

Biomedical Engineering 2013: The State of The Art

Radu NEGOESCU

National Institute of Public Health, Bucharest, Romania

radu.negoescu@insp.gov.ro

Abstract — The ubiquitous aspiration to health and life propels healthcare industry as the world's biggest industrial sector. Biomedical engineering (BME) occupies a central place in healthcare industry and it is one of the few areas of engineering that, as a whole, is expected to continue to grow for many years. The US Bureau of Labor Statistics projects a 21 percent growth for biomedical engineers, with an estimated 3,000 new careers created in the industry through 2016. Prospects are less optimistic in Europe and a recent analysis called for steps from the EU Parliament in order to offer biomedical engineering adequate funding and support. In Romania the gap is yet larger: a precarious setting is due not to schooling capabilities or total number of professionals but to the very weak absorption of the practitioners into the health public system. At present the Academy of Medical Sciences of Bucharest tries to promote improvements by means of programming the EU structural funds for 2014 – 2020. In Moldova the establishing of the Moldavian Society of BME in 2010 and the recent setting up of the Chair of “Microelectronics and Biomedical Engineering” within the Technical University's IT & C Department hold a good promise for the future of medical technologies and public health.

Index Terms — biomedical engineering, BME in Romania and Moldova, education and job growth in the US, EU setting, healthcare industry.

I. BIOMEDICAL ENGINEERING: CONTENTS, BRANCHES, EDUCATION

Aspiration to health and life, an inexorable datum of humans, propels healthcare industry as the world's biggest industrial sector, with a turnover approaching £100 billion and an expanding rate of 7% per annum [1]. Other estimates for the US, using more comprehensive definitions, spoke on a “bioengineering market” revenue close to USD 1 trillion, from which medical device slice amounts USD 200 billions and biopharmaceuticals USD 600 billions [2].

Healthcare industry includes 15,000 registered manufacturers, about 10,000 generic devices and > 1 million products & brands. About 50 percent of the 2007 diagnose & treatment technologies pertained to the last 10 years (GMDN Ag., Med. Techn. Brief 2007, quoted in [3]).

Biomedical engineering occupies a central place in healthcare industry and it is one of the few areas of engineering that is expected to continue to grow for many years, despite any crisis [1].

Debates upon the object of biomedical engineering (BME) concluded as early as 1975 [4].

Accordingly, BME is made up of bioengineering and clinical engineering.

Bioengineering is academically orientated towards theory and research in biology by using methods of so-called exact sciences emerging from maths and physics.

Clinical engineering (the term was first used in 1969) has rather a practical orientation given by the general

management of clinics and hospital equipment – particularly the interaction with suppliers, adapting to specific clinical needs, safe utilization of equipment systems, conducting maintenance and development *in situ* – and by the partnership with the medical staff in high technology diagnostic or therapeutic interventions.

The clinical engineer's partnership with the medical staff, first making public surface with the implantation of artificial pacemakers (a bioengineering product), has come along with the rapid growth of computerized X-scan/RMN techniques as a distinct mark of quality for medical diagnose. At the end of the 60's, due to the volume of advanced technologies rapidly growing, the most important hospitals have created specialized clinical engineering divisions. Subsequently, departments of clinical/biomedical engineering were established in all American hospitals from the sub-regional size up.

In Western-Europe establishing in biggest hospitals of specialized departments, if any, was made with a considerable delay.

Biomedical technology has been the only industrial sector that went through the US recession in the early 90's without losses.

Nowadays, the branches or domains of biomedical engineering are seen as in Figure 1. MEMS are micro electro-mechanic systems and MCT Engr refers to molecular, cell & tissue engineering.

The curricula of biomedical engineering was established in the US as early as in starting 60's within working groups from electrical or mechanical engineering departments having as task biology and medicine problem solving with the help of theoretical and methodological concepts of engineer's sciences.

management of clinics and hospital equipment –

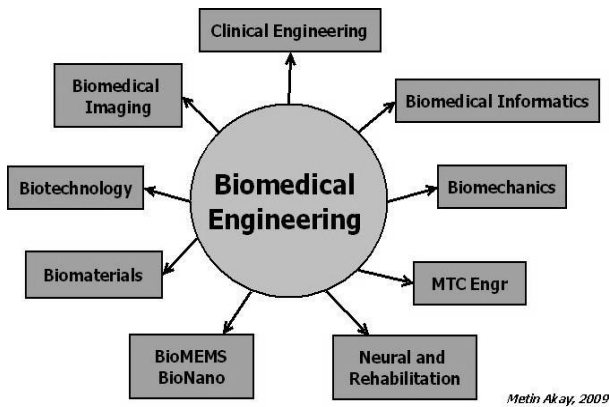


Fig. 1. Branches of biomedical engineering [cf. 2].

In fact, medical electronics and prosthetics & rehabilitation domains have been parts of university curricula since that time.

American College of Clinical Engineering (ACCE) has defined in 1992 the clinical engineer as “a professional that supports and contributes to patient’s care by applying managerial and engineering skills to the technologies used for this purpose” [5].

The Working Group for Clinical Engineering of the Europe-based International Federation for Medical and Biological Engineering (IFMBE), has accepted in November 1992 the definition given by ACCE and has recommended the bachelor of sciences (BS) degree in engineering as a minimal training standard for such a career. IFMBE International Registration as a Clinical Engineer in 2005 requires B.Sc. + 3 years experience in a clinical engineering job or MSc or PhD (in bioengineering) + 2 years experience [6].

Nowadays, education of biomedical engineers in the US often combine formal training in mechanics and electronics with focused biomedical training to operate confidently in the field. Notice that, uncommonly, many entry-level biomedical engineers hold a master’s degree. Some schools provide undergraduate degrees in biomedical engineering and typical coursework includes neuroengineering fundamentals; biofluid mechanics; electrophysiology; diagnostic imaging physics; and drug design, development, and delivery [7].

In the UK, most courses of Medical Engineering (this is the preferred syntagm in Europe) have today a mechanical or electronic foundation, others may be biased more to materials, physics or biology. E.g., the University of Hull offers core modules of mechanics and basic medicine, together with modules in biomechanics, biofluids and biomaterials, implant design and artificial organs, rehabilitation, computer and robotic assisted surgery, tissue engineering, physiological measurements, medical imaging, and regulatory issues & medical ethics [1].

II. THE US: GRADUATES AND JOBS JUST BEFORE AND DURING PRESENT CRISIS

Figure 2 shows rate of increase of BME under/graduation in the USA just before the present world financial crisis. Percent growth ratios versus other most

dynamic engineering domains lay between 3/2 and 3/1 as for 1999 to 2007.

Degree Growth Areas, from 1999-2007

Bachelors Degrees	1999	2000	2001	2002	2003	2004	2005	2006	2007	Percent Growth
Biomedical Engineering	1016	1156	1138	1315	1628	2019	2410	2917	2969	192%
Aerospace	1174	1296	1558	1171	2011	2323	2371	2722	2788	132%

Doctoral Degrees	1999	2000	2001	2002	2003	2004	2005	2006	2007	Percent Growth
Biomedical Engineering	187	203	219	213	240	339	333	436	536	186%
Computer Science	405	399	381	350	410	494	606	761	867	140%

Masters Degrees	1999	2000	2001	2002	2003	2004	2005	2006	2007	Percent Growth
Biomedical Engineering	428	276	526	652	762	862	1007	1156	1326	170%
Aerospace	641	705	633	735	720	915	1043	1094	1056	64%

Metin Akay, 2009

Fig. 2. BME graduation in the US 1999 - 2007 as compared with other key domains [cf. 2].

BME employment projections encompassing the years of crisis remained optimistic.

Thus, prediction for 2012 of BME job growth made by the US Bureau of Labor Statistics (BLS) [cf. 2] were (percent increase versus 2004-05) in order of importance:

1. Healthcare and social assistance: + 32.4
2. BME and biotechnology: + 21 - 35
3. Nanotechnology
4. Security and defense

The actual setting of BME jobs is illustrated by the 14,000 biomedical engineers employed US nationwide, most of them being employed in medical equipment and supplies manufacturing [7]. Other large employing groups include pharmaceutical and medicine manufacturing, scientific and research development services, and general medical and surgical hospitals. According to BLS quoted in [7], biomedical engineers’ mean annual earnings were about \$ 79,610 in 2007 (cf. BLS). Those working in medical equipment and supplies manufacturing saw slightly higher salaries, at \$ 81,950, while those working in scientific research and development earned \$ 92,870. Careers with strongest competition often require applicants to have a master’s degree.

Mid-term prospects say that, although some engineering specialties are expected to rise slowly or even decline in the coming years, biomedical engineers should see growth. The BLS projects a 21 percent growth for biomedical engineers, with an estimated 3,000 new careers created in the US industry through 2016. The demand for increasingly sophisticated medical devices is behind the predicted employment increase [7].

By the way and interestingly enough, job prospects for medical engineers in the UK are also seen as excellent, despite the gap actually separating Europe from the US, namely: companies working on the design, development and manufacture of medical devices; in hospitals working with clinical colleagues in providing non-clinical services; in academic or governmental research facilities; and in

government regulatory agencies. Medical engineers can also work as technical advisers for marketing departments [1].

Long term prospects in the US are suggested by the job datasheet for the biomedical engineer over 2010-2020 [8]:

- 2010 Median Pay: \$81,540 per year, \$ 9.20 per hour
- Entry-Level Education: Bachelor's degree
- Work Experience in Related Occupation: None
- On-the-job Training: None
- Number of Jobs 2010: 15,700
- Job Outlook 2010-20: + 62% (much faster than average)
- Employment Change 2010-20: + 9,700.

III. BME IN EUROPE: AN OBVIOUS GAP VERSUS THE US

The recent recommendations of the Expert Policy Workshop on BME held March 27th 2012 under EU Parliament and European Alliance for Medical and Biological Engineering & Science (EAMBS) aegis, include (excerpta from 9 items) [9]:

“1. [...] It is important that the European Union recognises the full potential of BME and consequently promotes collaborative research in this field. Furthermore, Biomedical Engineering should be understood as a stand-alone discipline [...]

2. [...] promoting growth and well being, including ad Active and Healthy Ageing.

3. Biomedical Engineering research should be made an explicit priority by introducing it into European Union policies and legislation [...].

4. Strengthening of funding for Biomedical Engineering research, by dedicating specific research programmes and by supporting the commercialisation of research results, is essential.

5. More emphasis should be given to covering the full innovation cycle and focus on the “missing mile”, the gap between the completion of a research project and the provision of sufficient (clinical) evidence to attract private investments.

6. Consideration should be given to the impact of the regulatory framework on research and commercialization of health technologies [...]

7. Biomedical Engineering should be included into Horizon 2020, in the section on *Key Enabling Technologies*, as a distinct and separate field from biotechnology [...].

8. A fair balance between biological, medical and technological research should be struck in EU research and innovation programmes [...]“.

In his conclusions, Dr. Thomas Ulmer - MEP, host of the meeting, pointed out that: European Union approach to biomedical engineering is fragmented and support for Biomedical Engineering is not seen as a priority on the EU agenda; given the societal challenges facing the Member States such as an ageing population, the current situation regarding biomedical engineering is unacceptable because it has gone unrecognised at the EU level and that it is not being included in EU projects; the need that biomedical engineering have adequate support

provided and that the European Parliament would ensure that this becomes a reality.

IV. BME IN ROMANIA: THE GAP YET LARGER

Diligences of Bucharest AISTEDA University and Iasi Univ. Med. & Pharm./Faculty of Medical Bioengineering succeeded an early 2000 introduction of professions of Clinical Engineer under code no. 221401 and Medical Bioengineer code no. 222907, respectively, into the Classification of Occupations in Romania (COR, see [10]). Clinical engineering appears the actualized cf. ISCO 88 edition under major group 22, minor group 221 with the (supplementary) numeric indicative 2214 - clinical engineers; this inclusion has the following specification: “clinical engineers cover general management of hospitals and clinical equipment - particularly professional interface with suppliers, adjustment to specific clinical needs, safe utilization, maintenance, and *in situ* development - as well as partnership with medical staff for high technology diagnostic or therapeutical interventions” and has as only occupational component: 221401 - clinical engineer.

Despite this salutary legal provision, setting is precarious not because of schooling capabilities and total number of practitioners but because of the very weak absorption into the health public system the majority of Romanians rely upon, due in part to the chronic underfinancing of the health sytem.

All these happen on a background of modest technological endowment of most hospitals & clinics and of under-usage of high-tech equipments available in big towns/university hospitals.

Most recently the Academy of Medical Sciences (AMS) tries to promote changes within the framework of Ministry of Health debate on programming of EU structural funds for 2014 – 2020.

BME education in Romania is based nowadays on 5 main national centers: Bucharest - Politehnica Univ, Fac. of Med. Engng. - undergrads, and Bioengng. & Biotechnology Dept. - master's of Bioengng.; Iasi - Univ. of Med. & Pharm., Fac. of Med. Bioengng - undergrads & master's; Cluj - Technical Univ., Fac. of Electrical Engng., major & master's of Med. Engng., also in Bistrita; Brasov - Transilvania Univ., Fac. of Mechanical Engng.- major of Med. Engng; and Timisoara - Politehnica Univ., Fac. of Mech. Engng., major & master's of Med. Engng. Intriguingly enough, collection of data from the above centers, needed for the AMS initiative, is rather hardly advancing.

As a rough guide, based on fragmental data collected from the web sites [11- 15], in 2012 Romanian universities are qualifying about 200 people at the undergraduate or master's level, as follows: Bucharest, undergrads, masters – 75; Iasi, undergrads & masters – 50; Cluj, undergraduate specialty & masters – 25; Brasov, undergraduate specialty – 25; Timisoara, undergraduate specialty & masters – 25. *Grosso modo* (see also next case study) one can count one thousand BME-trained Romanian professionals. Partition between clinical engineers and bioengineers seems to be fairly balanced. No accurate date on those working for the

health public system are available but general perception is that absorption is very weak.

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BME education in Timisoara: a case-study [16].

*Univ. Politehnica, Fac. of Mechanics, Major (specialty) of Med. Engng:

*2012: undergrads - 19; masters (implants/prostheses/biomechanics) - 12;

*Total undergrads (since 2007) - 181; total masters (since 2010) - 42;

*Main jobs: service engineers - 17%; technical sale agents - 11%; medical device manufacturing - 5 %;

*Practitioners in the health public system (HPS): 3 %.

*Steps seen as necessary to encourage absorption in the HPS:

1. novel personnel chart regulations in hospitals, e. g. requiring 1 technologist for every 5 - 8 medical staff depending upon technical endowment (US standards are 1 per 4-6);

2. incentives for development of indigenous manufacturing of medical devices beyond a few prostheses/orthoses and gait-aid devices offered nowadays by small companies mainly involved in imported equipment retail.

The AMS pledge concerning BME in Romania is structured as follows.

Goals.

Novel regulations concerning the technological support of medical care in Romania, as:

- establishing BME departments in big hospitals (county, university) starting from an 1/8 ratio between the specialized technical personnel (including bioengineers with research labs) and the medical staff (T to M ratio), with gradual evolution towards 1/5 until 2015;

- establishing clinical engineering departments with medium size hospitals or small hospital networks starting from an 1/10 T to M ratio with gradual evolution towards 1/6 until 2015;

- when updating hospital technological endowment, mandatory appropriation of 20 percent of the new technology value for biomedical engineers remuneration.

Appealing the EU structural funds 2014 - 2020 is a necessary condition, given the actual and future setting of budgetary appropriations for health in Romania.

Elements of the SWOT analysis.

Strengths:

- BME setting in countries with the most advanced HPS, offering models for the EU and Romania.

- National capability of education in BME.

- Significant increase in recent years of (bio)physics and informatics courses in the medical curricula; increased interest of medical students for basic knowledge of electricity, electronics, automation - in preview of their next involvement with top medical technologies.

Weaknesses:

- Unsatisfactory setting of BME in the EU (even if on a superior level versus Romania)

- Routine, information deficit, mentality of a part of the medical personnel for whom the health system is a professional fief where technical intruders stand for a threat.

- Inertia of managers of health system for whom the specialized personnel of non-medical or mixed training is

barely known and their integration looked at as a source of problems.

Opportunities:

- The professional framework of BME careers is already established with the COR: clinical engineer - code 221401 and medical bioengineer - code 222907.

- University/professional mobility of medical people in the European or Atlantic areas can configure mentalities towards communication and co-working with colleagues of technical education in the common interest of patients' health and own career progress.

- The model offered by the private health sector in which BME has its place according to American or British organizational charts.

- Opportunity offered by the HPS as for hiring personnel without previous working experience required as a rule in the private.

- Once recession overcome, resuming research in the biomedical area, together with increased experience in accessing EU research funds, could stimulate the demand for bioengineers in public institutions.

- The annual Ingimed conferences (edition XIII in 2012) under Romanian Federation of BME, and sister-conferences organized in Iasi and Cluj by Rom. Soc. Med. Bioengng. and National Soc. of Med. Engng. & Biol. Technology (3 editions each) respectively, have established salutary communication and science collaborations between medical and BME milieux.

Threats:

- World financial crisis, EU and Romania included, makes more and more difficult funding of novel medical technologies and BME personnel.

- Actual and future shortage of medical personnel in Romania, as related to migration towards Western more prosperous countries, will inherently decrease the demand of biomedical engineers whose number is correlated with the medical staff.

- Conflicts originated in communication difficulties (language, expression, approaching modes) generated by differences between medical education and the polytechnical one (even if the latter is somewhat alleviated by knowledge offered by preclinical courses taught to BME students).

V. PROSPECTS OF BME IN MOLDOVA

The Chair of "Microelectronics and Semiconductor Devices" (MSD) was founded in 1974 within the Department of the Technical University of Moldova called today the Faculty of Computing, Informatics & Microelectronics. The MSD Chair supervised a BME major beginning with 2006 and restructured itself as the "Microelectronics and Biomedical Engineering" in 2012. The quality of its specialized training in microelectronics and, more recently, in biomedical engineering is highlighted by over 200 PhD & doctor habilitatus degrees awarded on these topics and followed by successful professional tracks both in Moldova and abroad (Germany, U.S., Switzerland, Russia, Romania).

R & D subjects in BME currently include cardiosignal-based assessment of autonomic balance under stress, laser therapy, cold plasma coagulation, osteo-rehabilitation,

antimicrobial phototherapy, and medical technology management [17].

The 1st Int Conf on Nanotech & BME combined with a German - Moldovan Nanomaterials Workshop held July 2011 in Chisinau stood for a huge organizing effort and an undeniable success university seniors and young scientists of the concurrent summer school contributed and shared.

Under such auspices Moldavian BME holds a good promise for a significant contribution to a better public health in next future.

VI. CONCLUSIONS

Propelled by inexorable aspirations of human being, biomedical engineering holds good to recession, and progresses across the world under the impetus of the US scientists and practitioners.

Europe unfortunately trails, while Romania presents an undesirable contrast between educational capabilities and the level of intervention in the health public system the majority of Romanians relies upon.

However, an effort is in progress both in Europe and Romania to offer the status and the level of intervention into the public health BME obviously deserves.

More recently instituted Moldavian biomedical engineering forces the pace and pledges a significant contribution to a better public health in next future.

As a whole, biomedical engineering holds one of the best promise to improve health and save lives within world healthcare systems on medium and long terms.

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