IMPACT OF ISO STANDARD APPLICATION ON FINANCIAL PERFORMANCE OF PRIVATE HOSPITALS

Introduction
Health care is an organized activity aimed at preserving and improving the health of the population. It can be realized as a primary, secondary, and tertiary health activity. An important segment of a secondary level is a hospital health activity. As for an ownership criteria, hospitals can be public or private. The standards of the International Organization for Standardization (ISO standards) are applied in order to provide the conditions for adequate healthcare provision along with the economic sustainability of the functioning of hospitals. The subject of the paper is the analysis of the impact of the application of ISO standards on the financial performance of private hospitals. The aim of the paper is to outline the basic role of ISO standards and the degree of their impact on the financial performance of the aforementioned health care institutions based on the analysis. The paper consists of five parts. In the first part of the paper, there is a brief literature review which includes individual segments that are the subject of analysis in the paper. The second part of the paper presents an explanation of the research methodology. The features of ISO standards and their application in private hospitals are presented in the third part of the paper. Special attention, within the fourth part of the paper, is given to the financial performance of private hospitals. The fifth part of the paper is dedicated to the conclusions and recommendations as well as the theoretical and practical implications of the research.
part of the paper, is paid to the basic financial effects of the application of ISO standards in private hospitals. The discussion of empirical results (case study), obtained on the basis of a sample of 44 private hospitals in Belgrade in the Republic of Serbia, is presented in the fifth part of the paper.

**Literature review**

For the purposes of our paper, the analysis of the impact of the application of ISO standards on financial performance in private hospitals, we selected the following papers. Johannesen et al. [8] pointed out the reasons for the application of ISO standards in hospitals (such as Norway). Chaw et al. [3] identify key differences in quality management between accredited hospitals, i.e. certified, and those which are not. In the paper Heuel et al. [7] it is described how The Red Cross Hospital in Beverwijk, The Netherlands implemented ISO 9000 in the entire hospital and received ISO 9002:1994 and then ISO 9001:2000 certification. One of the goals in the paper of Stoimenova et al. [19] is an analysis of the application of ISO 9001 standard in European hospitals. Busse et al. [2] indicate the impact of the standards, inter alia, on clinical practice. In the paper of Dombradi et al. [5], the characteristics of the application of ISO 9001 standard on the quality of the work of the hospitals in Hungary are analysed and a comparative utility analysis is conducted together with applying other ISO standards. Mohamadi et al. [11] conducted a study that aimed to investigate the effect of ISO 9001 standards on improving hospital performance. The economic effects of the application of ISO standards are discussed in the study International Organizational for Standardization [6]; the economic viability of the implementation of ISO 9001 standard in the health sector in the paper of Petkovska et al. [13]; the impact of ISO 9001 standard on the overall quality of hospital performance with a special emphasis on the contribution of hospitals in the performance is presented in the paper of Noviantoro et al. [12]; the possibility of measuring the benefits of applying ISO standards in hospitals in the paper of Shaw [16], etc., all of them provide a solid basis for concrete analysis in our paper. According to our information, having researched the papers available on the Internet, no concrete analysis of the impact of ISO standards on the financial performance of private hospitals, in the case of the Republic of Serbia, has been conducted so far, which indicates that this analysis is the first attempt to do so.

**Research methodology**

In order to achieve the goal of the paper, it is first necessary to describe the general characteristics of ISO standards based on a description method and analyse the basis of their application in private hospitals. Based on a comparative analysis of different approaches in the selected papers, it is necessary to highlight the basic effects of ISO standards on the performance of private hospitals. Determining the relationship and their strength between the application of ISO standards and the operation of private hospitals implied planned collection, selection and the preparation of adequate data on the number of private hospitals that (do not) apply ISO standards as well as the preparation of comparable data on their functioning and business operation. The basis is the analysis of the impact of the application of ISO standards on the income of 44 private hospitals in the city of Belgrade (the Republic of Serbia) and a regression analysis.

**Characteristics of ISO standards and their application in private hospitals**

As already stated in the Introduction, at a secondary level, healthcare includes specialist consulting and hospital health activities [23, Article 61, 68]. Hospital management aims to achieve the maximum level of health service quality, optimization, and efficient management of key processes [17, pp. 445-451]. In order to achieve all of that, the application of ISO standards is the best solution [3]. ISO management system standards are most often applied in the institutions that provide medical and healthcare services [27].

International standards for management systems, quality (ISO 9001), environmental protection (ISO 14001), occupational health and safety (ISO 45001),
information security (ISO 27001), food safety (ISO 22000) and others, contain the requirements for organizations of all sizes and all business activities. The standards are of a general nature and they are applied voluntarily. They do not impose a uniform structure of management systems as technical standards do. Organizations can apply several management system standards and integrate them into Integrated Management System (IMS) through joint documentation. The basic requirements of all management system standards are identical, some of their sub-requirements differ, so the joint documentation includes the same requirements and sub-requirements, and it is supplemented by a specific documentation for each of these standards. The system certification is performed according to the requirements of each standard individually and it is valid for three years. There are also standards that contain instructions and according to them the management system is not certified, such as ISO 26000 standard – the guidance on social responsibility, ISO 9004 - Quality Management, the guidance to achieving sustainable success, etc. The application of these standards contributes to the further improvement of the overall business system of an organization [21. pp. 594-614].

The series of standards for quality management system ISO 9000 consists of three standards: ISO 9000, ISO 9001, and ISO 9004. ISO 9000 standard provides terms and definitions and specifies the key features of quality management: customer focus, leadership, engaging people, process approach, improvement, evidence-based decision making, and relationship management [18, pp. 12-22]. By applying the principle of customer focus, organizations can understand much better the needs and expectations of customers and define their goals accordingly [15, p. 80]. Customer satisfaction is continuously monitored so as to take appropriate corrective measures in a timely manner. Prompt and flexible response of an organisation to changes regarding customer requirements ensures customers’ greater loyalty along with increased income. To achieve sustainable business success, organizations need to achieve a balance between customer satisfaction and other stakeholders (owners, employees, suppliers, a local community, and a society as a whole). To balance the requirements of all stakeholders, organizations can be helped by the application of the already mentioned ISO 26000 standard as well as the Balanced Scorecard method – BCS [9, p. 9]. The leadership principle implies that leaders should establish the unity of goals and organisational leadership by creating an internal environment in which employees give their optimal contribution to business operations. The effects of applying the principle of engaging people also depend on successful leadership [21, p. 34]. It is essential for employees to be actively involved in business processes in order to increase their motivation [21, p. 11], responsibility, innovation, and creativity [4, pp. 411, 412]. A process approach implies that the entire quality system of an organization is viewed as a set of interconnected processes. By applying the approach, necessary activities are defined precisely so that the desired results can be achieved and responsibilities established for each activity [21, p. 85]. The processes are regularly monitored, enabling timely identification of errors and their causes followed by taking appropriate measures. ISO 9001 standard emphasizes the need for risk management which is more efficiently implemented by applying a process approach. The principle of improving the overall performance of organizations should be ongoing [15, p. 83]. Organizations need to develop the ability to respond promptly to opportunities and dangers to survive in an ever-changing market. Evidence-based decision making implies that decisions are based on the analysis of data and information. It is vital to keep appropriate documentation on all activities [13]. Key process indicators are monitored and measured, as well as customer satisfaction [21, p. 37]. The top management is obliged to regularly, at least annually, reassesses the quality management system of the entire organization. Relationship management is the establishment of the cooperation between an organization and its suppliers as well as other business partners [21, p. 38]. This increases the flexibility and speed of the joint response to market changes. An organization needs to optimize the number of its suppliers in order to build long-term partnership with them.

ISO 9001:2015 standard, Requirements for Quality Management System, is based on the continuous
application of the PDCA approach (Plan - Do - Check - Act) and contains the following basic requirements for a quality management system: subject and scope of the application, normative references, terms and definitions, the context of an organization, leadership, planning, support, realization of operational activities, performance evaluation, and improvement. Through the abovementioned requirements of ISO 9001 standard and its sub-requisites, the previously explained basic principles of quality management are applied. The requirement to determine the context of an organization refers to the identification of external and internal issues relevant to the purpose of an organization and its ability to achieve the intended outcome. An organization has to define its stakeholders and their requirements, consider the features of its products and services and determine the process-oriented quality management system [18, pp. 18-22]. Leadership is the requirement that emphasizes the leading role of the top management in establishing, maintaining and continuous improvement of quality management system [12]. The management adopts a quality policy, determines organizational roles, responsibilities and authorities and plans the necessary changes in the quality system [18, pp. 22-24]. The requirement for planning a quality system implies that an organization considers risks and opportunities and sets appropriate quality objectives accordingly. The objectives should be in line with the defined quality policy. They are adopted at different levels: at an organizational level, organizational parts, processes, products, and individuals [18, pp. 24-28]. Support is a requirement related to: resource management, competence and awareness of employees, communication in an organization and documentation (i.e. documented information) of a quality management system [18, pp. 28-34].

The realisation of operational activities includes several sub-requisites: planning and managing the realisation of operational activities; requirements for products and services; design and development of products and services; management of externally provided processes, products and services; production and providing services; the release of products and services; the management of nonconforming outputs [18, pp. 34-48]. Performance evaluation contains the following sub-requisites: monitoring, measuring, analysis and evaluation, internal audit, and reviewing by the management [18, pp. 48-54]. Within this requirement, the following things are evaluated: products and services, customer satisfaction, quality management system, the measures relating to risks and opportunities, external suppliers, improvement of quality management system, etc.

The request for improvement refers to: non-compliances, corrective measures, and continuous improvement [18, p. 54]. In the event of certain non-compliance with the specifications, it is necessary to take appropriate corrective measures to eliminate the consequences and causes of the non-compliance. Furthermore, an organization needs to select the opportunities for improvement and implement the measures needed to meet customer requirements.

As previously mentioned, ISO 9000 standards are successfully applied in healthcare systems [10, pp. 314-340]. The world’s best-known quality management standard is ISO 9001 [7]. This standard refers to, as stated, a management system (organizational structure, the responsibility of participants in an organization, the processes and resources necessary for a system management) whose application leads to the realization of defined goals regarding business quality and providing service [25]. ISO 9001 had its versions from 1987, 1994, 2000, 2008, and 2015. In the latest version of ISO 9001 standard, from 2015, the ultimate responsibility of the top management for a quality management system is highlighted and more requirements for risk assessment and management are established compared to the previous versions of the standard. The requirements for the existence of a procedure for corrective measures are retained, while preventive measures are no longer regulated by a special procedure, but by risk management procedures. Some terms, names of documents are altered. [27, 25].

By adhering to the standard, health institutions improve the efficiency of a management system and thus strengthen the trust that their patients have in their system [24]. By certifying the management system, health institutions can show their readiness to consistently comply with all the requirements of the standard aiming to constantly improve patient satisfaction which is reflected in improving their health by providing quality health care [8]. Health is a basic human right and one of the most
important prerequisites for economic development and quality life of inhabitants of a country [14, p. 168]. The application of ISO 9001 standard does not interfere, but only supports and improves the effects of compliance with relevant legislation in the field of health care. It affects better patient care [19]. The focus is on the efficiency of clinical, business and support processes to ensure quality care [11]. The standard promotes the adoption of a process approach, continuous improvement of processes and services through objective measurements, etc. [7, pp. 361-369]. The application of best business practices contributes to the improvement of a quality system and increases the satisfaction of patients and other stakeholders [28].

Financial effects of using ISO standards in private hospitals

Healthcare providers, hospitals, recognize the importance of the value system that combines the fulfilment of all criteria for quality management [2], which includes managing a system of interrelated processes and adherence to the established procedures [13, p. 912]. The proper application of ISO standards should provide a number of economic benefits for hospitals (increased income, reduced costs, saving time when proving health services, etc.). It is extremely difficult to measure the direct impact of ISO standards on financial performance of companies. However, the possibilities of determining the connection between the indirect impact of ISO standards and the business performance of private hospitals are much greater. One possibility is to apply the ISO methodology, based on a four-phase value chain, to assess these effects of ISO standards on enterprises, which could be applied to hospitals with some modifications. The first phase is understanding a value chain (identifying key business processes and activities that add value), and the second phase is identifying the impact of standards (determining business functions and activities in a value chain within which standards play an important role). The third phase refers to the analysis of value drivers (key organizational skills that affect competitive advantage) and the determination of operational indicators (time, price, the number of services provided, etc.), and the fourth phase is the assessment and calculation of results [6, pp. 4-65]. To put it differently, it is possible to single out key activities in hospitals (diagnostics, treatment, surgical interventions, rehabilitation) and especially emphasize those activities on which ISO standards have a significant impact (e.g. surgical interventions). Afterwards, it is possible to identify value drivers in order to prepare and realise fast and quality services (prompt laboratory analyses, check-ups, preparation for surgeries, surgeries), determine operational indicators (saving time, reducing costs, etc.), and determine results (impact on income etc.). It is important to compare the results with the results from the previous period in which there was no application of ISO standards and to make a comparison with the competition.

By applying the requirements of ISO 9001 standard, numerous benefits are achieved for an organization. Some of them are the following: good organization and implementation of work processes [13], achieving optimal employee results, continuous process improvement, cooperation with business partners, flexible response to changing market demands and the like, which should result in high customer satisfaction and increased customer loyalty. Simultaneously, there is an increase in the satisfaction of other stakeholders, and overall improvement in the financial indicators of business success [16].

A great contribution to the implementation of ISO 9001 standard is reflected in the continuous improvement of processes, especially the key ones. The processes are constantly monitored and appropriate process performance indicators are measured, so that pre-identified risks could be managed appropriately [1, p. 9]. If errors occur, the goal is to detect them as soon as possible, preferably at the time and place of their occurrence. In this way, the consequences of those errors are promptly eliminated at the lowest cost with appropriate corrective measures. By analysing the causes of those errors, adequate preventive measures are taken in order to minimize the risks of similar types of errors in the future.

Given that hospitals provide health services, the application of ISO 9001 standard has its own features [5]. A service is a product that is entirely or partially created in direct contact with a user, therefore, errors are much more noticeable here and are directly reflected...
on customer satisfaction [20, pp. 62-64]. The demand for hospital services is inelastic, it cannot increase in accordance with the attitudes of users, as it is the case with, for example, consumer products (clothing, footwear, going to the cinema, restaurants, travel, etc.). People are treated when they are ill, and in those moments they choose the hospital that is the most affordable for them in terms of quality of service and price.

The quality of hospital service is greatly influenced by competent and motivated employees - the expertise of doctors in establishing a diagnosis, recommending a therapy and performing surgical interventions, expertise and kindness of hospital staff, level of hygiene, etc. Proper definition of procedures for performing a process, development of appropriate instructions for the activities within a process, defining quality goals at the level of each employee are the documents required by ISO 9001 standard, and which significantly determine how well employees perform their activities, how easily newly employed get involved in the activities, how to reduce errors in case of incomplete communication between employees, etc. Proper sterilization of medical instruments, disinfection of all surfaces and materials where there is a risk of transmitting infections is immensely important. In order to properly perform these and other activities, it is vital to conduct appropriate education and training of employees.

If other management system standards are applied along with ISO 9001 (ISO 14001, ISO 45001, ISO 27001, etc.), the possibilities for continuous business improvement and achieving sustainable success of an organization are further increased. Some of significant benefits for hospitals are: good medical waste management and environmental protection, employee health protection and reduction of workplace injuries, maintaining the availability and integrity of information, and especially maintaining the confidentiality of personal data and patient diagnoses.

Organizations that have certified occupational health and safety management systems in compliance with the requirements of ISO 45001:2018 standard can integrate into their system the guidance from ISO/PAS 45005:2020 specification. ISO/PAS 45005:2020 specification is a document adopted in response to the COVID-19 pandemic and increased risk to human health in all work environments. By applying the guidelines from this specification, organizations can apply a systematic approach to risk management concerning COVID-19, take effective measures to protect workers and other stakeholders, and adapt effectively and timely to changing situations.

Since most of the requirements of the standard represent the minimum criteria that organizations need to meet, business excellence models are being developed to further improve business performance. According to the criteria of these models, quality awards are given. In the Republic of Serbia, the national award for business excellence “Oscar of Quality” is awarded according to the FQCE model of business excellence created by the Fund for Quality Culture and Excellence. The model has been revised several times, and its current version partially deviates from the version of the European Foundation for Quality Management (EFQM) excellence model. Actually, the model had to be adapted to the specifics of the business environment in the Republic of Serbia. The FQCE model consists of 9 criteria that altogether have 1000 points: leadership, strategy, the potentials of an organization, processes and technologies, market and users, business results, employee satisfaction, customer satisfaction, and social responsibility. The first five criteria show the capabilities of an organization (the mechanisms for achieving results), and the next four criteria relate to results. The ratio of the points of the criteria related to the mechanisms according to the result criteria is 600:400. In this paper, we are not going to deal in more detail with the analysis of the model, we want to emphasize the contribution of voluntary application of the model to business improvement. Hospitals and health centres are among the winners of the national quality award.

Due to, in general, standards, and, in particular, ISO 9001, it is possible to more clearly (precisely) define health services and application processes which should lead to the simplification of internal processes in hospitals, reducing healthcare supply costs, and saving unnecessary, excessive investments [13]. In other words, the inputs are of better quality and there are no redundant health services. The funds saved in the aforementioned way can be directed to the improvement and development of hospitals by innovating health services, implementing new, more
efficient ways of performing surgical interventions, etc. The roles of participants in the system of work processes and their responsibility regarding activities, procedures and results are clearly defined. The processes are documented and thus controlled.

As mentioned above, procedures are prescribed, so health services are provided faster which increases the productivity and better organization improves efficiency. It enables new patients an easier and better access to hospital services. Therefore, the application of ISO standards is of crucial importance, i.e. the number of patients increases which results in higher income. Competitive advantage is gained in this way. Supervision is of better quality which also leads to better control of the procurement of health material. Generally speaking, the application of ISO standards should affect the rationalization of internal processes which reduces costs, encourages innovation, and increases the number of health services and the number of insured persons, etc. [6, pp. 4-65]. One of the ways to determine the impact of ISO standards on the economic performance of hospitals is to determine the differences in operating income of private hospitals that have ISO certification and private hospitals that do not have this certification.

**Empirical results (case study)**

For the purpose of our research, we analysed 44 private health institutions, hospitals in the city of Belgrade (the Republic of Serbia). Among these institutions, 15 of them belong to the category of micro enterprises, 25 belong to the category of small enterprises, 3 belong to the category of medium, and only 1 is a large enterprise. Base on the available financial reports, we analysed the performance of these institutions. Operating income in 2020 was one of the variables we analysed. Figure 1 shows the market share of the analysed hospitals.

The average income in 2020 of all analysed market participants was 236058.2 thousand dinars. The average income of private hospitals that used ISO 9001 standard was 679810.9 thousand dinars, while the average income of private hospitals that did not use ISO 9001 was 152105 thousand dinars. Private hospitals that used ISO 9001 generated significantly higher income than the others which did not use the ISO standard. The difference in income is presented in Figure 2.


![Figure 1. Graphical presentation of the market share of the analysed health care institutions](https://www.apr.gov.rs)
The average income of private hospitals that used ISO 9001 or some other ISO standard (ISO 14001, ISO 45001, etc.) or received the quality award amounted to 530301.2 thousand dinars, while the average income of private hospitals that did not use any standards nor received any quality awards was 149516.1 thousand dinars. The difference in income is presented in Figure 3.

For the purposes of our research, we are going to analyse the following linear regression model:

\[ Y_i = \beta_0 + \beta_1 X_{i1} + \beta_2 X_{i2} + \beta_3 X_{i3} + \beta_4 X_{i4} + \beta_5 X_{i5} + \epsilon_i \]

where:
- \( Y \) – dependent variable (operating income in 2020 in thousands of dinars),
- \( X_{i1} \) – the first explanatory variable related to the application of ISO 9001 standard and takes values 0 or 1,
- \( X_{i2} \) – another explanatory variable related to the application of other ISO standards and takes values 0 or 1,
- \( X_{i3} \) – the third explanatory variable related to whether a company has received the quality award or not and takes values 0 or 1,
- \( X_{i4} \) – fourth explanatory variable representing the number of employees,
- \( X_{i5} \) – fifth explanatory variable representing the amount of intangible costs in dinars,
- \( \epsilon \) – random error,
- \( \beta_0, \beta_1, \beta_2, \beta_3, \beta_4, \beta_5 \) – regression coefficients (model parameters).

Business income depends on a number of variables; however, only few of them are listed here. Regression coefficients obtained by the OLS method are presented in Table 1. Based on Table 1, we can conclude that at the significance level of 0.10, all estimators are statistically significant, i.e. all explanatory variables affect operating income.

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- \( X_{i2} \) – another explanatory variable related to the application of other ISO standards and takes values 0 or 1,
- \( X_{i3} \) – the third explanatory variable related to whether a company has received the quality award or not and takes values 0 or 1,
- \( X_{i4} \) – fourth explanatory variable representing the number of employees,
we can conclude that in our sample the private hospitals that use ISO 9001 standard have an average of 54926.172 thousand dinars higher income than the private hospitals that do not use ISO 9001 standard (provided that they have the same value of other variables). The same situation is with the variable $X_2$. It affects business income as well. The null hypothesis states that the variable describing the application of other ISO standards does not affect, and the alternative one states that the variable affects the operating income. The $p$-value amounts to 0.0173, therefore, the null hypothesis can be rejected. Furthermore, observing the estimated value of the coefficient $\beta_2$, we can conclude that the private hospitals applying other ISO standards have an average of 137656.969 thousand dinars higher income than the private hospitals that do not apply other ISO standards (provided that they have the same value of other variables). Thus, we can conclude that the private hospitals that apply ISO 9001 or other ISO standards on average have more income compared to the private hospitals that do not apply them. This result should be taken with limitation. Only one set of explanatory variables has been analysed here, there are other variables that can affect income. Nevertheless, the obtained result is a motivation for the application of ISO standards.

**Conclusion**

Health institutions, hospitals, are a part of a secondary healthcare activity that have a significant role in the process of treatment and rehabilitation of patients. In order to improve the quality of health services and good business practices in hospitals, ISO management system standards are applied: for quality (ISO 9001), environmental protection (ISO 14001), occupational health and safety (ISO 45001), information security (ISO 27001), and other standards. The application of the aforementioned standards is expected to have a positive impact on the business operation of private hospitals. It is difficult to determine the direct economic impact of ISO standards on private hospitals. There is a greater possibility of determining the indirect impact of ISO standards on the financial performance of private hospitals. Based on the analysis of a sample of 44 private hospitals in the city of Belgrade (the Republic of Serbia), it was determined that there is a correlation between the application of ISO 9001 and other ISO standards and the average income of the analysed private hospitals. Based on a regression analysis, it was concluded that the private hospitals that apply ISO 9001 or other ISO standards have on average higher operating income compared to the private hospitals that do not apply ISO 9001 nor any other ISO standards. The interpretation of these results is limited by a sample size. The subject of further research can be the inclusion of a larger number of private hospitals in the analysis, as well as measuring the impact of ISO 9001 and other ISO standards on other economic results of private hospitals.

**Literature**


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