

BME and the EU

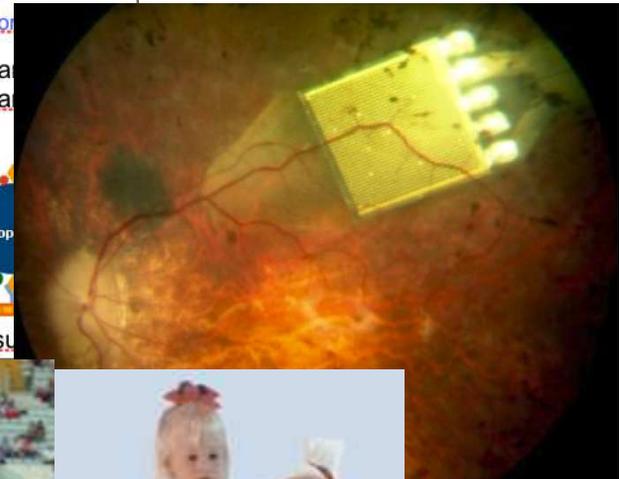
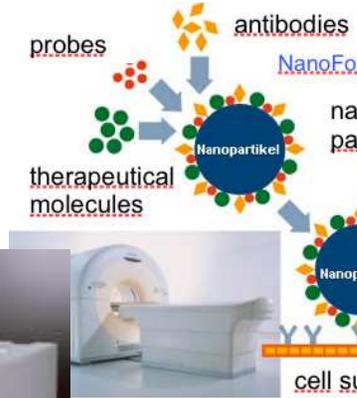
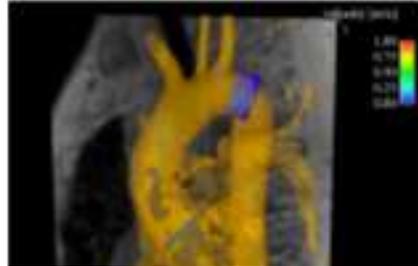
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Secretary General of EAMBES

Biomedical Engineering

- Diagnostics
- Therapy
- Rehab
- Research
- Prevention, surveillance, life style, sport...



A. Haverich and corlife GbR

What is BME

- (EESC) 2.1 *"Biomedical engineering is a cross-disciplinary science based on medicine, biology and engineering. It is fundamental for a variety of highly innovative technologies and products or processes of the health care sector. Biomedical engineering should be understood as a stand-alone discipline to better utilise resources and fully realise the corresponding opportunities. It is thus important that the EU recognises the full potential of biomedical engineering and consequently promotes collaborative research in this field". This was how biomedical engineering was defined at the **Expert Policy Workshop on Biomedical Engineering** held at the European Parliament on 27 March 2012.*
- **BME is everywhere, but not very visible.** We tend to talk to a doctor that uses his equipment without realizing somebody has developed that equipment at some point.
- Biomedical Engineering is not a subset of modern medicine, modern medicine is the product of biomedical engineering
- SMEs are vital to BME
- BME staff often work on many different projects at once. Some are specialists in one set of techniques, others are more specialist in e.g. an organ.

What is EAMBES

The European Alliance of Medical and Biological Engineering and Science (EAMBES) is a no-profit international organization incorporated according to the Belgian law, that federates most scientific societies and academic and research institutions located in Europe and involved with Biomedical Engineering or as it is more appropriately defined Medical and Biological Engineering and Science. The main objective of EAMBES is to improve the health, wealth, and well being of the citizens of Europe by the application of Medical and Biological Engineering and Science.

- 26 national BME societies
- 6 transnational BME societies
- 35 Academic Programmes or Institutions and Research Institutes

www.eambes.org

BME is a discipline in it's own right

- (EESC) 1.14 *Europe should follow the US example and recognise the discipline as a stand-alone science. This would also help to foster the international competitiveness of European companies.*
- (EESC) 2.4 *Although the discipline of biomedical engineering was recognised in 1998 by the 4th Framework Programme for Research and Innovation, current EU policy in this area is fragmented. Biomedical engineering in the United States is treated as a separate discipline, with distinct methodological and analytical techniques.*

Biomedical Engineering should be recognized in the EU Professional Qualifications Directive.

Biomedical Engineering is involved in research, development and clinical application, and has therefore many different job descriptions. Nevertheless it would be important to provide standardized certified courses, especially for the approval to work with patients self-responsible on an academic level.

SMEs are vital to BME

- SMEs are more important in BME than in pharma
- The majority of new developments in BME come from BME researchers and SMEs, either through technology transfer from Universities or R&D institutions, or by themselves.
- Biomedical engineering and health technology are important and growing industrial and service sectors in Europe
- SME have not the financial power to undertake large randomized prospective trial to deliver the evidence required for clinical acceptance of a device
- More Device and BME related calls for Investigator Driven Clinical trials are required

BME is a healthy discipline

- the demand for BME increases and the number of students increase (see EESC chapter 2)
 - at many places research staff is shrinking
 - even teaching staff is shrinking and replaced by teachers, temporary for a few years.
- European policy, national policy and university policy should complement one another to ensure a broad base of knowledge and experience from which it is easy to collaborate with industries (in particular SMEs), branch off startups, create international collaborations,...

'Quality' measures and funding

- impact factors for BME journals are low, publishing culture demands that you only cite articles that are most relevant for your subject
 - It is often more rewarding from an impact factor perspective to publish the results of the *application* of a new technology (in a medical journal) than about the *actual development* of that technology (in a BME journal), even if you are not the first author.
- BME has a great impact on society and on other (medical) disciplines (citations are mainly a measure of within discipline relevance only)
 - any system that uses **citations, h-index and/or impact factors** of journals will disproportionately harm BME
- in practice medical grants are often for **application** of a new instrument, R&D is just a small part of the whole grant.
 - any system that uses **grant money acquired** as an index will disproportionately harm BME

Reviewing process

- Peer review is the pillar of science
- Value is not acknowledged by many institutions
→ Difficult to find competent reviewers (especially for interdisciplinary work).

Longer time frame

- (PPH2020) 1) *Different types of projects - smaller ones with cutting edge approach and larger ones with integration approach - are needed. **In all types of projects a long term perspective to real applications in healthcare is needed.** These projects should also provide effective mechanisms that favour not only those consortia and research that include existing Small and Medium Enterprises (SME), but above all those that aim to create spin-offs and start-ups to commercially exploit the research output.*
 - (EESC) 1.5 ***A time frame of at least ten years** is needed to realise a coherent healthcare programme. This is at odds with the European Commission terms of only five years, meaning that visions and strategies change continuously. A stable vision and fixed objectives are greatly needed as the cornerstone for efficient healthcare in the future. It is necessary to ensure healthcare for all*
 - (EESC) 5.5 ***Member States should adopt long-term, coherent healthcare programmes** and action plans to develop innovative research, new technologies and high-quality education in biomedical and other relevant areas of engineering.*
- funding for longer periods smaller projects?

New Societal Challenges

- Increase of chronic disease and an ageing population-need for devices that enable active and healthy ageing
- Increased ability for citizens to work into their older years – need for technologies that can enable older workers to continue to work
- Personalised medicine – requires the diagnostic tools and advanced imaging devices that only BME can deliver

Other recommendations from EAMBES H2020 position paper

- 2) Funding schemes should include resources for **proof of concept studies** to ensure that clinical and commercial breakthroughs as novel clinical and biological and methods, procedures, industrial products and healthcare services.
- 3) Calls should aim at **integrating new emerging technologies**, medical and biological science to place **Europe as a global leader in medical technology**. A series of calls should be implemented each with an emphasis on the integration of different technologies to tackle real medical challenges.
- 4) To speed up the **transfer of research findings** new programmes are needed which allow the prosecution of successful projects towards commercialization.
- 5) To speed up the utilization of cutting edge technology and its integration to healthcare, the principles and ideas of Future Emerging Technology scheme should be extended towards **unproven but potentially high payoff novel concepts in health technology and biomedical engineering**.

BME education and importance of the recognition of the discipline

- Easier transfer of students between Universities - much improved Bologna process also for BME area
 - also easier collaboration between universities to organize BME education in specific expert areas
 - better European wide use of specialists and resources in education
 - better BME specialists that can contribute to patient safety and industry in Europe
- BME professionals that can find their work in European wide labor markets
 - opening of the European labor market also in hospital/health care area for BME specialists
 - much improved transfer of best practices
 - easier introduction of new standard, methods, practices and industrial products in European wide health markets

MDR

We support the introduction of investigational devices, improved and enforced common standards for Notified Bodies and advances in post-market surveillance.

- Some changes are reactions to incidents with implantable devices
 - Most BME is in other areas
- upgrading the classification of a device will increase development costs.
 - This will hurt SMEs more than the larger industries.

eHealth/mHealth

- (EESC) 5.6 *The EU should promote a single market for the European medical technology industry, among other things through adequate **standardisation** in the field of biomedical engineering in combination with the **care services industry, ICT and health informatics**. This could offer tremendous advantages for European industry and enhance the quality of medical care*
- tracking of individual devices: we would like to incorporate that when possible already in the design phase. But then we need to know what standards will be used.
- transferring data from a medical device to a database of measurements on patients is an EHR issue, but can have a big impact on device design.

Rare diseases

- In contrast to drug development, there is no “orphan scheme” supporting research and development of medical products for the diagnosis and treatment of rare diseases.

Involving the users

- (EESC) 1.7 *Access to health and care services should be considered a fundamental right. The EESC underlines the importance of closely **involving users** of the products of biomedical engineering – in particular **patients and their families**, but also medical and care personnel – **in decision-making processes to determine the direction of biomedical engineering research** and the subsequent design of products and services, so that they respond to real needs and preferences, can be easily managed, and thus better serve their purpose. Issues of accessibility, safety, dependency and data protection should also be taken into consideration.*

Patient involvement is important, however, we need also a backbone of experienced researchers and the freedom for fundamental research.

Conclusions

- BME is important for the future of EU
 - Should be reflected in opinions and proposals (H2020)
- BME should be recognized as a discipline in it's own right
 - Biomedical Engineering should be recognized in the EU Professional Qualifications Directive.
 - clinical engineering/research/industry
 - European wide collaboration in research, education and industry (SMEs)
- SMEs are vital for implementation of knowledge
- Decissions in other groups affect us
 - Grant/job market
 - EHR/privacy
- BME is knowledge/experience intensive discipline → long term planning