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Enhancing Professional Awareness of Informed Consent : Safeguarding the Rights of Patients and Practitioners

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Informed consent is a crucial communication process between doctors and patients for obtaining patients' approval before initiating medical treatment. It is derived from the legal principles of medical contracts and requires doctors to explain the treatment process to patients. Surgeons should be aware of informed consent not only to avoid unnecessary litigation risks but also to provide patients with the right to self-determination. The aim of the study is to help surgeons in Korea understand the legal doctrine on informed consent for practical application. This article reviews the legal doctrine of informed consent according to 5W1H—why, who, whom, what, when, and how—with judicial cases to communicate effectively with patients in clinical settings. Irrespective of the seniority and rank of a doctor, they have the responsibility to provide patients with the information required to protect their right to self-determination. Informed consent should be advanced for patients to consider, discuss with significant others, and determine whether or not to undergo medical treatment. At that stage, patients need to be informed of the necessity, risks, and so on. The most common method of informed consent is an oral explanation utilizing certain forms for documentation. However, the informed consent of patients can be exempted on certain occasions. Optimal informed consent, when implemented, leads to patient-centered care, which significantly improves patient satisfaction and outcomes. Ultimately, it not only protects doctors from litigation risks but also upholds patients' autonomy.

Key Words : Informed consent · Patient rights · Personal autonomy · Jurisprudence · Principle-based ethics.

INTRODUCTION

One of the most fundamental and traditional obligations of doctors was to play the role of a guardian by recommending the best treatment options for patients, a relationship described as paternalism[22]. However, in the late 20th century, a shift in patient-doctor dynamics from paternalism to patient autonomy emerged as a consumer movement, impelling patients to be independent[11]. This resulted in patients pursuing their expected health goals with their own beliefs and values in clinical decision-making[11]. Consequently, the development of the concept of informed consent (IC), that is, respecting patients' autonomy and right to self-determination was established.

IC is occasionally misunderstood as merely the act of signing a consent form or the consent form itself[36]. However, it is the communication process between patients and physicians, resulting in the patient's authorization or agreement to undergo a specific medical treatment[3]. Beauchamp addressed the five es-

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sential elements of IC : voluntariness, competence, disclosure, understanding, and consent[6]. Specifically, when a patient is informed and has consented, it means that a competent patient has understood the medical treatment following the disclosure of doctors and has voluntarily consented to undertake it[25].

In South Korea, medical disputes related to surgery (40.9%) and procedures (17.7%) have been filed for mediation, particularly in the last 5 years[18]. When classifying department-wise, the Department of Neurosurgery recently ranked the second highest in the number of cases filed (1076) among surgery departments. In 2023, neurosurgery patients claimed (KRW 118951480 = USD 86197) and settled (KRW 18775000 = USD 13605) the largest average amount of compensation, compared to other surgery departments[18]. Likewise, neurosurgeons and spinal surgeons are exposed to litigation risks because of the increasing volume of high-risk surgeries[21].

Several factors regarding IC have been reported to be associated with litigation risks[13]. Patients who lack information or have low health literacy occasionally misunderstand dissatisfaction as a patient safety incident and do not comply with a doctor's order[9]. Lack of information and noncompliance lead to chronic disease and re-hospitalization because of poor self-care[10].

Surgeons must be professionally aware of IC to avoid unnecessary litigation risks, respect patients' rights, and ultimately improve health outcomes. Therefore, this article reviews the legal doctrine of IC according to 5W1H—why, who, whom, what, when, and how—with judicial cases to enhance professional awareness and communicate effectively with patients.

WHY SHOULD IC BE OBTAINED

Doctors have a crucial duty to disclose. The obligation, which includes explaining what the medical treatment entails, reasonable alternatives, and the risks and benefits of the treatment[25], is not just a practice but a cornerstone of medical ethics[2]. This duty underscores the importance of IC, a fundamental right of human beings, and its implications.

As a strong authority in applying the law in clinical settings, the Supreme Court of Korea's landmark 94Da3421 judgment on January 20, 1995, specified the duty of doctors within the legal context[32]. The purpose of disclosure is to enable patients to consider the necessity, compare risks, and choose whether or not to undergo medical treatments[1]. The Supreme Court underscored the derivation of a physician's duty of explanation from the medical contract and the paramount importance of this duty in its 2009Da17417 judgment on May 21, 2009[29]. As part of their medical contract, doctors bear a profound duty of care to safeguard patients from potential risks[16]. A breach of duty signifies a failure to fulfill it, leading to a contract default[27]. Such a breach infringes upon the patient's self-determination and right of consent, which is the prerequisite for the legality of medical treatment, and constitutes an illegal act[16].

Legal precedents have developed the concept of a doctor's explanation since the 1995 judgment. After 20 years of conflicts between patient groups and the medical community, an amendment to the Medical Service Act stipulated the provision of an explanation of medical treatments on December 20, 2016[15]. Article 24-2 of the Act states that when doctors (including dentists and doctors of Korean medicine) offer treatments that could cause severe harm to life or body, they should explain the matters to the patient or a legal representative, if the patient lacks decision-making capacity, and obtain written consent[39].

The legal grounds for the right to self-determination are human dignity and values, as stated by Article 10 of the constitutional law of Korea[40]. In the case of the United States, the legal basis of the right to self-determination is regarded as a privacy right that respects the human right to privacy[23]. The concept of personal autonomy in Japan, which was introduced as "self-government" from Western sources[14], originated in the 1980s and later aligned with Beauchamp and Childress's concept[7]. In Germany, the personal injury doctrine, developed by Reichsgericht in 1894, stated that only the patient's will could exclude the offense of damage from medical procedures[10].

The right to self-determination is expressed as a form of consent. Medical procedures are performed to help patients recoup health, but they also entail risks, particularly authoritarian ones, without the patient's consent, which is a breach of law. At this time, the explanation must be appropriate for the subject, object, time, method, and contents. Therefore, if physicians fail to obtain patients' consent or obtain consent inadequately, they are accountable for wrongdoing regardless of the appropriateness of medical practice[27].

WHO SHOULD INFORM WHOM

Fundamentally, the subject of liability for explanation is the doctor in charge of the patient's overall treatment[26]. However, advanced technology has caused modern clinical settings to be fractionated or specialized. For example, a pulmonologist diagnoses a patient with small cell carcinoma, and subsequently, a thoracic surgeon performs a surgical removal procedure. In this case, the duty to disclose is owed by any of the doctors, who can explain in no particular circumstances[34]. If the one who explains is a doctor, the seniority or rank does not matter—so attending surgeons, residents, or interns can explain medical treatments[34].

The issue is whether the duty to provide explanations about invasive medical procedures or surgeries has been implemented by explanatory nurse practitioners—also known as explanation nurses, nurses in charge of education, or clinical coordinators[5]. This viewpoint is argumentative[19]. However, no judgment of the Supreme Court ruled that the explanation of those nurses fulfilled the duty of explanation of doctors. It is considered that the obligation of explanation, one of the doctor's accountabilities, cannot be delegated to (even skillful) nurses who are legally performance assistants of doctors, following Article 2 (2) 5 (b) of the Medical Service Act[19].

The object of explanation is the patient itself. Therefore, without first consulting with capable patients, doctors are not recommended to explain the status of a patient, care plan, or medical treatment to be performed and obtaining consent from a third person—even if the person is a legal representative of the patient[33]. This legal doctrine aims to ensure patients are protected by their own agency. Furthermore, capable patients are assured of the right to self-determination regarding their own bodies and medical treatments, exercising this right themselves rather than with a third party.

In some cases, it is not the competent patient who signs the written consent form for the invasive procedures but rather their children—sons, daughters, or in-laws—for various reasons. The written consent allows for the selection of reasons for proxy signature, including (a) lack of comprehension due to the patient's physical or mental disability, (b) lack of comprehension due to minority status, (c) potential for significant adverse impact on the patient's psychological or physical health through explanation, (d) patient's delegation of authorization, or (e) emergency or intensive care settings where the patient lacks capacity.

First, in cases where patients seem incompetent, seem to be minors, or appear to lack the ability to judge owing to physical or mental illness, their capacity needs to be examined thoroughly. If patients are minors or incapable, the legal representative would be the object of explanation. However, in cases where minor patients are judged to be fully capable, there are other theories about the information that would be provided and to whom[4]. Second, in cases where the explanation of the procedure would have a significant impact on the patient, the circumstances and reasons for the doctor explaining to the patient's family and obtaining consent should be thoroughly documented in the medical records. This is crucial because it is not a typical situation, and there is no way to substantiate the reason without written records. Third, even if the patient is able to ask their family members to sign in the presence of the doctor, verbal delegation is ineffective and cannot be substantiated[26].

The following case was problematic with regard to the issue of whom the doctors should provide information to[24]. A man with diplopia and blepharoptosis visited hospital A and took a brain magnetic resonance imaging (MRI), which showed a contrast-enhanced lesion along the left oculomotor nerve. While undergoing craniotomy for a biopsy by approaching the left posterior temporal lobe and traction of the brain, a sudden massive hemorrhage occurred, and cerebral edema worsened. Surgeons of hospital A found a mass, which was assumed to be angioblastoma, put pieces of cotton and a drainage line in the parenchyma, and closed the surgery site. After surgery, he remained vegetative, received conservative treatments, and expired after a year. A day before the surgery, his parents listened to the details of the surgery and signed consent forms, which showed the reason that the representatives signed was that the provision of information obviously would influence the patient's body and mind badly. However, there was no evidence that he was incapable of decision-making or that IC would have a bad influence on him. A court ruled that there was a breach of the duty of explanation, directing hospital A to compensate KRW 5000000 (USD 3623).

WHAT SHOULD BE INFORMED FOR CONSENT

Article 24-2 (2) of the Medical Act specifies that doctors should provide an explanation before invasive or other medical

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treatments that could cause serious complications, such as surgery, transfusion, or general anesthesia[39]. Matters requiring explanation and obtaining consent by written form are as follows : (a) (potential) diagnoses; (b) necessity, methods, and process of the treatment; (c) who the surgeons or physicians (including dentist and Doctor of Korean Medicine) are, who are, performing the treatment and explaining; (d) risks and complications expected to occur that are typically associated with treatment; and (e) caution before and after the treatment. If operating surgeons change, patients must be notified, and written consent must be obtained accordingly[39]. These items are indispensable contents of IC legislated by the Medical Service Act since 2016.

The Joint Commission suggested four key components included in consent forms for effective communication[36]—the nature of medical treatment, reasonable alternative treatment methods, risks and benefits of the treatment and alternatives, and how much patients comprehend the former four components[25]. In addition, the General Medical Council of the United Kingdom recommends providing further information to patients. It mandates the provision of information focusing on details that patients need or want to make a clinical decision, such as uncertainties about prognosis, options for treating the condition or taking no action. And minor relevant information could be shared—their right to seek another opinion, bills to be paid, or time limit on decision-making[25].

The following case highlights what information doctors should have provided patients before deciding on the treatment[37]. A 46-year-old woman underwent surgery for the removal of two tumors in the right collum and posterior region of the neck under local anesthesia, respectively. As the tumor of the posterior neck had severe inflammation, adhesion to surrounding tissues was not recommended. If tumor removal was attempted, nerve injury would be inevitable. However, the surgeons of hospital B removed all tumors, and amyotrophy occurred in her right arm. She complained of weakness and tingling in her right arm, shoulder, and posterior neck pain, which occurred immediately after the surgery. In this case, it was recognized that the surgeon explained the common complications such as bleeding, infection, and nerve injury. However, the court pointed out that the surgeon anesthetized locally, which inferred that he judged local anesthesia was enough and underestimated the risks of this surgery. The court ruled that the risks of nerve injury increased rapidly due to the adhesion of tissues when the surgeon could stop and obtain her IC again. Consequently, it ruled that Hospital B compensate KRW 10000000 (USD 7246).

WHEN AND HOW SHOULD PATIENTS BE INFORMED, AND CONSENT OBTAINED

The duty to explain or advise is imposed on doctors to ensure patients' right to self-determination. Therefore, doctors should explain to patients what the medical treatment entails before the due date and give them adequate time to consider whether to undergo the treatment by themselves[4]. Considering that the time when doctors explain medical treatment differs in each case, some rules cannot be applied in all cases. The time can be determined by the treatment's risks and urgency, the patient's status, alternative treatments, and prognosis when treatment is not performed. If doctors perform invasive medical treatments immediately after explanation, it may constitute an infringement on the patient's right to autonomy. Therefore, doctors do not fulfill the obligation of explanation in this case[26].

The 2021Da265010 judgment of the Supreme Court incorporates the time patients need to determine whether to undergo medical treatments[31]. It states that adequate time should be provided to listen to the risks and necessity of medical treatments, discuss with significant others, consider, and decide. However, as mentioned above, the specific amount of time differs with individual circumstances. The time can be shorter due to urgency—that is, if the treatment is not performed immediately, the patients could be in danger—but the time should be assured to exercise their right.

The following case provides an example of how long doctors should give patients to determine whether to undergo the treatments[35]. A 38-year-old former basketball player with both leg and back pain visited hospital C, took an MRI, and was recommended to undergo anterior lumbar interbody fusion, percutaneous pedicle screw fixation, and artificial disc replacement. He agreed and underwent surgery the same day. After the surgery, he continuously complained of back, leg, sacral, and inguinal pain and neurogenic vesical dysfunction. In this case, he visited hospital C at 1:38 PM, signed consent forms at 4:29 PM, two-and-a-half hours after arrival, and the surgeons of hospital C commenced the surgery at 1:45 PM the next day. A court ruled that surgeons did not ensure enough time to consider and determine whether to undergo surgery, which violated the duty of

explanation. It ruled that hospital C compensate KRW 10000000 (USD 7246).

In principle, only one method of explanation should not be considered correct. This is the oral explanation or explanation utilizing certain forms, such as pamphlets, pictures, or consent forms based on oral communication[20]; nevertheless, it is the most common method. Oral explanation is essential, but doctors need to record what they explain and obtain the patient's consent regardless of the importance of oral explanation[28].

Therefore, medical institutions use written material such as physical consent forms for invasive medical treatments[25]. After the oral explanation, doctors obtain the patient's signature on consent forms as an expression of consent, substituting additional medical records. This form is also used as a decision aid[17].

EXCEPTIONS

The duty of explaining is sometimes exempted depending on the circumstances of the subject (doctors) or the object (patients)[12]. The court characterizes these as exceptional circumstances and categorizes them into five constituents.

First, the duty of disclosure is exempted when there is a shortage of time to explain and obtain consent before the medical treatment because the patient is seriously ill[25]. Doctors put treatment-first explanations at this time, citing urgency. In an emergency, the benefits of protecting the patient's life and health justify non-compliance with the duty to explain. Article 9 of the Emergency Medical Service Act of Korea states cases in which emergency healthcare professionals do not need to provide an explanation and obtain consent from patients[38]. However, even in such cases, to respect the patient's right to self-determination, it is required that doctors should explain to the patient's legal representatives the status, what emergency medical treatment would be performed, and the consequences if the treatment is not administered.

Second, if patients are healthcare professionals or have a medical history indicating that they have undergone medical treatment multiple times or have sufficient background knowledge, the duty to explain is exempted[30]. Given that this duty is to protect patients' rights by providing information when they

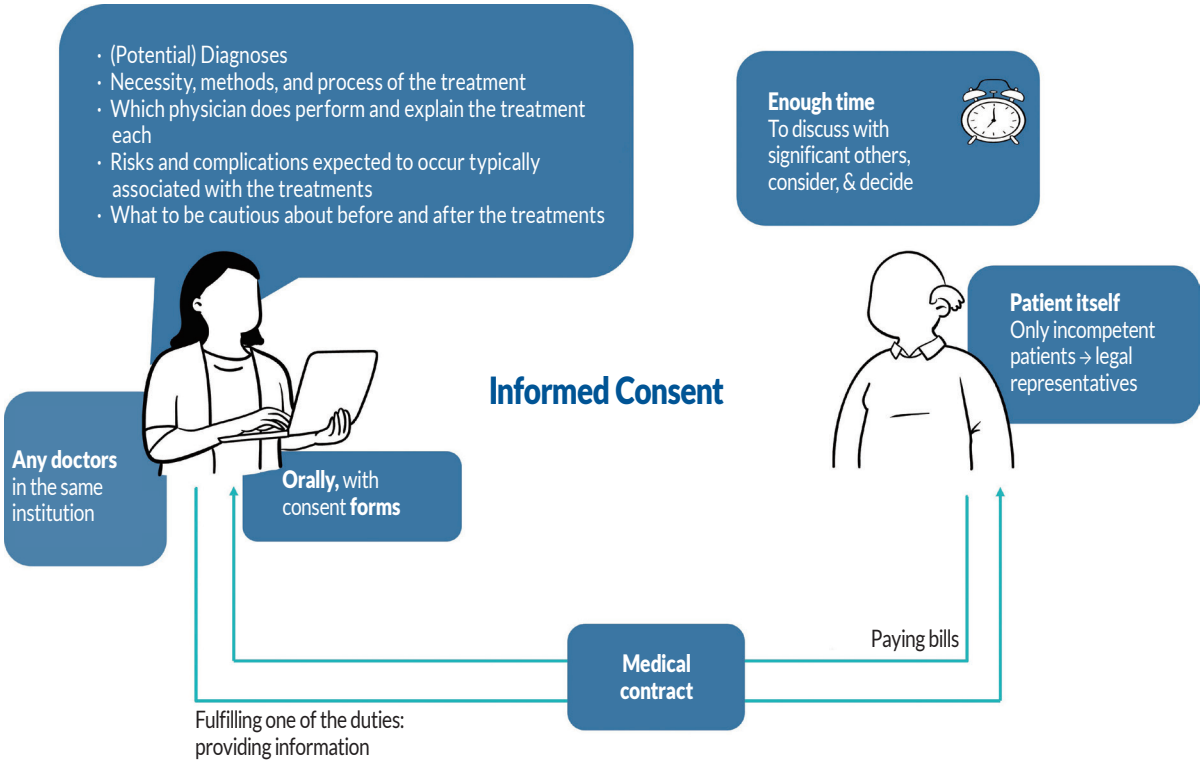

Fig. 1. Informed consent at a glance according to 5W1H-why, who, whom, what, when, and how.

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already have enough information without any explanation or can obtain information easily, doctors are not required to provide it.

Third, the duty is exempted when a patient entrusts a doctor with full or partial power of clinical decision-making and expresses or implies their intention as above[25]. Sometimes, patients refuse to receive an explanation or expect their family or doctor to make clinical decisions, which can be interpreted as giving up their right to self-determination. Fourth, there are circumstances where doctors' explanations might negatively impact the patient's body and mind[8]. Finally, the law gives the authority of treatment to doctors by force. For example, when a patient attempts suicide, doctors can rightly practice medicine to sustain their lives first[8].

CONCLUSION

This article reviewed the legal doctrine of IC, focusing on the grounds, subjects, objects, moments, methods, and exceptions to improve professional awareness and communicate effectively with patients (Fig. 1). Neurosurgeons and spinal surgeons exposed to high litigation risks should prepare for medical disputes by protecting themselves in various ways. Protection does not demand grandiose works. If doctors are aware that they are duty-bound to provide an explanation and professionally heed to the legal aspects, they will fulfill their obligations and protect their patients' rights.

AUTHOR'S DECLARATION

Conflicts of interest

No potential conflict of interest relevant to this article was reported.

Informed consent

This type of study does not require informed consent.

Author contributions

Conceptualization : MJK; Data curation : MJK; Visualization : MJK; Writing - original draft : MJK; Writing - review & editing : MJK

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