Medical Engineering and Physics 72 (2019) 19–26

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com/locate/medengphy

Health Technology Assessment and Biomedical Engineering: Global trends, gaps and opportunities

L. Pecchia[a,e,*], N. Pallikarakis[b,e], R. Magjarevic[c,e], E. Iadanza[d,e]

[a] School of Engineering, University of Warwick, Coventry, UK
[b] Biomedical Technology Unit, University of Patras, Patras, Greece
[c] Faculty of Electrical Engineering and Computing, University of Zagreb, Zagreb, Croatia
[d] Department of Information Engineering, University of Florence, Florence, Italy
[e] International Federation of Medical and Biological Engineering (IFMBE), Brussels, Belgium

ARTICLE INFO

Article history:
Received 28 August 2019
Accepted 28 August 2019

Keywords:
Health Technology Assessment
Medical Devices
Biomedical Engineering
Global Health

ABSTRACT

The diffusion of medical devices is expanding at an astonishing rate. The increasing number of novel patents per year suggests this growth will continue. In contrast to drugs, medical devices are intrinsically dependent on the environment in which they are used and how they are maintained. This created an unprecedented global need for well-trained biomedical engineers who can help healthcare systems to assess them. The International Federation for Medical and Biological Engineering (IFMBE) is the global scientific society of biomedical engineers in official relations with the United Nations World Health Organisation (WHO) and has been very active in promoting the role of the biomedical engineer in Health Technology Assessment (HTA). The IFMBE Health Technology Assessment Division (HTAD) is the IFMBE operative branch in this field, promoting studies, projects and activities to foster the growth of this specific and very important science sector, including summer schools, training material, an HTA eLearning platform, HTA guidelines, awards and more. This article describes the vision, the mission and the strategy of the HTAD, with a focus on the results achieved and the impact this is having on global policymaking.

1. Introduction

The past 10 years has seen a remarkable diffusion of Medical Devices (MDs). A proxy for future diffusion is the number of MD patent applications submitted per year [1]. While the yearly number of patent applications per pharmaceuticals and biotechnologies remains at a constant level year after year (about 6000 novel patent applications per year since 2006), the number of patents for medical technologies only keeps growing at a remarkable rate, moving from 9000 to more than 12,000 novel patent applications per year during the period 2006–2016 in Europe only [2]. Similar figures come from the United States of America (US), where patent filings show a significant uptrend from 2007 (about 22,000 applications) to 2018 (more than 34,000 applications). Should we consider this latter figure valid today, we could speculate that it equates to more than 93 novel patent applications per day, suggesting that while you are reading this manuscript three to four MD novel patent applications could have been filed. In addition, for many MDs, the time to market (TTM) has become shorter and shorter over the past years. The combination of those two trends (i.e., increased number of MD patent applications and shorter TTM) has already resulted in an unprecedented increase of novel MDs introduced in the market each year: a veritable 'tsunami' of medical devices! [3].

There is no doubt that the increase in quality and quantity of MDs has played a key role in the general improvement of global health as reported by the World Bank and the World Health Organisation (WHO) indicators (e.g., under-five mortality rate has never been so low [4]; life expectancy at birth has never been so long [5] etc.). However, huge disparities persist between high- and low-income settings, the former being where the majority of global population is diagnosed and treated [6].

Nonetheless, the exceptional availability of MDs, at least in higher-income countries, generated an exceptional request for novel profiles of professionals and scholars, highly qualified for supporting healthcare systems in assessing, procuring, managing and decommissioning MDs. The peculiarities of MDs require specific knowledge if compared to other healthcare technologies such as drugs or surgical procedures [7].

An extraordinary global [8] political interest has grown around the role of biomedical engineers and their contribution to the

* Corresponding author at: School of Engineering, University of Warwick, Coventry, UK.
E-mail address: l.pecchia@warwick.ac.uk (L. Pecchia).

https://doi.org/10.1016/j.medengphy.2019.08.008

Health Technology Assessment (HTA) in connecting researchers to policy maker communities [9].

In 2014 the World Health Organisation (WHO) stated that '*trained and qualified biomedical engineering professionals are required to design, evaluate, regulate, maintain and manage Medical Devices, and train on their safe use in health systems around the world*' [10]. In response to this statement, the European Economic and Social Committee (SEEC) engaged in close consultation with the European community of Biomedical Engineers represented by the European Alliance for Medical and Biological Engineering and Science (EAMBES) [11]. This discussion resulted in a study published in April 2015 (2015/C 291/07) in the Euro Lex (the official Journal of the European Union) stating that: '*Biomedical Engineering is not simply a subset of modern medicine. Modern medicine predominantly secures important advances through the use of the products of biomedical engineering*' [12].

Referring to HTA knowledge, the Biomedical Engineering (BME) community has been lagging behind other healthcare scientific communities (e.g., pharma, medicine, health economy), in terms of available training, discussion fora and also in defining HTA as one of the core topics for BME. Although some universities had introduced HTA topics in their curricula, it was only in 2011 that HTA was proposed as a core topic for BME by a consortium of European Universities [13–15] endorsed by the International Federation of Medical and Biological Engineering (IFMBE) [16].

This article describes the effort of the global community of Biomedical Engineers in talking these emerging challenges to foster the HTA culture among the BME community through the work of the Health Technology Assessment Division (HTAD) of the IFMBE between 2015 and 2018.

1.1. Global community of BME

The IFMBE is the global scientific society of Biomedical Engineers, federating 66 national societies from 60 different countries and 6 transnational societies (IEEE EMBS, EAMBES, ACCE, AAMI, CAHTMA and CORAL). These professional organisations represent the global interests in medical and biological engineering in the world. The IFMBE is also a Non-Governmental Organisation (NGO) in official relations with the United Nations World Health Organisation (WHO), which IFMBE serves as recognised stakeholder offering continuous support and expertise for delivering better and more accessible health care to the world, through a unique network of world leading experts of biomedical and clinical engineering.

The IFMBE governance is entrusted to five Officers (President, President-Elect, Past-President, Treasurer and Secretary General), which are elected by the IFMBE General Assembly during the World Congresses of Medical Physics and Biomedical Engineering. The officers are supported by the Administrative Council, whose members are in part elected during the General Assembly (4 members) and in part appointed ex-officio as Chairs of the Council of Societies, Fellows' Chapter and Divisions.

Important bodies of the IFMBE are the two Division: the IFMBE Health Technology Assessment Division (HTAD) [17] and the IFMBE Clinical Engineering Division (CED) [18], which together account for a large part of the IFMBE activities and budget. Division board members are elected during the IFMBE General Assembly among candidates nominated by IFMBE Affiliated societies. Those members are considered to be experts of HTA or Clinical Engineering. Among those elected board members, seven per Division, the Chair, the Secretary and the Treasurer are then elected. They are responsible for coordinating the Divisions' activities and reporting about their achievements to the IFMBE Administrative Council.

It is worth remarking that the all activities and work done for the IFMBE is on voluntary base, and none of the AC or Division members is compensated for their contributions by the IFMBE.

The IFMBE Division can also propose to the IFMBE President two additional board members to be co-opted on the base of their expertise. Finally, both Divisions have a significant number of collaborators directly appointed by Division Chairs.

The IFMBE teamed up the International Organisation for Medical Physicists (IOMP) into a larger association named the International Union for Physical and Engineering Sciences in Medicine (IUPESM). These three organisations coordinate the World Congress on Medical Physics and Biomedical Engineering every three years. The forthcoming World Congress will be held in Singapore in late Spring 2021. IUPESM is a member of the International Science Council (ISC), an NGO in official relations with the UN UNESCO, bringing together 40 international scientific Unions and Associations and over 140 national and regional scientific organisations including Academies and Research Councils.

2. Method

Through a series of focus groups and scoping literature reviews, the IFMBE HTAD elected and co-opted members defined the IFMBE HTAD Vision, Mission and Strategy. Once these where defined, the IFMBE HTAD Chair discussed and agreed with the IFMBE Officers on a three-year plan and program of activities. A series of surveys and numerous focus groups were run along the years, aiming at involving international scholars, promoting the Division activities, getting feedback and for continuously improving ongoing activities.

2.1. Vision

The IFMBE HTAD vision is that biomedical engineers "should be constantly involved in HTA studies focusing on MDs, in order to better serve the ultimate beneficiary of healthcare and biomedical engineering: the patient". The Vision is based on three enabling values:

- The expertise of Biomedical Engineers (unlike other HTA experts) spans across MD research, design, assessment and management;
- biomedical engineering has a multi-disciplinary nature, considering that biomedical engineers are employed in MD research and manufacturing as well as in hospitals and healthcare agencies;
- biomedical engineering has an inter-disciplinary nature, with BME students specifically educated in a wide range of topics, including physics, math, engineering, biology and medicine.

2.2. Mission

In order to achieve the above vision, the IFMBE HTAD performed a scoping review and a gap analysis, which resulted in the definition of four focus areas:

- Training: due to the lack of specific training material and courses suitable for biomedical engineers, the Division aimed to develop specific training events and contents on HTA, based on BME educational needs and background, which are different from those of other HTA experts.
- Research: reinforce the collaboration among BME scholars proactively involved in HTA research and studies.
- Publications: in order to fill the dearth of publication fora (i.e., conference and journals) for HTA research outcomes, often due to lack of HTA experts in the BME community, the HTAD board decided to support the IFMBE Conference Organizers and journal editors, by helping them in identifying networks of local experts and by providing them with a direct support.
- Events: organizing scientific events and workshops aiming at promotion collaboration among biomedical engineers, scientific societies with interest in HTA, policy makers and HTA stakeholders.

2.3. Strategy

In order to accomplish this mission, the IFMBE HTAD defined an articulated plan, made of 5 strategic goals further structured in 11 priority projects, aiming to overcome fragmentation and avoiding working "in silos":

- Establishing periodical training events on HTA for biomedical engineers,
- Developing and sharing free high-quality training material on HTA for biomedical engineers;
- Reinforcing collaboration on HTA among biomedical engineers and other HTA experts;
- Creating new spaces to facilitate BME publications on HTA; and
- Preparing IFMBE recommendations and guidelines for HTA.

Ten priority projects of the HTAD were defined:

(1) *Organise* HTA *summer schools for biomedical engineers*: starting a series of IFMBE Summer Schools on HTA, to be organised in different regions every 2 years;
(2) *Develop HTA training material*: publishing high quality HTA didactic contents, which could respond to biomedical engineers' learning needs;
(3) *Launch eLearning platform*: designing, refining and managing a web portal and an eLearning platform to spread HTA contents and promote BME experiences in HTA initiatives;
(4) *Foster HTA collaboration*: fostering international collaboration among biomedical engineers active in HTA, supporting students and early career researchers' mobility by providing funds to set new collaborations and organizing writing sessions to apply for future grants on collaborative actions on HTA;
(5) *Support HTA strategic communication*: aiming at reinforcing HTA related communication and exchange of experience and knowledge with other scientific societies, agencies and policy makers;
(6) *Preparing guidelines and recommendations*: promoting studies in HTA areas of particular interest for biomedical engineers, including early HTA (pre-market HTA studies) and HTA for medical devices, to develop IFMBE guidelines for MDs assessment;
(7) *Fostering capacity building in LMICs*: HTA-related capacity building in the LMICs (focusing on Africa in the first 3 years);
(8) *Continuous monitoring on biomedical engineering in HTA*: a survey to monitor BME involvement in HTA;
(9) *Establishing and promoting IFMBE HTA Awards* aiming at recognizing emerging BME talents in HTA, policy actions promoting BME involvement in HTA and individuals providing outstanding contribution to the promotion of biomedical engineering and
(10) *Supporting the WHO in the area of HTA* of MDs by providing BME knowledge

Each project was coordinated by a division elected or co-opted member together with a team of collaborators. Many projects were run in strict collaboration with ongoing projects led by partner institutions, in order to avoid duplications and maximise communication and impact.

2.4. Ethical approvals

When required, ethical approvals where sought at the home institutions of project coordinators.

Figure 1. Participants of summer schools on HTA for BME organised by the IFMBE HTAD respectively in 2015 (left) and 2017 (right).

3. Results

3.1. HTA summer schools for Biomedical Engineers

The first IFMBE HTAD Summer School was held in the UK, at the Warwick University in September 2015. The course was structured in three days. The first day an introduction to underlying concepts of HTA was offered, organised in three topics: evidence generation in medicine; systematic literature review; fundamentals of health economics. The second day was dedicated to the HTA of MD, introducing the main difference between medical devices and other healthcare technologies, and presenting methodological implications and existing tools, which could be used to assess medical devices. The third and last day was focused on two relevant topics for biomedical engineers: early stage HTA and Multi-Criteria Decision Making (MCDA) for HTA. Each day was organised in two sessions: frontal lectures were held in the morning, while the afternoon was open for practical group work facilitated by lecturers and tutors. Lectures were given from professors coming from seven countries: Croatia, Italy, Luxemburg, The Netherlands, Spain, UK and USA. The second Summer School was held at the University of Patras, Greece, in September 2107, following the same structure of the first edition (Fig. 1).

Further details and the detailed programs are published on the IFMBE HTAD website [17].

3.2. HTA training material

This project aimed at developing HTA training material, specifically designed considering the needs of biomedical engineers. A quick survey run in 2015 revealed that many biomedical engineers struggled using training material that was conceived for other scholars. The survey has identified five main aspects perceived as gaps: limited use of equations and schematic workflows; poor attention and limited examples on MDs; widespread use of verbose paragraphs; lack of attention to pre-market HTA, which is topic of great interest for many BME scholars; little or no attention to methods and tools (e.g., MCDA) to assist decision-making in healthcare.

All the lecturers participating to the IFMBE HTAD Summer Schools, agreed to create and share handouts specifically meant for an engineering audience. In addition, all the lectures given during those two summer schools where videotaped and became eLearning objects.

A gap-analysis revealed which essential HTA topics were missing from the two summer schools. IFMBE HTAD elected, co-opted and collaborator members volunteered to videotape lectures or keynotes given to IFMBE conferences to complete the missing subjects. This resulted in a significant production of novel HTA training material specifically designed for BME. Part of this material is freely accessible via the IFMBE HTAD eLearning platform, while the handouts are under review for publication on an upcoming open-book.

3.3. eLearning platform

The HTA didactic material produces is freely available on the IFMBE HTA eLearning platform, accessible via the IFMBE HTAD website [17]. It contains more than 30 h of HTA lectures organised in nine sections each composed by a variable number of presentations:

(1) Introduction to HTA: this section contains basic and advanced lectures to fundamental topics of HTA and health economics:
   (a) Intro to health economics & HTA of medical devices (Dr. Leandro Pecchia)
   (b) HTA, an Introduction (Dr. Patrizio Armeni)
(2) Evidence generation in medicine
   (a) Evidence generation in medicine and biomedical engineering (Dr. L Pecchia)
   (b) Evidence generation in medicine (Prof. S. Stranges)
   (c) The value proposition: promise versus evidence (Prof. D Clark)
(3) Systematic literature review and meta-analysis
   (a) Evidence based BME and meta-analysis (Dr. L Pecchia)
   (b) Introduction to the meta-analysis (Dr. P Melillo)
   (c) Practical lab on meta-analysis with OpenMetaAnalyst (Dr. P Melillo)
   (d) Meta-analysis with missing data (Dr. P Melillo)
(4) Multi-criteria decision analysis (MCDA)
   (a) Multi-criteria decision analysis (MCDA) for Early HTA (Dr. M Hummel)
   (b) Multi-criteria decision analysis (MCDA) in eHTA (Dr. L Pecchia)
   (c) Analytic hierarchy process and data-mining (Dr. P Melillo)
   (d) Multiple criteria decision aiding (MCDA) and its potentials to support sustainability and resilience assessment (Dr. M Cinelli)
(5) IFMBE HTAD activities
   (a) IFMBE HTAD activities 2015–2017 (Dr. L Pecchia)
   (b) Introduction to the II IFMBE HTAD Summer School (Prof N Pallikarakis)
   (c) Introduction to the first IFMBE Summer School on HTA (Dr. L Pecchia)
(6) Early HTA
   (a) Early health economic evaluations & eHTA (Dr. L Pecchia)
   (b) Early stage HTA via decision tree (Dr. M Craven)
   (c) Early sStage HTA via Markov models (Dr. M Craven)
   (d) Multi-criteria decision analysis (MCDA) in eHTA (Dr. M Hummel)
(7) HTA of medical devices
   (a) The industry of medical devices & medical devices regulation of in the EU (Prof. N Pallikarakis)
   (b) The industry, the regulation and the challenges in assessing medical devices (Prof. R Tarricone)
   (c) Institutional HTA: the European perspective (Dr. O. Ciani)
   (d) Medical device assessments at CADTH (Dr. J. Polisena)
(8) User need elicitation
   (a) User-need elicitation via AHP (Dr. L. Pecchia)
   (b) MCDA in user need elicitation for HTA (Dr. L. Pecchia)
(9) WHO, BME, medical devices and global health
   (a) Selection of priority medical devices (A. Velazquez, WHO)
   (b) The role of BME to develop appropriate technologies for low- middle-income countries and settings (A. Velazquez, WHO)

Launched in September 2016, the eLearning platform has had a significant and fast-growing number of users, from the entire world (Fig. 2), 76 different users from 14 countries in August 2017, 722 users from 48 countries in August 2018 and eventually 1423 users from 70 different countries in August 2019. It is certainly impressive, although expected, to see that the majority of users accessed the platform contents from the 'Great South', where there is a large number of LMICS, and the highest need for HTA, aiming to optimize the shortness of economic resources.

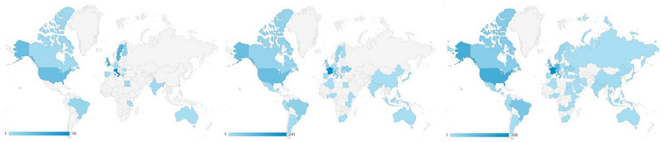

Figure 2. Distribution of users of the IFMBE eLearning platform since its launch. From left: 76 users from 14 countries in August 2017; 722 users from 48 countries in August 2018; 1423 users from 70 different countries in August 2019.

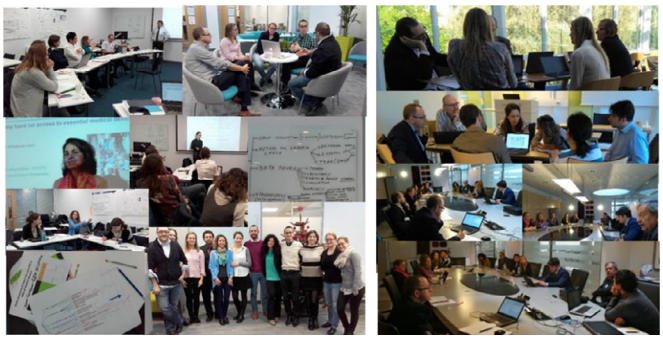

Figure 3. HTAD working groups meetings at the University of Warwick in November 2016 (left) and in Tampere in June 2017 (right).

3.4. HTA collaborative

The HTAD has supported several face-to-face meetings, often held during IFMBE conferences in order to facilitate experts' participation, given their busy agenda.

In order to prepare the IFMBE recommendation on the HTA of MDs, two focus groups were organised (Fig. 3): 15 IFMBE HTAD members and collaborators were invited for a 2-day structured focus group convened in 2016 November 26th and 27th, at the School of Engineering at the University of Warwick; the second focus group was convened in Tampere, Finland, in June 16th, 2017.

3.5. HTA strategic communication

This project was conceived for fostering HTA-related communication and exchange of experience and knowledge among the BME community as represented by the IFMBE and other scientific societies, agencies and policy makers. This project, as many others, was run in strict collaboration with other IFMBE Divisions and working groups, IFMBE affiliated societies, IFMBE HTAD collaborators and partner institutions. This activity was focused on three main actions:

- Collecting evidence to support the ongoing discussion among the IFMBE, WHO, UN ILO (United Nation International Labour Organisation) and the European Parliament for stronger recognition of BME as a profession.
- Establishing stable collaboration among the European biomedical engineering community and the European Parliament, aiming at mutual informing on political and other initiatives regarding medical devices regulation, management and assessment and fostering the ongoing discussion among relevant European and African institutions with the purpose of promoting the harmonisation of directives and regulations on medical devices, medical facilities and healthcare professionals.

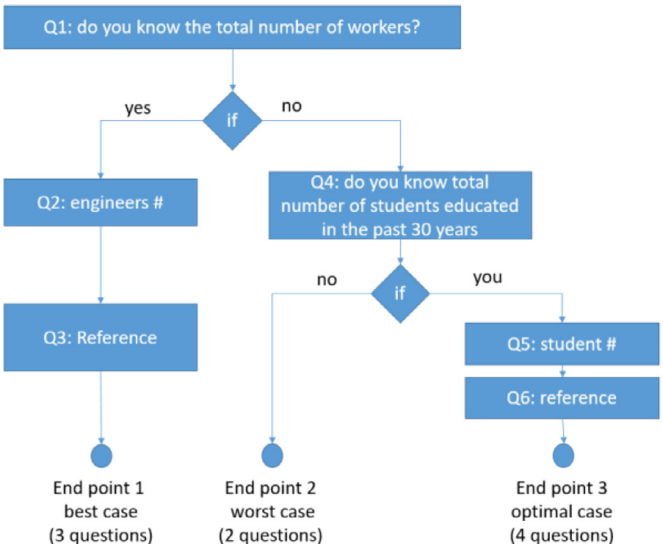

Figure 4. The flowchart of the survey on global numbers on biomedical engineers and biomedical technicians.

Regarding the stronger recognition of BME as a profession, the IFMBE has had an intensive discussion with the WHO aiming at ensuring that this profession will be listed in the next edition of the ILO International Standard Classification of Occupation (ISCO). The ILO global repository of occupations is recognised by UN member states, and consequently transferred to nationally regulations. The current version of this classification is the ISCO-08, which was adopted through a resolution of a Tripartite Meeting of Experts on Labour Statistics held in December 2007 and subsequently endorsed by the Governing Body of the ILO in March 2008. According to ISCO, BME is listed in the category 2149 '*Engineering professionals not elsewhere recognised*'. That BME is not yet classified in the classification of occupations as an independent occupation has hindered its recognition at several national levels generating lack of harmonised regulations (e.g., no harmonised professional requirements for pursuing this profession in public hospitals in Europe). In order to appreciate this difference, readers could compare the difference levels of professional recognition and regulation of BME and medical physics in different European countries.

One of the reasons for ILO not considering BME in the ISCO-08 classification in 2008 was the lack of worldwide evidence on the number of biomedical engineers employed as either engineering or medical professionals. In fact, the ILO policy is to consider for the ISCO classification a new occupation, if and only if, there is evidence that more than 100,000 professionals are employed. In order to meet the ILO requirement, the chairs of the IFMBE HTAD and Clinical Engineering Division met in Brazil with WHO representatives for MDs in September 2017 and designed a survey aiming at acquire the number of biomedical engineers employed in the profession worldwide. This survey was structured (Fig. 4) with the goal of optimizing the number of inquiries and maximize the collection of evidence supporting the numbers of employed biomedical engineers. The survey was then administered by WHO [19], which published the results in October 2018 [20], giving evidence of more than one million of biomedical engineers and biomedical technicians employed in 79 different countries.

At the European level, the IFMBE HTAD worked in strict collaboration with the EAMBES (European scientific society of biomedical engineers) aiming at supporting the European institutions by providing technical support for policy initiatives regarding medical devices, medical facilities and related human resources. This collaboration was also functional to foster the promotion and stronger recognition of BME as an independent occupation in Europe and to establish the European Community of BME as valuable stakeholder

Figure 5. EPIG on BME meetings: two top photos are from the 1st meeting in May 2015, the two on the bottom are from the 2nd meeting in October 2018.

for the development and revision of future European Regulations on medical devices. Since 2014, this activity resulted in significant achievements.

In April 2015, the IFMBE Division and the EAMBES supported the European Economic and Social Committee (EESC) report on BME in publishing the first *European report on BME social and economic impact* [12]. This was actually a significant milestone, which first stated in the official Journal of the European Union the importance of biomedical engineers and the great economic and social impact BME is having in Europe. Moreover, this publication facilitated further contacts with the European Parliament and the European Commission.

Following the EESC publication, the IFMBE HTAD supported the preparation of two *parliamentary questions* tabled by two Italian Members of the European Parliament (MEPs), Ms Lara Comi and Mr Nicola Caputo, in July 2015. The former, asking the Commission to explain why unlike the USA, the EU research and innovation program Horizon 2020 does not have a dedicated space for supporting BME research [21], obtained a written answer from the Commission in October 2015 [22]. The latter, asking the Commission to explain why BME is not listed among the professions that are officially classified by the European Commission [23], obtained a written response from the Commission in December 2015 [24]. Those two parliamentary questions raised significant attention around BME needs in Europe, resulting in the launch of the first *Euro Parliament Interest Group on Biomedical Engineering (EPIG on BME)*, on 31st of May 2016 (Fig. 5). The EPIG on BME aimed at working with the European Commission for support the recognition of BME in Europe and focusing on 4 strategic goals:

- ensuring that BME will be classified in the next revision of the European Commission Professional Qualifications Directive;
- recognizing BME scientific organisations as official stakeholders in the Medical Devices Coordination Groups, which is the group responsible for medical devices legislation revision in Europe;
- recognizing BME as an independent research area, creating independent panels in forthcoming funding European funding schemes and
- fostering collaboration among relevant European and African institutions aiming at harmonizing regulations on medical devices, medical facilities and relevant human resources.

Since its launch, the EPIG on BME got outstanding support from 8 MEPs elected in five EU member countries: Nicola Caputo (Italy), Lara Comi (EPP, Italy), Jens Gieseke (Germany), Neena Gill (UK), Lojze Peterle (Slovenia), Marijana Petir (Croatia), Davor Škrlec (Croatia) and Cécile Kyenge (Italy). The EPIG on BME worked intensively

Figure 5. Launch of the first African Working Group on BME in the Africa Union headquarters (top-left), IFMBE delegation meeting the Ethiopian ministry of Science and Research (top-left and bottom photos).

on those four points, achieving significant results presented in the last EPIG on BME meeting held in October 2018. Among others, one of the most impressive was the introduction of the BME profession in the European Skills, Competences and Occupation (ESCO) database, which is an equivalent of the UN ILO ISCO, and, likewise, was not yet listing BME as an independent occupation since 2016 [25] .

While this manuscript is being written, a new EU legislature has been elected and has been officially in place for 2 months. Linking the newly-elected MEPs with the BME community has started aiming at giving continuity to this very positive experience.

Regarding BME in LMICs, in collaboration with WHO, the IFMBE has also been proactively involved in fostering BME in Africa, creating the first IFMBE African BME working group, which was launched in the Africa Union Headquarters in January 2018 (Fig. 6) [26]. HTA has been one of the core topics for this African working group since its launch.

3.6. Guidelines and recommendations

As the first important topic, the HTAD members decided to focus on HTA of MDs. It is quite well known that differences among MDs and other healthcare technologies are substantial, and using the same methods to assess different healthcare technologies may lead to misleading conclusions. Starting from the table proposed in [7], the HTAD working group performed a systematic analysis on which key element of MDs lifecycle should be considered in a HTA studyand on how MDs interact with medical facilities and how this interaction may hinder HTA conclusions. In order to achieve consensus on those elements and their importance, an electronic Delphi study was lunched, involving 32 experts from 17 countries, 25% of which were experienced clinical engineers and 70% HTA experts. A grey literature review was performed, aiming at exploring how existing guidelines on HTA of MDs consider those factors. As a result [27], nine recommendations where given, with the purpose of improving the assessment of MDs:

(1) Ensure that all reasonable maintenance, installation, and ongoing facility costs are incorporated in the economic evaluation, or explicitly state the hypothesis of the study conducted.
(2) Describe the maintenance and installation organisational model considered in the economic evaluation (e.g., internal clinical engineering service).
(3) Understand and describe explicitly in the HTA report all possible maintenance, installation, and operational costs considered.
(4) Obtain additional insights on the maintenance required, and capture maintenance impact during the HTA process by using appropriate methods of contextual inquiry.
(5) Use both pre-market and post-market data to capture impact of context of use variables (i.e., user, tasks, physical and social environment) on HTA outcomes.
(6) Conduct a risk assessment by using appropriate and validated tools or standards.
(7) Simulate and use appropriate statistical methods to analyse the different types of evidence on the effectiveness and safety of the medical device.
(8) Conduct, when necessary, a simulation of use to empirically analyse safety in use and define procedures of risk reporting and processes to mitigate residual risks.
(9) Conduct an analytic assessment to estimate “what if” the minimum requirements are not met.

3.7. Capacity building in LMICs

The HTA Division members focused on supporting existing collaborations with the aim of:

(1) performing scoping exercise for better understanding the real needs of Africa in terms of BME and clinical engineering;
(2) ensuring that ongoing initiatives properly consider HTA-related topics.

Over 24 months, the division supported (co-sponsored) five field studies in SSA countries (Benin, Ethiopia and South Africa) and established proactive collaboration with the IFMBE African Working Group on BME. In addition, the division facilitated focus groups and electronic surveys involving world-leading scholars with experience of HTA, clinical engineering, medical device and medical settings. As a result, the division produced a series of evidence-based data, which demonstrated for the first time that the majority of researches on MDs in Africa are focused on economic and competence constrains. Conversely, very little attention has been given to how medical devices interact with the settings in which those are operationalised. This is mainly due to the fact that, although the majority of global population is still diagnosed and treated in low-sources settings, more than 90% of MD market is in high-income countries, namely in Europe, USA and Japan [28]. Thus, MDs are designed giving for granted that their installation and maintenance will be performed according to high-income medical facility standards. Therefore, MDs are not resilient to low-income medical settings. Accordingly, the division planned a series of training events aiming at informing African biomedical engineers on the international standards given as granted from MD designers with the purpose of increasing their capability to:

- recondition MDs, making them more resilient to African working conditions (e.g., temperature, dust, humidity; non-specialised users;
- contribute to the definition of international standards on MDs;
- be proactively involved in the design of medical devices and in use ICT to support MD maintenance [29].

The first two training events were piloted in Benin (May 2017 and January 2018) at the University of Abomey-Calavi. Two more events, namely summer schools, are planned for 2019 and 2020 in Uganda and Benin, respectively.

3.8. Continuous monitoring on BME in HTA

The HTA Division runs several surveys and focus groups aiming at involving international scholars, globally promoting the division activities, informing on current projects and acquiring feedback for continuously improving their execution. Those surveys were strictly coordinated with the other priority projects and researches running in partner institutions. When required, ethical approvals were sought at the project coordinator ethical committee. Five major electronic surveys have been implemented since 2015:

- BME recommendation for HTA of MDs [27],
- A survey aiming at identifying factors that may hinder MD safety and effectiveness in low-resource settings [3],
- A survey aiming at identifying the key priorities and finding consensus on the priority topics to be discussed with the European Parliament aiming at fostering the recognition of BME profession in Europe,
- A survey aiming at acquiring the number of BME and clinical engineers worldwide and
- A survey aiming at comparing the qualifications required to work as a clinical engineer in European public hospitals.

The results of these surveys have been published or submitted for publication elsewhere. Nonetheless, the overarching results achieved by this project was to highlight the importance of sociological methods in engineering, if necessary. Moreover, those surveys also emphasised the need for more evidence-based clinical engineering for building consensus and defining international standards regarding medical devices and medical locations.

3.9. IFMBE HTA awards

The HTA Division decided to recognize individuals and organisations that contributed to the promotion and support of BME in HTA. Two awards were delivered from June 2015 to June 2018.

The IFMBE HTAD Policy Award, awarded to policy makers that gave significant contribution to the recognition of BME, was granted to the Member of the European Parliament Nicola Caputo for his outstanding contribution to the recognition of BME profession and for establishing the first European Parliament Interest Group on Biomedical Engineering (EPIG BME) in the European Parliament.

The IFMBE HTAD Award for Outstanding Contribution, awarded to recognize outstanding contributions to promote or consolidate BME involvement in HTA, was awarded to Edgardo Maria Iozia for authoring the EESC report on BME impact in EU (2015/C 291/07).

3.10. Reinforce the collaboration between IFMBE and WHO on HTA

IFMBE collaborates with the WHO in matters on biomedical engineering and medical devices. As a NGO in official relations with WHO, the IFMBE hosts a seat in the WHO General Assembly. The IFMBE has supported the producing several WHO reports and technical books, and has been actively involved in organisation of WHO international events on health technologies. Since 2012, the IFMBE Division has extended this collaboration to HTA related activities. For instance, the IFMBE members have been continuously involved in organisation of the WHO Global Fora on Medical Devices, by giving plenary speeches, organising workshops on HTA of medical devices and HTA in LMICs, chairing the tracks on HTA, organising joint events in collaboration with both, the WHO and the European Parliament [3].

4. Conclusions

Medical devices are intrinsically dependent on the environment in which they are used. Consequently, HTA of medical devices is also intrinsically dependent on the environment where a medical device is required to work and this affects the generalisation of use of HTA reports across countries, in contrast with pharmaceuticals. HTA for medical devices should therefore find its own way and models of conductance to respond to the large and ever-expanding variety of technologies involved. Medical devices are becoming increasingly essential at all stages of healthcare delivery (i.e., prevention, diagnosis, treatment, rehabilitation, patient management, end of life). Therefore, HTA agencies in Europe and beyond are increasing their human resources experienced in MDs. WHO recommends employing experts of MDs such as biomedical engineers in HTA agencies.

The activities described in this manuscript had a significant impact among the biomedical engineering community and beyond, consolidating the concept that HTA is a core topic for biomedical engineering and that biomedical engineers are crucial actors of HTA, especially in regards to medical devices. A proxy for this change in BME culture is the number of papers, round tables, sessions and tracks dedicated to HTA to biomedical engineering events and conferences. For instance, reviewing the proceedings of the last four editions of the IUPESM World Congress on Medical Physics and Biomedical Engineering, held in the past 12 years respectively in Munch [30], Beijing [31], Toronto [32] and Prague [33], the number of papers focusing on HTA has grown exponentially. All the IFMBE conferences organised in Europe since 2016, had at least a whole track dedicated to HTA. Simultaneously, other international societies focusing on HTA (e.g., HTAi, ISPOR, INAHTA) recognised biomedical engineers relevance to HTA and included BME speakers and topics to conferences they organizing, and a collaborative cross-societies working group has been established to foster global cooperation among those organisations and the WHO [34]. This is also having a direct impact on other biomedical and clinical engineering areas, which are paying unprecedented attention to HTA topics. This is certainly the case of recent studies advocating in favour of a more evidence-based approach to health technology management [35] and clinical engineering [36].

Nonetheless, more training opportunities and learning material on HTA specifically addressing BME learning needs is clearly needed. The fact that the number of users of the IFMBE eLearning platform has been growing exponentially in the past 3 years is a significant proxy for this demand.

The collaboration with the European Parliament, the EESC and the WHO has been incredibly welcome, suggesting that there is a real need for biomedical engineers to provide valuable inputs to the policy-makers. Moreover, the collaboration with the WHO and the European Commission for fostering stronger recognition of BME profession has given tangible results beyond our initial expectation. The inclusion of BME in the ESCO has also been another important milestone in the journey of biomedical engineering, paving the way to more structural inclusion of biomedical engineers in the European initiatives (e.g., creating a BME panel in framework for excellence in research in Horizon Europe, consulting European BME scientific societies as stakeholder for forthcoming regulations on medical devices). Moreover, it is clear that more regulation is required in terms of *who-can-do-what* on MDs, in the best interest of patient safety and quality of life, especially now that healthcare services are becoming so dependent upon MDs.

In 2016, the WHO concluded that Biomedical Engineering professionals can be found in 129 of 194 Member States of WHO, based on the input from biomedical engineers proactively involved in national scientific BME societies and professional organisations [8]. In 2017, the Survey designed by the IFMBE in collaboration with WHO demonstrated that we can rely on one million of biomedical engineers and technicians employed in 79 countries worldwide.

Declaration of Competing Interest

The authors have no conflict of interest

Acknowledgement

The activities described in this paper have been supported by the IFMBE. LP acknowledge support received via the EPSRC IAA grant (EP/R511808/1) titled Grant titled ‘Health Technology Assessment (HTA) of Medical Devices (MDs) in low- and middle-income

countries (LMIC)' and via the GCRF funded project titled 'Supporting the harmonisation of regulations on medical devices and medical locations among Sub-Saharan African regions and Europe'.

Ethical approval

Not required.

References

[1] O'Cearbhaill RM, Murray TE, Lee MJ. Medical device patents—a review of contemporary global trends with an Irish comparison. Ir J Med Sci 2019;188(2):653–9 (1971-).
[2] MedTech Europe Report. The European medical technology industry in figures. Brussels: MedTech Europe; 2018.
[3] Pecchia L, et al. Harmonising medical device and medical location policies among Africa and Europe. In: Proceedings of the fourth WHO global forum on medical devices, Visakhapatnam, India. AMTZ-Kalam Convention Centre; 2018.
[4] The World Bank. Mortality rate, infant (per 1,000 live births). 2017; Available from: https://data.worldbank.org/indicator/SP.DYN.IMRT.IN.
[5] The World Bank. Life expectancy at birth, total (years). 2017; Available from: https://data.worldbank.org/indicator/SP.DYN.LE00.IN.
[6] Richards-Kortum R, Oden M. Devices for low-resource health care. Science 2013;342(6162):1055–7.
[7] Pecchia L, Craven MP. Early stage health technology assessment (HTA) of biomedical devices. the match experience. In: Proceedings of the world congress on medical physics and biomedical engineering, Beijing, China. Springer; 2013. May 26-31, 2012.
[8] Berumen Velazquez A, et al. Global dimensions of biomedical engineering Human resources for medical devices, the role of biomedical engineers. World Health Organization; 2017.
[9] Garrido MV, et al. Health technology assessment and health policy-making in Europe: current status, challenges and potential. WHO Regional Office Europe; 2008.
[10] WHO. Biomedical engineering global resources. 2017; Available from: https://www.who.int/medical_devices/support/en/.
[11] EAMBES. European alliance for medical and biological engineering & science (EAMBES) web portal 2019 26 August 2019]; Available from: http://eambes.org/.
[12] Iozia EM, Jarre D. Opinion of the European economic and social committee on promoting the European single market combining biomedical engineering with the medical and care services industry. 2015 /C 291/07; Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.291.01.0045.01.ENG&toc=OJ:C:2015:291:TOC.
[13] Pallikarakis N, et al. Promoting harmonization of BME education in Europe: the CRH-BME tempus project. In: Proceedings of the annual international conference of the IEEE engineering in medicine and biology society. IEEE; 2011.
[14] Jarm T, et al. Proposal for generic biomedical engineering programs based on European experience. In: Proceedings of the 5th European conference of the international federation for medical and biological engineering. Springer; 2011.
[15] Pallikarakis N, et al. Biomedical engineering education: need for harmonisation. In: Proceedings of the EMBEC & NBC. Springer; 2017. p. 888–91.
[16] IFMBE. International federation of medical and biological engineering (IFMBE). 2016 26 August 2019]; Available from: http://2016.ifmbe.org/.
[17] IFMBE HTAD. IFMBE health technology assessment division (HTAD). 2016 26 August 2019]; Available from: https://htad.ifmbe.org/.
[18] IFMBE CED. IFMBE clinical engineering division (CED). 2019 26 August 2019]; Available from: https://ced.ifmbe.org/.
[19] WHO. WHO global survey – professional and academic profiles on biomedical engineers and technicians. 2018; Available from: https://extranet.who.int/dataform/survey/index/sid/155764.
[20] WHO. Biomedical engineering and technician personnel data by country. 2018; Available from: http://apps.who.int/gho/data/node.main.HWF8?lang=en.
[21] Caputo N, Lara C. European parliament parliamentary questions titled: absence of biomedical engineering from horizon 2020. 20 July 2015 27 August 2019]; Available from: http://www.europarl.europa.eu/doceo/document/E-8-2015-011613_EN.html?redirect.
[22] Moedas C. Answer to the European parliament parliamentary questions titled: absence of biomedical engineering from horizon 2020. 14 October 2015 27 August 2019]; Available from: http://www.europarl.europa.eu/doceo/document/E-8-2015-011613-ASW_EN.html.
[23] Caputo N, Lara C. European parliament parliamentary questions titled: recognising biomedical engineering within the professional qualifications directive. 20 July 2015 27 August 2019]; Available from: http://www.europarl.europa.eu/doceo/document/E-8-2015-011612_EN.html?redirect.
[24] Bieńkowska E. Answer to the European parliament parliamentary questions titled: recognising biomedical engineering within the professional qualifications directive. 11 December 2015 27 August 2019]; Available from: http://www.europarl.europa.eu/doceo/document/E-8-2015-011612-ASW_EN.html.
[25] European Commission. European skills, competences, qualifications and occupations (ESCO). 2018 26 August 2019]; Available from: https://ec.europa.eu/esco/portal/search?term=biomed&resetLanguage=true&newLanguage=en.
[26] IFMBE. Kick-off of the first African scientific society of medical and biological engineering. 2018 12 September 2018]; Available from: http://htad.ifmbe.org/kick-off-of-the-first-african-scientific-society-of-medical-and-biological-engineering/.
[27] Polisena J, et al. 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.
[28] Piaggio D, et al. Donation of medical devices in low-income countries: preliminary results from field studies. In: Proceedings of the international conference on medical and biological engineering. Springer; 2019.
[29] Medenou D, et al. Medical devices in sub-Saharan africa: optimal assistance via a computerized maintenance management system (CMMS) in Benin. Health Technol (Berl) 2019;9(3):219–32.
[30] Dössel O, Schlegel WC. World congress on medical physics and biomedical engineering September 7–12, 2009 Munich, Germany: vol. 25/IX neuroengineering, neural systems, rehabilitation and prosthetics, 25. Springer Science & Business Media; 2010.
[31] Long M. World congress on medical physics and biomedical engineering May 26–31, 2012, Beijing, China, 39. Springer Science & Business Media; 2013.
[32] David AJ. World congress on medical physics and biomedical engineering, June 7–12, 2015, 1. Toronto, Canada: Springer; 2015.
[33] Lhotska L, et al. World congress on medical physics and biomedical engineering 2018: June 3–8, 2018, 1. Prague, Czech Republic: Springer; 2018.
[34] Iadanza E, et al. HTAi, ISPOR, INAHTA, IFMBE, IUPESM and who joint panel on HTA of medical devices. In: Proceedings of the fourth WHO global forum on medical devices, Visakhapatnam, India. AMTZ-Kalam Convention Centre; 2018.
[35] Iadanza E, et al. Evidence-based medical equipment management: a convenient implementation. Med Biol Eng Comput 2019:1–16 [Epub ahead of print]. https://link.springer.com/article/10.1007/s11517-019-02021-x.
[36] Badnjević A, et al. Evidence-based clinical engineering: machine learning algorithms for prediction of defibrillator performance. Biomed Signal Process Control 2019;54:101629.