

QUALITY MANAGEMENT IN HEALTH CARE - CONTRIBUTING TO PATIENT SAFETY AND EFFICIENCY OF BUSINESS OPERATION

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Abstract

In order to ensure efficient and effective health care, of equal high quality and accessibility, at all the levels of healthcare and across the entire Croatian territory, all operators in health services are required to establish, develop and maintain a system for assuring and improving the quality in healthcare. Legal requirement to introduce quality management systems into healthcare institutions notwithstanding, a quality management system is equally important in regard to the provision of cross-border healthcare, which guarantees to the patients from other EU countries that they would receive treatment under clearly defined standards of quality healthcare, ensuring safe and high-quality medical services. For this very reason it has become imperative that exact criteria for the basic standards of medical services and for the needs of medical tourism be determined, as so far they have neither been defined nor harmonised. To compete in foreign markets it is necessary to possess quality certification for both healthcare facilities and business processes, with the overarching goal of ensuring as good and as safe medical services as they are possible. The institution which holds a clear classification and/or accreditation for its facilities and/or services receives more recognition and has more competitive potential in foreign markets. Considering that the system for assurance and improvement of quality in healthcare represents one of the Croatian accreditation standards, introducing integrated systems for healthcare quality management has recently gained significant importance. The quality management system according to the ISO 9001 standard is employed today worldwide, and certifying the system is a generally accepted way of proving that the product or service meets the requirements of quality. The ISO 9001 standard is a generic standard that defines certain requirements for the qual-

ity management system which are applicable to all organizations, regardless of their type and scope, and consequently to healthcare organisations as well. Preparing to enter the demanding market of medical tourism, St. Catherine Specialty Hospital has introduced a quality management system as the first stage on its course to obtaining an international accreditation. St. Catherine Specialty Hospital received its first certification in 2013 for six quality improvement goals (diagnostics, treatment and rehabilitation of diseases and injuries of the locomotor system, magnetic resonance imaging of children and adults, minimally invasive interventions and spine surgery, acute pain treatment, one-day surgery and nursing care) and fourteen quality improvement indicators, the achievement of which was confirmed at the beginning of 2014 in the re-certification procedure which renewed its ISO 9001:2008 standard certification.

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1. Why quality management system in health care?

The quality of health care is a result of measures undertaken on the basis on modern insights regarding healthcare procedures, and which ensure the most favourable treatment outcome possible, as well as reduce the risk of adverse consequences for human health. All patients are guaranteed universal and equal right to quality and continuous healthcare suitable to their state of health, in accordance with generally accepted professional standards and ethical principles, in the best interest of the patients and with respect to their personal views. In order to ensure efficient and effective healthcare, of equal high quality and accessibility, at all levels of healthcare and across the entire Croatian territory, all operators in health services are required to establish, develop and maintain a system for assuring and improving the quality in healthcare in compliance with the Plan and programme of measures adopted by the Minister of Health at the proposal of the Agency for Quality and Accreditation in Health Care and Social Welfare.

So as to avoid unfair competition, it has become imperative to determine the exact criteria for the basic standards of medical services and for the needs of medical tourism, which is, according to UNWTO, the fastest growing tourism industry with an annual growth rate of 15-20 % at the global level. The strategies of both the Ministry of Tourism and the Ministry of Health have identified this form of

tourism as an important segment of tourism in Croatia, with a great potential to launch a number of parallel services. It represents a real opportunity for Croatia to take advantage of its potentials: quality medical service, highly qualified medical staff, competitive prices, well-equipped and staffed private healthcare sector, tradition, preserved environment, a healthy and diverse wine and food offer and priceless natural riches and its healing factors. Specifying the basic service standards would achieve a higher quality of service and lead to it being more highly valued. To compete in foreign markets it is necessary to possess quality certification because an institution which holds a clear classification and/or accreditation for its facilities and/or services receives more recognition and has more competitive potential in foreign markets. The number and type of certified and accredited institutions, and of licensed personnel, is an essential reference in the international market, both for the institutions and for the country as a whole.

The quality management system is equally important for the implementation of Directive 2011/24 EU which concerns cross-border healthcare, and which enables every EU citizen to receive treatment in any of the EU countries under clearly defined standards of healthcare, which guarantee safe and quality medical services. The safety of patients and the standardised quality of healthcare services are precisely some of the most important reasons underlying the introduction of quality management systems into healthcare facilities worldwide. In Croatia, most medical institutions in public health have failed to recognise the need to introduce this type of system, while on the other hand there are hardly any major private medical institutions that have not implemented some form of the quality management system and which are not in the course of preparing themselves for obtaining an accreditation.

2. Healthcare facility accreditation

Accreditation represents an external evaluation of quality of healthcare institutions. It is a process voluntarily undergone in order to establish the compliance of a healthcare institution with the accreditation standards, its validity is limited in terms of duration and it relies on periodic audits. An accreditation is controlled by an agency that sets the standards and schedules the visitations from quality assessment teams (who are trained to assess the extent to which a healthcare facility complies with the prescribed standards). If a healthcare facility meets the prescribed standards it receives the accreditation. The umbrella organization for the accredita-

tion agencies is the International Society for Quality in Health Care (ISQua), with its headquarters in Ireland, while in Croatia this role is occupied by the Agency for Quality and Accreditation in Health Care and Social Welfare. ISQua has 25 member agencies throughout the world (the most important representatives are JCI - Joint Commission International, ACI-Accreditation Canada International, DNV Healthcare Inc. and ACHS-Australian Council on Health Care Standards) which conduct 57 accreditation standards programmes. The accreditation standards are the foundation of accreditation programmes. The standards represent a document which is adopted by consensus and approved by a competent body, which, for the purposes of general and ongoing application, establishes the rules, guidelines and prescribed features of services, or their aimed results in terms of striving to achieve the highest degree of standardisation in the given context. The accreditation standards are part of the ongoing effort to improve the quality of healthcare. They are focused on the patients as end-users of healthcare protection and are founded in the current legislation. The accreditation standards serve as a framework for achieving quality; however, they do not prescribe how to reach the goal, but rather describe the path towards it, which may differ from one country to another, as well as on the level of healthcare institutions. Indicators are an integral part of accreditation standards, and are applied as a tool to concretely measure the compliance with the standards. In accordance with the Regulation on accreditation standards for hospital healthcare institution (OG 3111) the Croatian accreditation standards are the following :

- System for assuring and improving the quality of healthcare
- Hospital healthcare institution management
- Hospital healthcare institution employees
- Overview of the use of healthcare services
- Rights of patients
- Medical records service
- Nursing care and hospital discharge planning
- Infection control and the safety management system

The Croatian Agency for Quality and Accreditation in Health Care and Social Welfare is currently developing a national accreditation programme and plans to obtain an international ISQua accreditation for the Croatian accreditation standards for hospitals in the course of this year. Considering that the system for assur-

ing and improving the quality of healthcare protection is also one of the accreditation standards, and that all operators in healthcare services in the RoC are required to establish, develop and maintain it in accordance with Article 10 of the Act on the Quality of Health Care, it is becoming increasingly important to introduce the system of quality management into the healthcare.

3. Quality management system

A management system is a system that uses an established policy to fulfil the organization's objectives. Management systems in organizations can be implemented and maintained individually; however, the use of integrated management systems has been on the rise. The most common examples of implemented integrated management systems relate to the management systems which are dedicated to quality, environmental protection, health and safety protection. Each management system has a different focus. The quality management system is focused on customer needs, the environment, energy efficiency and the like. The historical development of quality management goes back to the distant past when the Babylonian king Hammurabi imposed order on the business activities of his subjects, introducing his famous law on the protection of customers and small businesses from fraud around 2100 b.c. It is anticipated that the 21st century will be the century of quality, which is to say that the consumers (patients) will prefer only the highest quality products and services regardless of their geographic and national origin. In the Croatian practice the most commonly applied standards and management systems are the following:

- ISO 9001:2008 – quality management system
- ISO 14001:2004 – environmental management system
- OHSAS 18001:2007 – occupational health and safety management system
- ISO 22000/HACCP – food safety management system
- ISO 26000:2010 – social responsibility management system
- ISO 27001:2005 – information security management system
- ISO 50001:2010 – energy management system

ISO 9001 is the most widely used international standard that sets the requirements for the establishment and maintenance of quality management systems, and is applicable to all types of organizations (profit/non-profit, product/service, small/medium/large). This standard is most commonly used in Croatian practice as it

allows organisations to establishment good preconditions for the implementation of other management systems. A well developed and maintained quality management system will positively contribute to the achievement of business operation goals, improving customer satisfaction and trust, as well as the overall results and performance. The impact of an implemented quality management system can provide organisations with numerous advantages over their competitors. How quality affects the company's business revolves around two key aspects: the impact on costs (quality means the absence of errors, higher quality simply means fewer errors, fewer deficiencies) and the impact on revenue (quality represents those features that meet the requirements of customers, such features ensure customer satisfaction, higher quality means the higher number of features that ensure satisfaction). The advantages of organisations which have implemented quality management systems according to the ISO 9001:2008 standard may be divided into external and internal. The internal advantages are defined as those that the organization may gain within its processes (greater employee satisfaction, increased employee and process efficiency, reduced operating costs and increased revenue) and the external advantages are those that the organisation gains in relation to other organizations (a more competitive marketing position, the status of a more desirable employer, easier access to the global market, easier recognisability of the quality of the organisation and its product in the previously unknown markets and brand strengthening).

4. ISO 9001 standard

Following the introduction of mass production in the 19th century there has been an increasing need for quality and for setting up the standards that define it. The first conference on standardization was held in Dresden in 1886, and the first national standardization organization was founded in 1901 in the United Kingdom (BSI - British Standards Institution). In 1906 in London, the first international standardization organization was founded, the IEC (Electrotechnical Commission), and in 1926 the International Standardization Association (ISA) was founded which was the predecessor of ISO (International Organization for Standardization). ISO is an international non-governmental organization for standardization that has existed since 1946 when it was founded in Brussels, and it covers the standardization across all the fields except electrics and electrotechnical engineering, which falls into the domain of IEC (International Electrotechnical Commission). In 1987 the International Organization for Standardization issued international standards of the ISO 9000 series, which were adopted by all the members of ISO,

including Croatia. The ISO 9001 standard has undergone two revisions since its establishment (in 2000 and 2008). The currently valid version is the ISO 9001:2008 standard. The ISO 9001 standard is a generic standard that defines certain requirements for the quality management system which are applicable to all organizations, regardless of their type and scope. This standard prescribes how an organization needs to set up, document, implement and maintain a quality management system and continually improve its effectiveness. In 1987, when the standards prescribing quality assurance were introduced, a need occurred to provide certification of quality management systems.

5. Certification

The term certification implies a process of verification conducted by a third party, i.e. in which an independent organization, based on the assessment of compliance establishes whether a product, process, management system or persons meet the criteria contained in a relevant standardisation document. Certification bodies can be divided into certification bodies for products, persons and management systems (e.g. the ISO 9001 standard on quality management systems). Certification bodies prove their competence by undergoing an accreditation procedure which is conducted by a national accreditation body, in which case it is required to bring its management systems in compliance with the requirements of relevant international standards (which is in Croatia the HRN EN ISO/IEC 17021 standard for the certification bodies in charge of management systems). A certification body that is carrying out a certification procedure evaluates the documentation and work conducted in practice by the organisation which wishes to obtain a certification in accordance with relevant standardisation documents. On the basis of conducted conformity assessment, the certification body awards a certificate, if all the conditions prescribed by the standardisation documents have been met. In Croatia there are 21 certification bodies in charge of quality systems certification. According to the ISO Survey, in 2012 there were issued worldwide: 1,101,272 certificates for ISO 9001, out of which 43% in Europe (474,574), in the U.S. 3.5% (38,586), in Croatia 0.2% (2614), in Slovenia 0.14% (1614), and 0.11% in BiH (1239).

6. Quality management system at St. Catherine Specialty Hospital

St. Catherine Specialty Hospital for Orthopaedics, Surgery, Neurology and Physical Medicine and Rehabilitation in Zabok is a European center of excellence with the most advanced infrastructure for diagnostics, therapy and rehabilitation.

The hospital employs the latest technology and methods of treatment in collaboration with leading European and American institutions and professionals, which is a guarantee of excellence for the work performed at the hospital in accordance with the highest international standards of good medical practice. Considering that the potential of this hospital extends beyond the boundaries of the Croatian market, a plan has been made to introduce it into the market of medical tourism. Therefore it was necessary to set up a quality management system as a preparatory step on the way to achieving international accreditation, and the fact that the European market has become open to cross-border healthcare services has only further emphasized the need to do so. Consequently, in the course of 2012, relying on its own means, the hospital began the process of implementing a quality management system according to the ISO 9001:2008 standard, by means of introducing quality improvement indicators which are based on international accreditation standards, as well as the international guidelines and recommendations that contribute to increasing patient safety.

St. Catherine Specialty Hospital received its first certification in 2013 for diagnostics, treatment and rehabilitation of diseases and injuries of the locomotor system, magnetic resonance imaging of children and adults, minimally invasive interventions and spine surgery, treatment of acute pain, one-day surgery and nursing care. Every segment of the process has with it associated quality improvement indicators and goals which are to be achieved within one year. The quality improvement goals for 2013 were set as very demanding (85% -100% achievement rate was required), and many were correspondingly established. For six quality improvement goals seventeen quality indicators were set up: four indicators associated with diagnostics, treatment and rehabilitation of injuries and diseases of the locomotor system and one-day surgery, three indicators associated with magnetic resonance imaging of children and adults, two indicators associated with minimally invasive interventions and spine surgery, two indicators associated with the treatment of acute pain and six indicators associated with the nursing care. The set quality improvement goals and indicators were defined by the teams for their respective hospital domains and organisational units. The aim was that all hospital staff would become involved in the defining of the quality improvement goals and indicators, as well as of the ways in which they might take part in their daily tracking and achievement.

The World Health Organization (WHO) launched five years ago an initiative to increase patient safety in operating rooms in order to reduce the number of surgical

deaths. The aim of this initiative was to assist the teams in operating rooms with reducing the number of undesirable events such as: inadequate anaesthesia, surgical infections and poor communication among team members. For this purpose, a number of safety checks in the operating room were identified that should contribute to the prevention of errors and omissions, and reduce the mortality of patients undergoing surgery. The intention of the WHO is that the implementation of the surgical safety checklist becomes a standard procedure for the assessment of all the hospitals around the world. This list was integrated at the St. Catherine Hospital as part of the standard surgical procedure and in a way that one of the quality improvement indicators requires 100% of the patients undergoing surgery to have a completed surgical safety checklist for verification purposes. In this manner St. Catherine Specialty Hospital has become the first hospital in Croatia which has introduced this document, which is recommended by the World Health Organization for the daily practice of surgical teams in operating rooms.

Figure 1: Surgical safety checklist in the St. Catherine Specialty Hospital and Surgical safety checklist recommended of the World Health Organisation

ST. CATHERINE SPECIALTY HOSPITAL	Department:	Page 1 / 2
	Operating block and sterilization	Issue: 2/ 01/01/2014
	Name: Surgical safety checklist	Designation: OPR-OBR-i2

Patient name: _____ No: _____ Number of op. protocol: _____
Date: _____

BEFORE INDUCTION TO ANAESTHESIA	BEFORE START OF PROCEDURE	BEFORE PATIENT LEAVES OPERATING ROOM
Has the patient confirmed: identity name of the procedure site of the procedure consent	Confirm all team members have introduced themselves by name and role	Nurse/technician verbally confirms: Name of procedure Instrument and needle counts Bandaging material counts How sample data are labelled Whether there are any technical issues which need to be reported
	Verbally confirm patient name, type and site of procedure	

Has the site of procedure been marked? Yes No applicable	Has antibiotic prophylaxis been given within the last 60 minutes?	Instructions for proper care and rapid patient recovery: Med. nurse/technician
Does patient have any known allergies? Yes No	Is radiology imaging displayed?	Anaesthesiologist: Does patient require specific care? Yes No
Is there risk of difficult intubation or aspiration risk? Yes, and equipment is available No	Critical event anticipation: surgeon Unwanted course of procedure _____ Procedure duration _____ Anticipated blood loss _____ Anaesthesiologist: Additional venous access in case of >500 ml of blood? Yes No	Operator:

Performed: _____ Performed: _____ Performed: _____

Source: St. Catherine Specialty Hospital documentation

Surgical Safety Checklist			World Health Organization	Patient Safety <small>A World Alliance for Safer Health Care</small>
Before induction of anaesthesia <small>(with at least nurse and anaesthetist)</small>	Before skin incision <small>(with nurse, anaesthetist and surgeon)</small>	Before patient leaves operating room <small>(with nurse, anaesthetist and surgeon)</small>		
Has the patient confirmed his/her identity, site, procedure, and consent? <input type="checkbox"/> Yes	<input type="checkbox"/> Confirm all team members have introduced themselves by name and role. <input type="checkbox"/> Confirm the patient's name, procedure, and where the incision will be made.	Nurse Verbally Confirms: <input type="checkbox"/> The name of the procedure <input type="checkbox"/> Completion of instrument, sponge and needle counts <input type="checkbox"/> Specimen labelling (read specimen labels aloud, including patient name) <input type="checkbox"/> Whether there are any equipment problems to be addressed		
Is the site marked? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	Has antibiotic prophylaxis been given within the last 60 minutes? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	To Surgeon, Anaesthetist and Nurse: <input type="checkbox"/> What are the key concerns for recovery and management of this patient?		
Is the anaesthesia machine and medication check complete? <input type="checkbox"/> Yes	Anticipated Critical Events To Surgeon: <input type="checkbox"/> What are the critical or non-routine steps? <input type="checkbox"/> How long will the case take? <input type="checkbox"/> What is the anticipated blood loss? To Anaesthetist: <input type="checkbox"/> Are there any patient-specific concerns? To Nursing Team: <input type="checkbox"/> Has sterility (including indicator results) been confirmed? <input type="checkbox"/> Are there equipment issues or any concerns?			
Is the pulse oximeter on the patient and functioning? <input type="checkbox"/> Yes	Is essential imaging displayed? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable			
Does the patient have a: Known allergy? <input type="checkbox"/> No <input type="checkbox"/> Yes Difficult airway or aspiration risk? <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available Risk of >500ml blood loss (7ml/kg in children)? <input type="checkbox"/> No <input type="checkbox"/> Yes, and two IVs/central access and fluids planned				

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

© WHO, 2009

Source: WHO, (2008). WHO surgical safety checklist. Available at www.who.int/patientsafety/en/ (13 February 2014)

One of quality improvement indicators associated with the nursing care is the prevention of patient falls in accordance with the Morse scale for assessing the risk of patient fall incidents (with the goal of preventing fall incidents in 90% of patients under this risk). The World Health Organisation (WHO) and the World Alliance for Patient Safety have defined 200 opportunities for the five moments for hand hygiene of healthcare staff engaged in the nursing care. The quality improvement indicator at St. Catherine Hospital requires that 90% of medical nurses/technicians adhere to the concept of five moments for hand hygiene in accordance with the recommendations of the WHO. It has been determined that a 10% increase in the proportion of nurses holding higher education degrees, reduces patient mortality by 5%. For this reason, the continuous and permanent education of nurses at St. Catherine Hospital has been set up as a quality improvement indicator in the following manner: 90% of nurses/technicians with secondary education will acquire 20 points for continuous professional education in accordance with the regulation of the Croatian Nursing Council, 90% of nurses/technicians with bachelor degrees

will acquire 25 points for continuous professional education in accordance with the regulation of the Croatian Nursing Council, and 95% of nurses/technicians will once a year attend education on the basic resuscitation procedures in case of emergency. All these quality improvement indicators directly contribute to the safety of patients of St. Catherine Hospital and in this way improve the quality of health-care services that the hospital provides. All this has been recognised by patients themselves, 93% of whom, in an anonymous survey, expressed the level of their satisfaction with the quality of medical service at St. Catherine Hospital with an excellent grade. A year from receiving the certification, an analysis was conducted for all fourteen quality improvement indicators, eleven of which had been achieved, while it was determined that for three of them it was required to employ a different methodological frame (their achievement was not fully within the competence of the hospital staff, for example, the surveys which the patients were required to return by mail after having been released from the hospital).

During 2013, 35 business processes were changed because the quality management system revealed opportunities for improvement. This resulted in savings being made in the course of business operation and the quality management system in the first year already demonstrated how it could contribute to cost rationalization. Furthermore, it was determined that new indicators for 2014 need to be set up (introducing daily monitoring of the technical condition of operating rooms through the so-called health technology assessment). The quality management system at St. Catherine Specialty Hospital has in this way become a powerful tool for the monitoring of our business processes, with the overarching goal of improving the quality of the offered medical services and the safety and satisfaction of patients. The certification procedure has aided the emergence of the “culture of quality” which is crucial for the process of obtaining an international accreditation, which St. Catherine Hospital plans to embark on (the first contact has been made with the JCI, the first world accreditation agency for hospital accreditation). In the beginning of 2014, St. Catherine Hospital underwent a procedure of re-certification in accordance with the ISO 9001:2008 standard.

Conclusion

Croatian healthcare has a highly educated and expert medical staff, there are few healthcare institutions that have an implemented quality management system and there are fewer still that hold an accreditation. Legal requirement to introduce

quality management systems into healthcare institutions notwithstanding, doing so is equally important in regard to the provision of cross-border healthcare, which guarantees to the patients from other EU countries that they would receive treatment under clearly defined standards of quality healthcare, ensuring safe and high-quality medical services. In order to avoid unfair competition, a need has arisen to establish exact criteria for the basic standard service and the services related to medical tourism. The institution which holds a clear classification and/or accreditation for its facilities and/or services receives more recognition and has more competitive potential in foreign markets. For this reason, St. Catherine Specialty Hospital introduced a quality management system in compliance with the ISO 9001:2008 standard for six quality improvement goals and fourteen quality indicators and obtained the first certification in the beginning of 2013 (for diagnostics, treatment and rehabilitation of diseases and injuries of the locomotor system, magnetic resonance imaging of children and adults, minimally invasive interventions and spine surgery, acute pain treatment, one-day surgery and nursing care). The set quality improvement goals and indicators encompass all the activities of the hospital and the organisational unit and in this manner all hospital staff are actively involved in their day-to-day tracking and achieving. The quality management system has revealed many opportunities for the improvement of work processes and rationalization of costs. A series of indicators have been set up in accordance with international guidelines and recommendations for the betterment of patient safety. St. Catherine Hospital is in this respect unique in Croatia. The quality management system at St. Catherine Specialty Hospital has in this way become a powerful tool for the monitoring of our business processes, with the overarching goal of improving the quality of the offered medical services and the safety and satisfaction of patients. The “culture of quality” which has flourished at the hospital since the implementation of the quality management system is also of importance for the process of obtaining an international accreditation, which St. Catherine Hospital plans to embark on.

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