



Biomedical/clinical engineering education and certification: fifty years of actions

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Received: 27 March 2022 / Accepted: 4 April 2022 / Published online: 10 May 2022

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Abstract

Health care is today technology driven and biomedical engineering is behind the impressive developments that reshaped medicine during the last 50 years. Biomedical Engineers (BMEs) as professionals are playing a vital role during the whole life cycle of Medical Devices (MDs), from the innovative idea to their final use and decommissioning. This rapid evolution creates a constant pressure for new knowledge and skills for the BMEs and therefore for continuous curriculum updates of education in BME, to meet current trends and market demands. Biomedical Engineering is relatively new when compared with other engineering disciplines. The earliest programs during the 1970s, most of which were at Doctoral and M.Sc. levels. B.Sc. programs were developed in most European Universities from the 1990s. Today there is an impressive trend to create new programs and the number of higher education institutions offering a BME degree is almost two hundred, just in Europe. Although biomedical engineering is playing a vital role in innovation, development, maintenance, and safe use of medical technology, BMEs are not yet recognized as a distinct professional entity and do not appear in the International Labour Organisation (ILO) lists. This is partly because biomedical engineering covers a very broad domain and includes professionals with very heterogeneous areas of specialization. Unlike in other engineering fields, where certification is a prerequisite for being a licensed professional, even for the clinical engineering, certification is not widely applied. This is mainly due to the lack of motivation since certification is not mandatory. In contrast with other health care professionals, that cannot practice their profession if they are not officially registered, such requirement does not exist for clinical engineers. In the present paper a review of the developments in BME educational programs in Europe, fifty years long, is attempted, focusing on some important initiatives and actions well known to the author. Additionally, some aspects of Clinical Engineering certification are addressed.

Keywords Biomedical Engineering · Clinical Engineering · Education · Certification · Europe

1 Introduction

Over the last half century, the developments of medical technology radically reshaped the way health care is delivered and continue to do so in an accelerated pace. Medical devices (MDs) that encompass from single use pieces to the most sophisticated equipment, are produced today by the most active industrial sector, in terms of innovation, as indicated by the number of patents registered per year. At the beginning of this era, a new multidisciplinary domain appeared: The Biomedical Engineering (BME). Through its

more than 50 years of existence, BME has been developed very rapidly and is playing a pivot role, being behind all major advancements of medical technology and involved in the whole life cycle of medical devices, from the innovative idea and R&D phase to their use and decommissioning.

Responding to these developments, graduate education in BME started to appear initially as engineering specialisation, MSc or PhD studies in US and European universities already in the late 60 s, followed by undergraduate study programs in the 70 s. The driving force was the research interest of engineering departments, mainly electrical and mechanical, in medical and biological problems and the application of technology in health care. The creation of new BME programs during the 80 s, was rather limited and a few tens of universities, both in the US and Europe, were offering BME studies up to the early 90 s. In the years following 2000

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however, an impressive number of educational programs appeared [1], mainly driven by the massive application of technology in health care and relevant forecasted job market needs. The same happened in the US, where the number of available undergraduate programs increased from 20 in year 2000, to almost 120 in 2020, according to a comprehensive study on BME education in the US, published in 2020 [2].

2 The biomedical engineering education in Europe

The evolution of educational programs in the field of BME in Europe has also been remarkable, especially during the last 3 decades. It is estimated that at the end of the 80 s only about 20 graduate study programs were available in European Universities. However, this situation has been changed during the last thirty-five years. An important factor was the European policy on higher education, mainly marked by the launch of the Erasmus program in 1988 and the Bologna declaration ten years later. The creation of the European Higher Education Area (EHEA), aiming to harmonise educational structure is based on two main cycles: undergraduate and graduate studies, and the establishment of the European Credit Transfer System (ECTS) to improve mutual recognition of degrees.

In parallel, the European Commission (EC) had launched several programs to pave the path to the Bologna declaration of the 90 s. Namely ERASMUS-TEMPUS-SOCRATES, LEONARDO da VINCI and Marie Curie are the most well-known, supplemented by a number accompanying measures and concerted actions. The basic idea behind these initiatives, was to promote collaboration, exchange of knowledge and experience amongst European academic institutions, facilitate staff and students' mobility through inter-University bilateral agreements and therefore facilitate harmonized, consensus-based curricula of studies and commonly accepted systems for recognition of acquired knowledge and skills. However, due to differences in the national educational systems, autonomy of the universities, professional rights and restrictions between different countries, the goal of degree equivalence at a European level is not easy to reach. Although the BME field belongs to the broader Engineering subject area with traditionally 5 years of studies for graduation, some countries rapidly adopted the 3 years model for a BSc cycle, while others didn't change their five years' schemes at all, assuming that their graduates receive an engineering MSc level degree with BME orientation at end of their studies.

A study performed by the Institute of Biomedical Technology (INBIT) in 2000, under an initiative of the International Federation for Medical and Biological Engineering (IFMBE), revealed that: more than 50 Universities were

delivering at least one program in the field of BME; 26 were offering an undergraduate program; 33 Institutions were running their program within an inter-university national or international collaboration scheme, and 20 Universities were applying the ECTS. An extensive review performed ten years later, in the framework of the "Curricula Reformation and Harmonisation in the field of Biomedical Engineering" (CRH BME/2009–2012) project, identified that approximately 150 Universities across Europe offered in total 300 BME programs (~ 30% BSc, ~ 50% MSc, ~ 20% PhD) which was 3 times greater compared to the year 2000 [3].

A more recent follow-up survey on the BME educational programs offered in 44 European countries, which was performed in 2020 by INBIT and endorsed by the European Alliance on Medical and Biological Engineering and Sciences (EAMBES), compared the situation with the one twenty years ago, while identifying potential trends and approaches. The results demonstrated the growth of the field. According to these findings 182 Universities across Europe were offering 344 BME educational programs, of which 115 Undergraduate leading to BSc degrees, and 229 postgraduate programs, 175 of them leading to MSc and 54 to PhD degrees. Specialised programs in the subdomain of Clinical engineering were still around ten, but their number is increasing. In conclusion, BME education is getting a leading role in engineering studies, almost everywhere in Europe [1].

Apart from the EHEA policy expressed by the Bologna declaration, BME education in Europe was also influenced by 3 additional factors: a) the EU research & development (R&D) funding programs, b) the regulatory framework for medical devices and c) the industry demands. To promote collaboration and coordination in R&D, the EC in the 80 s has created several experts' groups, under the name of coordinated actions (COMACs), in various fields and the biomedical technology sector was covered by the COMAC BME. All member states were represented in these experts' groups by one or two representatives and the proposals and advises of the COMACs, greatly influenced the R&D programs funded by the Commission. The BME field was very well represented and succeeded in obtaining a substantial part of the available R&D funds. This scheme was unfortunately abandoned in the 90 s.

Also in the 1980s, the EC decided to establish the so called 'New Approach' as common regulatory framework, based on common procedures, rules and harmonised standards, thus eliminating the national barriers for free movement of goods and achieving a uniform, common European market. Medical devices (MDs) were one of the first kind of products that were put under this new approach, with 3 directives, that started to be prepared in the 80 s and finalised and voted by the EU parliament in the 90 s. According to the new approach, the EU regulatory framework for MDs,

the medical devices directives (MDDs) aimed to balance safety issues and protection of health with innovation and free movement of products. The main responsibility for placing medical devices on the European market lies on the manufacturers, where the market surveillance belongs to the national competent authorities (CAs) of the member states. Other parties involved under this regulatory scheme are the notified bodies (NBs), that certify the compliance of the devices with the directives and the harmonised standards. Additionally, the directives indicated that all necessary steps should be taken to ensure that devices may be put into service only if properly installed, maintained, and used in accordance with their intended purpose. For this reason, broad “essential requirements” for devices are laid down in the medical device directives (MDDs), as opposed to the detailed and prescriptive “old approach” procedures. European standardization bodies are playing an important role, as they are mandated to prepare harmonized standards for conformity to the relevant essential requirements for each device group. If a device complies with the MDDs under replacement now by the more strict MD Regulations (MDRs) [4], it is allowed to bear the CE mark and may be freely placed on the European market. All these actions are within the scope of BME profession, and the involvement of biomedical and clinical engineers is essential, although not mandatory yet.

Finally, according to European Medical Devices Manufacturers Association—MedTech Europe, the European medical device market is estimated at 140 billion euros, being the second largest after the US, with products produced by more than 33,000 enterprises, with 760,000 employees, many of them from the BME field. The European leading role in medical technology innovation is demonstrated by more than 14,000 patent applications that were filed in 2020 with the European Patent Office [5]. These developments also led to a new environment, opening various job opportunities for biomedical engineers, a fact that also explains the creation of new educational programs during the last 20 years. It is important to observe that free movement of professionals and goods in the EU was promoted in parallel through harmonisation by the EU initiatives.

3 Some more specific initiatives and projects in Europe

In the following paragraphs, some elements concerning the remarkable evolution of BME education in Europe will be provided, based on the author’s experience and involvement. Right from 1987, with the launch of the European Erasmus program mentioned above, Prof. Vassilis Proimos, representing Greece at the COMAC BME, had the pioneering idea to propose a common collaborative graduate MSc program

in Biomedical Engineering between European Universities from most of the 13 member states at that time, who would contribute with both teachers and students. The idea was approved and adopted by the panel of experts, most of which were academics. A proposal was submitted for funding in the Socrates program and was accepted in the same year. The first curriculum was drawn up, teachers were appointed, and the way the students would be selected was decided. The program was assigned to be organized at the University of Patras (UPAT) and in 1989 the call for the first students with Erasmus scholarships was announced. Since the beginning of this program, a quality system has been used and evaluation by both students (for the courses, their content and teaching), as well as by teachers (on the structure and organization of the program) was implemented. It is worth to mention that during the first 10 years the program was combined with a similar MSc program in Medical Physics. Very well-known colleagues from the two disciplines, like: J. C. Barbenel, J. A. Blom, M. Bracale, B. Brown, A. Capello, J. Cornelis, E. Gomez J. Horrocks, J P. Morruci, J. Nagel, A. Pedotti, F. Del Pozo, A. Ruggeri, W. Sanchez, R. Speller, T. Stapper and R. Wilkinson, were amongst the creators of this program and most of them remained academic teaching staff for many years, or even for the whole 25 years period of its existence.

Already in 1994, the final curriculum was agreed through a consensus based process and the group of teaching staff from the participating universities became quite constant. Awards for the best students and lecturers have been established. There were dozens of lesson notes, books and eLearning material in English produced and freely distributed. Annual collaborating university meetings, workshops, summer schools or Symposia (like the series of the European Symposia in BME), were regularly organised. During its 25-year course, this European collaboration program was attended by more than 600 BME students, half of whom Greeks, while the other half from most European countries. More than 100 teachers have lectured, 60 universities collaborated, and more than 60 bilateral agreements have been signed. The program started in the academic year of 1989–90 and went through a 25-year cycle, with some specific features and performances worth to be mentioned. It was the first course in a Greek university officially held in English language, and one of the first MSc programs in Europe that applied the ECTS. Foreign students obtained their diplomas from their Universities of origin, by transferring the credit units that corresponded to their studies in Patras. Some of them returned as teachers 15 years after their graduation.

By the end of the 90 s, the TEMPERE thematic network (Education and Training and Accreditation, Competences for training and education in Medical Physics (MP) and Biomedical Engineering), coordinated by UPAT, addressed

issues of education harmonisation, accreditation and quality assurance, with the participation of 40 European academic institutions, as well as the European Federation of Medical Physics (EFOMP) and the IFMBE. The outcomes and recommendations of this project on Suggested Curricula and practical application of the TEMPERE recommendations were published in 2001 by IOS Press in a book entitled: “Towards a European Framework for Education and Training in MP and BME”, edited by Z. Kolitsi [6]. Most of the previously mentioned colleagues were participants in this thematic network, also joined by: H. Hutten, M. Gardar, L. Lamm, F. Nusslin, N. Richter, C. Roberts, A. Santos, N. Saranummi, S. Sheriff, S. Tabakov and many others.

In 2004, many experts from IFMBE and EAMBES participated in the BIOMEDEA initiative, coordinated by Prof. Joakim Nagel, aiming to establish criteria for quality assurance in Biological Engineering education, including guidelines for harmonization of programs and accreditation of education programs with international coordination for health care professionals [7]. Within the BIOMEDEA project, various workshops were organized: in Eindhoven (2004), Warsaw (2005) and Stuttgart, in June 2005. The last meeting involved an impressive number of well-known participants from all over the world and provided a set of Criteria and Guidelines for the Accreditation of Biomedical Engineering Programs.

Collaboration between European Universities became even closer with the occasion of two more recent TEMPUS projects that were coordinated by the Biomedical Technology Unit (BITU) of the University of Patras, between 2005 and 2015, addressing universities from the eastern European Neighbouring Area (ENA). The first one, Curricula Reformation and Harmonisation in the field of Biomedical Engineering (CRH-BME), established a generic curriculum for BME studies that took into consideration recent and future developments, but also the necessity to provide similar knowledge to BME students all over Europe, to harmonise studies, professional recognition, staff exchange and student’s mobility [8]. Nineteen Universities from EU and another four from eastern European countries participated in this project with a lot of well-known BME academics representing them: Jan Cornelis and Edgard Nyssen (Vrije Universiteit Brussel), Kalju Meigas (Tallinn University of Technology), Jiri Holcik (Masaryk University), Timo Jamsa (University of Oulu), Akos Jobbagy (Budapest University of Technology and Economics), Zhivko Bliznakov (INBIT), Ivan Bouliev (Tehnicheski Universitet of Varna), Michalis Zervakis (Technical University of Crete), Rita Stagni (University of Bologna), Marcello Bracale and Leandro Pecchia (University Federico II of Naples), Yuri Dekhtyar (Riga Technical University), Krzysztof Penkala (Szczecin University of Technology), Paul Dan Cristea (University “POLITEHNICA” of Bucharest), Damijan Miklavcic

and Jarm Tomaz (University of Ljubljana), Andres Santos (Universidad Politecnica de Madrid), Heikki Terio (Karolinska University Hospital), Ratko Magjarevic (University of Zagreb), Dejan Popovic (Faculty of Electrical Engineering, Belgrade), Armen Sargsyan (Orbeli Institute of Physiology), Hafiz Aliyev (Khazar University), Sergo Dadunashvili (Georgian Technical University), joined by Joseph Barbenel (University of Strathclyde), Dimitris Koutsouris (National Technical University of Athens) and Zoi Kolitsi (Greek Ministry of Health) on the advisory board. The main objective of this project was to update existing curricula in the field of BME, to meet recent and future developments in the area, address new emerging interdisciplinary domains that appear as a result of the R&D progress and respond to the BME job market demands. The generic BME programs assisted participating Institutions to restructure their existing programs in full compliance with the Bologna Declaration and the ECTS and especially those that were in the initial stage of their educational system reform. Amongst the achievements of the project were an extensive review of the BME education status in Europe, a consensus-based proposal for Generic Programs for studies in BME and a Template guidance document for their implementation [9].

The second TEMPUS project, BME-ENA (Biomedical Engineering Education Tempus Initiative in Eastern Neighbouring Area), was based upon knowledge transfer from EU Partners to four (Armenia, Georgia, Moldova, and Ukraine) Eastern Neighbouring Countries (ENA) and aimed to promote, establish and improve BME Education in this ENA region through the creation of four joint multidisciplinary MSc BME programs, based on the above CRH BMR recommendations. The consortium was formed mainly by most of the previously mentioned establishment and colleagues, with the addition of ten institutions from ENA countries: Ruben Aghgashyan (Hayastani Petakan Tchartaragitakan Hamalsaran), Georgi Chaltikyan (Armenian Association of Telemedicine), Suzana Shamakhyan and (Russian-Armenian (Slavonic) University), (Georgian Technical University), Tamara Sanikidze (Tbilisi State Medical University), Irine Pkhakadze (Akaki Tsereteli State University), Victor Son-tea (Technical University of Moldova), Victor Vovk (State University of Medicine and Pharmacy Nicolae Testemitanu), Anatolii Orlov and Vitaliy Maksymenko (National Technical University of Ukraine), Kostyantyn Kyrychenko (Sumy State University). The project was successfully completed, and all programs created were accredited and continue to run today.

4 BME recognition

Even though the term biomedical engineering is quite broad and includes professionals with heterogeneous specialization, the profile of biomedical engineers shares common

characteristics which define and make them unique among other engineers. There is no doubt that a biomedical engineer must first be an engineer and as such must possess a sound and relatively broad knowledge of fundamental engineering and physical science. Furthermore, he/she must be able to apply this knowledge to solve problems of medical and biological origin, requiring at least basic knowledge in Biology, human Physiology and Anatomy and understanding of risks associated with the use of technology in diagnosis and therapeutic procedures. Problems that biomedical engineers are expected to solve vary tremendously and this diversification is expected to increase further on, with new and rapidly emerging technologies and demands in the health sector. For this reason, any BME study program must provide, in addition to a sound BME foundation, specialization elements within various narrower fields of BME.

Biomedical Engineers today should be prepared to meet existing or forecasted needs by means of knowledge, skills, and attitudes, to successfully face current challenges. Despite differences in the extent of adoption of new technologies in different countries, the problems addressed by BMEs are similar and due to the rapid evolution of technology create a constant pressure to respond to the demands of the work environment in the industrial and the broader health care related sectors all over the world. However, diversity in the way education is provided today presents obstacles in the mutual recognition of degrees and collaboration amongst the institutions in terms of staff and students exchange, as well as access to the global job market. This involves academia, medical industry, hospital facilities, as well as administration and, in turn, it is necessary to frequently review and adapt the core curriculum of BME educational and training programs, to achieve harmonisation [10].

In spite of the fact that biomedical engineering is playing a vital role in innovation, development, maintenance, and safe use of medical technology, BMEs are not yet recognized as a professional entity on its own and do not appear in the International Labour Organisation (ILO) lists. This is partly because biomedical engineering covers a very broad domain and includes professionals with very heterogeneous areas of specialization. Since 2015, EAMBES has been very active in professional recognition of BMEs. Through a very successful initiative by Leandro Pecchia, chair of the EAMBES Policy Affairs Working Group (PAWG) at that time, EAMBES succeeded the creation of a European Parliament Interest Group in BME (EPiG-BME), chaired by the European parliamentarian Nicola Caputo from Italy. Two important meetings were held in Brussels in 2016 and 2018, with the participation of European parliamentarians, the EAMBES and IFMBE officers and representatives of European Commission as well as members of The International Union for Physical and Engineering Sciences in Medicine (IUPESM), WHO, and MedTech. The main aim of the initiative was

the recognition of BME as independent profession and its inclusion as independent discipline in the European Skills, Competences, Qualifications and Occupations (ESCO) classification scheme, relevant for the EU labour market and education and training. A follow up action starting with an event entitled “Practices, impact and promises of biomedical engineering for advancing the EU’s health priorities” is organised by EAMBES in collaboration with the European Parliament at the end of March 2022 [11].

5 Clinical engineering and IFMBE

The only branch of BME that has a more focused area of professional engagement and job description is that of Clinical Engineering, addressing safe use and effective management of medical technology in the clinical environment. Following a proposal of Prof. Ake Oberg in 1979, the IFMBE set up in 1981 a “Working Group for Clinical Engineering” with the aim of developing this branch of biomedical engineering, recognizing the role and the importance of the clinical engineering profession [12]. The intention, from the start, was to clearly specify the role and qualifications of clinical engineers and to establish criteria for the mutual recognition of qualifications among member countries, with the long-term goal of achieving wide recognition of their role in the medical care sector and helping to establish their status. A first definition of Clinical Engineering was published in 1981, in an internal document of CED, entitled “Mutual recognition of qualifications for Clinical Engineers”, which was subsequently revised, during the following years. According to that document, “Clinical Engineering means the safe and effective management of technology and the application of medical and biological engineering within the clinical environment, for the advancement of health care”. In 1985, this Working Group was transformed into the specialized “Clinical Engineering Division (CED)”. In 1989 Monique Frize performed a survey on the functional involvement of clinical engineering departments in their health care institutions by questionnaires mailed to such departments in Canada, the US, European Community (EC) member states, Sweden and Finland, to identify their resource levels, their workload volumes, and the types of technologies which they supported. She found that North America respondents performed higher levels of in-house corrective maintenance than their counterparts in Europe and the Nordic countries, whereas Nordic countries showed the highest commitment to provide user training and education for the medical staff [13]. In 1990, the division decided also to collect data on clinical engineers around the world and to promote information exchange both between clinical engineers and CED/IFMBE. In April 1992, a preliminary list of individuals collected and compiled by the board members of the Division consisted of more than

300 names from 36 countries, whereas in its first edition, the directory contained 1200 names of CEs from 62 countries. Also, during its annual meeting in November 1992, the CED board agreed upon the following definition: "A clinical engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology", practically adopting the one from the American College of Clinical Engineering (ACCE).

Another review has been performed ten years later, under the auspices of the CED/IFMBE, by Mariana Gluchova, as part of her PhD, addressing the main tasks, responsibilities and roles of clinical engineers worldwide [14]. The Division also explored new means of communication through its participation in the EU "BEAM II" project (1995–98), which developed an internet-based facility for information exchange (FINE) between clinical engineers [15].

Over its forty years of existence, the CED has promoted the role of Clinical Engineers and established effective communication channels between them. Focusing on the last decade, the CED has been reorganised under the chair of Yadin David, followed by Saide Calil and Ernesto Iadanza, and has become very active and extrovert, mobilising hundreds of clinical engineers world-wide. This momentum has been accelerated during the Covid-19 pandemic and the activities and initiatives of the division have been exploded under the present chairmanship of Tom Judd and the whole CED board. Regular monthly meetings are taking place with the participation of hundreds of BME/CEs collaborators and tens of Webinars and Workshops are organised [16]. The collaboration with WHO has been reinforced, and the extraordinary work done by Adrianna Velasquez and her team in WHO [17] is supported by the IFMBE and its two divisions. In parallel, the successful launch of the International Clinical Engineering Journal [18], by Yadin David in 2019, and the establishment of the International Clinical Engineering Conferences demonstrated the importance this branch of BME is getting during the last years. As a result, a new international organisation was created in 2020; the Global Clinical Engineering Alliance (GCEA), aiming to foster and promote the advancement of the clinical engineering profession, for improving healthcare outcomes [19].

Along with the creation of the CED, a Division on Healthcare Technology Assessment (HTAD) was established by IFMBE with the goals to promote participation of biomedical and clinical engineers in comprehensive health technology assessments, to "encourage multidisciplinary co-operation, to stimulate the biomedical and clinical engineering communities, to strive for appropriate and costeffective technologies, and to enrich the biomedical and clinical engineers' understanding of policy-making and encourage their participation in these processes"[20]. The division experienced a very productive 15-year period under Jan Persson, followed by Heikki Terio, but became less active and finally dormant

latter on. The HTA division was revitalised in 2012, following an appointment of Herb Voight, president of IFMBE at that time, to the author. A new board was elected, and an extremely active period started, especially under Leandro Pecchia's chairmanship, followed by Ernesto Iadanza. The division has a very active role in the international HTA area today, with an important number of collaborators, participation in international conferences, and training activities. The demonstration of the crucial role of BMEs in HTA of medical devices, due to their differences from drugs, has been published recently [21] stressing the HTAD/IFMBE perspectives.

6 On certification and licencing of clinical engineers

Currently, only a small part of the individuals practicing clinical engineering are certified, even in countries where certification is available. This mainly concerns the biomedical equipment technicians (BMETs) and much less the CEs graduates from university BME programs. This is mainly due to the lack of motivation since certification is not mandatory. In contrast with physicians and medical physicists, that cannot practice their profession if they are not officially registered, such requirement does not exist for clinical engineers. Since the beginning of its existence, the CED/IFMBE formulated minimum qualification criteria to be used by the international clinical engineering profession to assess qualification levels and to set up certification structures. In connection with the International Certification Commission for Clinical Engineers (ICC) and later in collaboration with ACCE, the division promoted the importance of certification for Clinical engineers.

It is interesting to mention a statement in an article from the CED/IFMBE in the early 90 s. "As in any profession, the value of certification is closely coupled with the recognition it receives, which in turn is directly related to the quality of the individuals who carry and promote it. At this time, not all individuals practicing clinical engineering in countries where certification is available are certified. While the situation continues, the credibility of the profession, if in fact it can be called a profession when judged by the above criteria, is in jeopardy. Barriers to the establishment of national certification for clinical engineers include diversity of academic qualifications and clinical engineering experience, lack of recognition by health care administrators, differing opinions on what the entry requirements would be, and the lack of strong motivators among individuals who currently form part of the 'profession'. Just as physicians cannot practice medicine if they are not registered with the medical profession, will there be a day when clinical engineers cannot practice their profession unless they are registered? The answer

lies with the collective will of the individuals involved, and their desire to become a coherent professional component of national health care systems” [22]. This statement is valid until today.

To be successful, the introduction of a certification approach should: respond to real needs for public safety and health protection, be enforced by national regulations, promote professional development, and be widely accepted by the professionals it addresses. In other engineering fields, like civil or electrical engineering, certification is a prerequisite for being a licensed professional. There are several benefits associated with licensure of engineering professionals including recognition of competency, ability to sign and seal drawings for a public authority, provide expert testimony in a court of law, recognition as an ethical professional etc. Other professionals in the health care sector like, Physicians or Medical Physicists, take board exams to prove their practicing competences.

Biomedical engineers generally do not have established licensing status. There are several reasons for that. On one side the BME itself is a multidisciplinary field, very large in scope and including professionals that are not engineers in their undergraduate studies. Even the BME graduate studies are not harmonised and not addressing specific professional requirements. Therefore, licencing is becoming impossible. However, the Clinical engineering branch is addressing the much more focused and sensitive domain of reliable, cost effective and safe use medical devices that is directly affecting patient safety and in principle could be more adequate to certification requirement and licencing.

There is however an inconsistency in the regulatory framework on medical technology that is not in favour of this licensing potential. Although it is quite demanding about the way that medical devices are getting access to the market, like for instance the new EU Medical Devices Regulations 2017/745 [4], there is no clear provision for the safe and effective use of them. There are some general statements that devices must be used according to the manufacturer’s instructions and properly maintained, but there are no requirements for certification of personnel that apply them, apart from devices related to ionising radiation. This lack of regulatory requirements is an obstacle for licencing and therefore certification of clinical engineering professionals.

There are three axis of action that should be considered to achieve a new status for clinical engineers: The establishment of a common widely accepted Clinical Engineering Certification system based on a frequently updated “Body of knowledge” and “Body of practice” that will improve the value of certification; The harmonisation of studies through a widely accepted core curriculum and practice procedures that will improve student mobility and exchange of experience and lead to mutual recognition of degrees; The introduction of regulatory requirements on the safe use and management of medical technology that will reveal the

importance of clinical engineers as key professionals in the health care environment and drive to licencing and certification of CEs. All national and international clinical engineering professional associations should be mobilised and involved under a common effort, preferably under a joint action of CED/IFMBE, EAMBES, ACCE, GCEA and as many as possible established national certification bodies, to demonstrate the importance of reaching this goal and advance its wide acceptance, not only for the profession, but more importantly for patients’ safety and the efficiency of the health care systems.

Authors' contributions Not applicable.

Funding No funding was received for this work.

Data availability Not applicable.

Code availability Not applicable.

Declarations

Ethics approval Not applicable.

Consent to participate Not applicable.

Consent for publication Not applicable.

Conflict of interest None.

References

1. Dermitzakis A, Alexandropoulos C, Fermani M, Pallikarakis N. Biomedical Engineering Education in Europe: A 30 Years Review. In: Jarm T., Cvetkoska A., Mahnič-Kalamiza S., Miklavcic D. (eds) *EMBEC 2020. IFMBE Proceedings*, vol 80. Springer, Cham. 2021. https://doi.org/10.1007/978-3-030-64610-3_24
2. Linsenmeier RA, Saterbak A. *Annals of Biomedical Engineering*, 2020;48(6):1590–1615. <https://doi.org/10.1007/s10439-020-02494-0>
3. Magjarevic R, Lackovic I, Bliznakov Z, Pallikarakis N. Challenges of the biomedical engineering education in Europe, *Proc. 32nd Ann. Int. Conf. IEEE EMBS, Buenos Aires, Argentina*. 2010;2010:2959–62.
4. *Medical Devices Regulations 2017/745*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745>
5. *MedTech Europe*. <https://www.medtecheurope.org/about-the-industry/facts-figures/>
6. Kolitsi Z (ed.). *Towards a European Framework for Education and Training in Medical Physics and Biomedical Engineering*. IOS Press, Amsterdam 2001
7. Nagel JH, Slaaf DW, Barbenel J. *Medical and Biological Engineering and Science in the European Higher Education Area - Working Toward Harmonisation of Biomedical Programs for Mobility in Education and Employment*. *IEEE Eng Med Biol Mag*. 2007;26(3):18–25.
8. Pallikarakis N, Bliznakov Z, Miklavcic D, Jarm T, Magjarevic R, et al. *Promoting harmonization of BME education in Europe: The CRH-BME Tempus project*. *Proc Annual Int Conf IEEE Eng Med*

- Biol Soc 2011;6522–6525. <https://doi.org/10.1109/IEMBS.2011.6091609>
9. Jarm T, Miklavcic D, Pallikarakis N, Bliznakov Z, Magjarevic R, et al. Proposal for generic biomedical engineering programs based on European experience. *Proc 5th European Conf Int Federation for Med Biol Eng* 2012;1418–1421.
 10. Bliznakov Z, Rodina-Theocharaki A, Pallikarakis N. Management and implementation of the TEMPUS IV BME-ENA project in the field of biomedical engineering education. *Proc 3rd Int Conf Nanotechnol Biomed Eng* 2016;489–492. https://doi.org/10.1007/978-981-287-736-9_115
 11. <https://eambes.org/epig-activities/>
 12. Saito M. Meeting Challenges in Medicine & Health Care through Biomedical engineering, a History of the IFMBE. Jack A. Hopps, Masao Saito (Editor-in-Chief), Nandor Richter, IFMBE, Amsterdam. 1997.
 13. Frize M. Results of an international survey of clinical engineering departments, part 1: Role, functional involvement and recognition. *Med Biolog Engng Comput.* 1990;28:153–9.
 14. Glouhova M, Kolitsi Z, Pallikarakis N. International Survey on the Practice of Clinical Engineering. *J Clin Eng.* 2000;25(5):269–76. <https://doi.org/10.1097/00004669-200025050-00009>.
 15. Krotopoulou A, Panagopoulou G, Sirmakessis S, Spirakis P, Tambakas V, Terpou D, Tsakalidis A, Pallikarakis N. “FINE DataBase: A Database for Information Exchange Among Clinical Engineers”. In: *Proceedings MIE '94*, P. BARAHONA, M. VELOSO and J. BRYANT (eds), Lisbon, 1994;512–516.
 16. <https://ced.ifmbe.org/>
 17. WHO compendium of innovative health technologies for low-resource settings 2021. COVID-19 and other health priorities. ISBN 978–92–4–003250–7 (electronic version)
 18. <https://www.globalcea.org/globalcejournal>
 19. <https://www.globalcea.org/home?hsLang=en>
 20. <https://htad.ifmbe.org/>
 21. Polisenia J, Castaldo R, Ciani O, ... Pecchia, L. Health technology assessment methods guidelines for medical devices: how can we address the gaps? The international federation of medical and biological engineering perspective. *Int J Technol Assess Health Care.* 2018;34(3):276–89. <https://doi.org/10.1017/S0266462318000314>.
 22. Bostrom U, Bravar D, Kanai H, Ku P, Pallikarakis N, Smith J, Oberg PA. *Clinical Engineering world-wide*, IEEE Eng. Med. Biol. 1993;34–46.

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