SPECIAL PAPER

Application of ISO 13485:2003 in Biomedical Engineering: a Systematic Review

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Abstract

Introduction: Quality is the foremost objective of healthcare organisms and it is frequently the subject of intense discourse because of not only the citizens-patients' requirements but health administrations and professionals' goals and aims as well.
Objectives: The aim of the present study is to show the significance of quality system ISO 13485:2003 and modern tendencies round this in the international reality and in our country.
Method: An online, systematic peer-reviewed search in Medline, Pubmed and the Cochrane Database with meta-analysis of the search results was conducted. The retrieved studies were then screened to meet certain inclusion criteria, i.e. relevance, significant meanings in correspondence with this paper's objectives and of interest to an international health-professional readership.
Results: The present study constitutes a theoretical approach of quality in healthcare environment, as well as a presentation and description of the ways and processes for quality measurement and quality of health care services improvement. Initially, quality is conceptually determined as a general idea, but mainly focusing on health sector and the providing services. Acute importance is given on quality measurement methods and tools, as well as on the administrative processes that can be applied to continuously improve and ensure an adequate level of quality. An important part of this study is the delineation of quality system of ISO 13485:2003, as this is internationally and domestically applied in the field of Biomedical Engineering.
Conclusion: Given the need for implementation of the prevalent European and National legislation, in order to ensure the safe distribution of medical equipment and the prevention of possible adverse incidents, the present study was realized.

Keywords: Healthcare, Healthcare Quality, Biomedical Engineering, ISO 13485

Introduction

Quality in health services is an intension that it is not easy to be precisely determined. The offer of health services is not a standardized process that is always based on predetermined models. The subjective perception of patient, but also the relation between patient and health professional encumbers even more the precise determination of quality.
The measurement of quality is also important. It is supported by the existing structure, the processes that are followed during the provision of health care and by the results that are achieved. These measurements can be performed individually or simultaneously and they are accompanied by administrative processes aiming at the provision of high standard health services. For this reason, quality assurance programs are applied (Shipley et al., 2000; Turnbull and Hembree, 1999; Crawford and Kessel, 1996; Short and Rahim, 1995).
In modern health systems, is particularly intense the need for provision of high standard health services that will cover the needs and users' expectations. Health systems adopt permanently more directives, based on scientific studies, focusing in the reduction of medical errors and in

the enhancement of patient's safety that uses this particular health system (Tountas, 2003; Eklof et al., 1999; Sitzia and Wood, 1997; Brashier et al., 1996).

As results from the study of modern bibliography, onto subject of health services quality, the modern tendencies require, as their sanitary organisms in its entirety, they apply similar administrative processes, in all spectrum of their operations, so that they ensure a high and continuously improved level of quality in the services that provide. Of course, several writers examine also other aspects of quality. Thus, many perform studies, in order to realize the existing level of health services' quality of a health organization, drawing their data from patients' opinions that became receptors of the provided health services and then to propose ways of quality improvement, in cases where the provided quality is judged low (Tsirintani et al., 2010; Niakas and Gnardelis, 2000; Kyriopoulos et al., 1994).

The sector of Biomedical Engineering could not be excluded from the above frame. The nature of this science, it's objective, it's entanglement with the rapid development of technology as well as the being in effect legislative frame impose the application of quality systems in each of it's aspect. Biomedical Engineering is the application of positive sciences' principles in the analysis and resolution of problems in the sectors of Medicine and Biology. In many health sectors as are the prevention and the confrontation of illnesses or patients' rehabilitation e.g. with kinetic problems the role of Biomedical Engineering is essential. The creation of life supports systems, the design and creation of artificial organs but also the creation of appliances and systems e.g. for persons with special needs aiming at their education with computers and their rehabilitation and employment into social community, constitutes the modern applications of Biomedical Engineering. The advancement and requirements of Medicine as well as the rapid and specialized progress of Biomedical Engineering, created the need for specialized executives with final aim the narrow collaboration of clinical medicine with technology and specifically with Biomedical Engineering. The role of a biomedical engineer is closely connected with the management of health technology inside hospitals, clinics and more generally in the sector of Health. Unfortunately, in our country there is big scientific void in the application of quality systems in the area of Biomedical Engineering (Biomedical Systems, 2011; Samaras, 2011).

ISO 13485 and Application in Biomedical Engineering

The International Standard 13485:2003 (ISO 13485:2003), determines the requirements for a quality management system that can be used by an organization for the design, the development, the production, the installation and the maintenance of medical devices, as well as the design, the development and the provision of relative services. It can be also used from parties inside and outside an organization, including certification institutions so that is assessed the ability of an organization to meet customers' and law requirements. The requirements of the quality management system that are determined in this International Standard are complementary to technical requirements for the products. There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. (ELOT EN ISO 13485:2004 §0.1).

ISO 13485 Process Approach

ISO 13485:2003 constitutes a process of quality management. As a process, it can be considered any activity that it receives inputs and converts them to outputs. In order to function effectively an organization must determine and manage many linked processes. Often the produced outputs from a process constitute the immediate inputs of the next process (ELOT EN ISO 13485:2004 §0.2). While this is a stand-alone standard, it is based on ISO 9001:2000 (ELOT EN ISO 9001, 2000).

ISO 13485:2003 determines the requirements for a quality management system, when an organization needs to prove its ability to provide medical devices and relative services that consequently satisfy customers' requirements and the applicable law requirements in the medical devices and their relative services. The fundamental objective of this standard is to facilitate the accordance of law requirements of medical devices for the quality management systems. It includes certain concrete requirements for the medical devices and it excludes certain of the requirements of ISO 9001:2000 that are not suitable as law requirements.

Application

All requirements of this standard concern organizations that provide medical devices, independently type or size of the organization. If

the law requirements allow exceptions in the controls of designing and development, this can be used substantiation for their exception from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is organization's responsibility for ensuring that conformity statements with this standard reflect the exception of controls of design and development. The processes required by this standard, that are applicable in medical device, but that are not executed by the organization, constitute organization's responsibility and are accounted for in the organization's quality management system (ELOT EN ISO 13485:2004 §1.2).

Quality Management System

The organization shall establish, document, implement and maintain a quality management system in order to increase his effectiveness, according to this standard requirements. Initially it will be supposed it locates the processes needed for the quality management system and their application in all the organization's extent as well as to determine the queue and the interaction between these processes. Also it should determine the criteria and the methods needed so that it ensures that so much the operation, as the control of these processes will be effective. Then, it will be supposed it ensures the availability of resources and information that is required for the support, operation and the follow-up of these processes, but also it watches, measures and analyzes these processes, so that it places in application action essential for the achievement of planned in advance results as well as it maintains the effectiveness of these processes. In cases that an organization selects to assign, in institutions outside the organization any process, which influences the conformity of product with requirements, the organism should ensure the control on these processes. The control of these processes, that are s assigned to institutions outside the organization, should be determined inside the quality management system. In the mentioned above processes that are needed, it will be supposed are included processes for management activities, for the disposal of resources, for the concretisation of product and for measurement purposes (ELOT EN ISO 13485:2004 §4.1).

Documentation Requirements

The documentation of a quality management system should without fail include the argued policy statements and objective aims on quality, a quality handbook, the argued processes that are required by this standard, the documents that are needed from the organization in order to ensure the effective designing, operation and control of its processes, the required files by this standard but also any other documentation that is determined by national or local law regulations.
In cases that the standard determine that a requirement, process, activity or special regulation is argued, this should be placed in application and maintain itself. For each type or model of medical device, the organism should establish and maintain a file, that or he contains or recognizes documents that determine the product's specifications and the requirements of quality management system. These documents should determine the complete activity of manufacture and, if he it is applicable, the installation and maintenance. The extent of documentation of the management quality system can differ in each organization, due to the size of it and the type of activities, the complexity of processes and their interaction and the personnel's ability (ELOT EN ISO 13485:2004 §4.2).

Quality Handbook

The organization owes to establish and maintain a quality handbook, which includes the objective of quality management's system containing details and justification for any exception and/or for anyone with no application, the argued processes that are established for the quality management system or report in them but also the description of quality management system's processes interaction. Also, it will be supposed it describes the documentation structure that is used in the quality management system (ELOT EN ISO 13485:2004 §4.2).

Control of Documents

The documents that are required by the quality management system should be checked. In other words it should be established an argued process that would determine the controls needed in order to:

- be reviewed and approved for their sufficiency, before publication,

- be reviewed and be updated, wherever it is necessary and to be approved again,
- be ensured that the changes of identity is recognized as much as the documents' current revision situation,
- be ensured that the relative publications of applicable documents are available in the points of use,
- be ensured that the documents remain readable and easy traceable,
- be ensured that identity is attributed in the exterior origin's documents and that their distribution is also checked
- be anticipated the no aimed use of outdated documents and in order to be applied suitable identity attribution of these, if they are still maintained for any use.

The organization shall ensure that document changes are reviewed and are approved by either the one that made the initial approval or from other authorized personnel that has access to relevant reference information on which his decisions are based.

The organization shall determine the period for which it should be maintained at least one copy of old checked documents. This period shall ensure that the documents of all medical devices that have been manufactured and checked are available for a time interval at least equal to the lifetime of the medical device, as it is determined by the organization, but no least by the keeping period of any arising file or from any other time period determined by the relative law requirements.

The files should be established and maintained in order to be provided proof of requirements' conformity and proof of effective operation of the quality management system. These files should remain readable, easily traceable and retrievable. An argued process shall be established in order to determine the controls needed for the identity attribution, the storage, the protection, the retrieval, the keeping time and the final files' disposal.

The organization should keep the files for time interval equal to the life time of the medical device as it is determined by the organization, but not less than two years from the product's release date by the organization or as it is determined by relative law requirements (ELOT EN ISO 13485:2004 §4.2).

Management Responsibility

The Central Administration owes to provide proof of her engagement for the growth and implementation of the quality management system and for the maintenance of its effectiveness. In order to achieve it, it shall notify inside the organization the importance of customers' satisfaction requirements, as also the law and control requirements and to establish its quality policy. Moreover, to ensure that objectives for quality are established, to carry out reviews from the Administration and to ensure the required resources' availability (ELOT EN ISO 13485:2004 §5.1).

Customer Focus

The Central Administration shall ensure that customer requirements are determined and satisfied (ELOT EN ISO 13485:2004 §5.2).

Quality Policy

The Central Administration owes to ensure that its policy for quality is suitable for the organization's objective, to include engagement for conformity with the specified requirements and for maintenance of quality management system's effectiveness and to provide a frame for the establishment and examination of its quality objectives. Moreover this policy shall be notified and become comprehensible inside the organization and also reviewed as for its continuing appropriateness (ELOT EN ISO 13485:2004 §5.3).

Legislative Frame

The manufacture industry and its medical devices' supply and maintenance processes, are conditioned by law provisions. Anyone wishes to obtain a medical device owes to take into consideration the being in effect legislation of his country. International Standards EN ISO 9001:2000 and EN ISO 13485:2003 place comprehensively the mentioned above conditions and act accordingly. (Karapiperis, 2009; Quality Assurance & X-Ray Protection Advisers, 2010; National Organization for Medicines, 2009).

In order a product to be disposed for medical use it should essentially bring CE labelling for medical products.

Any product that was sold or it was installed or by any way was disposed in healthcare sector afterwards 13-06-1998 it should obligatorily bring CE labelling according to the directive 93/42/EC. The company that supplies the product should essentially provide certification from promulgated organization that it applies the system of principals and prescriptive lines of suitable distribution and declaration of conformity of EN ISO 9001:2000 quality system for the products that merchandises. According to 93/42/EC directive, as medical product is assessed:

"Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- *supporting or sustaining life,*
- *control of conception,*
- *disinfection of medical devices,*
- *providing information for medical purposes by means of in vitro examination of specimens derived from the human body,*

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means". (ELOT EN ISO 13485:2004 §3.5; Karapiperis, 2009; Quality Assurance & X-Ray Protection Advisers, 2010; National Organization for Medicines, 2010).

Medical devices are classified depending on the degree of invasion in the human organism in category **I** (furniture equipment, urine sample collectors, beds, orthopaedics for exterior use, invalid chairs etc), **II a** (dental alloys, contact lenses, surgical gloves, syringes etc.), **II b** (blood sacs, hemodialysis solutions, X-Ray sources, orthopaedic implants etc.) and **III** (absorbable stitches, heart valves, cardiovascular catheters etc.) (National Organization for Medicines, 2010; Giannakaras and Christofidis, 2010; Quality Net Foundation, 2001).

Each medical product shall bring in an obvious point with easy readable and indelible way, onto product, in packing but also in the user instructions CE labelling accompanied from a four digit number which corresponds in the certification organization that granted him. Also, each medical product shall bring in an obvious point its tracking elements, in other words its serial number if it's a high technology product or lot number for simpler technology products. Also, it shall be accompanied essentially by the following certificates:

- Certification from a certifying organization, in which it will be declared the product's conformity with Directive 93/42/EC.
- Manufacturer's Declaration of Conformity with Directive 93/42/EC and certification from a certifying organization in which will be declared the award of manufacturer's right to place CE labeling with his unique four digit number on the product.
- A manufacturer's ISO 13485:2003 certification from a certifying organization that it is conformable with the regulations of the relative standard for production and medical products' disposal (International Organization for Standardization, 2003).

Conclusions

The problems of our country's healthcare system require radical changes and particular management policy. Are realised decreased citizens' satisfaction and lack of qualitative control in all levels of healthcare system's operation, according to Greek publication and citizens and expert's opinion (Andaleeb, 2001; Murfin et al., 1995; Breedlove, 1994; Bowers et al., 1994). Some of the problems that are indicated in wide range concern in:

- decreased confidence and low patient's satisfaction and their families in the all levels of the healthcare system,
- lack of infrastructure in equipment and trained personnel,
- absence of medical control,
- absence of management systems of medical files,
- defective sensitization and training of healthcare professionals on qualitative control issues,
- lack of programs of qualitative control in the all levels of healthcare system,
- decreased researching efforts of measuring patient's satisfaction degree from the offered health services (Donabedian, 2005).

The guarantee of citizen's health and the provision high quality health services, are more major social question and objective of each respected state. The achievement of this objective is difficult work and requires the conjunction of many forces, organisation, political will and maturity (Kahan & Goodstadt, 1999; Palmer, 1991).

Particular importance should be given in the provided services inside hospitals. Hospital care (secondary and third degree) constitutes today, worldwide, the bigger sub system of each health system. This fact is owed in the orientation of medicine in patients' treatment and not in sickness prevention. Thus, we have the creation and organisation of high technology hospital units, that require increased resources, so much for the construction and their equipment, what for their operation (Sigalas, 1999). The expenses that are been disposed for hospital care (public and private), in all developed countries, constitute the bigger component of health expenses and they correspond roughly in percentage of 60% of their total health expenses.

The quality of hospital care, that is to say the quality of services provided by hospitals, is that sector of health services, which up to today has attracted eminently the interest of the scientific community, of the institutions in charge for its provision, but also hospital's patients.

Certain positions that could contribute considerably in the qualitative upgrade of health services are the following; it shall be given particular importance in the organisation of first degree care and in its interconnection with the remainder health services. The upgrade of Health Centres' role, as well as the institution of familial doctor is commended as necessary. In this way relatively simple and daily incidents might be faced effectively, without charging the operation the prefectural and academic hospitals with incidents, which, thus and differently do not rise in the competences of last ones. According to the existing situation, the hospitals are charged with duties which do not belong to them, with result important functional aggravation, particularly the days of general duties, with patients, which their cases could have been faced by Health Centres.

One still problem, which should be faced, is the enormous inhomogeneousness between hospitals, even if they are of same rung as for their quality, size and cost of provided health services.

Henceforth, is imperative the need of hospitals' modernisation with the import of new methods of rational management, in step with their multilayer reformation. For the successful application of these actions, it is imposed:

- The determination, in central level, explicit and concrete health policy, which will be called to be applied at hospitals, with base concrete annual planning of their activities.
- The change, in any cases required, of legal and institutional frame of hospitals' operation, so that, on one side will deprive from them their public character and on the other hand, will allow their management and administrative flexibility.
- The re-establishment of uniform hospitals' management, with the entrusting of their administration-management in capable managers, the choice of which will exclusively become with base professional criteria and in which will be given motives for goals' achievement.
- The restriction of competences of Hospitals' Administrative Councils, exclusively in the decision-making of Health Policy application, excluding any possibility of intervention in management's application.
- The syntax and application of modern, special single accountant plan, with which will be possible the explicit depiction of financing situations of hospitals or other institutions of medical care (e.g. Health Centres), as well as the comparison of these situations from each other.
- The import of modern methods of measurement and evaluation of real final hospital product and the distribution of available resources in the various hospitals, with base the efficiency and their effectiveness, but also the real needs of population that they are called to cover.
- The extensive use of carefully drawn Hospital Informative Systems, which will contribute in the improvement of quality, in the increase of effectiveness of provided health services, in step with the possibility of services' operational cost reduction.
- The sensitization of health professionals on quality issues, make that presupposes their right information and awareness of their important role as co-managers.
- The establishment of motives connected with the concept of productivity and with the qualitative level of provided health services.
- The extensive information and sensitization of leadership on quality issues.

- The application of quality programs in health organizations. With this way all personnel participates to the direction of quality. Is progressively shaped the required culture inside the organization and constitutes objective the satisfaction, not only of the final services' recipient, but also of the internal customers.

Constitutes necessity the whole society to realise that all of its members should have the possibility of receiving high level health care independent of their economic situation and social status.

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