

## SCIENTIFIC REVIEW

# IMPROVEMENT OF THE QUALITY AND SAFETY OF HEALTHCARE THROUGH THE PROTECTION OF PATIENT RIGHTS

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## ABSTRACT

The quality and safety of provided services are crucial aspects of the success of any institution, including healthcare facilities and the overall healthcare system of a particular country. This work emphasizes the fundamental provisions of healthcare regulations, where standards of quality and safety represent the primary determinants of successful healthcare service delivery. The authors believe that respecting patients' rights constitutes a significant segment in enhancing the quality and safety of healthcare. They argue that the Law on Healthcare of Republika Srpska is largely aligned with the basic principles observed in neighboring countries' healthcare sectors. The study employed a method of analyzing positive legal regulations, along with a comparative approach in comparing legal systems of neighboring countries.

The new Law on Healthcare of Republika Srpska has established a nominally greater number of patient rights compared to previous regulations, thereby leading to a more effective and secure healthcare service provided by healthcare institutions and professionals. Additionally, the chapter of the Law on Healthcare of Republika Srpska that regulates patient rights, quality, and safety of healthcare is reasonably harmonized with the positive regulations governing these issues in Serbia and Croatia.

**Keywords:** quality, safety, healthcare, improvement, patient rights

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## INTRODUCTION

In recent years, the quality and safety of healthcare delivery have become central themes in many countries. Effective access to primary health care is also of great importance for the health of the population[21]. Most nations advocate a healthcare concept based on three pillars: healthcare professionals, patients (or citizens), and insurance companies. Risks regarding the protection of patient rights have been both potential and real from the earliest days, necessitating legal regulation of patient rights in the context of healthcare.

The development and maintenance of an internal system for continuous improvement of healthcare quality and safety are mandatory for healthcare institutions. To meet a certain level of healthcare quality and safety, the director of a healthcare institution is required to implement a Program for the development and maintenance of a system for continuous improvement of healthcare quality and safety. In this regard, safe and high-quality healthcare includes: respecting patient rights, involving patients in decisions about their health, and applying modern clinical practices based on scientific evidence. In Republika Srpska, the Minister of Health, upon the proposal of the Agency for Certification, Accreditation, and Quality Improvement of Healthcare of Republika Srpska, adopts the Regulation on the internal system for continuous improvement of healthcare quality and safety [1].

Modern times have established mechanisms to protect patient rights through legal regulation of healthcare issues in general, and therefore, the issue of protecting patient rights. In addition to legal solutions that regulate patient rights, there are other mechanisms for their protection, including: competent and well-informed healthcare professionals, quality healthcare services, ethical codes, independent and efficient bodies and protection mechanisms such as: councils and commissions for the protection of patient rights, patient advocates in healthcare institutions, healthcare inspections, courts, citizen associations for the protection of patient rights, informed and educated patients, and the general public [2].

## IMPROVING QUALITY AND SAFETY IN HEALTHCARE

Advances in technology, radical changes in communication and access to information, cheap transportation and the growth of global transnational corporations are influencing the shaping of the relief of our daily lives [20]. Quality is a frequently used term in everyday life, where everyone has a general idea of what constitutes good or poor quality. It denotes the value of something relative to specific requirements and standards. When it comes to healthcare quality, it refers to the degree to which healthcare services contribute to achieving desired health outcomes for individuals and populations. This concept encompasses various characteristics considered desirable in healthcare, such as adequacy, efficiency, comprehensiveness, fairness, accessibility, and satisfaction [3].

In the legislation of the Republic of Serbia, healthcare quality is defined as a set of measures and activities that utilize modern achievements in medical, dental, and pharmaceutical practices, aimed at improving the chances of favorable outcomes and reducing risks to individual and community health [4]. In Croatia, healthcare quality implies a system coordinating, promoting, enhancing, and monitoring all activities to improve healthcare quality in accordance with internationally recognized standards and scientific-technological development [5].

In the healthcare system of Republika Srpska, the evaluation of healthcare quality is conducted through user satisfaction surveys, external evaluations against prescribed quality standards, and the use of indicators measuring processes and outcomes of healthcare delivery. Similarly, the assessment of healthcare safety includes external evaluations against prescribed safety standards and the use of indicators measuring safety in healthcare processes and outcomes [6].

In the Republic of Serbia, the assessment of healthcare quality is carried out through the evaluation of professional work based on healthcare quality indicators and through the accreditation process [4]. Quality indicators cover various aspects such as staff training and development, management of waiting lists, patient safety, assessments of healthcare institution operations, user satisfaction with services, and employee satisfaction [7].

Safe and high-quality healthcare requires the development of internal systems for continuous improvement in every healthcare institution, while respecting patients' rights established by law. Comprehensive plans and programs for improving healthcare quality in Croatia are developed by the Ministry in consultation with relevant professional bodies [8].

## **BODIES AND PROCEDURES FOR IMPROVING QUALITY AND SAFETY IN HEALTHCARE**

Improving the quality and safety of healthcare is achieved through competent bodies responsible according to current legal provisions. In Republika Srpska, these tasks are carried out by the Agency for Certification, Accreditation, and Quality Improvement of Healthcare, which plays a role in professional, regulatory, and developmental activities related to the assessment and enhancement of healthcare quality and safety [9]. On the other hand, in Serbia, the Agency for Accreditation of Healthcare Institutions is responsible for accrediting healthcare facilities [10].

In Croatia, mandatory monitoring of healthcare quality indicators defined by the plan and program is conducted by the Ministry responsible for healthcare. All healthcare providers are obliged to establish, develop, and maintain a system to ensure and improve the quality of healthcare [11].

Safe and high-quality healthcare involves respecting the rights of citizens and patients, applying modern clinical practices based on scientific evidence, and involving patients in the decision-making process about their health [12]. Internal verification of continuous improvement in healthcare quality and safety is regularly conducted in healthcare institutions based on an annual program, at least once a year, while the director can initiate an extraordinary internal review upon the initiative of the unit manager or the responsible person for continuous quality improvement [13]. Similar standards for internal quality assurance are prescribed in Serbia as well [14].

External quality verification of professional work can be regular or extraordinary. The Ministry of Health of Serbia regularly conducts quality verification upon the recommendation of public health institutes and relevant chambers of healthcare professionals, while extraordinary external controls can be initiated upon the request of citizens, companies, institutions, health insurance organizations, or state authorities [15].

## **THE IMPACT OF PATIENT RIGHTS ON THE IMPROVEMENT OF HEALTHCARE QUALITY AND SAFETY**

Patient rights are fundamental human rights that apply to all individuals using healthcare services, regardless of their health condition. The concept of patient rights emerged from the idea of personal rights defined in the Universal Declaration of Human Rights by the United Nations in 1948. In addition to this Declaration, numerous other international documents regulate patient rights. One of the key documents at the European level is the European Charter of Patients' Rights, adopted in Brussels in 2002. This Charter serves as the basis for many patient rights accepted by most modern legislations in Europe. The European Charter defines rights such as the right to preventive measures, right to access healthcare, right to information, right to consent, right to free choice, right to innovation, right to respect for privacy and confidentiality of data, right to safety, right to avoid unnecessary suffering and pain, right to individual treatment, right to complaint, and right to compensation for harm [16].

The number and scope of patient rights vary among different legal systems in the countries of the region, which also reflects the degree of their harmonization. In the former republics of the Socialist Federal Republic of Yugoslavia (SFRY), including Republika Srpska, patient rights include the right to privacy, right to access medical records, and the right of patients to participate in medical research. Less represented rights include rights such as the right to information, free choice of doctor and healthcare institution, right to consent, and right to leave a hospital at own responsibility. Some of the least represented rights include the right to confidentiality of health data, relief of suffering, and respect for patients' time [2].

In Republika Srpska, patient rights are regulated by the Law on Healthcare, which specifically distinguishes patient rights from general civil rights. The Law guarantees citizens' rights to healthcare, preventive measures, free choice of doctor at the primary healthcare level, and access to waiting lists [17].

## **PATIENT RIGHTS ACCORDING TO CURRENT REGULATIONS IN REPUBLIKA SRPSKA**

The current Law on Healthcare of Republika Srpska formally prescribes a wide spectrum of patient rights compared to previous legislative acts. Accordingly, in Republika Srpska, the following patient rights are defined: the right to healthcare, the right to self-determination, the right to freely choose a healthcare institution, the right to information, the right to consent, the right to refuse healthcare services, pre-hospital emergency care for the sick and injured, the right to confidentiality of personal data, the right to privacy, the right to seek a second medical opinion, the right to access medical records and treatment costs, the right to relief of suffering and pain, the right to complaint, the right to compensation for harm, the rights of patients participating in medical research, and the right of foreign nationals or stateless persons to healthcare [17].

The right to healthcare encompasses a wide range of possibilities, including prompt scheduling of examinations, therapeutic, diagnostic, and rehabilitative procedures. Exceptions to this right are made for pregnant women, civilian war victims, victims of war torture, war military invalids, families of deceased and captured fighters, victims of domestic violence, persons with disabilities, and transplant patients.

The patient's right to self-determination implies the right to freely make decisions about their life and health, except when it directly endangers the life and health of others. It is important to note that this right does not include euthanasia.

The right to freely choose a healthcare institution within the territory of Republika Srpska allows the patient to independently select a healthcare institution that provides services in their region.

The patient's right to information entails the right to receive detailed information from healthcare professionals. Basic information that the patient must receive relates to their health condition, potential risks, and consequences of healthcare interventions.

The right to consent requires healthcare institutions to obtain written consent from the patient for each proposed healthcare intervention, except in exceptional situations where the intervention is urgent and life-saving, and the patient is unable to give consent.

The right to refuse healthcare services allows the patient to decline a proposed healthcare intervention, with mandatory information about the consequences of refusal.

The patient's right to confidentiality of personal data ensures that information shared with healthcare professionals remains confidential, except in cases where access to data is justified by law or medical necessity.

The right to privacy allows the patient to protect their privacy during the provision of healthcare services, with the option to approve the presence of others during medical procedures.

The patient's right to seek a second medical opinion provides them with the opportunity to request an opinion from another medical expert regarding their health condition.

The right to relief of suffering and pain ensures that the patient receives adequate therapy to reduce suffering, in accordance with medical standards and ethical principles.

The right to complaint allows the patient to submit a complaint to the director of the healthcare institution if they are dissatisfied with the healthcare service provided, with the right to an administrative procedure and potentially legal resolution.

The right to compensation for harm allows the patient to seek material and non-material compensation in case of professional error by healthcare personnel during the provision of healthcare services, resolved through the competent court.

The rights of patients participating in medical research include clearly defined conditions for participation in research, including written consent, information on all aspects of the research, and the right to compensation in case of harm.

Pre-hospital emergency care for the sick and injured enables the provision of emergency medical assistance to patients in situations where the patient is unable to consent due to vital endangerment or unconsciousness. In such cases, immediate family members or legal representatives are informed about the procedure.

The right to access their own medical records and treatment costs allows the patient, parent, or guardian to access medical records, adhering to appropriate procedures.

These rights are crucial for maintaining trust between patients and healthcare professionals and contribute to transparency and respect for patient rights in the healthcare system.

## EMPIRICAL RESEARCH

For the purposes of this paper, empirical research was conducted in the territory of Republika Srpska, from January to June 2022, regarding citizens' awareness of the Law on Patient Protection and their rights as patients.

In order to investigate citizens' awareness of their patient rights, empirical research was conducted. The research involved interviews with a sample of 380 respondents from January to June 2022. The research covered the territory of Republika Srpska. The survey questionnaire included questions about knowledge of patient rights in Republika Srpska.

Of the total respondents, 58% reported being unfamiliar with the Law on Healthcare in Republika Srpska, 24% reported partial familiarity, and 18% reported no familiarity with this law. Regarding patient rights, 60% reported being unfamiliar, 24% reported partial familiarity, and 16% reported no familiarity with patient rights.

A significant number of respondents, 58%, stated they did not know whom to contact if their patient rights were denied; 24% would contact the institution's director, 10% the ministry, and only 8% would contact the inspection authority.

Table 1 presents the mean values of respondents' perceptions regarding the respect for rights in healthcare, using a Likert scale with values ranging from 1 to 5, where 1 indicates rights are not respected at all and 5 indicates rights are fully respected.

| <b>Rights</b>                                        | <b>Mean value</b> |
|------------------------------------------------------|-------------------|
| right to healthcare,                                 | 3,45              |
| right to self-determination,                         | 3,01              |
| right to freely choose healthcare institution,       | 3,90              |
| right to information,                                | 3,76              |
| right to consent,                                    | 2,98              |
| right to refuse healthcare service,                  | 3,06              |
| prehospital emergency care for the sick and injured, | 3,67              |
| right to confidentiality of personal data,           | 4,02              |
| right to privacy,                                    | 3,05              |
| right to a second opinion,                           | 3,98              |
| right to access medical records and treatment costs, | 2,88              |
| right to relief from suffering and pain,             | 3,02              |
| right to complain,                                   | 3,89              |
| right to compensation                                | 2,78              |

The highest level of respect for rights according to respondents is perceived to be with the right to confidentiality of personal data, which ensures that information shared by patients with healthcare professionals remains confidential, except in cases justified by law or medical necessity.

The lowest level of respect for rights according to respondents is perceived to be with the right to compensation, which allows patients to seek material and non-material compensation in case of medical errors by healthcare professionals, resolved in the appropriate court.

## CONCLUSION

The quality and safety of healthcare are primarily regulated by law, emphasizing the fundamental aspects of improving healthcare quality and safety. The study highlights that the Law on Healthcare, which governs the issue of healthcare quality and safety, is largely aligned with legal systems in neighboring countries, indicating that healthcare quality and safety in Republika Srpska will be commendable in the future.

Considering that the Law on Healthcare of Republika Srpska first distinguishes citizen rights from patient rights and clearly regulates rights that protect patients from certain abuses by healthcare workers and collaborators, as well as healthcare institutions, and that the Law specifically addresses the issue of healthcare quality and safety in terms of bodies overseeing quality improvement, indicators, and the degree of healthcare quality enhancement, it can be concluded that patient rights adopted by the new Law on Healthcare of Republika Srpska serve to enhance healthcare quality and safety.

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