Research in Education and Rehabilitation 2026; 9(1): 61-69 **DOI**: **10.51558/2744-1555.2026.9.1.61**

EXPERIENCES IN PRACTICE OF THE APPLICATION OF INFORMED CONSENT IN THE CLINICAL CENTER OF THE UNIVERSITY OF SARAJEVO

ISKUSTVA U PRAKSI PRIMJENE INFORMIRANOG PRISTANKA U KLINIČKOM CENTRU UNIVERZITETA U SARAJEVU

Emina Nikšić[1], Amer Ovčina[1,2*], Almedina Alihodžić[1,2]

[1]Clinical Center of the University of Sarajevo, Sarajevo, Bosnia and Herzegovina

[2]Faculty of Health Studies University of Sarajevo, Sarajevo, Bosnia and Herzegovina

Professional Article

Received: 02/02/26
Accepted: 13/04/26

ABSTRACT

Informed consent in medicine is a fundamental institute of modern health care, the essence of which is to preserve patients' autonomy and ensure their active role in making decisions about their own treatment. It implies that the patient, before agreeing to any diagnostic or therapeutic procedure, is thoroughly, clearly and comprehensibly informed about the nature of the disease, possible treatment options, expected benefits, risks and possible complications. In practice, informed consent is seen as a complex process of communication that requires a high level of ethical responsibility and professional dedication of healthcare workers. In the clinical environment, especially in large tertiary institutions such as the Clinical Center of the University of Sarajevo, this process is fully regulated, but often faced with numerous challenges. Lack of time, administrative burden, differences in the level of understanding between patients and the use of professional terminology represent obstacles that make it difficult to consistently apply informed consent. At the same time, experience from practice confirms that a well-conducted information process significantly reduces the risk of misunderstandings, complaints and legal consequences. Therefore, informed consent should be viewed as an important indicator of the quality of medical practice, professional integrity and respect for human rights in the modern health system.

Keywords: informed consent, patient, practice, University of Sarajevo Clinical Center

* **Correspondence author: Amer Ovčina**, Clinical Center of the University of Sarajevo, Sarajevo, Bosnia and Herzegovina
E-mail: **amerovcina@yahoo.com**

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SAŽETAK

Informirani pristanak u medicini predstavlja temeljni institut savremene zdravstvene zaštite, čija je suština očuvanje autonomije pacijenata i osiguravanje njihove aktivne uloge u donošenju odluka o vlastitom liječenju. On podrazumijeva da pacijent, prije pristanka na bilo kakav dijagnostički ili terapijski postupak, bude detaljno, jasno i razumljivo upoznat s prirodom bolesti, mogućim opcijama liječenja, očekivanim koristima, rizicima i mogućim komplikacijama. U praksi, informirani pristanak se posmatra kao složen proces komunikacije koji zahtijeva visok nivo etičke odgovornosti i profesionalne posvećenosti zdravstvenih radnika. U kliničkom okruženju, posebno u velikim tercijarnim ustanovama poput Kliničkog centra Univerziteta u Sarajevu, ovaj proces je u potpunosti reguliran, ali nerijetko suočen s brojnim izazovima. Nedostatak vremena, administrativna opterećenost, razlike u stepenu razumijevanja među pacijentima te upotreba stručne terminologije predstavljaju prepreke koje otežavaju dosljednu primjenu informiranog pristanka. Istovremeno, iskustva iz prakse potvrđuju da kvalitetno sproveden proces informiranja značajno smanjuje rizik od nesporazuma, pritužbi i pravnih posljedica. Stoga informirani pristanak treba promatrati kao važan pokazatelj kvalitete medicinske prakse, profesionalnog integriteta i poštivanja ljudskih prava u savremenom zdravstvenom sistemu.

Ključne riječi: informirani pristanak, pacijent, praksa, Klinički centar Univerziteta u Sarajevu

INTRODUCTION

Informed consent is one of the fundamental institutes of modern medicine and bioethics, as it integrates the legal, ethical, and professional dimensions of the relationship between patients and healthcare professionals. Its essence lies in the protection of patients' rights, freedom of decision-making, and autonomy in the process of treatment and research. In the broadest sense, informed consent is defined as the freely and consciously expressed agreement of a patient or research subject that permits the performance of certain diagnostic, therapeutic, or research procedures, with the obligation that the patient is previously informed of all relevant information regarding the nature of the procedure, possible benefits, risks, and alternatives (Bilajac, 2011). Thus, informed consent cannot be regarded exclusively as a legal category, but also as an ethical domain that connects fundamental bioethical principles with clinical practice (Šegota, 1994).

The legal framework of informed consent is based on universal human rights, primarily the right to bodily integrity and the right to private life. The European Court of Human Rights (ECHR), in several judgments, including the case Pretty v. the United Kingdom, emphasized that the right to self-determination also includes the possibility for an individual to refuse medical treatment, even when such a decision may lead to deterioration of health or death (ECHR, 2002). Constitutional and legislative solutions in Bosnia and Herzegovina, as well as in neighboring countries, follow these international standards, emphasizing that no medical procedure may be carried out without freely given consent, except in exceptional cases where the preservation of life or the protection of public health is at stake (Clinical Center of the

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University of Sarajevo, 2025). For informed consent to be legally and ethically valid, three basic conditions must be fulfilled: patient competence, adequacy of information, and voluntariness of the decision. Competence refers to the patient's ability to understand the information provided and to make a rational decision based on it. Adequacy of information denotes the moral and professional duty of the physician to present the nature of the procedure, risks, possible outcomes, and alternatives clearly, comprehensibly, and in sufficient detail (Jukić & Puljak, 2018). Voluntariness means that the decision must be made freely, without coercion or manipulation, which is a particularly sensitive issue in the context of power imbalance between physicians and patients, as well as among vulnerable groups such as children, psychiatric patients, prisoners, or socially disadvantaged persons (Jeremić, 2013). However, patient autonomy is not absolute and in practice often encounters limitations. The right to refuse medical treatment may be restricted in cases where such a decision could endanger the patient's own life, the lives of others, or where the protection of the professional integrity of the medical profession is concerned. Particularly complex situations arise in relation to minors, pregnant women, or individuals with diminished decision-making capacity, where a balance must be struck between respecting their will and the principles of beneficence and protection of life (Radović, 2017). The principles of bioethics—autonomy, beneficence, non-maleficence, and justice—thus function as a coordinating framework within which the most acceptable solution is sought (Beauchamp & Childress, 2019). In modern healthcare systems, active patient participation in the decision-making process is increasingly emphasized. This participatory model, based on social interaction and a partnership relationship between physician and patient, increasingly presents the patient as an equal participant rather than a passive recipient of medical services.

It includes the patient's right to information, the right to choose a physician and procedure, the right to a second opinion, and the right to refuse treatment deemed unacceptable (Šunjić et al., 2021). In addition to rights, patients also have certain obligations, referred to in legal theory as compliance. This concept denotes the patient's willingness to align their behavior with medical recommendations, to cooperate with physicians and healthcare staff, and to actively contribute to the success of treatment (Conti, 2000). Further developments in medical science have expanded the meaning of informed consent. The concept of P4 medicine (predictive, preventive, personalized, and participatory medicine) places the patient at the center of the process and transforms consent from a formal act into a dynamic process of cooperation and education. The patient is no longer merely an object of medical intervention, but an active partner in its planning, implementation, and evaluation. Consequently, informed consent acquires a new dimension—it becomes a tool for patient empowerment through knowledge, personalized approaches, and involv ement in decision-making (Hood, 2011). Due to this expanded significance, informed consent is today regarded as an indicator of the quality of healthcare and the ethical maturity of the healthcare system. Its application is not reduced to the signing of a form, but represents a genuine process of communication, trust, and respect between patients and healthcare professionals. Although the patient's right to autonomy is one of the fundamental rights, its application must always be considered within a broader social and ethical context, balancing individual freedoms with the protection of life, health, and public interest (Andorno, 2004). Therefore, informed consent is not only a legal obligation but

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also an ethical standard and an indicator of professional integrity in medicine. It ensures that the patient remains a subject rather than an object of medical procedures, placing dignity and the right to decision-making at the center of healthcare. Only through the continuous development of communication skills, ethical education of healthcare professionals, and empowerment of patients can informed consent fully achieve its purpose—preserving trust, respecting autonomy, and protecting fundamental human rights in medical and research practice (Faden & Beauchamp, 1986).

MATERIALS AND METHODS

Participants

The research did not involve direct respondents, nor was any empirical primary data collection conducted. The unit of analysis consisted of published scientific and professional papers, books, legal and ethical documents, as well as institutional reports, which deal with the issue of informed consent in healthcare practice. Special attention was paid to sources that deal with experiences from clinical work and healthcare institutions in Bosnia and Herzegovina, including the University of Sarajevo Clinical Center.

Measuring instrument

Data collection was carried out by analyzing secondary sources, without the use of standardized measuring instruments or questionnaires. Referral publications, scientific and professional books, and original scientific and professional articles available in relevant databases, including PubMed, Google Scholar, EBSCO, Medline and Web of Science, were used.

Statistical Analysis

Given the qualitative character of the research, statistical analysis was not applied. The collected data were analyzed through descriptive and thematic analysis, where key concepts, patterns and findings related to the ethical and legal significance of informed consent, obstacles in its application and experiences from clinical practice were singled out. The results were interpreted narratively, in accordance with the research objectives.

RESULTS AND DISCUSSION

The analysis of the reviewed literature demonstrates a consistent discrepancy between the normative understanding of informed consent and its implementation in everyday healthcare practice. Despite differences in study design, healthcare settings, and national contexts, the reviewed publications converge on the conclusion that informed consent is frequently reduced to a formal administrative procedure rather than being implemented as a meaningful process of patient participation in decision-making. A summary of the reviewed studies is presented in Table 1.

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Table 1. Overview of empirical and theoretical findings on informed consent in healthcare

Author / Source	Key Conclusion
Velagić M., Ovčina A., Konjo H. (2024). The importance of informed consent in the process of patient treatment. Reformator, No. 2, ISSN 2831-1396.	In practice in Bosnia and Herzegovina, informed consent is often reduced to a formality, as patients are insufficiently informed about their rights and make decisions superficially and under pressure, creating a gap between legal regulations and real-life practice.
Pantović S., Zrnić D. (2024). Informed Consent in Clinical Studies in the Republic of Srpska. Review of European and Comparative Law, 57(2), 97–119.	Although the legal framework of the Republic of Srpska is aligned with international standards, serious deviations exist in practice: patients often do not receive complete information, the process is bureaucratized, and largely dependent on the discretionary power of researchers.
Kumru S., Yiğit P., Demirtaş M., Fındık H. (2023). Informed consent in surgical practice with patient experiences. Patient Experience Journal.	The study shows that patients frequently sign consent forms without fully understanding their content, while communication quality and time dedicated to explanation are key factors determining the quality of informed consent.
Perić O., Mišić M., Tirić D., Penava N., Bušić D., Tomić V. (2018). Patients' experience regarding informed consent in elective and emergency surgeries. Medical Gazette (Zenica).	Patients undergoing elective procedures more frequently seek additional explanations, while emergency patients tend to sign consent forms without reflection, confirming that situational pressure directly affects the quality of informed consent.
Gabay G., Bokek-Cohen Y. (2019). Infringement of the right to surgical informed consent: negligent disclosure and its impact on patient trust in surgeons at public general hospitals – the voice of the patient. BMC Medical Ethics.	Formal signing of consent without dialogue undermines patients' trust in surgeons and may lead to feelings of deception and insecurity, thereby diminishing the ethical value of informed consent.
Frković, Aleksandra (2004). Informirani pristanak u teoriji i praksi kliničke bioetike. Medicinski fakultet Sveučilišta u Rijeci.	Informed consent is the basic moral standard of clinical bioethics, which recognizes the patient as an autonomous person and an active participant in treatment. In Croatia, it is implemented through legal consent for medical interventions, but it has not been developed as a consistent doctrine, and the level of actual patient information is often

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	insufficient. Continuous bioethical education of physicians and improvement of the practice of informed consent are necessary for a better doctor-patient relationship.
Brkljačić, M. (2013). Etički aspekti komunikacije u zdravstvu. Medicina Fluminensis, 49 (2), 136-143	Modern technology and the fast pace of work must not replace conversation: without clear, empathetic and continuous communication, treatment outcomes are poorer and misunderstandings are more common. Communication in medicine is a clinical skill that is learned, taught and constantly practiced (verbally and non-verbally), with language and messages adapted to the patient and their family. Successful communication builds the patient's respect and trust in the doctor and the healthcare team, reduces fear and suffering and facilitates decision-making. Informed consent is not just a signature on a form, but a process of dialogue and partnership, through which the ethical principles of autonomy and fairness are realized, including the patient's right to accept or refuse a procedure.

Velagić, Ovčina, and Konjo (2024) report that, in Bosnia and Herzegovina, informed consent is commonly treated as a legal obligation fulfilled through the patient's signature on a consent form, while the quality of patient information remains inadequate. Patients are often unfamiliar with their rights and make decisions under time pressure or without fully understanding the implications of the proposed intervention. These findings indicate a substantial discrepancy between legislative provisions and their practical implementation.

Similarly, Pantović and Zrnić (2024) demonstrate that the existence of a legal framework aligned with international ethical standards does not necessarily ensure effective protection of patient autonomy. Their analysis of clinical research in the Republic of Srpska reveals that the consent process is frequently bureaucratized and dependent on the individual practices of researchers, resulting in inconsistent quality of patient information.

The importance of communication emerges as one of the dominant themes across the reviewed literature. Kumru et al. (2023) found that patients undergoing surgical procedures frequently sign consent forms without fully understanding their content. The authors emphasize that the quality of informed consent is determined primarily by the clarity of explanations provided, the time devoted to communication, and the willingness of healthcare professionals to ensure patient understanding. These findings support the concept that informed consent is fundamentally a communicative rather than merely a legal process.

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The situational context in which consent is obtained also significantly influences its quality. Perić et al. (2018) report that patients undergoing elective procedures are more likely to seek additional information and actively participate in decision-making because they have sufficient time for reflection. In contrast, patients facing emergency interventions often sign consent forms under considerable psychological pressure and limited opportunity to consider alternatives. This suggests that patient autonomy may be substantially constrained by the clinical circumstances in which consent is requested.

The consequences of inadequate informed consent extend beyond legal considerations. Gabay and Bokek-Cohen (2019) demonstrate that obtaining consent through formal signatures without meaningful dialogue negatively affects patients' trust in physicians and healthcare institutions. Patients frequently perceive such practice as impersonal and insufficiently transparent, leading to feelings of insecurity and reduced confidence in medical professionals.

From a bioethical perspective, Frković (2004) emphasizes that informed consent represents one of the fundamental principles of clinical bioethics because it recognizes the patient as an autonomous individual who actively participates in healthcare decisions. However, the author argues that legal regulation alone is insufficient unless accompanied by a culture of effective communication and continuous bioethical education of healthcare professionals.

This perspective is reinforced by Brkljačić (2013), who argues that technological advances and increasing workload must never replace direct communication between healthcare professionals and patients. Effective communication requires empathy, understandable language, active listening, and adaptation of information to patients' educational background and health literacy. Within this framework, informed consent becomes a process of dialogue and partnership rather than a simple legal document.

Collectively, the reviewed evidence demonstrates remarkable consistency across different healthcare systems and research contexts. Regardless of geographical setting or clinical environment, the principal challenges associated with informed consent remain similar. Patients frequently receive incomplete or overly complex information, communication is often constrained by time limitations, and consent is commonly perceived as a procedural requirement instead of an ethical process supporting shared decision-making.

These findings suggest that improvements in informed consent should extend beyond legislative reform. Greater emphasis should be placed on strengthening physicians' communication competencies, allocating sufficient time for physician–patient discussions, improving patients' health literacy, and promoting continuous bioethical education. In addition, healthcare institutions should implement mechanisms for monitoring not only whether consent forms have been signed but also whether patients have genuinely understood the information provided and participated voluntarily in the decision-making process.

Overall, the reviewed literature indicates that the ethical and legal value of informed consent depends primarily on the quality of communication and the patient's actual understanding rather than on the existence of a signed consent form. Consequently, future efforts should focus on transforming informed consent from a predominantly administrative obligation into a patient-centered process that genuinely supports autonomy, trust, and shared clinical decision-making.

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CONCLUSIONS

The present review demonstrates that informed consent in the healthcare practice of Bosnia and Herzegovina has not yet fully achieved its intended function of safeguarding patient autonomy. Although formally established as an integral component of medical documentation and the legal framework, its practical application is often limited to the signing of a consent form. Such an approach neglects the fundamental purpose of informed consent, namely that patients should understand the nature of the proposed medical procedure, its potential risks, expected benefits, possible consequences, and available alternatives before making a decision.
A particularly important finding is that patients are often insufficiently informed about their rights, meaning that the consent they provide does not always represent a genuinely informed, voluntary, and autonomous decision. Consent that is not based on adequate understanding remains merely a formal confirmation rather than evidence of meaningful patient participation in healthcare decision-making. Consequently, patient autonomy cannot be considered independently of the quality of information provided before consent is obtained.
Communication between physicians and patients plays a central role in this process. Clear, patient-centered, and comprehensive explanations determine whether informed consent fulfills its intended purpose or remains merely an administrative procedure. When explanations are limited to technical terminology, brief conversations, or routine referrals to written consent forms, patients are placed in a passive role and deprived of the opportunity to participate actively in decisions directly affecting their health.
The quality of informed consent is further influenced by the circumstances under which it is obtained. Patients undergoing elective procedures generally have sufficient time to ask questions, reflect on the information received, and seek additional clarification. By contrast, in emergency situations, decisions are frequently made under conditions of urgency, fear, and dependence on the professional judgment of healthcare providers. These circumstances demonstrate that informed consent is not simply a matter of obtaining a signed document but also of ensuring that patients have a genuine opportunity to understand, evaluate, and decide.
For these reasons, informed consent should be regarded as a process of professional dialogue rather than as a final administrative step. Without transparent communication and meaningful explanation, a signed consent form may undermine patients' trust in physicians and healthcare institutions, create feelings of uncertainty, and diminish the ethical quality of medical practice. Trust is established not through formal documentation but through a therapeutic relationship in which patients understand the information provided and feel that their decisions are respected.

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