AIT Austrian Institute of Technology
Expert view of Biomedical Engineering and Care Services

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EESC, Jacques Delors Building, Room JDE 61, rue Belliard 99

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Generell perspectives of „Biomedical Engineering and Care Services“

The surrounding conditions for Biomedical Engineering and Care Services in Europe are

- **Societal changes:**
  Demographic pressure (e.g. ageing society, low birth rate, increased outside family care, lack of healthcare professionals, need to reduce inequalities, …)

- **Clinical challenges:**
  Communicable chronic & lifestyle diseases (e.g. addiction, nutrition, metabolic diseases, …)

- **Economic changes:**
  Financial pressure on healthcare systems is increasing

Facing these changes/challenges → This is a „historic“ chance for biomedical engineering and care services in Europe especially at the interface intramural and extramural domain area.
Opportunities of „Biomedical Engineering and Care Services“ for economics and job market

The *ageing society* offers increased outside family care but there is a lack of healthcare professionals and the mean residence time of caregivers is quite low compared to other branches. What can be done to change that? E.g. Ambient Assisted Living (AAL) technologies and Telemonitoring services can help to make this area more attractive and generate additional jobs in service, technology and research sector.

The *clinical challenges* can be solved via a focus on prevention and early diagnosis as well as new technologies (e.g. implants made of Mg could reduce explantations where implants have to removed after they have done their job, Europe is leading in Mg-alloy technology).

The *economic challenges* can be solved via efficiency-based medicine not just evidence-based medicine (e.g. implement new processes in health care via technology support like tele-services).
Challenges/Hindrances of „Biomedical Engineering and Care Services“

Generally

• Biomedical Engineering is a highly interdisciplinary domain area.

• Research & Development phase is long and cost-intensive

• Regulatory Framework: A lot of regulations have to be fulfilled (e.g. MDD 2007, AIMDD 2007, IVDD or the handling of sensitive medical data – health data protection laws, specific standards for different applications, …)

• Proof of cost-efficiency is often very difficult because of the heterogenous financing systems in the health care domain area in Europe.

• Therefore reimbursement & the funding situation is mostly very difficult.
Challenges/Hindrances of „Biomedical Engineering and Care Services“

Europe vs. national level

• Reimbursement & the funding situation at the national level are mostly very different. (Multi-stakeholder situation)

• The healthcare and care systems on the national level are mostly very different.

• The financing situation at the national level are mostly very different. (Multi-stakeholder situation and competing interests between different stakeholders)
Challenges of „Biomedical Engineering and Care Services“

Example regulatory framework and the long development phase
Challenges of „Biomedical Engineering and Care Services“

The long way from first Clinical Values to Reimbursement

Why does it take so long?

- This means, an innovation in biomedical engineering and care services need much more time because of all these needs have to be fulfilled. Therefore, much more funding/investment is needed to overcome all the challenges/hindrances in order to succeed.

- Depending on the medical device classification and invention it can take up to 10 years from the idea stage to reimbursement.
Example for challenges mentioned before: Austrian Success Story MED-EL

- 1975  Development of the first prototype Cochlea implant @ Technical University of Vienna.
- 1977  First successful implantation

Up to 1989 extensive negotiations with licensing partners (e.g. 3M, …)

- 1989  Own company foundation
- 1992  Company MED-EL was nearly bankrupt (public support Tyrol)
- 2002  MED-EL implants in more than 50 countries
- 2004  MED-EL in more than 70 countries
- 2011  27 branch offices world-wide
    900 employees
- 2014  MED-EL in more than 100 countries, more than 1.500 employees
Threats for innovation in Biomedical Engineering in Europe

- The steadily increasing financial reporting efforts in national and European R&D projects apart from all the other regulatory framework in the health care domain area which have to be fulfilled!

- But also beside the necessary R&D activities, patent generation, scientific publications, presentations at conferences, acquisition of partners and customers as well as patients for first proof of concepts.

- Worst case funding structure at the moment are EFRE funded projects for structural developments which are often used in the transition from applied research results to large scale trials.

- It would be much better to change the system to outcome measurement instead of micro financial controlling!
What could be political activities and national programs do to overcome the difficulties mentioned before?

- More visibility of scope and role of MD’s industry in the economy and healthcare e.g. An own category for Biomedical Engineering and Care Services under the [http://ec.europa.eu/research/health](http://ec.europa.eu/research/health) Homepage.
What could be political activities and national programmes do to overcome the difficulties mentioned before?

- Identification of the fields of innovation due to the changes and challenges
- Improvement of basic conditions for cooperations (universities – applied sciences – companies)
- Improvement of biomedical and clinical research
- Consolidation of funding for research & development AND product development
- Consolidation of certification & reimbursement in Europe
- Funding of innovation management, dissemination & exploitation because of the very long way mentioned before
Some trends in Biomedical Engineering and Care Services

Market growth: 5% to 7% p.a. (in some areas up to 20% p.a.)

- Trend 1\(^1\) Home Care & wireless technologies
- Trend 2\(^1\) Miniaturization & new materials
- Trend 3\(^1\) Medical sensor platform for multiparameter monitoring
- Trend 4\(^2\) Increase pharmacodynamic and pharmacokinetic imaging studies
- Trend 5\(^3\) Personalized Medicine
- Trend 6\(^4\) Point-of-Care (POC) Diagnostics
- Trend 7\(^5\) Companion Diagnostics

2) PricewaterhouseCoopers (PwC): „Pharma 2020: The Vision – Which Path will you take?“
4) Cowin Report: Analysis of Main Challenges to bring minaturizes smart systems to in vitro diagnostic, food quality and environmental markets, Feb 2012
5) ecancer medicalscience: Companion Diagnostics: Changing patient management, 2012
Market growth for Medical Devices till 2020

Analysis on Top 10 Device Areas in 2020, Market Share & Sales Growth (2013-20)
Source: EvaluateMedTech® (18 SEP 2014)

Note: Bubble = WW Sales in 2020
% Sales Growth: CAGR 2013-20
Innovative Biomedical Engineering areas

But there are a lot of other and new opportunities
Innovation fields in Biomedical Engineering

- Micro systems for active implants, in vivo and in vitro diagnostics, DNA-Chips, Lab on a Chip, drug delivery systems
- Technologies for minimal invasive interventions, image guided interventions
- New and better imaging technologies
- Technologies for regenerative medicine and tissue engineering
- Computer based diagnostics
- New materials for diagnostic and therapy, functionized surfaces, passive implantats made of new materials
- eHealth systems, electronic patient records, Telemonitoring
- Medical expert systems to support decisions and therapy

But this innovation fields need:
- Innovative physicians and engineers
- Excellent fundamental and applied research
- Strong cooperation science – medicine/care - industry
- R&D orientated industry landscape
- An innovative health care market

Quelle: DGBMT, Prof. Dr. Dössel
Care services and technologies
Innovations for a self-determined living

- Technologies to increase the quality of life and ease the work for caregivers
  - medical devices for patients/caregivers
  - gerontotechnologies
  - smart home technologies
  - smart textiles
  - Robotics for home use
  - consumer electronics
  - Telecare & Telehealth services
A practical example in the service area from Austria showing all the difficulties apart from technology development.
A practical example – challenges – Health care responsibilities in Austria

(1) Draft legislation by the federal government (minister responsible) to Parliament, or by the Land government (minister responsible at Land level) to the Landtag.
(b) Agreement of federal law by Parliament, or Land law by the Landtag.
(2) Support to the Federal Ministry of Health.
(3) Support to the Federal Ministry of Health, particularly in the context of licensing medication (AGES = Agency for Food and Health Safety).
(4) Health administration:
(a) at federal level (e.g., health-care policing, sanitary supervision of hospitals, monitoring of social security institutions and legal bodies representing interest groups);
(b) at Land level (e.g., concerning permits to build and run hospitals, licensing processes for outpatient clinics and group practices, implementation of planning in the region, investment finance).
(5) Appointment of members of the Federal Health Commission or regional health platforms.
(6) Consultation mechanism between the federal level and local and regional authorities with regard to legislative measures (laws and regulations) which require additional expenditure.

(7) Sanction mechanism: the Federal Health Agency (Federal Health Commission) can withhold financial resources from a regional health fund (health platform) if it contravenes compulsory plans and guidelines regarding quality and documentation.
(b) Regional health funds (health platforms) can designate a corresponding sanction mechanism for hospitals.
(8) Negotiations on market entry, services and tariff charges (collective and individual contracts).
(9) Legal membership of social security institutions (compulsory insurance).
(10) (a) Fundamental freedom of choice for patients over hospitals and independently practising members of the health-care professions.
(b) Obligation to treat, which exists for public and private non-profit-making hospitals and contracted independently practising members health-care professionals.
(11) Legal representation of patients in every Land.

Source: Ministry of health.
A practical example – challenges – Financial flow in Austria
A practical example – challenges – Facilitators

- Governance Mechanisms
- Policy Commitment
- Reorganisation of services
- Interoperable Information Systems
- Patient Focus
- Engaged Professionals
- Incentives and financing
- National investments and funding programs
A practical example – challenges – Critical success factors

Enabling service deployment:
18 Critical success factors

1. Strategy and management
2. Organisation and management
3. Legal and security
4. Technology and market

Plan
- Resource aggregation
- Primary client
- Change management
- Potential to scale-up
- Business plan
- Legal & sec. conditions

People
- User friendliness
- Stakeholder involvement
- Leadership
- Patient centeredness

Run
- Service monitoring
- Privacy awareness
- IT & eHealth infrastructure
- Legal & sec. guidelines
- Market procurement
- Legal & sec. experts

Contex
- Compelling need
- Cultural readiness
Outcome data from VAEB – Health Dialog: Analysis after 12 months new patients were acquired
Outcome data from VAEB – Health Dialog: Analysis from patients after 24 months

→ Significant reduction of the HbA1c values from 8.2% to 6.4 % (24 month follow-up)
A suggestion for a new start-up funding approach for Biomedical Engineering and Care Services

In identifying good ideas and entrepreneurs the following suggestion could improve the situation in Europe:

• Installation of several Europe wide expert teams (5 to 6 persons) which consists of people who have developed new products or have founded successfully companies in the Biomedical Engineering or Care Services domain area.

• They should work like the Dragon`s Den in England (http://www.bbc.co.uk/programmes/b006vq92) but focus on Biomedical Engineering and care services and give a suggestion if the idea and the team should be funded or not, and how much money and time would roughly be needed to succeed.

• At the beginning the money should come from the EU and/or the country where the start-up will be founded.
Conclusion Biomedical Engineering and Care Services

- Europe has a strong fundamental research basis in this domain area but companies in the US invest much more in R&D than in Europe.

- A long term strategy for this domain area as well as better visibility is necessary.

- More investments in applied research to bring inventions from universities nearer to the market and make it more attractive for investors (VC, private, Companies)
Short vitae Manfred Bammer

• Study at the Technical University of Vienna – Automation and control Engineering - and Danube University Krems – Communication and Management development
• Since 1997 different management functions @ AIT in applied research at the interface basic research at universities and industry
• In 2002 founding of a completely new Biomedical Engineering division @ AIT
• Inventor and co-inventor of more than 10 patents. Several of these patents are used already by one of the top 10 pharmaceutical companies.
• Several new technology developments are invented under my leadership e.g. non-invasive pulse wave analysis algorithm (ARCSolver) via the upper arm cuff measurement and already licensed to three companies (I.E.M., Schiller, Welch Allyn), a new Mg-alloy with very low biocompatible alloying elements and degradation on demand in cooperation with ETH Zurich and medical industry.
• Through my activities more than 180 jobs are already created directly @ AIT and the founded new companies.
• Personell strength: Bridging the gap between research and economic exploitation.
Thank you for your attention!
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