

# IMPLEMENTATION AND FURTHER DEVELOPMENT OF QUALITY MANAGEMENT SYSTEM ACCORDING TO ISO 9001:2000 STANDARD AT THE DEPARTMENT OF CARDIAC SURGERY, DUBRAVA UNIVERSITY HOSPITAL

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## **Summary**

*The need for quality management system (QMS) at cardiac surgery department has been recognized for some time. QMS should help in management of all processes prevent organizational mistakes and provide a tool for unbiased outcome analysis. Comprehensive process analysis of surgical treatment of cardiac patient has been carried out. Requirements of the ISO 9001:2000 standard: quality management system, management responsibility, resource management, product realization, measurement analysis and improvement, were customized to specifics of cardiac patient treatment. All documentation was written in plain language to serve as practice manual. QMS emphasis is routine investigation of all adverse events and statistical analysis of trends in treatment. After 22 months, QMS has been certified according to ISO 9001:2000 standard for scope of cardiac surgery, cardiac anaesthesia, intensive care and perfusion. The implemented QMS has ensured consistency and improvement of working practice, which in turn provided better control over achieved medical results and higher patient satisfaction.*

**Key words:** *quality management system, cardiac surgery, ISO 9001:2000, scope, improvement.*

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## 1. INTRODUCTION

### 1. 1. Quality in medicine

Quality in medicine is usually defined as achievement and maintenance of internationally accepted standards of treatment and health care. Indicators and standards are the basic terms related to quality in medicine. *Indicators* are measurable facts within the process of treatment, e.g. mortality of a particular operative procedure, incidence of particular complications, incidence of unsatisfactory results of treatment, patient satisfaction, length of hospital stay, or cost *per day*. Satisfaction is a subjective category; however, it can be exactly measured by use of questionnaires and scales. *Standards* are values set for indicators, mostly based on agreement or others' experience published in professional literature or as guidelines for treatment. Accepted standards are also known as Good Clinical Practice. The main modes of quality control in medicine include continuous recording of indicators, identification of trends and signals, analysis of causes, and use of corrective measures [1].

### 1. 2. ISO 9001:2000 and its requirements

The International Organization for Standardization (ISO) is a non-governmental organization established in 1947 which presents today a worldwide federation of national standards bodies from more than 157 countries (on the August 1<sup>st</sup>, 2006) [2]. Its original purpose was to provide standardization of technical specifications for products traded in the international marketplace [3]. Today, the vast majority of ISO standards are highly specific to a particular product, material, or process. However, the standards that have earned the ISO 9000 and ISO 14000 families a worldwide reputation are known as "generic management system standards" [2].

The ISO concept was first brought by the automobile industry in the late 1980s because of a need to qualify the thousands of suppliers used by automobile manufactures. This effort was a concrete example of competitors working to develop a quality framework that would serve them and their customers. However, over the years, this idea has evolved from specific technical specifications to a broader concept of generic quality management systems standards [4].

The ISO 9001:2000 is a generic standard, which means that all standard requirements are general and can apply to any organization irrespective of its type, size, product or service it offers. It should be noted that a *particular process* is being certified rather than a *particular product* or *service*. The ISO 9001:2000 standard requirements are based on the fundamental principles of process approach to the system of quality management, according to the principles issued by W. Edwards Deming, father of the quality management system (QMS) [5]. The standard is based on the following:

- determination of all processes relevant for quality management,
- determination of the course and interaction of the processes,

- determination of the criteria and methods for verification of the process efficiency,
- ensuring availability of resources and information for the processes,
- measurement, control and analysis of the processes,
- continuing process improvement.

An organization seeking certification according to ISO 9001:2000 norm must describe and implement quality management system requirements into their process. This involves writing a quality policy, quality manual and quality objectives according to the official norm (HR EN ISO 9001 in Croatia) [6]. The conventional ISO saying is that you:

- Document what you do ("Say what you do"),
- Establish a process for the service,
- Perform to your documentation ("Do what you say"),
- Provide the service based on the process,
- Record the results of your work ("Record information"),
- Appropriately maintenance all recorded information,
- Audit the documentation for effectiveness ("Audit effectiveness"),
- Audit using the process approach.

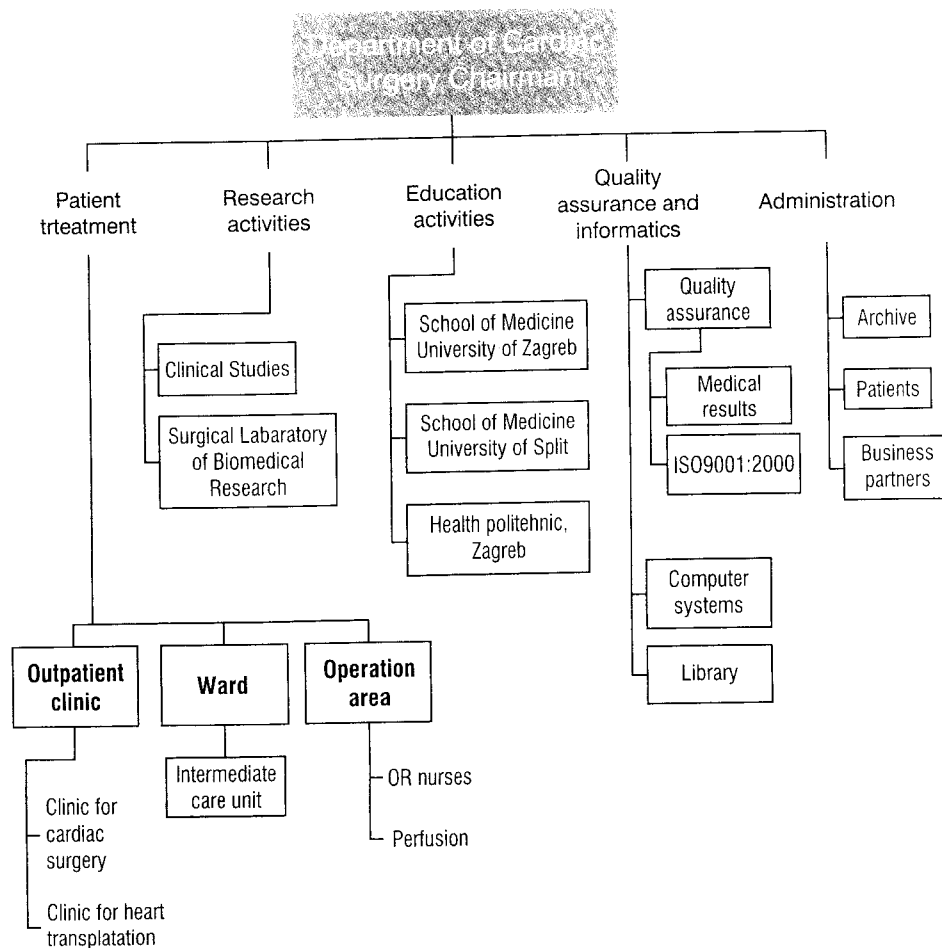
### **1. 3. Purpose of article**

The aim of this article is to describe our experience in the development and implementation of a QMS at a hospital department and the process of certification according to ISO 9001:2000 standard.

### **1. 4. Department of Cardiac Surgery**

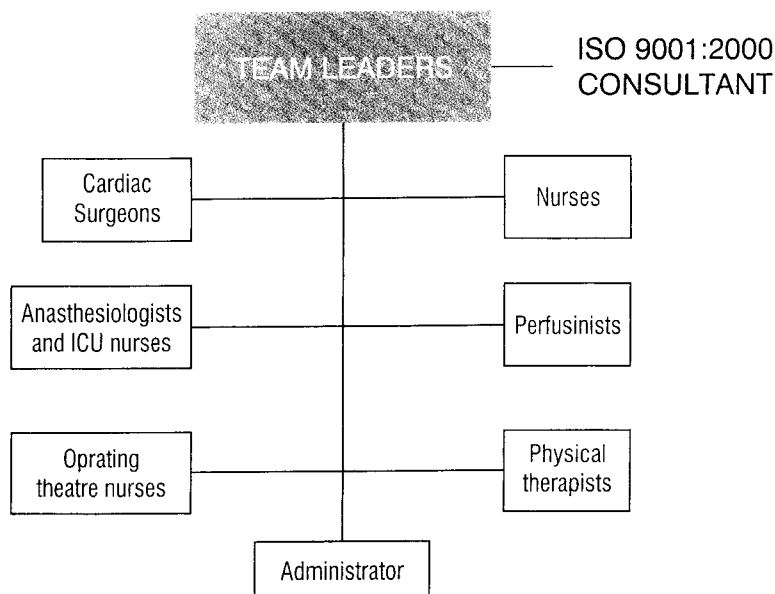
The Department of Cardiac Surgery is a part of Dubrava University Hospital, which is one of several state hospitals in Zagreb, Croatia. The Department consists of a ward with an intermediate care unit with total of 31 beds. It is closely related to the Department of Cardiac Anesthesia with 5 beds in intensive care unit (ICU) and to the operating block with 2 operating theatres. Highly educated staff of about 50 health workers closely involved in surgical treatment of cardiac patients, include surgeons, anesthetists, perfusionists, OR nurses, ICU nurses, ward nurses, physiotherapists, administrator and supporting staff. Over 450 surgical procedures on open heart are performed annually in two operating theatres. Structure of department is presented as organization chart in Figure 1.

**Figure 1:** The Department of Cardiac Surgery: organization chart



### 1.5. Implementation of QMS

The process of the implementation of the QMS took 22 months. Introduction of the QMS was initiated in May 2003, when a task force (Figure 2) was formed at Department. Training and support in QMS development was provided by consultant with previous experience in ISO 9001:2000 certification. The EN ISO 9001:2000 norm was chosen since it enables certification of single departments in complex organization (as in our case). The consultant delivered several training sessions for all employees accept QMS as a supporting framework to be used in improvement of their everyday job and not as a threat.

**Figure 2:** Task force for implementing ISO 9001:2000 at Department of Cardiac Surgery

During the first year of QMS development, task force leaders identified and thoroughly analyzed main process of treatment of cardiac surgery patients. Due to its complexity, all employees were actively engaged in production of a series of standard operating procedures (SOP), each defined by its purpose, responsibility, general description, resources (personnel, qualification, tools, hard- and software, infrastructure) and documentation requirements. All generally acknowledged standards for different procedures in cardiac surgery, cardiac anesthesia, intensive care, perfusion and nursing, as well as existing protocols of Dubrava University Hospital were registered, evaluated regarding their applicability and, finally, incorporated in our QMS. Several additional forms were developed and included in patient medical documentation, thus making routine job easier.

During the second year, the task force was focused on the resources management: all locations, infrastructure, surgical equipment, medical instruments and other resources used in the process of treatment of cardiac patients were described and systematically entered in custom-made databases. Complex relations with other units and services of Dubrava University Hospital were analyzed and formal protocols of communications were agreed.

At the end, comprehensive documentation (Figure 3) was finished and distributed in written and electronic forms. Standard operating procedures on each particular segment

of the process of treatment are available to each employee. Terminology and documentation system were standardized, but a plain and friendly language was used to facilitate routine usage.

Planned internal audits were started to confirm the correct performance and suitability of the revised processes [1]. These audits were performed by quality management representatives of the department and covered the whole QMS. Results and their consequences are reported in the quality management manual.

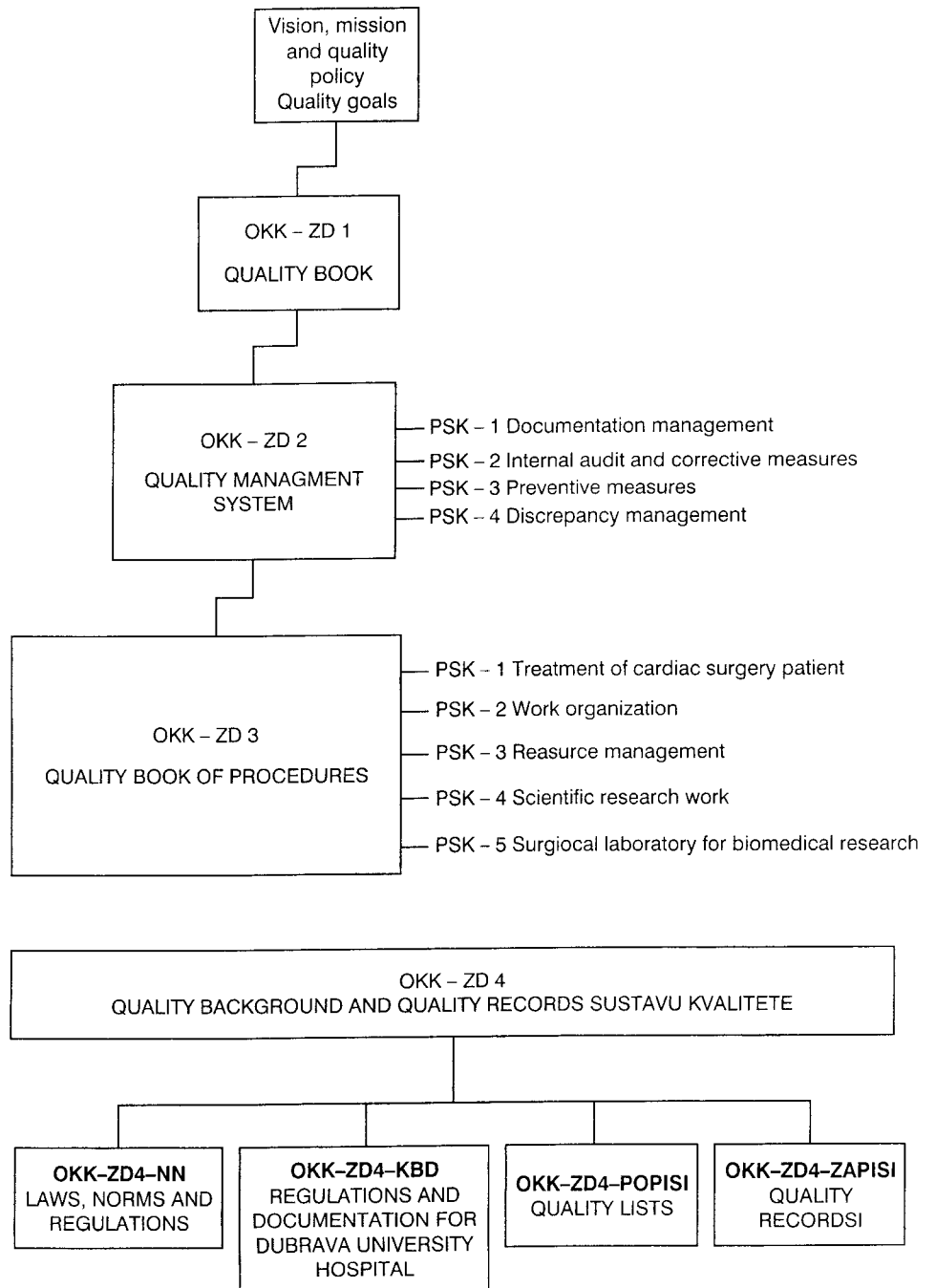
### **1. 6. Measurement of the quality of treatment of cardiac surgery patients**

In addition to usual monitoring of the patients satisfaction by means of questionnaires, our QMS includes continuous measurement of medical result, i.e. objective analysis of treatment outcomes. The process of outcome analysis uses database and statistical methods, and consists of data collection, risk adjustment of data, comparison with external data, and consequential feedback upon the process of treatment. Perioperative mortality is the major quality indicator in cardiac surgery. QMS includes continuous follow-up of overall mortality and mortality according to particular types of operation. The results obtained are compared with the expected mortality according to EuroSCORE, a model of preoperative risk assessment that has found widest application all over Europe [7]. Besides mortality, other treatment complications such as the rate of infection, need of urgent reoperation or repeat sternal closure are also regularly monitored. Along with the analysis of treatment trends, all cases of unfavorable outcome analysis are regularly presented and discussed at Department staff meetings.

### **1. 7. Research activities of Department of Cardiac Surgery**

Research activities in our Department are based on the following standards: Good Laboratory Practice [8] and Good Clinical Practice [9], together with the Declaration of Helsinki [10]. There are two types of research activities: clinical research - routine collecting and analysis of clinical data concerning various topics in cardiac surgery; and science research performed in Surgical Laboratory for Biomedical Research (SLBR). The idea of a research laboratory at our Department was launched at the beginning of 2003, in line with the worldwide trend of establishing so-called "cardiothoracic research laboratory" at many renowned cardiac surgery departments (Cleveland Clinic Foundation (<http://www.clevelandclinic.org/heartcenter/>), Boston University Medical Campus (<http://www.bumc.bu.edu>), Medizinische Hochschule Hannover (<http://www.mh-hannover.de/kliniken/thg/lebao/index.html>)).

**Figure 3:** Schematic diagram of documentation in our QMS



This Laboratory is the first of that type in Croatia. Its main objective is to grow into the leading biomedical research laboratory for applied molecular biology in surgery in the Republic of Croatia and neighboring region. The mission includes the following: teaching the surgeons-to-be in applied molecular biology and research methodology to make them fully competent and independent physicians-scientists, and solving clinical problems encountered in cardiac surgery while comprehending basic physiology and pathology of the issues. The whole process, from the main research idea to the evaluation of the results, were defined and presented in cross-functional flowchart

We have implemented the ISO 9001:2000 requirements to our research unit in the May 2006, according to the steps described in section 2.2.

## **2. RESULTS**

### **2.1. Certification of the QMS**

The implementation of the quality management system was completed in March 2005, when the international certification company Det Norske Veritas (DNV) (<http://www.dnv.org>) performed documentation review and certification audit, and confirmed the process of treatment of cardiac surgery patients (cardiac surgery, cardiac anesthesia and intensive treatment, perfusion) to completely meet the requirements set by the ISO 9001:2000 standard. It should be noted that our quality management system has been set as a flexible system, thus modifications of procedures being readily applicable.

### **2.2. Extension of QMS scope**

As already mentioned, ISO 9001:2000 norm requires not only effective implementation and maintenance of the QMS, but also continual improvement. In May 2006 we extended the scope of certification to the field of design and development. Today's scope is: treatment of cardiac surgery patients: cardiac surgery, cardiac anesthesia and intensive treatment, perfusion; and research with Surgical laboratory of biomedical research.

### **2.3. QMS benefits**

The benefits from all quality management systems generally are long-term and become evident only after several years of their implementation. The majority of companies and organizations observe improved productivity and success, higher satisfaction of their users and employees, and cost reduction. As the quality management system has just been fully implemented at Department of Cardiac Surgery, its benefits will only be able to assess in a certain lapse of time. Yet, some benefits have already become obvious during the introduction and initial implementation of the system, as follows: standardization of procedures – existence of working instructions; mechanism of identifying deviations and their correction (unspoken but present problems); better communication and understanding of the entire process; better maintenance and calibrating of the equipment; medical documentation is complete and properly kept; and imposed obligation of continuous result monitoring.



### 3. CONCLUSION

Effective quality management systems are rarity in our troubled health system and there are no consultants with necessary combination of basic medical knowledge and experience in field of quality assurance. Development of a QMS is both costly and time-consuming process. Bearing all that in mind, we have started pioneering job of QMS implementation in a single department of highly specialized medical field inside a huge state hospital. The success of our job was proven by certification according to ISO 9001:2000 norm in 2005 and by the extension of certification scope in 2006. Finally, we can conclude that implemented QMS has ensured consistency and improvement of working practice, which in turn provided better control over achieved medical results and higher patient satisfaction.

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## IMPLEMENTACIJA I DALJNI RAZVOJ UPRAVLJANJA SUSTAVOM KVALITETE PREMA NORMI ISO 9001:2000 NA ODJELU ZA KARDIJALNU KIRURGIJU SVEUČILIŠNE BOLNICE DUBRAVA

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### **Sažetak**

*Potreba za sustavom upravljanja kvalitetom na Odjelu za kardijalnu kirurgiju je postojala neko vrijeme. Sustav upravljanja kvalitetom je iskorišten da bi pomogao u upravljanju procesima i sprječavanju organizacijskih pogrešaka te kao sredstvo za nepristranu analizu rezultata. Napravljena je sveobuhvatna analiza procesa kirurške obrade pacijenata na Odjelu za kardijalnu kirurgiju. Zahtjevi norme ISO 9001:2000: sustav upravljanja kvalitetom, odgovornost upravljanja, upravljanje sredstvima, ostvarivanje proizvoda, analiza mjerenja te poboljšanja su prilagođeni posebnostima liječenja pacijenata sa srčanim tegobama. Sva je dokumentacija napisana jednostavnim jezikom kako bi služila kao praktični priručnik. Naglasak na sustavu upravljanja kvalitetom uključuje rutinsko istraživanje svih nepovoljnih događaja i statističkih analiza trendova u liječenju. Nakon 22 mjeseca, sustav upravljanja kvalitetom je certificiran prema normi ISO 9001:2000 tako da obuhvaća kardijalnu kirurgiju, kardijalnu anesteziologiju, intenzivnu njegu te perfuziju. Uvedeni sustav upravljanja kvalitetom je osigurao dosljednost i poboljšanje prakse, što je zauzvrat osiguralo bolju kontrolu nad postignutim medicinskim rezultatima te veće zadovoljstvo pacijenata.*

***Ključne riječi:** sustav upravljanja kvalitetom, kardijalna kirurgija, ISO 9001:2000, opseg, poboljšanje*

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