patient consent process, understood as computer animations and videos of treatments within a medical specialty, enriched with commentary, is a breakthrough in improving the quality of the process. This corresponds to the current standards of communication and fits well with the growing trend to empower patients and provide them with appropriate information. The use of media in the doctor-patient relationship may also be another factor in overcoming communication barriers. The patient’s age, their previous experience with treatment procedures, and the level of education are important factors in patient education. The use of multimedia is particularly beneficial for patients with a lower level of education, which is another positive aspect of the use of media in preoperative patient education. This is confirmed by the analysis of results obtained by Bollschweiler et al. in their research on the use of multimedia technology in patient education prior to cholecystectomy [11]. This aspect is particularly important because the new standard of patient education in the informed-consent process helps overcome the disparities in the amount of information assimilated by patients with different education levels and from various backgrounds. In the aforementioned

work, Wollinger notes that elderly patients particularly benefited from the use of a multimedia presentation [6].

In their paper, Mulsow et al. analyzed the results of studies carried out by other researchers on the degree of patient understanding of information provided by physicians in the patient consent process. Owing to the introduction of multimedia, the amount of information assimilated by patients increased by an average of 13.6% compared to the standard procedure [12].

There is still another aspect of the use of multimedia techniques in the process of obtaining consent for surgery that has also been analyzed – whether an increase in the amount of information about the course of treatment and the possibility of complications increase patient concern about the surgery. Ellett et al. found that the use of multimedia techniques increases patient knowledge about the operation. In a test of knowledge about the planned procedure, the group that used the multimedia presentation scored 11.3 points, and the control group scored only 7.9 points. It has also been found that a greater knowledge of the operation does not increase the fear of surgery – 81% of patients reported that the use of the media either did not affect or decreased their level of concern [10]. Similar results have been obtained by Cornoiu et al. In a test of knowledge about the planned surgery (arthroscopy), patients who received a multimedia presentation in the consent process gave 98% correct answers. Patients who derived knowledge of the surgery from a medical interview gave 88% correct answers, and those who used an information brochure gave 76% correct answers. There was no difference in the level of anxiety before the surgery between the 2 groups [13]. In a study on female patients undergoing laparoscopic sterilization, Mason et al. also reported there was no negative effect of an increased amount of information on the anxiety of patients before surgery [14]. Furthermore, Thomas et al. found a significant decrease in anxiety associated with the proposed treatment (chemotherapy or radiotherapy) in patients who were given additional information in the form of video recordings [15]. Different results, however, were obtained by Torres-Lagares et al. in their study on fear of a tonsillectomy, which showed an increase in anxiety before surgery in patients who watched a video [16].

Like any knowledge, information received by a patient before surgery is forgotten over time. In the study conducted by Cornoiu, subjects who had used multimedia in the process of obtaining consent for treatment had a higher level of knowledge in a follow-up examination conducted 6 weeks after the surgery, compared to the other groups [13]. However, Ellett notes that in this group, the decrease in the amount of stored information was higher than in the control group; a study conducted 6 weeks after the surgery showed no statistically significant difference in the level of knowledge about the surgery

between the experimental and control groups (the results were 8.4 and 7.8 points, respectively) [10].

Another issue is informed consent in clinical trials. However, studies show that the use of multimedia techniques in obtaining such consent may be a process more focused on patient autonomy. Hutchinson et al. report that the proportion of consent to a clinical trial was similar in patients who had received additional information in the form of multimedia presentations and the control group – 72.1% and 75.9%, respectively. However, the first group of patients assimilated more information about the examination through multimedia [17]. Similar conclusions are presented by Hazen et al. The results of their study on parents of children diagnosed with leukemia were as follows: 92% of parents indicated that the video presentation helped them to better understand the disease and the treatment process, and 67% of parents said that the media material allowed them to more easily ask their doctor questions [18].

Similar studies have been carried out for diagnostic procedures such as computed tomography and genetic testing, and the results also confirm that the introduction of multimedia improves the quality of the patient consent process. In a study conducted by Sonne et al., 78.7% of patients preferred education supported by video presentations, and only 12.9% chose patient education based only on printed material [19].

It is worth noting that long-term research on doctor-patient communication has begun also in Poland as part of the “Communication in healthcare project: the doctor-patient relationship and its conditions” conducted jointly by the University of Silesia and the Independent Public Clinical Hospital No. 5 of the Medical University of Silesia in Katowice [20].

Another aspect of surgeries of high technical complexity is that the course of treatment and the location of organs to be operated on may be confusing for the patient, which may cause their incorrect assessment of a diagnosis, proposed and possible diagnostic and treatment methods, and the consequences of their application or omission, as well as the results of treatment or prognosis. At this point, it is worth noting that the Polish Supreme Court’s judgment of 16 May 2012 (III CSK 227/11) determines the patient’s right to choose treatment and requires the physician to present a variety of possible treatment methods, even if they are not used in the medical unit. This seems to be particularly important in the case of patient education prior to surgical procedures with a high degree of complexity (e.g., related to the possibility of using different types of devices) or, as in the case of the Supreme Court’s decision cited above, informing the patient about the choice between classical and laparoscopic surgeries. Due to the rapid development of medical technology, the issue of informing

about different surgical methods may be a problem that requires special attention.

An additional benefit from the introduction of multimedia in the patient consent process is an opportunity to improve its quality in relation to people with sensory disabilities because of the possibility to adjust the image size and volume of playback devices. The ease of updating or modifying digital media and the possibility of creating a simple control panel tailored to the needs of the elderly are also worth emphasizing.

The use of modern technology to facilitate patient understanding of relevant information related to treatment is an opportunity that can increase patient satisfaction with the treatment process and thereby improve the image of health care in a broader sense and increase its quality. This also gives doctors confidence that the informed consent process has been carried out properly and the invalidity of consent will not be a prerequisite for the recognition of a claim for damages and holding the doctor accountable.

When discussing issues bordering on law, medicine, and multimedia technology, it should be noted that doctors' acts are to a significant extent determined by their moral views. Autonomy in expressing a patient's will must be respected, not only because of the law, but also due to the doctor's freedom of action, which should be subject to an internal, moral order that directs them toward acting in the best interests of the patient. Having more knowledge about diseases and technologies, as well as having more years of experience, a doctor should strive toward values that can be morally evaluated as positive. "Man is free because he has the ability to take the side of truth and goodness... To be free means to be able to sacrifice and subordinate oneself to truth, and not subordinate the truth to oneself" [21]. By acting in this way, a doctor can be both free and responsible at the same time, while fully respecting their patient.

Prior to multimedia methods being incorporated as tools for improving the process of obtaining consent for surgery, their quality must be validated. Before being put into service, presentations or videos must be subjected to technical assessment by a relevant committee or association (e.g., AAO or SOE in the case of ophthalmology). After obtaining the approval of a particular institution, the files can be used in the process of obtaining consent for surgery.

The validation process should involve 3 areas. First, it should be assessed whether multimedia materials correspond to the requirements of the law (contain information required by the law). It is also necessary to make a substantive assessment in terms of compliance with the current state of medical knowledge. The final element to be evaluated is the quality of the multimedia materials (e.g., photos, videos, and films) and their

adaptability to the specific requirements of certain groups of patients, such as individuals with sensory disabilities. It appears that the assessment of multimedia by a competent and independent committee that takes into account the above aspects will guarantee the compliance of the information contained therein according to law and medical knowledge.

These considerations suggest that it is necessary to conduct further research on these problems that are located in the area of medicine and law, and in some way include technological and medical issues, as well as the doctor-patient relationship. The research procedure will require a multi-center collaboration – data on individual surgical specialties can lead to a general conclusion concerning the influence of different multimedia technologies in the informed consent process. These studies should take into account the level of patient education or their different social backgrounds (e.g., big city, town, or village) and assess whether the media will help to reduce the differences in the amount of information absorbed by patients from different groups. Large-scale studies of this type conducted in Poland may become an important contribution of the country to the development of standards of medical practice in the European Union.

It is also worth noting that the enrichment of proceedings prior to surgery through additional elements will lead not only to further formalization of the procedure, they should be also introduced to the process of obtaining patient informed consent for surgery to better meet the provisions of the law and, perhaps most importantly, to pursue personalistic values.

The introduction of multimedia technology to this very important area of human life is a natural step in the technological evolution of the media.

Conclusions

The issue of proper patient education about a proposed treatment is difficult and always requires an individual approach to each patient. However, the extent of information that needs to be provided to the patient seems to be interpreted quite broadly, particularly with regard to treatments carried out for relative indications, with some easing of requirements in the case of life-saving treatments [3]. Patient education should undergo modification and modernization, without changing the basis thereof – the need to talk with an attending doctor or surgeon – which is an essential element of the direct doctor-patient relationship and written consent for high-risk procedures.

Conflicts of interest

None.

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