

Biomedical Engineering

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safety

Biomedical Engineering (BME) is a relatively new field of engineering originating from an interdisciplinary background of different engineering sciences and principles, as well as from study of biology, medicine, behavior and health. BME aims to improve human health and quality of life. Research in biomedical engineering creates knowledge from molecular and cellular level to the level of organs and the body as a system, resulting in new devices, materials, processes and software. New technologies are implemented in prevention, prediction, diagnostics and treatment of disease, patient care and rehabilitation.

It is difficult to enumerate all successful achievements for patients and health care rising from biomedical engineering research and development in such a short article, but a visits to the Hall of Fame of the American Institute for Medical and Biological Engineering (AIMBE),1 reminds of many devices which we today take for granted in our healtcare: from X-ray imaging devices, artificial kidney, cardiac pacemaker,² antibiotic production technology and others from the early days up to genomic sequencing & micro--arrays, positron emission tomography and image-guided surgery from previous decades. Different technologies will continue to develop as a result of research in basic and applied sciences. For example, in 2009, Nobel Prize for physics has been awarded to Willard S. Boyle and George E. Smith for the invention of the charge-coupled device (CCD), which is used in most digital camera sensors and has a spread medical application for imaging the inside of the human body, in diagnostics and for microsurgery.³ The technology will develop also due to the altered needs of the health care.4,5 In Europe, population projections show dramatic changes: those aged 65 years or over (17.2 % in 2009) will account for more than 30.0 % of the EU's population by 2060.6 The impact of ageing populations will cause increased social expenditure related to healthcare while at the same time, population will expect high quality care that is both readily available and reasonably priced. Technological advances will enable the industry to meet these conditions. Healthcare industry will intensify efforts for solutions of the long-term treatments for chronic diseases in the aging patient population. One of the challenges will be how to achieve healthcare services and healthcare quality. Health care will transit to patients home, patients will use e-health and m-health services much more. 7,8 Intelligent, autonomous devices that communicate with the experts in the health care system will be set in use in a large number of private environments. These devices will to a much large extent, as compared to today, provide visits to virtual MD's office, enable remote access to medical devices, remote diagnostics and therapy, include implantable devices that can detect physiologic changes and transmit data to physician or other health care providers, or clothing with embedded sensors that will enable monitoring of a wide range of physiologic conditions for patients at risk.... However, the idea of enhanced use of advanced and emerging technology also rises the questions of patient safety and security of data.

In case of European legislation, the matter of safe medical products is regulated by the Medical Device Directives. They state that all parties in the chain of using medical devices are responsible for the safety of patients, operators, environment and data. The industry and the clinic need experts for engineering aspects of medical devices and processes.

The best way to get expertise in a field is proper education. Therefore, there is a need, worldwide, for biomedical engineering university programmes that meet the needs of all parties: industry, vendors, and patients. In 2009, a group of European Universities started working on a project with the aim to deliver recommendations for harmonisation of Biomedical Engineering Programs (primarily) in Europe. The harmonized guidelines defined BME topics which should be covered as basic in development of new BME programs and in renewing those ongoing. The guidelines stressed also the importance and value of strong research background of biomedical engineering groups offering courses and programmes in BME. The group from the University of Ljubljana, Faculty of Electrical Engineering, has developed a new Biomedical Engineering Programme at Master level according to the guidelines and the BME programme obtained all necessary accreditation documents to start in the academic year 2011/12.9

In health care, building a safer system means designing processes of care to ensure that patients are safe from accidental injury. When agreement has been reached to pursue a course of medical treatment, patients should have the assurance that it will proceed correctly and safely so they have the best chance possible for achieving the desired outcome.

Biomedical engineers, as all other engineers, have the ability to design and produce, in their case medical products, devices and systems. BME is small, but growing, compared to the traditional engineering fields, like electrical or mechanical engineering, but the number of BM engineers working in research and development is rapidly growing. Most of the BM industry still relays on electrical and electronic engineering including the currently fastest developing industries of active implants and mobile health services. New opportunities open in engineering the organisation of large datasets from biology combining computer based approaches. On this edge between engineering sciences and biology, an opportunity for new studies and applications open. Research in general is so complex today that hardly any research institution can cover all knowledge and skills

necessary for successful outcome of the research goals alone.

Once the devices are installed in clinical settings and procedures clinically accepted, there is another group of engineering professionals taking care of them: clinical engineers. The American College of Clinical Engineering (ACCE)¹⁰ defines a clinical engineer as "a professional who supports and advances patient care by applying engineering and management skills to healthcare technology." Clinical engineering became a distinct profession in the 1960s when an increased use of medical devices and technology in healthcare called for proper maintenance and servicing, following the safety model of commercial aviation.¹¹ Since that time, clinical engineers have become a part of the healthcare delivery system¹² and a regulated profession in many countries,¹³ providing safe and effective application of contemporary medical technology and introduction of new medical technologies into clinical practice.14

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