Basic ISO Standards Related to the Quality and Safety/Security in Health Care Institutions

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Health systems are under significant pressure in many countries. Every day, with the introduction of new methods/techniques, expensive equipment of high technological value, the latest very expensive drugs... the price of health care is growing much faster than the growth of the national product and the most developed countries, despite the fact that in many countries the percentage of health expenditures in the national product is growing. Funding constraints in health systems are evident even in wealthy countries. The cost of health care is significantly influenced by: the increase in the number of the population, changes in the age structure of the population, constant demands for increasing the level of quality of health services, as well as an increase in the demand for new services.

The application of international management standards in healthcare institutions and in state institutions in charge of healthcare can significantly alleviate evident problems in healthcare.

Key Words: *health care, ISO standards, quality, safety, security, education*

1. INTRODUCTION

Every stable and prosperous state relies on a tripod: education, health, economy. The most important leg of the tripod, in our opinion, is health. If this leg is not in good condition, the other two will not be in good condition either.

Also, the three significant reforms that are taking place in our country during the transition process, which is still ongoing: economic, education and health, cannot be viewed independently, because their connection is great. Viewing these reforms autonomously could lead to the reforms being less successful or even unsuccessful.

This, in turn, could lead to an even deeper crisis in the economy, education and health. One of the links that firmly connects these three reforms, and perhaps the most significant, are integrated management systems (IMS) based on a basic set of ISO standards, listed in references [1-3]. The ISO/IEC/EN standards, listed in references [4-19] are also important for health.

When establishing an IMS in a health institution, about 80% of the work is common to the three main basic branches of the IMS: quality, environmental protection, and occupational health and safety.

It should be emphasized that the introduction of IMS and the principles of TQM (Total Quality Management) in a healthcare institution requires knowledge, abilities and skills, as a set of personal characteristics that express the potential of each individual. IMS and the principles of TQM are realized, therefore, with the help of all employees in a healthcare institution, that is, with the help of all participants in the implementation of any process from the network of processes of that healthcare institution. Such an approach represents a good basis for increasing the efficiency and effectiveness of any healthcare institution.

Here, the importance of the mentioned international standards for the safety and security of the work of the health institution should be emphasized, which requires a serious risk analysis due to the occurrence of dangers (threats), general non-compliance, in

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certain processes of the health institution. Risks can occur anywhere in a healthcare facility, at any time, and affect both providers (doctors, nurses and technicians...) and service users (patients, relatives and friends of patients who come to visit patients...), but and the equipment and infrastructure elements of the healthcare facility. The safety and security of the work of health institutions is imperative today, when the world is still fighting the disease of COVID-19 (the World Health Organization officially declared the global pandemic of the corona virus on March 11, 2020).

2. QUALITY AND SAFETY/SECURITY IN HEALTH CARE INSTITUTIONS – REVIEW OF SOME PAPERS

The references given in this paper, as well as the standards mentioned in the INTRODUCTION, provide a solid base for further expansion and deepening of knowledge in the areas of quality and safety/safety of work in healthcare institutions.

We have to point out that in order to fight the global fight against COVID-19, the Presidential Committee of CEN and CENELEC, and then the International Organization for Standardization ISO, made a decision to inform those interested in the industry of protective equipment and medical devices, as well as patients and the public, provide free access to a certain number of standards in this area [20]. This decision refers also to our Institute for Standardization [21]. In order to help companies in Serbia to, during the state of emergency caused by the COVID-19 pandemic, establish and maintain their business and contribute to the faster production of medical devices and equipment essential in the fight against the corona virus, the Institute provided free access to the Serbian versions of 14 European standards in the field of safety equipment and medical devices.

The international standards on which IMS are based are universal - they apply to all sectors (economy, education, health). Healthcare institutions work in an environment that requires: quality, safety/security, performance, effectiveness and efficiency. Management systems create a strategic framework within which each health institution and the health system as a whole can meet these requirements.

In papers [22-27] special attention is paid to health institutions and the health care sector, generally to the entire health care system of the Republic of Serbia. One of the main reasons that the established IMS does not lead to full success in the health institution (HTI) is that it is not fully integrated into the existing business system of the health institution. There must be a sign of identity between the IMS and the business system. In other words, the established IMS must permeate the entire business system of HTI and significantly increase its performance.

It was pointed out that the general advantages of the application of IMS in HTI should be: minimization of documents and records („a documented system, not a system of documents“); less bureaucracy; more creativity; breaking down barriers between individual specialties and organizational parts (improving communication and teamwork); greater focus on mutual connections - synergy, as well as on the exchange of data and information between the functions of quality, ecology, safety and health at work, and social responsibility; improvement of compensation programs in order to increase motivation and constant improvement of ZU; encouragement of training and individual training; introducing the principles of a learning organization; minimization of costs through optimization of time and resources of the ZU business system; simplification of internal and external audits; improvement of mutual relations and cooperation with interested parties. Also, one of the main obstacles for the establishment of IMS is that in our healthcare institutions the traditional approach to management prevails. Traditional management is organized hierarchically. The transition from traditional management to process management requires radical changes in thinking and a transition from a command-control hierarchy based on individuals and directed from the top down to a horizontal structure based on processes and teams.

In HTI, whose structure is based on process management, responsibility also shifts from individuals to teams. Teams are now responsible for: meeting patient requirements, reducing cycle times, reducing costs and improving the conformance of their outputs to given specifications.

At the time when the papers [22-25] were published and reviewed, very few health institutions in Serbia had an established quality system (QMS) or IMS. As an example of a system that functioned well, the quality system of the Institute for Health Protection of Workers of „Serbian Railways“, which was successfully certified and periodically checked by our respected certification body JUQS. However, with the changes in the management of the Institute, this system died. Admittedly, the Institute is now accredited by the Agency for Accreditation of Healthcare Institutions in Serbia. As of August 15, 2019, accreditation is being done in accordance with the Rulebook on Accreditation of Health Institutions, Other Legal Entities and Private Practices (*Official Gazette of RS*, No. 56/2019).

It is good that health institutions are entering the accreditation process in accordance with the aforementioned rulebook. And what is not good? It is not

good that the Agency has a monopoly, and monopoly stifles the quality of work. It would be best to create a professional network of accreditation and certification bodies capable of monitoring and quality control in healthcare institutions (at healthcare service providers).

What is the situation today in healthcare institutions in Serbia? A very small number of health institutions in Serbia establish a quality system or IMS according to international standards. The reasons for this are the same as before. The principles and requirements of IMS sound nice, but are difficult to implement. Too often, the process of introducing IMS principles is accompanied by a lot of management rhetoric, and very little management participation in the practical implementation of these principles. The inability of employees to act outside of their narrowly defined roles and management's focus on short-term goals rather than long-term increases in patient satisfaction and other stakeholders most often undermine efforts to implement IMS.

A good IMS is based on the patient (customer of the health service) and his satisfaction, establishes a partnership between individual organizational parts in HTI, emphasizes the final result, not the partial results of individual organizational parts. In this way, many problems that arise in traditional, cemented organizational structures are avoided or solved. With process management, dynamic organizational structures that easily adapt to demands and changes in the health services market, modern information technologies, new approaches to education/training and intelligent personnel management are kept in mind. Such an organizational structure can be realized by applying the requirements of IMS and principles of TQM.

The rewiev paper [28] presents the results of research into the application of international standards in Institutes of Public Health in Croatia. The research results showed that out of 21 institutes, six (29%) have a certified system in accordance with ISO 9001:2008. All institutes for health care, except two, accredited their testing laboratories in accordance with ISO/IEC 17025: 2007 (90%) and four (19%) accredited their medical laboratories in accordance with EN ISO 15189:2008. Two institutes (10%) are certified in accordance with ISO 14001:2004 for environmental management and protection. The rewiev also showed that most of them plan to establish ISO 15189 (11 or 65% of those who have not yet established it). There are institutions that plan to introduce ISO 9001 (6 or 40%). The obtained research results indicate that health care institutes in Croatia recognize the importance of quality and its role in a global, competitive environment.

What about the Institutes of Public Health in Serbia? In order to maintain good laboratory practice and improve the quality of work in all areas Institutes for Public Health in Serbia deals with, many Institutes for Public Health in Serbia have established and certified IMS and accredited their laboratories according to ISO/IEC 17025:2017. For example, the Institute for Public Health Leskovac has established, documented, applies and maintains an IMS, in accordance with the requirements of ISO 9001:2015, ISO 14001:2015 и ISO 45001:2018.

As the quality of services provided by the Institute for Public Health Leskovac is directly related to the quality of laboratory tests at the Center for Hygiene and Human Ecology, the work of the Institute's laboratories is accredited in accordance with the requirements of the ISO/IEC 17025:2017. Also, the Institute for Public Health of Vojvodina has established, certified and accredited systems according to ISO 9001, ISO 14001 and ISO/IEC 17025 standards. And the Institute for Public Health Nis is certified according to the ISO 9001:2015 standard.

Among the certified/accredited institutes for public health in Serbia, we also include institutes in: Užice, Sombor, Ćuprija, Zrenjanin, Vranje, Valjevo, Pančevo, Subotica, Belgrade, Kragujevac, Kosovska Mitrovica, Pirot...

We note that auditing (internal and external) of the quality system and IMS is done in accordance with the international standard ISO 19011:2018 – Guidelines for auditing management systems.

In papers [29-31] the issues of certification of the quality system of HTI, the methodology of auditing and monitoring processes in HTI and instructions and principles for the development of health and social standards are discussed. The question of whether certification and accreditation are different or the same thing is also discussed [29]. The conclusion is that the patient-centered accreditation standards guarantee the technical quality of the service at HTI, while the quality management system according to ISO 9001 guarantees the continued success of HTI. The joint application of both types of standards makes it possible to achieve and maintain the high quality standards of medical care that society needs.

Therefore, the accreditation of HTI and its certification according to ISO 9001 are important instruments for the continuous improvement of the quality of health services provided by HTI and the constant increase of the trust of patients and other interested parties. The basic conclusion of the paper [31] is that the international standard ISO 9001:2015 has at its core the provision of high-quality services,

analyzed for possible risks and aimed at the users of services (patients...), which are the basic wishes of all professional providers of health and social services.

Nurses-technicians and midwives in Serbia, especially those who belong to the middle medical staff, and on this occasion, as many times before, make a great contribution, not only in suppressing the infection caused by the corona virus in our country, but also in their daily professional activities related to the preservation and improvement of the health of our population of all ages. Papers [32, 33] discuss nursing audits based on the nursing process model for developing and improving nursing care and achieving patient safety.

In the papers [34, 35] there are two good rules of procedure on quality, which can serve as samples for the creation of rules of procedure on quality in HTI. In the paper [36], detailed programs for the education of managers in healthcare were proposed, which could still be applied today, with minor changes. The papers [37, 38] were created on the basis of the experience and newly acquired knowledge of the authors of the papers during the establishment of the quality system at the Institute for Biocides and Medical Ecology (today's name).

Paper [39] deals with the implementation of activities for the implementation of the Protocol on Water and Health, which was adopted in 1999. at the Third Ministerial Conference on Environment and Health, and entered into force in 2005. and became legally binding for all countries that ratified it. The Republic of Serbia ratified the Protocol in April 2013. In order to take joint measures and activities important for the implementation of the Protocol, the Minister of Health of the Republic of Serbia established a Joint Body, which includes several members from several ministries and other institutions.

The paper [40] provides an approach to the development of a sustainable model of health care with „disruptive“ innovations. Innovative trends and new ideas are the driving force behind positive changes in medicine and health care. These changes are complex and challenging. Many talented people are involved, who have different views and apply different decision-making processes in implementing innovative trends and new ideas. Many major changes in health systems are inevitable under the pressure of technological development and medical progress. The essence of this rapid progress through the application of „disruptive“ innovations (innovations that disrupt the existing situation with their application, by bringing to the market a simpler, better solution, which then becomes available to many and instantly becomes a new standard), is in fact a struggle between the old and the new, in in which something of the old survives through transformation, but much of the old disappears.

Previously, for example, you had to go to the doctor to measure your blood sugar level. Today, every patient can do this at home, and control their disease in the best way, and only occasionally go to their doctor to possibly do an HbA1c test that shows the degree of glycolysis of hemoglobin, that is, what is the long-term control of glycemia. Until one day a device for measuring HbA1c is produced for wide home use. Then it will probably be necessary to do a microglobulin test (determines kidney function) from time to time at the doctor's until it is done more simply and possibly at home. In the US today, both of the latter tests can be done with a kit that is used at home, sent for analysis, and wait for the result. Or, for example, laser surgery for the treatment of myopia is almost completely robotic and a surgeon is almost not even needed. Skill (but also power) has shifted from the surgeon to the machine. Although a highly educated person still needs to make the diagnosis, the operation itself is fully automated. Another interesting example is cardiac surgery and conflicts with interventional endovascular cardiology. What is better is decided for each patient separately. But it is easy to assume that we would all choose a less invasive, shorter, cheaper procedure for ourselves. This, however, shifts the center of power from cardiac surgeons to cardiologists, and causes resistance to change despite the clear benefits it brings. The true and greatest wisdom is to measure what should remain and what should disappear, and this reflects the importance of a visionary view of the future organization of the system by leading people who create changes in the health system. That may be their greatness but also their downfall.

Since the advent of the ISO family of standards (ISO 9001/9002/9003:1987), there has been a dilemma as to whether they can be used in healthcare. Many considered these to be industry standards. And what is healthcare? Well, the health industry. Therefore, the ISO 9001:1987 and ISO 9002:1987 standards could be used in healthcare, but carefully.

It was also often believed that the establishment of a quality system according to ISO 9001 was pure bureaucracy. In a paper from 17 years ago [41], this dilemma is considered, whether the quality system established in HTI according to ISO 9001 is pure bureaucracy with a bunch of unnecessary documents or the quality system brings only benefits to HTI.

The authors of the paper provided data on HTI in the world that established a quality system according to ISO 9001:2000. They have successfully done this in their hospital and received a certificate of compliance for the whole hospital. Their experiences with ISO

9001:2000 are very positive and they have made numerous improvements in the work of the hospital. The focus was on the patients of the hospital, and all processes in the hospital were identified and subject to continuous improvement. They established a documented system, not a system of documents.

This kind of system does not lead to bureaucracy, on the contrary - it is easy to monitor and for constant improvements. They have introduced performance measurements that provide an overall and integrated picture of hospital performance.

These measurements led to continuous improvement in the quality of care and improvement of the entire quality management system. They also emphasized the positive impact of establishing a quality system on patient safety.

3. THE FOUNDATIONS OF QUALITY

Regarding the foundations of quality, we will only mention Deming's PDCA concept, which is the basis of the management system, which includes the following steps: P (Plan) - plan; D(Do) – do; C(Check) – check; A (Act) – correct/advance. Quality assurance embedded in the healthcare system should reflect these four steps and define the responsibilities of state institutions (Ministry of Health...) and healthcare institutions at each step. This is shown schematically in Table 1.

Table 1. Deming's quality cycle (continuous improvement cycle) in healthcare

Responsibilities of healthcare institutions (service providers) for quality improvement	Step	The role of state institutions in improving quality
Defining quality: Systematic management planning to ensure compliance with requirements.	1. Plan	Determine requirements in relation to the quality of health care in accordance with the social interest and needs of users/patients (policy goals, legal requirements, etc.).
Execution and maintenance of services.	2. Do	Dissemination – Notifications/instructions, establishing organizational frameworks, creating economic incentives, indicating areas of action through action plans, etc. to support compliance with requirements.
Quality control (monitoring): Internal control of quality (system).	3. Check	Supervision, control and provision of evidence that the work in the health institution (at the service provider) is in accordance with the requirements.
Quality improvement: Reviewing systems and processes and improving service delivery.	4. Act	Dissemination of experiences from supervision and control (to others as a basis for correcting/improving requests and recommendations).

4. SAFETY/SECURITY OF WORK IN HEALTH CARE INSTITUTIONS

At first glance, safety and security are interchangeable terms. And in many languages there is only one word for the concepts of safety and security. In German, for example, that word is Sicherheit, in Spanish - seguridad, in French - securite, and in Italian - sicurezza [42]. In our literature, the word security is most often used for both terms, and e.g. in Croatia - security.

However, these two terms are different. There are multiple definitions of safety and security. We will list the definitions that perhaps best indicate the differences between the two terms: Safety is protection against random incidents. Random incidents are unwanted incidents that happen as a result of one or more coincidences; Security is protection against intended incidents. Wanted incidents happen due to a result of deliberate and planned act [42].

In order to realize the safety of the work of the healthcare institution, an adequate risk analysis is needed due to the occurrence of dangers (threats), generally non-compliance, in certain processes in the network of processes of the healthcare institution.

As stated in the INTRODUCTION, risks can occur anywhere in a healthcare facility, at any time, and affect both providers (doctors, nurses and technicians...) and users of services (patients, relatives and friends of patients who come to visit patients...), but also the equipment and elements of the health institution's infrastructure.

Application of the "risk based thinking" model in a health institution

What is risk-based thinking?

Risk-based thinking is something we all do automatically and often unconsciously in order to get the best outcome. The concept of risk has always been implicit in the ISO 9001 standard; the latest version of

the ISO 9001:2015 standard explicitly mentions the concept of risk and incorporates it into the entire management system. Risk-based thinking ensures that risk is considered from the beginning to the end of the observed activity or process. It makes preventive measures part of strategic and operational planning.

If the concept of „risk based thinking“ is used in HTI, then:

- HTI is obliged to respond to the risks and opportunities related to its QMS processes, that is, to determine the risks in order to achieve the desired outcomes (results).
- Management of HTI is required to: promote the concept of risk-based thinking throughout HTI; determination of risks in relation to the desired outcomes (results), whereby the determination of risks affecting the compliance of health services is explicitly required.
- HTI is obliged to identify risks and opportunities related to QMS performance and take appropriate measures to address them.
- HTI is obliged to determine and provide the necessary resources taking into account the seriousness of the risk.
- HTI is obliged to manage its operational processes (e.g. execution of health services, development of new services, control of external services, control of purchased products (e.g. protective masks...) ...).
- HTI is obliged to foresee, measure, analyze and evaluate the effectiveness of measures taken to address risks and opportunities.
- HTI is obliged to correct, prevent or reduce the unwanted effects of the risk and improve the QMS and reassess the risks and opportunities.

Why do we use risk-based thinking?

Successful health care institutions intuitively take an approach based on risk management because it brings the following advantages: it improves the management of the HTI; establishes a proactive culture of continuous improvement; helps to align with set goals; ensures the consistency of the quality of health services; increases patient trust and satisfaction.

How does „risk-based thinking“ apply?

Risks should be identified in the particular HTI - it depends on the context. Risk-based thinking should be used to choose the best way to manage processes/services in a particular HTI.

Please note that ISO 9001:2015 does not require formal risk assessments. The ISO 31000:2018 standard can be a useful reference for HTI that wants a formal approach to risk management (its application is not mandatory).

In HTI, you should make a balance between risks and opportunities, analyze the risks in HTI and make priorities, i.e. determine what is acceptable.

Also, in HTI, you should plan the measures that you will implement with regard to the identified risks (how the identified risks can be avoided, removed or mitigated). When the measures are implemented, the effectiveness of the implemented measures should be checked (whether the implemented measures produce results). And, normally, one should learn from experience and constantly improve the process of avoiding, removing or mitigating identified risks.

To conclude, risk-based thinking:

- is nothing new;
- is something that HTI probably already implements;
- is constantly applied;
- provides greater knowledge about risks and raises the level of preparedness;
- increases the probability of reaching the set goals in HTI;
- reduces the probability of negative outcomes (results);
- makes prevention become a habit.

In this paper, we will not deal with risk analysis and management in HTI. This is explained in detail in reference [43] using the example of an ophthalmologic ambulance.

5. CONCLUSION

ISO Management System Standards (MSS) sets requirements to help health institutions to manage their policies and processes to achieve specific goals. As is well known, there are more than 80 ISO MSS. The ISO 9000 family standard represents the most known ISO MSS. The ISO 9001 standard from this family is the only standard in the family that can be certified.

Without the application of international standards in which the requirements for management systems are given, without the application of other standards, without the application of modern technologies, without the constant improvement of education/training in health care, improvements and innovations in health care will not be able to be accepted to the extent that ensures the stable development of health care. The management in our healthcare institutions must understand this, and the authorities in state institutions must support it.

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REZIME

OSNOVNI ISO STANDARDI KOJI SE ODNOSE NA KVALITET I BEZBEDNOST/SIGURNOST U ZDRAVSTVENIM USTANOVAMA

Zdravstveni sistemi su pod značajnim pritiskom u mnogim zemljama. Svakim danom, uvođenjem novih metoda/tehnika, skupe opreme visoke tehnološke vrednosti, najnovijih veoma skupih lekova... cena zdravstva raste mnogo brže od rasta nacionalnog proizvoda i najrazvijenijih zemalja, uprkos činjenici da u mnogim zemljama raste procenat zdravstvenih izdataka u nacionalnom proizvodu. Ograničenja u finansiranju zdravstvenih sistema očigledna su čak i u bogatim zemljama. Na cenu zdravstvene zaštite u značajnoj meri utiču i: porast broja stanovništva, izmene u starosnoj strukturi stanovništva, stalni zahtevi za povišenjem nivoa kvaliteta zdravstvenih usluga, kao i porast zahteva za novim uslugama.

Primena međunarodnih menadžment standarda u zdravstvenim ustanovama i u državnim institucijama zaduženim za zdravstvo može u značajnoj meri da ublaži evidentne probleme u zdravstvu.

Ključne reči: *zdravstvena zaštita, ISO standardi, kvalitet, bezbednost, bezbednost, obrazovanje*