QUALITY MANAGEMENT IN BIOMEDICAL ENGINEERING

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Abstract

Romania is registering an improvement in the demand of good quality health care services, financial accessible, safety and always reliable, in a moment when there is a significant pressure over the public expenses. Therefore, it's time that Romania reconsider her health care systems in a way of making them accessible for everyone, efficient and sustainable, allocating enough resources.

For a healthier population, we need approaches at the engineering systems' levels, in which the health care methodology should redesign, in the same time with the changing of needs, and also, to integrate locally, regionally, national and globally health care informatics networks.

The following presentation shows the use and benefits of quality management in biomedical engineering industry, a field still unknown for many.

Keywords*: health care system, biomedical engineering, quality management*

JEL classification:

1. Introduction

The 21st century is regarded as the century of continuous improvement in the physical science and engineering. Romanian hospitals still need an approach that could improve their internal and external quality. It is believed that using engineering methods, the health care process could be optimized and aligned at the international standards. Hospitals' managers organize constant meetings in order to identify and remove the difficulties and process that block the hospital's progress and innovation.

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Biomedical engineering represents an interdisciplinary field that combines biology, biochemistry and medicine, with engineering in order to solve specific problems for living organisms. It has large and immediately application in medicine, in the field of diagnosis, treatment and monitoring. From work object's and finality's point of view, biomedical engineering is divided in 2 components: bioengineering and clinical engineering.

While bioengineering is theory and research oriented, using methods borrowed from exact sciences for investigating the biological mechanisms, clinical engineering has a more practical orientation: the general equipment's management and high technology procedures from clinics and hospitals.

The biomedical engineering studies the research equipment, the therapy equipment and the monitoring and laboratory equipment used in biology and medicine, as well as the principles, methods and techniques underlying the operation of this equipment.

What is more, the biomedical engineering has the ability to create functional models, medical devices, implants and mechanical prostheses and artificial organs. Also, this field not only produces performance biomedical equipment, but also uses them in terms of quality of care and safety for patients and for medical staff. The simple actions of everyday life are the study object for bioengineering specialists (biologists, physicists, engineers and doctors). The progresses achieved in bioengineering represent the teamwork results of bioengineering and doctors.

Biomedical engineering is the engineering field with the fastest progress all over Europe, and, nowadays, is considered to be one of the most promising careers. This domain represents also a connected bridge between medicine/biomedicine and engineering, contributing to strengthen and improving the healthcare efficiency in general. Biomedical engineering conceives innovative devices, like artificial members and organs, improving the genetic testing processes, as well as the fabrication and medicines' administration processes.

2. Biomedical engineering in Romania

The "National Society of Medical Engineering and Biological Technology" (NSMEBT) was established on the 2nd of June, in 2000, starting with 49 founders, and legally recorded on 30th of March 2001.

The NSMEBT has the following objectives:

- The development and promotion of biomedical engineering field in Romania
- Organizing national and international conferences
- Improving the curriculum for training and education
- Generating and disseminating field-related information to different partners in the technical, biological and medical community.

According to the Romanian Engineering Society of Medicine and Biology, the biomedical engineering fields are:

- Biomechanics – studies the fluid mechanics (simulation for cardiovascular and urinary functioning devices, laboratory tests, specific treatments like hemodialysis) and also, the solid body mechanic (the study of implant and prosthetic, fractures, etc).

Biomechanics supervises also the sport techniques and the improvement of the athletes' performance.

- Biomaterials – occupies with the study of intervention medical devices (needles, electrodes, operator instrument etc), anatomic prostheses (implants, dental surgeries), from the quality of materials used point of view, especially of biocompatibility.
- Medical biotechnologies – refers to the design, production and use of new materials (instrumentation, medicines, etc) and the development of therapeutic technologies.
- Biosensors – study the physiological signal detection (information) and their conversion into "technical" standardized signals, most often electrical, to be quantified.
- Modeling, simulation and biological system control – follows to establish theories regarding the mechanisms of physiological processes and the mathematic simulation in order to limit the so-called experiments "in vivo".
- Biomedical instrumentation – is closely related to the biosensors and biomaterials field; aims to increase the quality and safety of medical investigations used in diagnosis, therapeutic and surgical interventions.
- Signal analyses in medicine and biology – statistically processes and analyses the recorded signals through different measures, aiming to extract the maximum of useful information in diagnostic and monitoring.

- Recovery bioengineering – presents therapeutic aspects through recovery medical procedures (spa and physiotherapy, electric and magnetic simulation), assisted by specialized equipment and by prosthesis, according to biomaterials and biosensors areas).
- Implants, prostheses and artificial organs – closely linked to the biomaterials, simulation and physiological modeling field. The main objective consists in replacing some anatomical segments with similar artificial structures; here, we could find issues like tolerance and functional compatibility from the organism. From functional point of view, implants could classify in active implants (artificial organs) and passive implants (prostheses).
- Biological effects of the electromagnetic field – represents the interaction between live organisms and electric and magnetic fields. It is also a continuous process by the development of modern civilization. Here, we can find both negative influences (”electromagnetic pollution”) as well as positive influences (medical therapy in electromagnetic field), but also, dosing problems and exposure control.
- Medical informatics, presents several aspects like :
    - Data management within medical institutions records (personal, financial, medical records, treatment sheets, etc);
    - Databases with medical information accessible for extensive medical communities (telemedicine, imagistic collection, tomographic images, etc);
    - Computerized assistance in conducting or preparing the clinical interventions (monitoring, modeling, etc);
    - The use of multimedia facilities for informational and educational purpose.
- Electromagnetic radiation (computed tomography, nuclear magnetic resonance, ultrasounds) – modern and widespread method for medical diagnosis. Is associated with mathematical modeling and is very useful in medical research.
- Clinical engineering – aims to design and develop medical facilities (equipment, construction, therapeutic techniques) in order to provide technical solutions for issues raised by doctors.

3. Classification of medical devices

An important category of medical devices is represented by electronic devices, equipped with computers and specialized software. These devices allow obtaining the result immediately, offering the possibility of exploring without destructive results, as well as, transmitting and storage the information in database, and also, time controlling investigations. Another important thing to mention is that these devices do not influence the bio systems activity.

Nowadays, another important category of biomedical devices is represented by the devices worn by people, meaning those devices that could be used in people's house for monitoring the physiological parameters for a specified treatment (thermometers, sphygmomanometers, devices for measuring the level of glucose, dialysis machines etc).

The main principle for classifying the medical devices represents the purpose for which these can be used. So, from destination's point of view, we have the following biomedical devices:

- Laboratory equipment – intended for the performance of various microbiological tests, in order to establish a diagnosis or to have the ability of knowing the biochemical or biophysical properties or structure for physiological parameters for certain chemical compounds or samples from various organs.
- Equipment for diagnostic and research – designed to investigate the human body, in order to know its normal or pathological state: thermometers, stethoscopes, phonocardiograph, electrocardiographs, electroencephalography, electromyography, devices for measuring skin conductivity, Rötgen devices, etc.
- Therapy devices – designed for the treatment of a certain diseases like. Here we can find nervous system stimulants, electrolytic baths, electrophoresis device, X-rays devices, Gamma rays, laser devices, physiotherapy devices (ultrasounds, microwaves, laser, and vacuum).
- Surgery instruments and devices – meant for surgery interventions: scalpels, electro cautery devices, surgery tables, surgical vacuum, devices for sterile water, etc.
- Anesthesia devices – for anesthetic processes and for patient monitoring during the anesthesia period: monitors, defibrillators, etc.

- Sterilization devices – for sterilizing the tools used in medical interventions.
- Emergency devices – winches, portable vacuum extractors, resuscitation equipment, defibrillators, portable ventilators.

In Europe, as well as in Romania, a lot of medical progresses, like the use of artificial organs, peacemakers, medical imagistic, computer assisted surgery, implants, systems for artificial support of life; all these examples are the result of a close cooperation between engineers and doctors.

Education in the bioengineering field consistently differs worldwide. Biomedical engineers and bioengineers need to have a profound knowledge both for engineering and for biology. As the interest in bioengineering grows, more and more European Institution offer educational programs in this field.

4. Quality Management In Biomedical Engineering

Quality management is a relatively new concept. In Romania, comparative with other European members, hospitals and clinics do not have a bright concept of what quality management means. Our hospitals do have quality standards and over 90% of health care institutions are quality accredited according to ISO norms, but, unfortunately, hospitals" managers do not form specialized trainings for medical staff, in order for them to learn and apply the quality management principles. In the initial state, medical stuff has to be accustomed with the right definition and meaning of "quality management".

Briefly, quality management represents the act of overseeing all activities and tasks that have to maintain a certain level of excellence. The quality in Romanian healthcare is related to healthcare safety, attitude staff, doctors, delays, rate of errors, etc. Basically, quality in healthcare refers to improving patients' satisfaction, to reduce costs and to improve efficiency and provide high quality patient care.

Total quality management is composed of several principles. In the following rows, we will discuss the applicability of some of these principles in Romanian hospitals, more exactly with the focus on biomedical engineering field:

1. Customer focused. The first principle is step by step implemented in our country, regarding the biomedical engineering. In Romania, the Ministry of Health has paid 5 million RON for achieving implantable cardiac defibrillators for those in need. This means that, in order to save as many patient's lives as possible, the Romanian authorities with the Ministry of Health, have decided to implement automatic defibrillators in shops, in train stations, in airports, in malls etc.

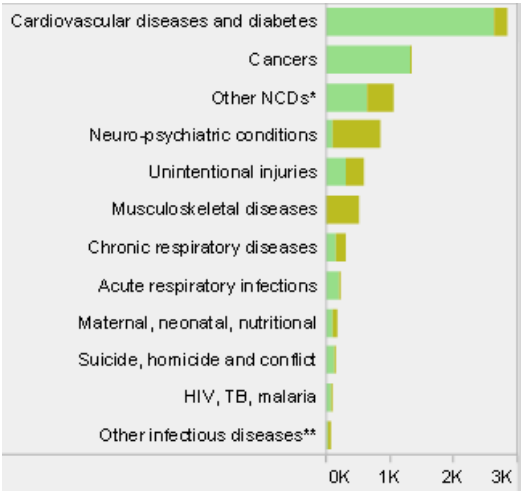

Fig 1. Main causes of deaths in Romania http://www.who.int/gho/countries/rou.pdf

2. Leadership. The 2nd principle refers to the ability to influence behavior. The health care leaderships are able to develop strategies and to generate short term wins, but, unfortunately, their awareness of the need to change is low. In order to implement the biomedical engineering, in our health care institution, as a basic subject, the leaderships must, first of all, understand its importance. Once they understand it, they need to have the desire and support to implement and encourage some of the medical staff to graduate a formation like biomedical engineering.

3. Involvement of people. In every Romanian hospital should exist team of trained biomedical engineers, who are capable of assuring a good quality of work. If people are involved, the medical devices are properly fixed, and the medical results are specified to the patient.

4. Continuous improvement. The health care managers, as well as the medical staff, should constantly improve their work. From the biomedical engineers' point of view, they should have continuous training regarding the use of medical devices, so in that way, they could be able to respond to the needs of doctors.

Analyzing on national scale, in hospitals, research services, educational institutions, technical medical schools, or technical assistance, there is a significantly need for biomedical engineering specialists. To respond to this demand, consistent educational programs in biomedical engineering are needed.

5. Short Summary of an Example Where Principles of Quality Management Weren't Applied and Its Consequences

The short case took place in a public clinic from Bucharest. At generalist comes a patient whom blood and urinary analysis weren't made for a long time. The doctor decides to give the patient a set of test, in order to consult its health condition from the inside also. Every time a patient is sent to a laboratory of analyses, he goes with the referral ticket from his family doctor.

The patient decides to take his analyses at a private laboratory, in order to be sure that the accuracy of the tests is bigger and that there won't be any risk. We have to mention, once again, that beside the blood test, the patient had to take also a urine test.

So, the patient went to one of the most famous private clinics in Bucharest. In the last moment, he decided to test the device's accuracy, so he replaced his urine sample, with tea. The nurses take the sample, record it, and announce a deadline for the result, of 3 days.

After 3 days, the patient returns for his results. He receives both his blood results and his urinary results. The next step is to return to the family doctor to read the results.

The generalist sees the result, and, surprisingly, the urinary results were perfect (the blood results were also perfect, but there was real blood); no anomalies, no higher values, no errors. The urinary results were at perfect as they could be, even if instead of urine was tea.

Practically, the moral of this event is that if the medical devices, controlled by the biomedical engineers are not in perfect quality, and present damages, the clinical results will reveal to be wrong, and the generalist, according to them, can diagnose the patient with something that he doesn't have and in consequence, give him inappropriate medication, or worst, if the results come out to be perfect (like the example mentioned), but instead, in the patient organism lies a virus, that bacteria won't be revealed and it will continue to bring damages to patient's body, in some cases, even causing him death.

This is way biomedical engineers are very important for every hospital. They need to assure the quality of medical devices and of equipment already mentioned at the beginning of the presentation.

The fact is, if the medical device is broken, than the patient is the one who will suffer the most.

That's why, a quality management needs to exist in every medical act.

6. Romania's Issues that Need to be Fixed Through a Quality Management Approach

- Limited educational opportunities. In Romania, there are very few bioengineering specialists, even though our hospitals are eager for them. This thing is possible, because people are not trained and learned about the bright future that could be done for all of us, if we would have promoted and dedicated sections, at faculties, that would teach the medical bioengineering.

- Limited opportunities for career advancement. Most of the students that want to follow the Faculty of Medicine from Bucharest, are not aware of the opportunities that medical bioengineering could bring for them. Since this area is not promoted, students prefer to follow any other specialization, instead of bioengineering. And even if they chose this one, the immediately change their minds, thinking that the maximum stage for them, from professional point of view, would be only "biomedical engineer". What they do not realize, is that the bioengineering field is so vast, that they could make miracles if they know how to use it well.

- Insufficient number of qualified personnel to fill posts. Bioengineering is not easy. It is a field that needs time, involvement and dedication to be able to follow it. Unfortunately, since there are no qualified students, hospitals hire people with a different specialty diploma, other than biomedical engineering. The consequence: even if is a future domain, bioengineering will not be able to progress as long as we do not have qualified and well trained personnel.

Moreover, a good health care condition is essential for the welfare, economic prosperity and sustainable development of our country. The evolution of the health care system is influenced by scientific and technological developments, which affect the employment, innovation, economic growth.

According to the World Health Organization, medical technology is important for improving quality of health care services, including the solving of the health care issues and improving the standard of life.

The establishment of a single market that would integrate the biomedical engineering and the health care services, combined with the technology of information and communication and with systematic approaches in health care, will have enormous advantages for Romania and will lead to a significantly increase of quality and efficiency of health care.

All in all, Romania should follow the USA"s example and to admit this discipline as a scientific one. This would contribute also to the promoting of international competitiveness of Romanian enterprises.

It is expected that in the next years, in USA, the biomedical engineering will represent the labor market with the fastest growth. According to the US Bureau of Labor Statistics, jobs for biomedical engineering will increase with 27% till 2022.

Measures for implementing a quality management in biomedical engineering

- The attention for a solid prevention and an early diagnose, through the use of new technologies;
- Creating a medicine act based on efficiency, not only on clinical dates (for example, the implementation of new processes in the field of health care through technology – like distance medical services);
- The prove of efficiency from the cost's point of view;
- The ease of adopting several efficient measures, from the cost's point of view, based on emerging technologies, and eventually, at distance, through creating several reimbursement systems.

7. Conclusions

The biomedical engineering sector will become more and more important due to technological development and due to the potential of new ways of improving health care services, representing an important step forward for health care system.

The access at the health care services must be seen as a fundamental right. Also, it is important to involve in decisional processes, the potential users of biomedical engineering" products, especially the implication of patients and their families, but also the medical staff, along with the field's experts. In this way, they are able to determine the creation of products and services able to respond to patient needs and preferences. Also, it is mandatory to take into consideration some aspects regarding the accessibility, safety, and data protection.

European Commissions recommend the initiation of a study in the field of biomedical engineering, where could be presented its benefices for industry and for medical services. It is very important to analyze the interdependence

between the politics that affect the health care market and those referring to biomedical engineering sector.

The aging society, the worsening of chronic diseases as well as the rise of health care costs becomes, step by step, global challenges. Since the technology has an important role in health care services, in research, innovation and in the development activities of biomedical engineering, represents important challenges and become of great importance for today's society.

The health care technology industry has an enormous contribution to the Romanian economy and competitiveness, assuring a large number of jobs of high quality, attracting important foreign investments and creating innovation centers. This sector offers for Romanian industry, a huge potential that needs to be explored.

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