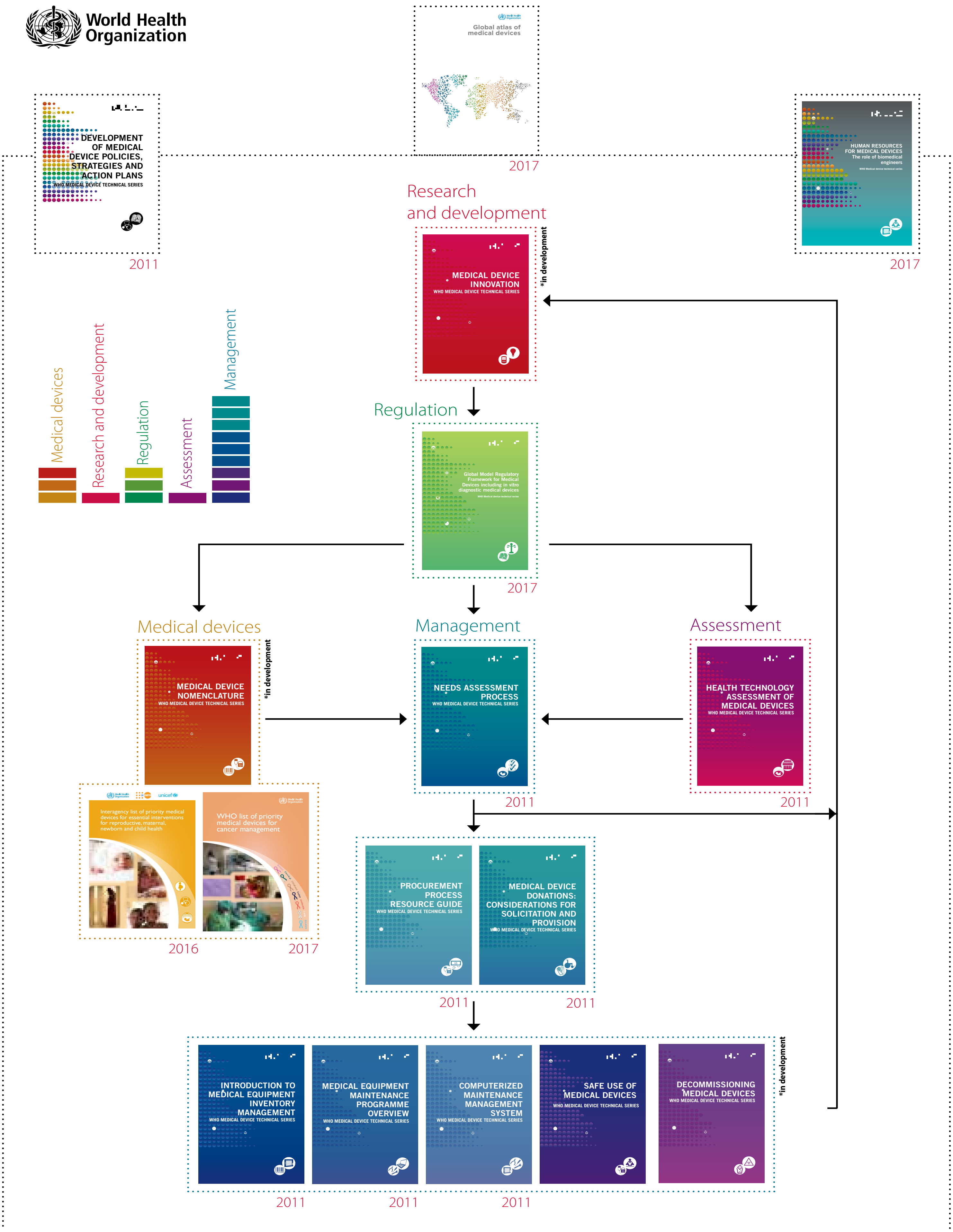
World Health Organization

HUMAN RESOURCES FOR MEDICAL DEVICES

The role of biomedical engineers

WHO Medical device technical series

WHO MEDICAL DEVICE TECHNICAL SERIES: TO ENSURE IMPROVED ACCESS, QUALITY AND USE OF MEDICAL DEVICES



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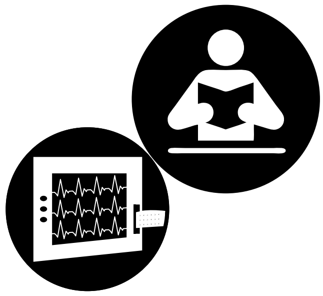

Human resources for medical devices, the role of biomedical engineers
(WHO Medical device technical series)

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Contents

Preface

Health technologies are essential for a fully functioning health system. Medical devices, in particular, are crucial in the prevention, diagnosis, treatment and palliative care of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices.

This publication has been produced in accordance with the request to the World Health Organization (WHO) by Member States in the WHA60.29.*(1)* The resolution:

1. URGES Member States:
"(1) to collect, verify, update and exchange information on health technologies, in particular medical devices, as an aid to their prioritization of needs and allocation of resources;

(2) to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies, in particular medical devices, in collaboration with personnel involved in health-technology assessment and ***biomedical engineering****…"*

2. REQUESTS the Director General:
"to work with interested Member States and WHO collaborating centres on the development, in a transparent and evidence-based way, of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices"(2)

By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals, urging expansion of expertise in the field of health technologies, in particular medical devices, and requesting that WHO take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." To meet this objective, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to good quality, appropriate medical devices. The *Medical device technical series* developed by WHO already includes the following publications:

- Development of medical devices policies*(3)*
- Health technology assessment for medical devices*(4)*
- Health technology management
  - Needs assessment process of medical devices*(5)*
  - Procurement process, resource guide*(6)*
  - Medical devices donations, considerations for solicitation and provision*(7)*
  - Introduction to medical equipment inventory management*(8)*
  - Medical equipment maintenance overview*(9)*
  - Computerized maintenance management systems*(10)*

- Priority medical devices
  - Interagency list of priority medical devices for essential interventions on reproductive, maternal, new born and child health *(11)*
  - Protective equipment for Ebola *(12)*

And will include, in 2017, the following publications, which are under development:

- Human resources for medical devices (the present document)
- Model regulatory framework for medical devices
- Priority medical devices for cancer management

These documents are intended for use by policy-makers at ministries of health, biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional and global levels.

Medical device technical series – methodology

The first documents in the *Medical device technical series* were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the Global Initiative on Health Technologies (GIHT). The group met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions.

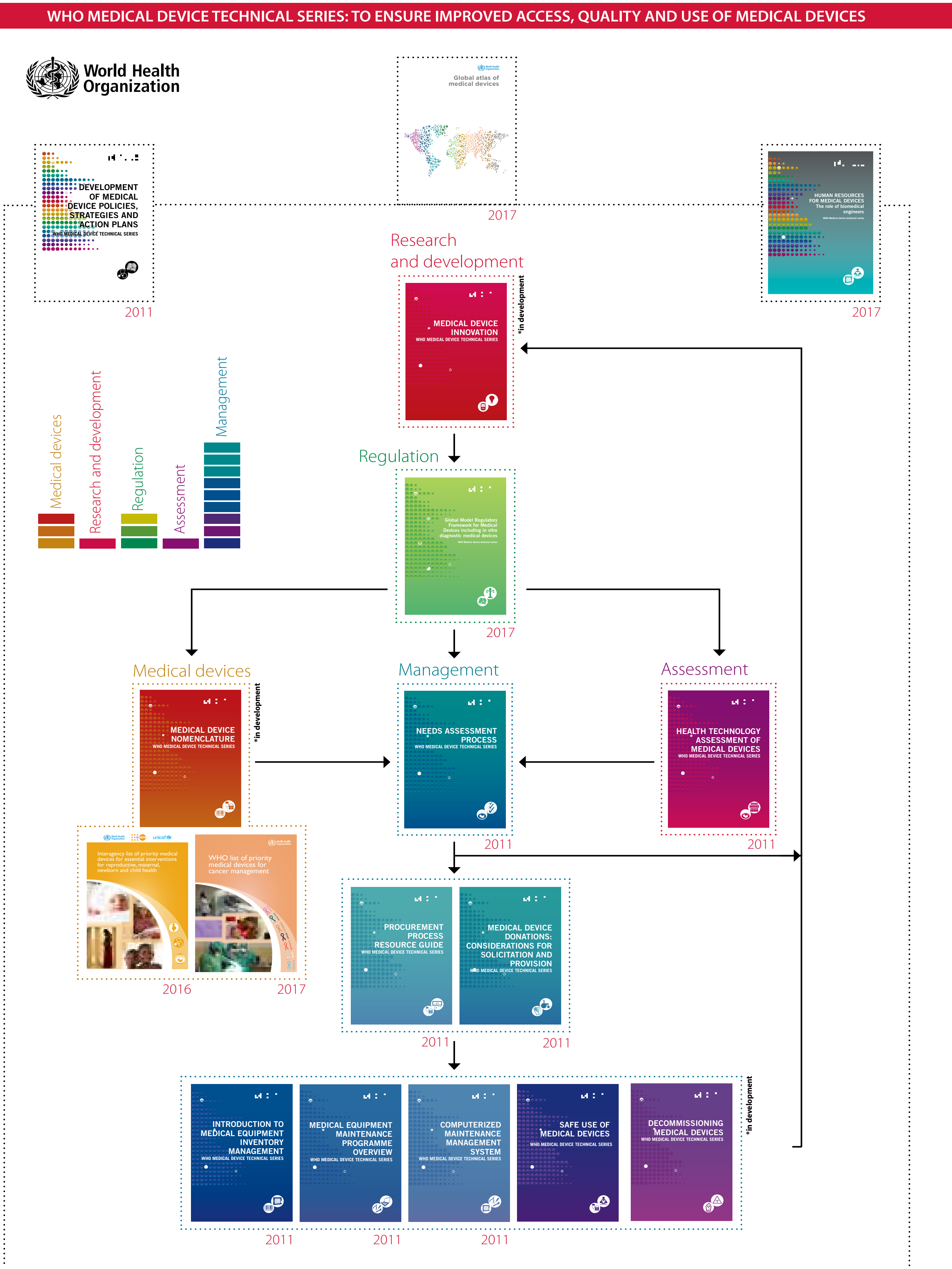
The last meeting was held in Cairo in June 2010 to finalize the documents and to help countries develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts addressed in the *Medical device technical series* were discussed further during the First Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level. *(13)* These extensive discussions formed the background for the current book in the series: *Human resources for medical devices.*

For the development of the current book the following activities took place:

1. Global BME surveys, the outcomes of which are highlighted in this book and results presented in the WHO medical devices website and in the WHO Global Health Observatory. *(14)*

In 2009, WHO launched “Biomedical engineering global resources,” *(15)* a WHO programme to gather information on academic programmes, professional societies and the status of BME worldwide.

Figure 1 WHO Medical device technical series



Since the programme began, WHO has collected and compiled data in five stages with different institutions, colleagues and tools, all coordinated by Adriana Velazquez from WHO. Table 1 outlines the details for each stage.

Table 1 WHO surveys on biomedical engineering availability

Year	Lead	Methodology	Outcome
2009	S Calil (University of Campinas)	Conducted active search for universities and professional societies	First global database of BME resources (http://who.ceb.unicamp.br/)
2013	Survey developed by D Desai (Boston University) with support from J Barragan (WHO), S Mullally (WHO) and N Jimenez (WHO)	Developed survey with IT tool that was sent to WHO BME contacts	Updated global database of BME resources (http://apps.who.int/medical_devices/edu/)
2014	C Long (WHO) and R Magjarevic (IFMBE)	Developed survey with LimeSurvey tool to collect the specific number of biomedical engineers per country and integrate it with information from the IFMBE database of national societies	Information on biomedical engineer density (http://hqsudevlin.who.int:8086/data/node.main.HRMDBIO?lang=en)
2015	D Rodriguez (WHO), M Smith (WHO) and R Martinez (WHO)	Developed survey with WHO DataForm tool. Collected data were integrated with data from the 2009, 2013 and 2014 investigations	Organization of data from 85 countries
2016	D Rodriguez (WHO), C Soyars (WHO) and R Martinez (WHO)	Compiled information from all stages of data collection	Annex 1,2 and 3 of this publication

To collect the information, an electronic survey was tailored for each of the four stages of the project. Surveys were distributed through a network of over 3200 BME professionals using the WHO medical devices Listserv tool.*(16)* Survey participants were encouraged to resend the survey to other key informants with the intention of collecting a greater amount of current global information.

The surveys were consistently structured into three sections: (1) country profile; (2) educational institutions; and (3) professional societies. An additional section (4) was added to the 2015 version targeting international organizations and including questions regarding female presence within the profession. The survey was designed so respondents only completed the section for which they held information, ensuring that information was supplied by national health authorities or similar for section 1, BME academics for section 2, professional societies secretariats for section 3 and international organization focal points for section 4. For the data analysis, 140 fully completed survey forms were retrieved from the data collection tool (WHO DataForm).*(17)* Additional information was collected from IFMBE reports, other BME professional organizations and web-based inquiries.

The collected data are available at the WHO medical devices site: http://www.who.int/medical_devices/support/en/ and the density of biomedical engineers is available on WHO Global Health Observatory (GHO) as a new indicator of global health: http://apps.

who.int/gho/data/node.imr.HRH_40?lang=en and further information can be found at: http://apps.who.int/gho/data/node.main.504?lang=en.

WHO intends to collect data annually and expects to retrieve data from unreported countries, validate reported data, maintain accurate estimates and record global trends in BME.

2. Professionals of different branches of biomedical engineering (BME) were invited by WHO in 2013 to become chapter coordinators. The chapter coordinators wrote sections and organized the input of 40 collaborators from around the world who contributed their expertise on design, development, regulation, assessment, management and safe use of medical devices.

3. The Second Global Forum on Medical Devices, held in November 2013, included a session focused specifically on human resources for medical devices and the required survey methodology addressing the role of the biomedical engineer.*(18)* The forum had diverse country representation, with a total of 572 participants representing 103 countries.

4. Formal discussions about the role of BME in Hangzhou, China, at a global BME summit on 23 October 2015, following the First International Clinical Engineering and Health Technology Management Congress, which was sponsored by the Chinese Society of Biomedical Engineering. The congress was organized by a leadership panel of 25 representatives of national and international organizations related to BME. The group produced a document that lays out the scope of professional activities of biomedical engineers and provides a rationale and evidence for the recognition and proper classification of BME.*(19)*

5. Review of whole text by international experts on biomedical engineering.

Scope

WHO invited global collaboration of biomedical engineering professionals to support the development of the present publication in order to describe the different roles of biomedical engineers as specialized human resources on medical devices, in order to support their classification in Member States as well as labour and other organizations.

It should be noted that there are many professionals who use medical devices, for example radiographers, sonographers, laboratory technicians, surgeons, anaesthetists, ophthalmologists, orthopaedists, neurologists, radiologists, radiotherapists, pathologists, nurses, and almost all health-care workers. And, there are others who manage their supply, such as procurement and logistics officers, others that evaluate them as health economists, others that support the design and manufacture, including engineers, industrial designers, chemists, physicists, etc.

This publication addresses only the role of the biomedical engineer in the development, regulation, management, training and use of medical devices in general, and it should be noted that this happens with interdisciplinary collaboration according to rules and regulations in every country.

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this publication of the WHO *Medical device technical series.*

"Biomedical engineering" includes equivalent or similar disciplines, whose names might be different, such as medical engineering, electromedicine, bioengineering, medical and biological engineering and clinical engineering.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.*(20)* It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.*(21)* This category includes medical equipment, implantables, single use devices, in vitro diagnostics and some assistive technologies.

Medical equipment: Used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices. Medical equipment is a capital asset and usually requires professional installation, calibration, maintenance, user training and decommissioning, which are activities usually managed by clinical engineers.*(22)*

Health technology assessment (HTA): The term refers to the systematic evaluation of properties, effects and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision-making process.*(23)*

Biomedical engineering (BME): Medical and BME integrates physical, mathematical and life sciences with engineering principles for the study of biology, medicine and health systems and for the application of technology to improve health and quality of life. It creates knowledge from molecular to organ systems levels, develops materials, devices, systems, information approaches, technology management and methods for assessment and evaluation of technology, for the prevention, diagnosis and treatment of disease, for health-care delivery and for patient care and rehabilitation.*(24)*

Among the sub-specialities of biomedical engineering, or engineering and technology related professions, are the following:

Clinical engineer: In some countries, this defines the biomedical engineer that works in clinical settings. The American College of Clinical Engineering defines a clinical engineer as, “a professional who supports and advances patient care by applying engineering and managerial skills to health care technology”.*(25)* The Association for the Advancement of Medical Instrumentation describes a clinical engineer as, “a professional who brings to health-care facilities a level of education, experience, and accomplishment which will enable him to responsibly, effectively, and safely manage and interface with medical devices, instruments, and systems and the user thereof during patient care…”.*(26)*

Biomedical engineering technician/technologist (BMET): Front-line practitioners dedicated to the daily maintenance and repair of medical equipment in hospitals, meeting a specified minimum level of expertise. BMETs who work exclusively on complex laboratory and radiological equipment may become certified in their specialism, without needing to meet the more general professional engineering requirements. The difference between a technician and a technologist relates to the level and number of years of training. Normally technicians train for two years, technologists for three years, but this can differ per country.

Rehabilitation engineers: Those who design, develop and apply assistive devices and technologies are those whose primary purpose is to maintain or improve an individual’s functioning and independence to facilitate participation and to enhance overall well-being.*(27)*

Biomechanical engineers: Biomechanical engineers apply engineering principles to further the understanding of the structure of the human body, the skeleton and surrounding muscles, the function and engineering properties of the organs of the body, and use the knowledge gained to develop and apply technologies such as implantable prostheses and artificial organs to aid in the treatment of the injured or diseased patient to allow them to enjoy a better quality of life.

Bioinstrumentation engineers: Bioinstrumentation engineers specialize in the detection, collection, processing and measurement of many physiological parameters of the human body, from simpler parameters like e.g. temperature measurement and heart rate measurement to the more complex such as quantification of cardiac output from the heart, detection of the depth of anaesthesia in the unconscious patient and neural activity within the brain and central nervous system. They have been responsible for the development and introduction of modern imaging technologies such as ultrasound and magnetic resonance imaging (MRI).

In order to raise awareness on the importance of biomedical engineers within health systems worldwide, WHO is producing the present publication, in conjunction with a global BME survey. WHO, along with international professional organizations, such as IFMBE, is also advancing a proposal to update the ILO classification,*(28)* requesting a specific classification for biomedical engineers as a distinct professional category.

Acknowledgements

The publication *Human resources for medical devices: The role of biomedical engineers* was developed under the coordination of Adriana Velazquez Berumen, WHO Senior Advisor and Focal Point on Medical Devices, with the supervision of Gilles Forte and Suzanne Hill in the WHO Essential Medicines and Health Products Department, and from James Campbell and Giorgio Cometto, in the Health Workforce Department under the Health Systems and Innovation Cluster of the World Health Organization.

Each chapter of the book was authored by an expert in the field, along with contributions from collaborators from different regions of the world and diverse sectors of the BME field during 2014 and 2015.

The BME 2015 survey was developed in January 2015 by Daniela Rodriguez-Rodriguez and Megan Smith. The first results were presented in the World Congress on Biomedical Engineering and Medical Physics in Toronto, June 2015, and are included in this publication.

The first draft of this book was edited in 2015, for discussion at the First International Clinical Engineering and Health Technology Management Congress in China.*(29)*

The International Federation of Medical and Biological Engineering (IFMBE, an NGO in official relations with WHO, chaired by James Goh, Singapore) generously supported the development of this publication, including technical editing and graphic design, and appointed Fred Hosea to support the compilation of the chapters, conducting teleconferences with the authors and collaborators.

Data analytics and editorial reviews were done by Daniela Rodriguez-Rodriguez, Ileana Freige and Ricardo Martinez. Final integration of edits was done by Anna Worm and Adriana Velazquez.

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Biomedical engineers as human resources for health

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Chapter contributors: Michael Flood, Australia, Fred Hosea, Ecuador; Anna Worm, Benin.

1 Global dimensions of biomedical engineering

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10 Role of biomedical engineers in the evolution of health-care systems

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Chapter contributor: Fred Hosea, Ecuador.

Acronyms and abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ABEC	African Biomedical Engineering Consortium
ABET	Accreditation Board for Engineering and Technology
ACCE	American College of Clinical Engineering
ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
AEMB	Alpha Eta Mu Beta
AFR	African Region (WHO)
AFPTS	Association Francophone des Professionnels des Technologies de Santé
AHF	Asian Hospital Federation
AHT	assistive health technology
AIIC	Associazione italiana ingegneri clinici (Italy)
AIMBE	American Institute for Medical and Biological Engineering
AMR	Region of the Americas (WHO)
ANS	affiliated national society
ANVISA	Agência Nacional de Vigilância Sanitária (Brazil)
BME	biomedical engineering
BMES	Biomedical Engineering Society
BMET	biomedical engineering technician
CAHTMA	Commission for the Advancement in Healthcare Technology Management in Asia
CBET	certified biomedical equipment technician
CCE	certified clinical engineer
CE	clinical engineer
CED	Clinical Engineering Division (IFMBE)
CEO	chief executive officer
CET	certified electronics technician/certified engineering technologist
CFO	chief financial officer
CIO	chief information officer
CIS	cardiology information system
CLES	clinical laboratory equipment specialist
ComHEEG	High-Level Commission on Health Employment and Economic Growth
CORAL	Consejo Regional de Ingeniería Biomédica para América Latina
CPD	continuing professional development
CQI	continuous quality improvement
CRES	certified radiological equipment specialist
CSE	clinical systems engineer
CTO	chief technology officer
DBE	Directorate of Biomedical Engineering (Jordan)
EAMBES	European Alliance for Medical and Biological Engineering and Science
ECA	Economic Commission for Africa
ECG	electrocardiogram
ECTS	European Credit Transfer System
EESC	European Economic and Social Committee
EHEA	European Higher Education Area
HER	Electronic health records
EMBS	Engineering in Medicine and Biology Society
EMR	Eastern Mediterranean Region (WHO)
ENA	Eastern Neighbouring Area
ESEM	European Society of Engineering and Medicine
EUnetHTA	European Network for HTA
EUR	European Region (WHO)
EWH	Engineering World Health
FDA	Food and Drug Administration (USA)
GHO	Global Health Observatory (WHO)
GIHT	Global Initiative on Health Technology
GHTF	Global Health Task Force
GMP	good manufacturing practice
HIC	High income country
HIT	health information technology

HRM	health risk management
HTA	health technology assessment
HTAD	Healthcare Technology Assessment Division (IFMBE)
HTAi	Health Technology Assessment international
HTM	Health Technology Management
HTCC	Health Technology Certification Commission (ACCE)
HTTG	Health Technology Task Group (IUPESM)
IAIE	International Atomic Energy Agency
ICC	Certification Commission for Clinical Engineering and Biomedical Technology
ICMCC	International Council on Medical and Care Compunetics
ICSU	International Council of Science
IEEE	Institute of Electrical and Electronics Engineers
IFMBE	International Federation for Medical and Biological Engineering
ILO	International Labour Organization
IMDRF	International Medical Device Regulators Forum
INAHTA	International Network of Agencies for Health Technology Assessment
INCOSE	International Council on Systems Engineering
IOMP	International Organization for Medical Physicists
ISO	International Standards Organization
IRB	International Registration Board
ISCO	International Standard Classification of Occupations
ITIL	Information Technology Infrastructure Library
IUPESM	International Union for Physical and Engineering Sciences in Medicine
LIC	Low income country
LIS	laboratory information system
LMIC	low- and middle-income countries
MNCH	maternal, newborn and child health
MRA	mutual recognition agreement
MRI	magnetic resonance imaging
NEA	national examining authority
NGO	nongovernmental organization
OEM	original equipment manufacturer
PACS	picture archiving and communication system
PAHO	Pan American Health Organization
PET	positron emission tomography
PPE	personal protective equipment
PPM	planned preventive maintenance
QA	quality assurance
QMS	quality management systems
R&D	research and development
RAC	Regulatory Affairs Certification
RAPS	Regulatory Affairs Professionals Society
RCEC	Registered Clinical Engineer Certification
RedETSA	Red de Evaluación de Tecnologías Sanitarias de las Américas
RIS	radiology information system
SDG	Sustainable Development Goals
SEAR	South-East Asia Region (WHO)
SoS	systems of systems
SoSE	systems of systems engineering
TAGHT	Technical Advisory Group on Health Technology (WHO)
THET	Tropical Health & Education Trust (UK)
TSBME	Taiwan Society for Biomedical Engineering
UCT	University of Cape Town
UHC	universal health coverage
UNECA	United Nations Economic Commission for Africa
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNOPS	United Nations Office for Project Services
V&V	verification and validation
WHO	World Health Organization
WMDO	World Medical Device Organization
WPR	Western Pacific Region (WHO)

Country acronyms

AFG	Afghanistan
ALB	Albania
ARE	United Arab Emirates
ARG	Argentina
AUS	Australia
AUT	Austria
BEL	Belgium
BEN	Benin
BFA	Burkina Faso
BGD	Bangladesh
BGR	Bulgaria
BHR	Bahrain
BIH	Bosnia and Herzegovina
BLZ	Belize
BOL	Bolivia (Plurinational State of)
BRA	Brazil
BRB	Barbados
BRU	Brunei
BTN	Bhutan
CAN	Canada
CHE	Switzerland
CHL	Chile
CHN	China
CIV	Côte d'Ivoire
CMR	Cameroon
COD	Democratic Republic of the Congo
COL	Colombia
CUB	Cuba
CYP	Cyprus
CZE	Czech Republic
DEU	Germany
DJI	Djibouti
DNK	Denmark
DOM	Dominican Republic
DZA	Algeria
ECU	Ecuador
EGY	Egypt
ESP	Spain
EST	Estonia
ETH	Ethiopia
FIN	Finland
FRA	France
FSM	Micronesia (Federated States of)
GBR	United Kingdom
GEO	Georgia
GHA	Ghana
GIN	Guinea
GMB	Gambia
GRC	Greece
GRD	Grenada
GTM	Guatemala
GUY	Guyana
HND	Honduras
HRV	Croatia
HTI	Haiti
HUN	Hungary
IDN	Indonesia
IND	India
IRL	Ireland
ISL	Iceland
ISR	Israel
ITA	Italy
JAM	Jamaica
JOR	Jordan
JPN	Japan
KEN	Kenya
KGZ	Kyrgyzstan
KIR	Kiribati
KOR	Republic of Korea
LAO	Lao People's Democratic Republic
LBN	Lebanon
LBR	Liberia
LKA	Sri Lanka
LTU	Lithuania
LVA	Latvia
MDA	Republic of Moldova
MEX	Mexico
MKD	The former Yugoslav Republic of Macedonia
MNE	Montenegro
MNG	Mongolia
MOZ	Mozambique
MYS	Malaysia
NAM	Namibia
NGA	Nigeria
NLD	Netherlands
NOR	Norway
NPL	Nepal
NZL	New Zealand
PAK	Pakistan
PAN	Panama
PER	Peru
PHL	Philippines
POL	Poland
PRT	Portugal
PRY	Paraguay
ROU	Romania
RUS	Russian Federation
RWA	Rwanda
SAU	Saudi Arabia
SDN	Sudan
SEN	Senegal
SGP	Singapore
SLE	Sierra Leone
SLV	El Salvador
SRB	Serbia
SUR	Suriname
SVK	Slovakia
SVN	Slovenia
SWE	Sweden
SWZ	Swaziland
TCD	Chad
THA	Thailand
TLS	Timor-Leste
TTO	Trinidad and Tobago
TUN	Tunisia
TUR	Turkey
TZA	United Republic of Tanzania
UGA	Uganda
UKR	Ukraine
URY	Uruguay
USA	United States of America
VEN	Venezuela (Bolivarian Republic of)
VNM	Viet Nam
VUT	Vanuatu
YEM	Yemen
ZAF	South Africa
ZMB	Zambia

Executive summary

Continuous developments in science and technology are increasing the availability of thousands of medical devices – all of which should be of good quality and used appropriately to address global health challenges. It is recognized that medical devices are becoming ever more indispensable in health-care provision and among the key specialists responsible for their design, development, regulation, evaluation and training in their use – are biomedical engineers.

In this book, part of the *Medical device technical series,* WHO presents the different roles the biomedical engineer can have in the life cycle of a medical device, from conception to use.

It is important to mention that for this publication, the concept "biomedical engineer" includes medical engineers, clinical engineers and related fields as categorized in different countries across the world and encompasses both university level training as well as that of technicians.

Working together with other health-care workers, biomedical engineers are part of the health workforce supporting the attainment of the Sustainable Development Goals, especially universal health coverage.

This book has two parts. The first looks at the biomedical engineering profession globally as part of the health workforce: global numbers and statistics, and professional classification, general education and training, professional associations and the certification process.

The second part addresses all the different roles that the biomedical engineer can have in the life cycle of the technology, from research and development, and innovation, mainly undertaken in academia; the regulation of devices entering the market; the assessment or evaluation in selecting and prioritizing medical devices (usually at national level); to the role they play in the management of devices from selection and procurement, to safe use in health-care facilities.

Finally, the annexes present comprehensive information on academic programmes, professional societies and relevant WHO and UN documents related to human resources for health, as well as the reclassification proposal for ILO.

This publication can be used to encourage the availability, recognition and increased participation of biomedical engineers as part of the health workforce, particularly following the recent adoption of the recommendations of the UN High-Level Commission on Health Employment and Economic Growth, the WHO Global Strategy on Human Resources for Health, and the establishment of national health workforce accounts. The document also supports the aim of reclassification of the role of the biomedical engineer as a specific engineer that supports the development, access and use of medical devices, within the national, regional and global occupation classification system.

The biomedical engineer can play a crucial role in supporting the best and most appropriate use of medical technologies to help in achieving universal health coverage and the targets of the Sustainable Development Goals. Biomedical engineers can take their share of responsibility and develop continuously better competencies to help achieve these goals, so vital for those in most need in and with least resources.

Credit: Clark Daniel, Medical Physics and Clinical Engineering, Nottingham University Hospitals NHS Trust, UK.

Biomedical engineers as human resources for health

Biomedical engineering is one of the more recently recognized disciplines in the practice of engineering. It is a field of practice which brings many, if not all of the classical fields of engineering together to assist in developing a better understanding of the physiology and structures of the human body, and to support the knowledge of clinical professionals in prevention, diagnosis and treatment of disease and modifying or supplementing the anatomy of the body with new devices and clinical services.

Biomedical engineering is considered as the profession responsible for innovation, research and development, design, selection, management and safe use of all types of medical devices, including single-use and reusable medical equipment, prosthetics, implantable devices and bionics, among others.

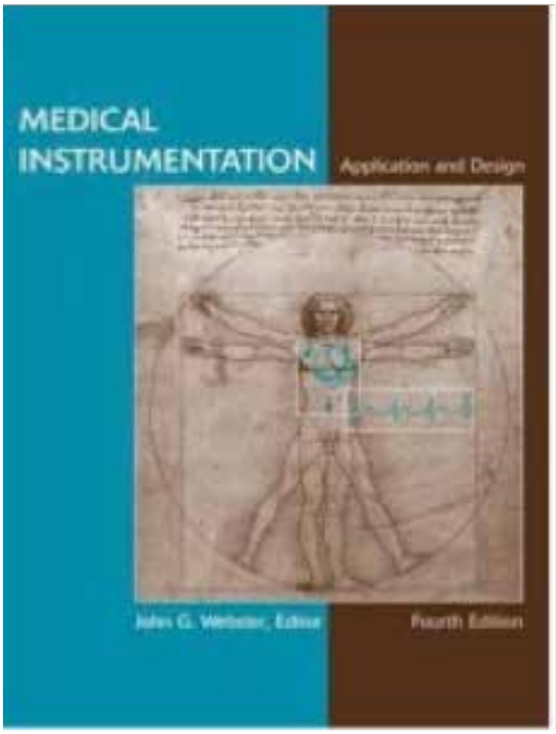
A key objective of biomedical engineers is to have devices that are of good quality, effective for the intended purpose, available, accessible and affordable. When these objectives are met and devices are used safely, patients' lives may be saved, quality of life increased and there will be positive economic outcomes; the final goal is attainment of better levels of care. The prerequisites for this to happen are health technology policies in national health plans, available human and financial resources, and scientific and technological advances that lead to usable knowledge and information. The interrelations of these concepts are presented in Figure 2.

Figure 2 Medical devices process from policies to health outcomes

Input	Process Biomedical engineering	Device use Health-care worker/ patient	Outcomes
• Health technology policies • Human resources • Financial resources • Technology development industry • Knowledge and information	• Innovation • Research and development by industry and academia • Regulation by national authorities • Assessment by national or local committees considering also equity, ethics, feasibility • Management by national or local units: selection, procurement, installation, maintenance and safe use	• Quality • Safety and effectiveness • Affordability • Appropriateness • Accessibility • Availability • Acceptability	• Quality of life • Life saving • Independence • Economic development • Attainment of highest level of health (WHO)

The practice of BME is not new. Indeed, the first known use of a functioning medical prosthesis for a toe is traceable to the African continent; specifically, to Egypt. It could be argued that Leonardo da Vinci (1442–1519) and many of the ancient philosophers could be considered among the first biomedical engineers. Among his other interests, da Vinci studied the anatomy of the human skeleton, the muscles and sinews of the body.

Figure 3 Da Vinci's *Vitruvian Man* drawing (from around 1490) featured on a key reference book on medical instrumentation



Responsibilities and roles

Biomedical engineering professionals are key players in developing and advancing the usage of medical devices and clinical services. Depending on their training and sector of employment, the responsibilities of biomedical engineering professionals can include overseeing the research and development, design, safety and effectiveness of medical devices/systems; selection and procurement, installation, integration with electronic medical records systems, daily operations monitoring, managing maintenance and repairs, training for safe use and upgrading of medical devices available to health-care stakeholders. Biomedical engineering professionals are employed widely throughout the health technology and health-care industries, in the research and development (R&D) of new technologies, devices and treatment modalities, in delivery of health-care in hospitals and other institutions, in academia, government institutions and in national regulatory agencies.

Research and development

When employed in research and development including both industry as academic institutions, the role of the biomedical engineering professionals is typically one of bringing together the specialist skills of the other engineering disciplines such as mechanical, materials, signal processing and others, using their broad engineering knowledge, coupled with their knowledge of medical practice, the human physiology and body structures to ensure the end result of their collective work is a product that is safe, effective and performs as intended for the benefit of the patient. As devices become "smarter" through the inclusion of increasingly powerful hardware and software capabilities, devices can take on increasingly comprehensive monitoring, alert and control functions that define clinical best practices. This "smart device" revolution is extending the domain of BME into wider and wider realms of creativity and professional practice, extending health-care services far beyond the hospital.

Health-care providers

When biomedical engineering professionals are employed in health-care institutions, their roles can include asset management, equipment selection, installation and maintenance, planning of clinical areas for health-care delivery, support other health-care professionals to define appropriate technologies for patient diagnostic, treatment and rehabilitation as well as development of specialized instruments or devices for research or treatment and customized, patient-specific devices.

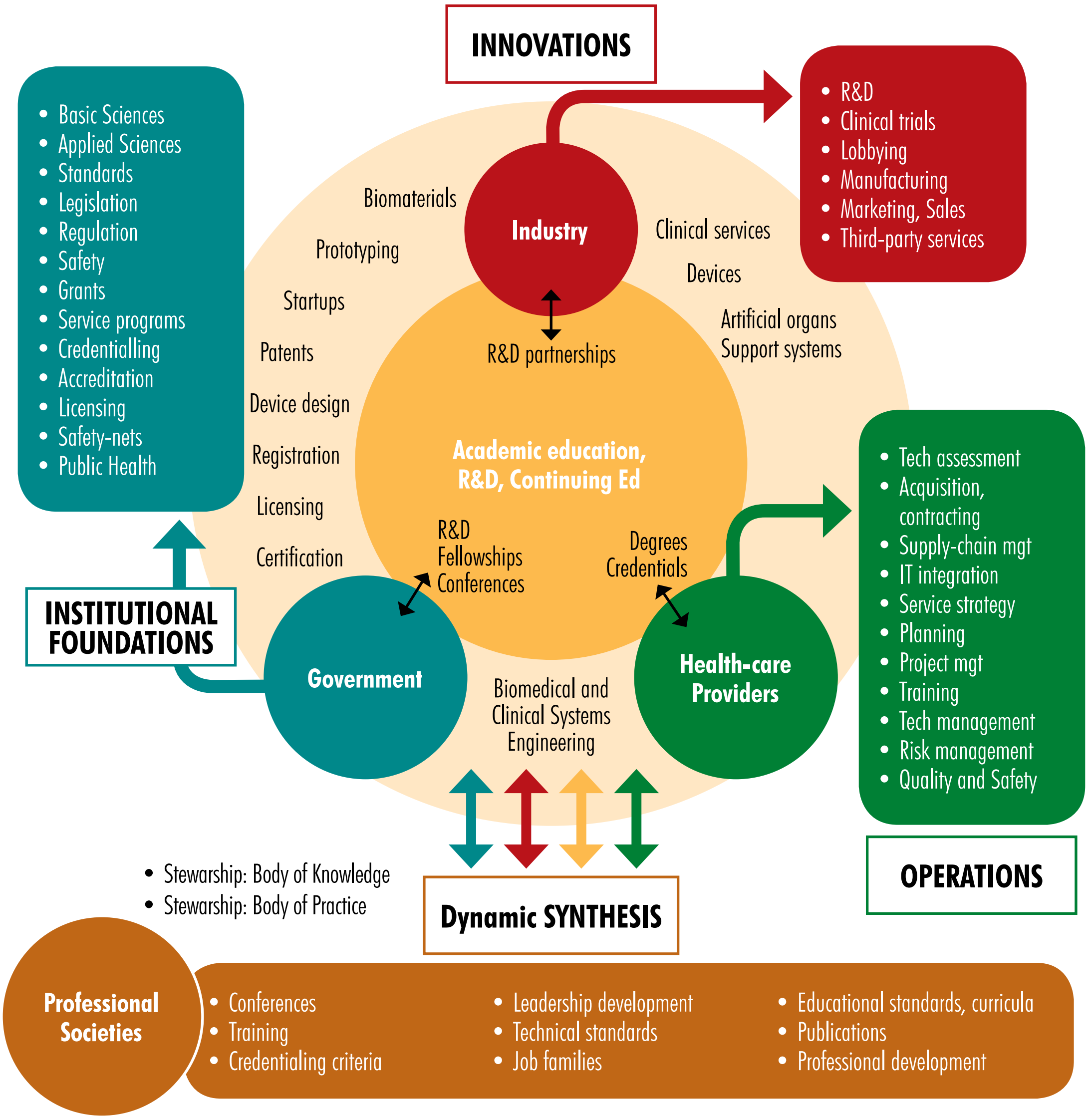
Government

Many biomedical engineering professionals are also engaged by government such as ministries of health, working on central or regional level health-care technology management, or governmental organizations such as health technology assessment or regulatory agencies, where their skills are applied to the evaluation for selection of public procurement, reimbursement schemes or examination or testing of medical devices to ensure those to be placed on the market are safe and in compliance with international standards and regulatory requirements.

Industry

A part of the biomedical engineering professionals in industry work in R&D. Another branch of activities is in sales and service, where biomedical engineering professionals can play a role in assuring customers are supported in making choices and providing after-sales service, like training, maintenance and repair.

Figure 4. Roles of biomedical engineers



Source: Fred Hosea, 2016.

Biomedical engineering tasks and responsibilities defined

During the 2015 Global Clinical Engineering Summit (2015)*(30)* the following roles and responsibilities were defined, as well as the subspecialisms of BME (shown in Table 1).

Applying knowledge of engineering and technology to health-care systems to optimize and promote safer, higher quality, effective, affordable, accessible, appropriate, available, and socially acceptable technology to populations served by:

1. Advancing health and wellness using technologies for prevention, diagnosis, treatment, rehabilitation and palliative care across all levels of the health-care delivery;

2. Innovating, designing, developing, regulating, managing, assessing, installing, and maintaining such technologies for their safe and cost effective use throughout their life cycle;
3. Applying engineering principles and design concepts to medicine and biology for the pursuit of new knowledge and understanding at all biological scales;

Table 1. Subspecialisms of BME

Research and development	Rehabilitation	Application and operation: clinical engineering
Biomechanics	Artificial organs	Technology management
Biomaterials	Neural engineering	Quality and regulatory assurance
Bioinformatics	Tissue engineering /regenerative	Education and training
Systems biology	Mechatronics	Ethics committee, clinical trials
Synthetic biology	Assistive devices and software	Disaster preparedness
Bionics	Prosthetics	e-health (telemedicine, m-health)
Biological engineering		Wearable sensors/products
Nanotechnology		Health economics
Genomics		Health systems engineering
Population health/data analytics		Health technology assessment/ evaluation
Epidemiology (computational)		Health informatics
Intellectual property/innovation		Service delivery management
Theranostics		Field service support
Biosignals		Security/privacy/cybersecurity
		Forensic engineering/ investigation
		Manufacturing QMS, GMP
		Medical imaging
		Project management
		Robotics
		Virtual environments
		Risk management
		EMI/EMC compliance
		Technology Innovation strategies
		Population- and community-based needs assessment
		Engineering asset management
		Environmental health
		Systems science

4. Designing devices, software, processes and techniques to be used in wellness and health care, including consumables, artificial organs and prosthesis, diagnostic and therapeutic instrumentation and related systems such as magnetic resonance imaging, and devices for automating insulin injections or controlling body functions;
5. Designing, developing and managing technologies used to promote and support life quality and longevity, including assistive technologies and technologies for monitoring or rehabilitating activities of daily living; such as wheel chairs, prosthesis leg, hearing aid and personal emergency response systems;
6. Designing, developing and managing technologies for focus areas such as reproductive, maternal, neonatal, and child health;
7. Designing, developing and managing systems for optimal sustained health-care operations in both resource-scarce and well resourced settings as well as during challenging events such as disasters; and
8. Designing, developing and applying safety programme methodologies to mitigate risks when dealing with medical devices and procedures throughout their life cycle. Including biosafety and environmental health such as waste disposal and personal radiation protection.

Health-care technologies include: health, wellness and rehabilitation products and systems, artificial biological structures, organs, and prostheses, instrumentation, software and multi-technology systems.

Biomedical engineering

Trained and qualified BME professionals are required within health-care systems in order to design, evaluate, regulate, acquire, maintain, manage and train on safe medical technologies. The BME profession, however, is often not included in the official definitions of the health workforce or policy frameworks, and this absence significantly impairs the advancement and sustainability of these health-care systems, even in settings with available resources.

The International Labour Organization (ILO) manages the International Standard Classification of Occupations (ISCO), which organizes the tasks and duties of jobs, with the objective of having international reporting and statistical data of occupations and serves to enhance national and regional classification of occupations. The current system, ISCO-08, classifies BME professionals as a part of Unit Group 2149 "Engineering Professionals not Elsewhere Classified." *(31)* The classification of and statistics regarding biomedical engineering professionals by the ILO are undergoing formal review as part of the ILO's 10-year cycle for classifying the world's professions.

According to the current ISCO-08, from 2008, "biomedical engineering" professionals are considered to be an integral part of the health workforce alongside those occupations classified in Sub-major Group 22: Health Professionals. It is important to recognize that although ISCO-08 has "noted" biomedical engineers as an integral part of the health workforce, the profession has not yet been independently re-classified as a specialized type of engineering. Specialized classification has been requested in the past, but the small number of countries with biomedical engineering professionals and the shortage of professionals at that time made this impossible.

In the past, biomedical engineering professionals have worked "in the shadow" of more recognized professions, such as doctors and nurses. This has been in part due to lack of official research and dissemination of information about the presence and essential value of biomedical engineering professionals worldwide. This gap in acknowledgement and inclusion of BME within the health-care workforce, and the lack of current data on the profession, both urgently need to be addressed, to ensure that the health-care sector has the necessary mix of professionals to guide the dynamic changes in science, technology and services in the 21st century.

In recent years, numbers have increased significantly, with documentation showing biomedical engineering professionals in 126 out of 194 WHO Member States (64%), and the scope and depth of BME expertise increasing with a growing presence of the profession globally in health-care systems. In 2012, data from the United States Bureau of Labor Statistics and other governmental agencies ranked BME as the second best profession based on five criteria: physical demand, work environment, income, stress and hiring prospects.*(32)*

Should ISCO re-classify biomedical engineering professionals along with other health-care professions in 2018 or future years, more statistics and data will be available at the country level, and formal recognition processes could be initiated by member countries to recognize BME as a profession within their national or regional labour organizations and ministries.

According to the International Federation of Medical and Biological Engineers (IFMBE) — an NGO in official relations with WHO that represents professional and scientific interests of 59 national member societies from around the world – BME is defined as follows:

> Medical and biological engineering integrates physical, mathematical and life sciences with engineering principles for the study of biology, medicine and health systems and for the application of technology to improving health and quality of life. It creates knowledge from the molecular to organ systems levels, develops materials, devices, systems, information approaches, technology management, and methods for assessment and evaluation of technology, for the prevention, diagnosis, and treatment of disease, for health care delivery and for patient care and rehabilitation.*(33)*

In order to update these issues on the classification, statistics and recognition of the BME profession, WHO began efforts to track the presence of BME professionals and technicians worldwide. In 2009, WHO launched "Biomedical engineering global resources,"*(34)* a WHO programme to gather information on academic programmes, professional societies and the status of BME worldwide; the results of which are presented in this publication.

Global Strategy on Human Resources for Health: Workforce 2030

In May 2014, the Sixty-seventh World Health Assembly adopted resolution WHA67.24 on Follow-up of the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage. In paragraph 4(2) of that resolution, Member States requested the Director-General of WHO to develop and submit a new global strategy for human resources for health (HRH) for consideration by the Sixty-ninth World Health Assembly. A summary of the Global Strategy on Human Resources for Health: Workforce 2030 can be found in Annex 5.(35)

The goal of the global strategy is: to improve health, social and economic development outcomes by ensuring universal availability, accessibility, acceptability, coverage and quality of the health workforce through adequate investments to strengthen health systems, and the implementation of effective policies at national, a regional and global levels.

The global strategy, includes all cadres involved in delivery of health services, as described section 16 of the strategy:

16. *"This is a cross-cutting agenda that represents the critical pathway to attain coverage targets across all service delivery priorities. It affects not only the better known cadres of midwives, nurses and physicians, but* ***all health workers****, from community to specialist levels,* ***including but not limited to:*** *community-based and mid-level practitioners, dentists and oral health professionals, hearing care and eye care workers, laboratory technicians,* ***biomedical engineers,*** *pharmacists, physical therapists and chiropractors, public health professionals and health managers, supply chain managers, and other allied health professions and support workers. The Strategy recognizes that diversity in the health workforce is an opportunity to be harnessed through strengthened collaborative approaches to social accountability, inter-professional education and practice, and closer integration of the health and social services workforces to improve long-term care for ageing populations."*

The global strategy requests the support of professional organizations to regulate the workforce competency as described below:

36. *"Professional councils to collaborate with governments to implement effective regulations for improved workforce competency, quality and efficiency. Regulators should assume the following key roles: keep a live register of the health workforce; oversee accreditation of pre-service education programmes; implement mechanisms to assure continuing competence, including accreditation of post-licensure education providers; operate fair and transparent processes that support practitioner mobility and simultaneously protect the public; and facilitate a range of conduct and competence approaches that are proportionate to risk, and are efficient and effective to operate. (49) Governments, professional councils and associations should work together to develop appropriate task-sharing models and inter-professional collaboration, and ensure that all cadres with a clinical role, beyond dentists, midwives, nurses, pharmacists and physicians, also benefit in a systematic manner from accreditation and regulation processes".*

The United Nations High-Level Commission on Health Employment and Economic Growth was established in March 2016, to recommend the creation of 40 million jobs in the health and social sector, particularly in low- and middle-income countries (LMIC), for 2030. It made 10 recommendations to transform the health workforce for the SDG era. These recommendations include job creation, gender and women's rights, education and training skills, health service delivery and organization, partnership and collaboration, and data, information and accountability (further information can be found in Annex 6). It is important to note the Commission already acknowledges the role of technological advances related to medical devices in encouraging economic development and supporting the health sector:

"*The innovation and diversification pathway illustrates how some countries have invested in their health sector specifically to promote economic growth. The health sector has been driving technological innovations in many areas, including genetics, biochemistry, engineering and information technology. Exports of pharmaceuticals, equipment and medical services have also been an important driver of growth in many countries.*"

http://www.who.int/hrh/com-heeg/reports/en/

The commission's recommendations are aligned with the SDGs. The specific target and goals related to this publication on human resources for medical devices are:

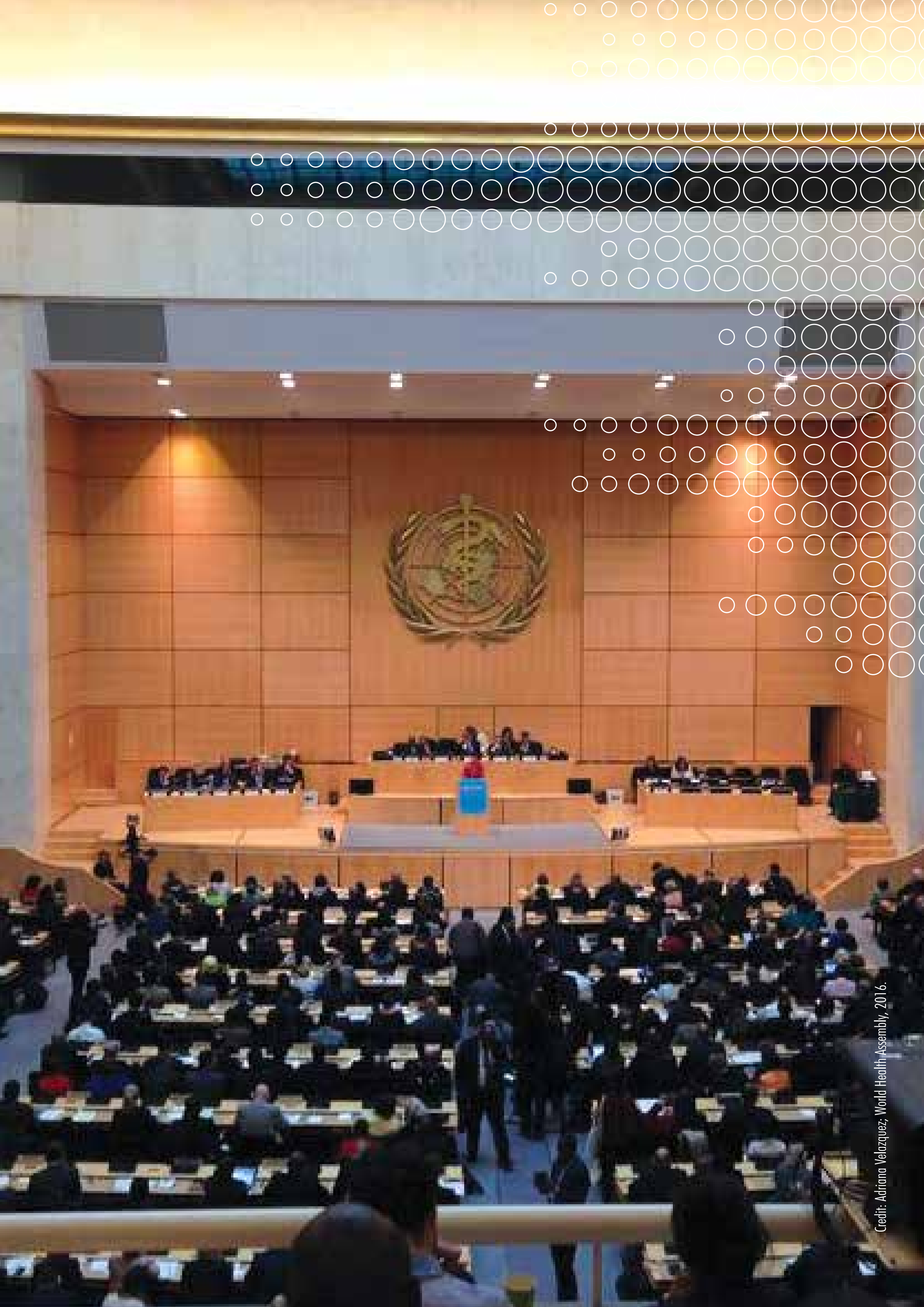
SDG 3: Good health and well-being

Target 3.c: Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States.

SDG 4: Quality education

Target 4.3: By 2030, ensure equal access for all women and men to affordable and quality technical, vocation and tertiary education, including university.

Target 4.b: By 2020, substantially expand globally the number of scholarships available to developing countries, in particular least developed countries, small island developing States and African countries, for enrolment in higher education, including vocational training and information and communications technology, technical, engineering and scientific programmes, in developed countries.



Credit: Adriana Velazquez; World Health Assembly, 2016.

PART I: THE INSTITUTIONAL FOUNDATIONS OF BIOMEDICAL ENGINEERING

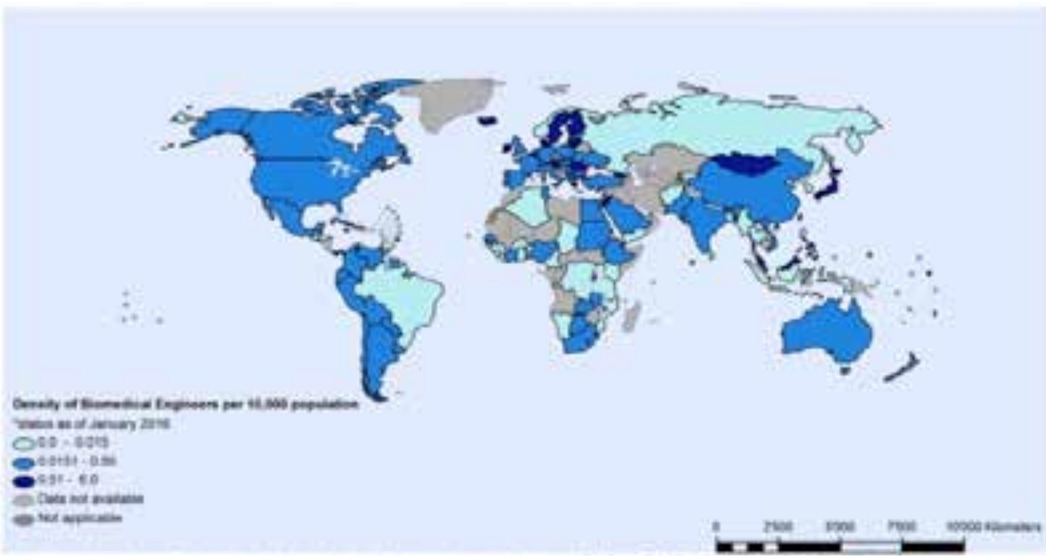
1 Global dimensions of biomedical engineering

1.1 Biomedical engineers – global data

This section presents a baseline distribution of BME professionals globally, based on data collected by government offices and ministries of health, the IFMBE and other professional societies and universities offering BME programmes. The total number of biomedical engineers identified in 2015 was 117 935, distributed in 129 countries. It is very important to note that the 129 countries listed in this present chapter, include many low- and middle-income countries with a small but emerging BME labour force due to only recent creation of in-country academic programmes. This chapter presents baseline data that indicate the availability of professional biomedical engineers by country without specifying the distribution by professional sector. Further studies need to be conducted to retrieve this workforce information.

Figure 1.1 illustrates the estimated number of biomedical engineers per 10 000 population by country. As shown, the lowest densities occur in low- and lower middle-income countries, which emphasizes the need for promotion of educational programmes for biomedical engineers in developing health systems. Additionally, the WHO African Region and Eastern Mediterranean Region presented the highest number of unreported

Figure 1.1 Density of biomedical engineers per 10 000 population globally (as at January 2016)



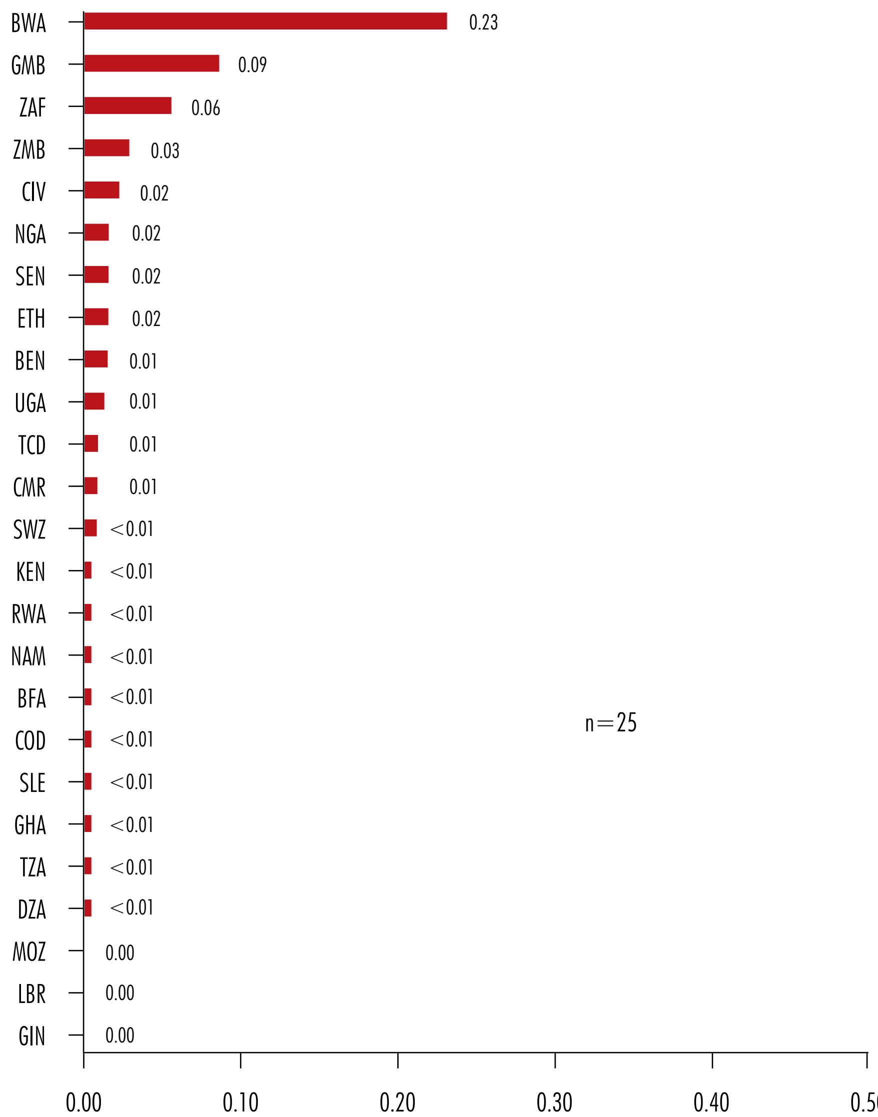
Source: Data was collected from three different sources: government offices and ministries of health (through surveys launched by WHO between 2010–2015); IFMBE; and universities offering BME programmes.

countries. Region-specific figures and more detailed information by country are described below.

The figures in the following section describe the density of biomedical engineers per 10 000 population. Annex 1 includes a complete list with all surveyed countries' "absolute numbers of biomedical engineers" and demographic indicators used to compute the distribution shown in Figure 1.1. Tables 1.1–1.6 show the density of BME professionals for each WHO Region. Zero indicates that it was specifically reported that no biomedical engineer is available in the country.

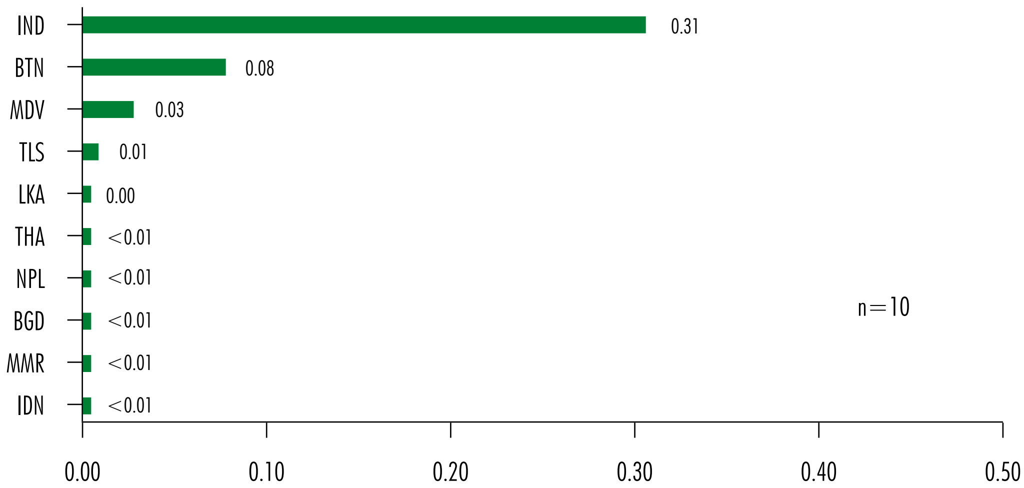
These figures highlight the lack of BME professionals especially in the African Region (AFR) and some countries of the South-East Asia Region (SEAR). Compared with AFR and SEAR, the Region of the Americas (AMR) reported a higher density of biomedical engineers; for instance, Mexico, Trinidad and Tobago, El Salvador, Argentina, Chile, United States of America and Panama show a density over 0.2 biomedical engineers per 10 000 population or one per 50 000 people. Nevertheless, distribution within AMR varies greatly and some countries, such as Jamaica, Haiti, Honduras and Guatemala have a presence of BME professionals less than 0.01 or one per million people.

Table 1.1 Biomedical engineering professionals per 10 000 population in the WHO African Region



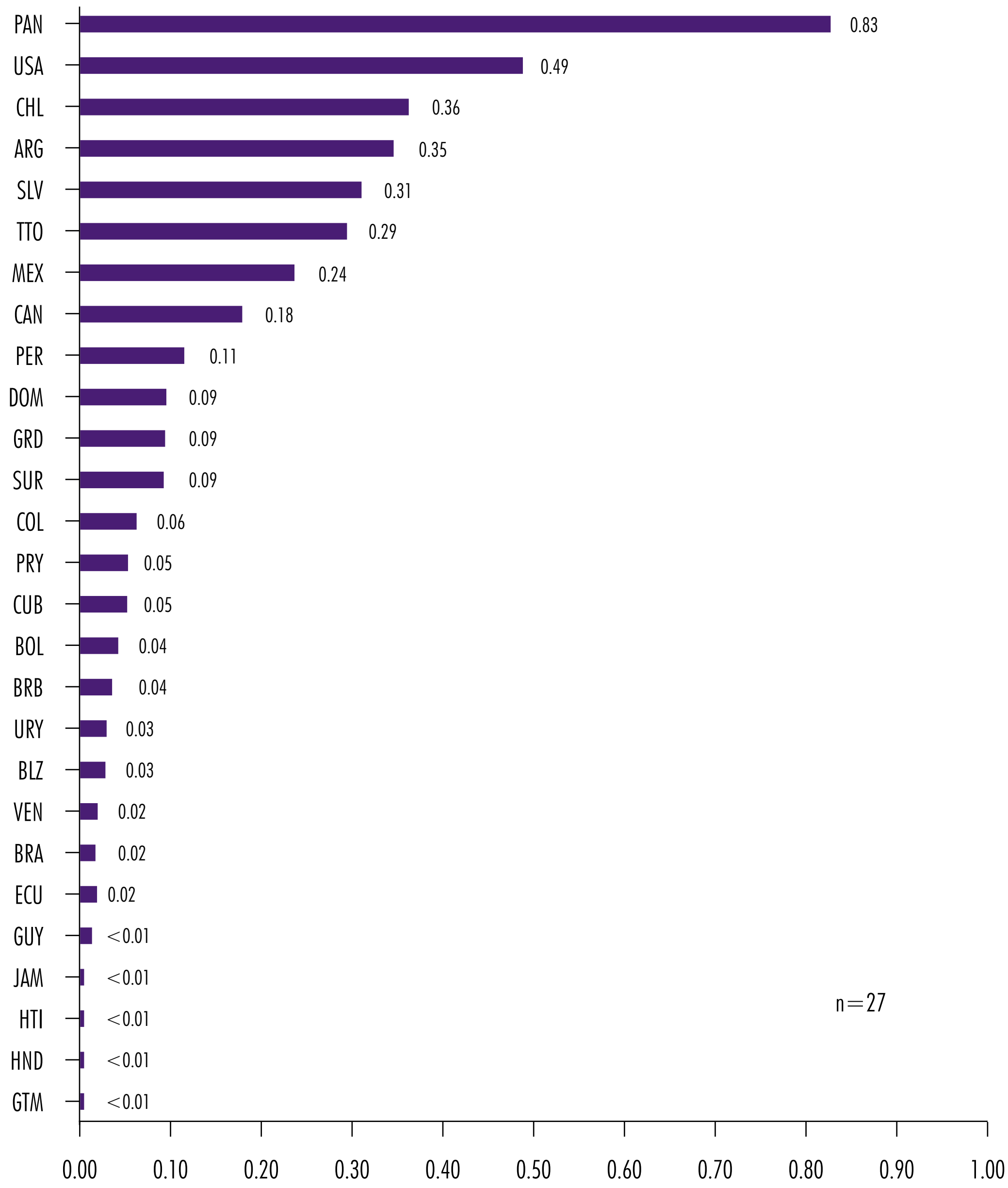
Source: Data was collected from three different sources: government offices and ministries of health (through surveys launched by WHO between 2010–2015); IFMBE; and universities offering BME programmes.

Table 1.2 Biomedical engineering professionals per 10 000 population in the WHO South-East Asia Region



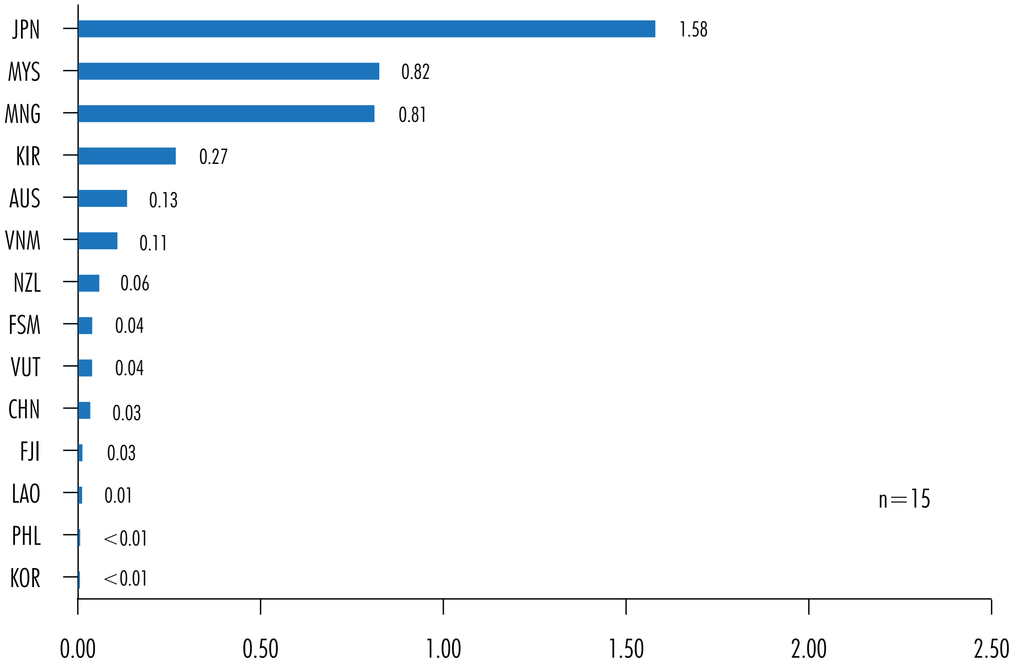
Source: Data from surveys launched by WHO 2010–2015.

Table 1.3 Biomedical engineering professionals per 10 000 population in the WHO Region of the Americas



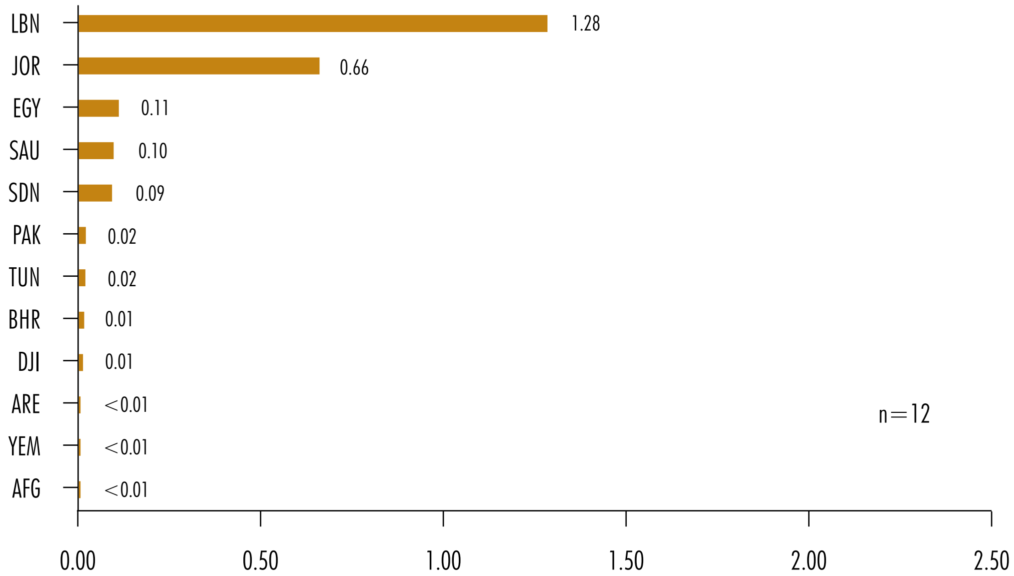
Source: Data from surveys launched by WHO 2010–2015.

Table 1.4 Biomedical engineering professionals per 10 000 population in the WHO Western Pacific Region



Source: Data from surveys launched by WHO 2010–2015.

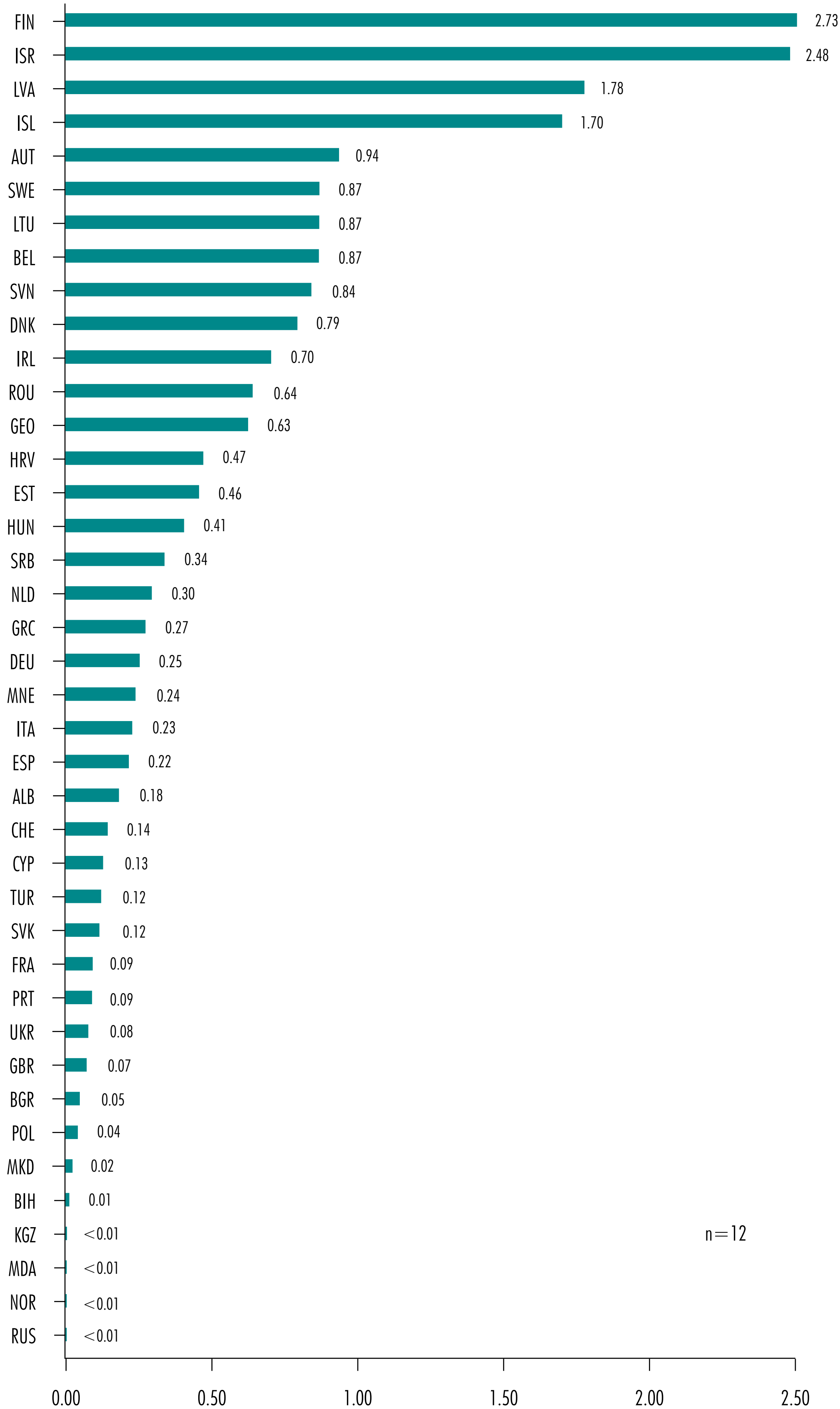
Table 1.5 Biomedical engineering professionals per 10 000 population in the WHO Eastern Pacific Region



Note: Lebanon reported the highest density in the region, though information from 10 of the 22 countries in the region is missing.
Source: Data from surveys launched by WHO 2010–2015.

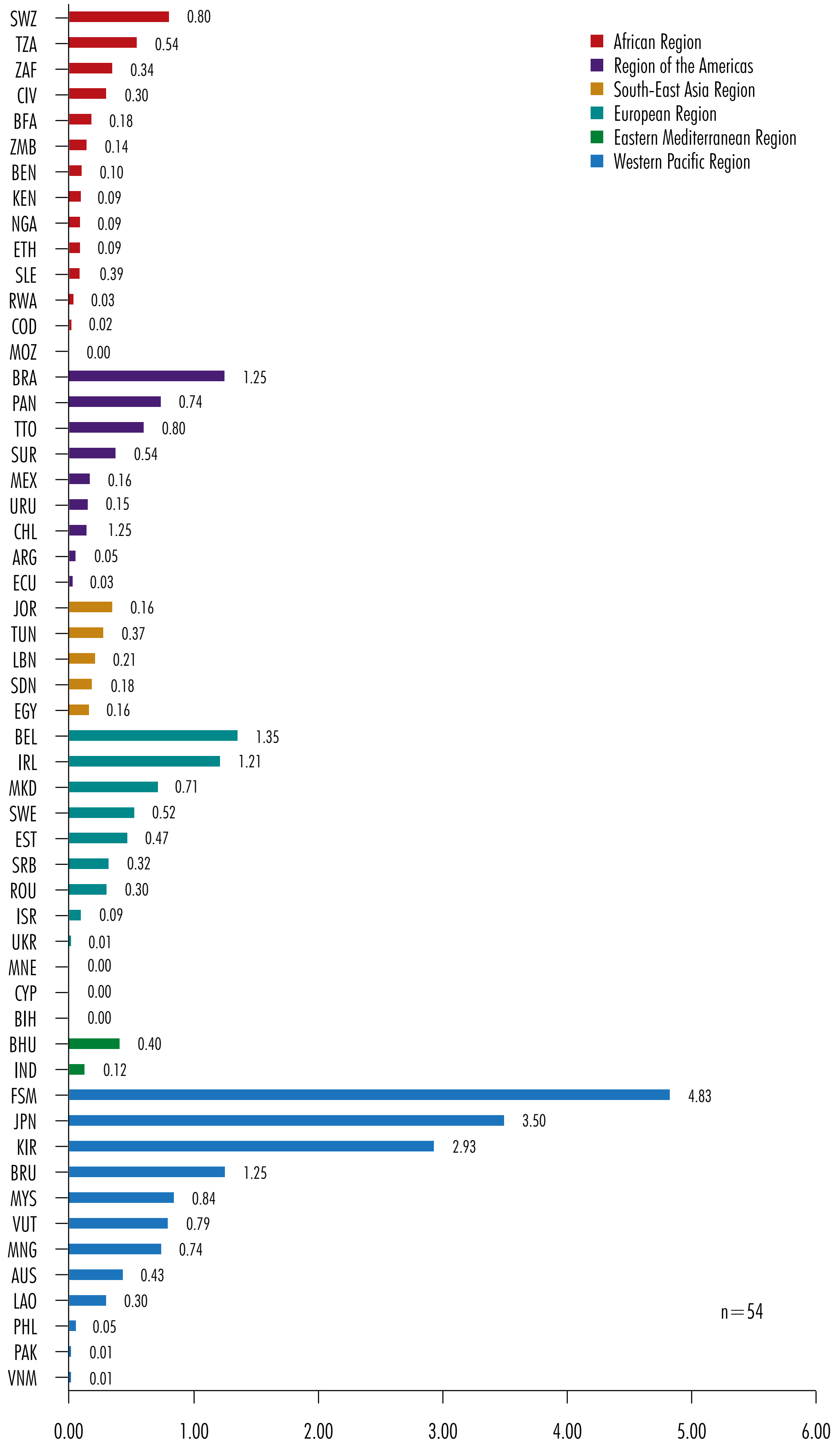
The European Region (EUR), Eastern Mediterranean Region (EMR) and Western Pacific Region (WPR) reported the greatest density of BME professionals; nonetheless all regions reported some country densities below 0.01 (one per million people). Japan, in the WPR, reported the highest density (1.58). In the European Region, Finland (2.73 or one per 3663 people) and Israel (2.48 or one per 4032 people) reported the highest densities. All three are classified as high-income countries.

Table 1.6 Biomedical engineering professionals per 10 000 population in the WHO European Region



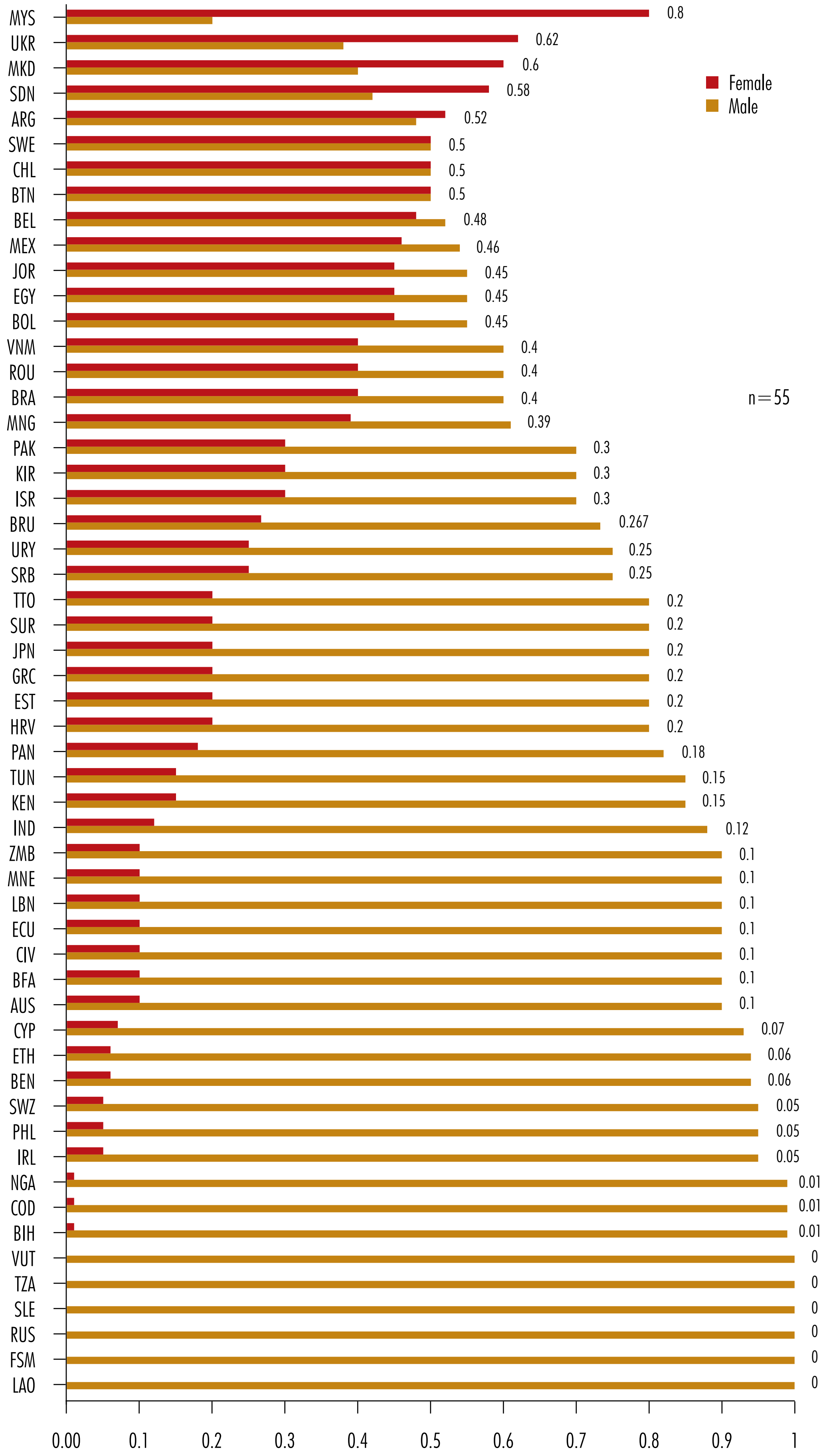
Note: Finland and Israel reported the highest densities in this region, with more than five BME professionals per 10 000 of the population.
Source: Data from surveys launched by WHO 2010–2015.

Table 1.7 Reported density of hospitals with biomedical department/unit/service per 100 000 country population by WHO region.



Source: Data were taken from responses to January 2015 Global Survey - Professional and Academic Profiles on Biomedical Engineers and Technicians launched by WHO.

Table 1.8 Reported proportion of male and females (2015)



Source: January 2015 Global Survey - Professional and Academic Profiles on Biomedical Engineers and Technicians.

Table 1.7 depicts the density of hospitals with a BME department/unit/service per 100 000 population. This indicator is calculated considering the data provided by some Member States that reported BME units in hospitals. It provides a first glance of the availability of biomedical engineers in country health systems and shows disparity between Member States and regions. In order to increase the relevance of this indicator, further information needs to be gathered and validated by the pertinent in-country health authorities.

1.2 Women in biomedical engineering

The most recent stage of the survey compiled gender information by country. Table 1.8 shows the three times greater proportion of male biomedical engineers (77%) compared with female (23%). Nevertheless, five countries (Argentina, Ukraine, Macedonia, Malaysia and Sudan) reported more women than men. In contrast, countries like Lao People's Democratic Republic, Micronesia, Rwanda, Sierra Leone, United Republic of Tanzania and Vanuatu reported no female biomedical engineers at all.

1.3 Biomedical engineering in international organizations

Many international organizations with an agenda in public health, including WHO, Doctors Without Borders and the United Nations Children's Fund (UNICEF), engage biomedical engineering professionals. However, according to the 2015 survey, their numbers are few. The reported numbers of biomedical engineers are listed in Table 1.9. More are needed to increase advocacy of emerging and existing medical technologies and their role in achieving the missions of these institutions.

Table 1.9 Reported numbers of biomedical engineers at some international organizations (2015)

Organization	BME staff
Doctors Without Borders	13
Global Medical Equipment Repair Training	1
Medics Without Vacations	1
MedShare International	3
United Nations Children's Fund	3
United Nations Office for Project Services	1
World Health Organization	4

Conclusion

As of 2016, Biomedical engineering professionals can be found in 129 of 194 Member States of WHO. Many new BME programmes are being initiated in different LMIC, therefore it is expected that the number will increase. It is important to note also that there is an increasing female population of BME and that more are being hired in international organizations. The following chapters will present more information on the academic programmes as well as the national and international professional societies.

Credit: Tropical Health & Education Trust (THET)/Anna Jennings; students at Northern Technical College, Zambia, learning the working principles of a resuscitaire.

2 Education and training

2.1 Defining training and education

In general, learning can be split into education and training; education is about acquiring knowledge whereas training is about acquiring skills. When both forms of learning are related to the biomedical profession and teaching institutions, education relates to universities creating biomedical engineers and vocational training institutes creating biomedical engineering technicians and technologists. Training includes pre-service training, meaning a training one finishes before joining the workforce, normally being full time and in-service training, which can be via short-term courses or part-time training. Where vocational training institutes normally teach pre-service training, commercial companies, professional associations or other stakeholders can provide in-service training.

2.2 Core curriculum and elective specialization

The biomedical profession includes many different professions, normally coming from a similar base (the core curriculum), with different specializations (elective specializations).

2.2.1 Core curriculum

Human anatomy and physiology: Biomechanical engineering professionals apply engineering principles to further the understanding of the structure of the human body, the skeleton and surrounding muscles and the functioning of the body's organs. They use the knowledge gained to develop and apply devices such as implantable prostheses and artificial organs to aid in the treatment of the injured or diseased patient to allow them to enjoy a better quality of life. Biomechanical engineers have been responsible for the development of devices such as prosthetic implants to replace diseased or damaged skeletal joints such as hips, knees and shoulders. Their understanding of the biomechanics and fluid dynamics of the central circulatory system has helped the development of artificial heart valves and implantable stents used to improve blood flow in diseased blood vessels. Development of other, less complex, implants such as bone plates and screws also benefits from the skills and knowledge of the biomechanical engineer in understanding the mechanical loading requirements imposed on bone structures to ensure these devices can safely replace or supplement the bone.

Engineering: Biomedical engineers working in areas associated with diagnosis and treatment of disease or injury, biological signal measurement and processing, diagnostic imaging and ensuring a safe environment for patient treatment, need exposure to knowledge often associated with electronic engineering. As examples, biomedical engineers working on bioinstrumentation specialize in the detection, collection, processing and measurement of many physiological parameters of the human body, ranging from the simple, such as temperature measurement, ECG detection and heart rate measurement, to the more complex, such as quantification of cardiac output from the heart, detection of the depth of anaesthesia in the unconscious patient and neural activity within the brain and central nervous system. They have been responsible for the development and introduction of modern imaging technologies such as ultrasound and MRI for scanning the soft tissues of the body, digital X-ray imaging of the skeletal structure and organs of the body, and tumour localization using PET scanning and other technologies. Biomedical engineers working in areas of tissue engineering, material biocompatibility, organ systems, fluid flow and dynamics need knowledge common to basic mechanical and chemical engineering. Thus, core subjects in circuits, electronics, fluid mechanics, solid mechanics, materials, systems, signals, instrumentation, programming and controls are often part of the undergraduate BME curriculum.

2.2.2 Elective specialization

Artificial organs and support systems: When developing artificial organs or support systems such as haemodialysis systems for removal of toxins from the blood, wearable insulin pumps or an artificial pancreas for the treatment of diabetes, the biomedical engineer needs to understand the chemistry of the blood and the biochemical and physiological operation of the kidneys that normally remove toxins from the blood, or the normal role of the pancreas in producing the hormones responsible for glycaemic control within the body.

Biomaterials: In this field, biomedical engineers study and have technical understanding of the physical and chemical properties of the tissues of the body, and use that knowledge to develop new and safe materials for use in implantable medical devices. The human body has natural defence mechanisms and tends to reject any introduced foreign bodies, so developing new materials, with appropriate physical properties to allow for long-term implantation without provoking autoimmune rejection, is very challenging. The material needs to be non-toxic, non-carcinogenic, chemically inert, stable and mechanically strong enough to withstand the environment and stresses imposed in the body and perform as intended for its projected lifetime. Biomaterials research and development by biomedical engineers has led to the development of new alloys, ceramics, composites and combination materials and polymers that have all found successful application in implantable devices.

Clinical engineering: Clinical engineers use their specialized engineering knowledge in implementing health-care technologies and strategies in hospitals and other health-care settings. The selection, installation and ongoing support of appropriate technologies and associated equipment used by health-care professionals are critical to the delivery of safe and effective health-care.

Clinical engineers play a central role in defining technology needs and identifying planning options for institutions; participating in assessment and acquisition of appropriate technologies; supervising or undertaking installation of equipment; managing and maintaining assets through their working life; integrating devices with IT and business systems and electronic medical records. Finally, they manage the removal, safe disposal and replacement of devices or technology at the end of their useful life, or when superior technologies become available and affordable. In undertaking this role, which may involve managing thousands of individual items of equipment ranging from patient beds, infusion pumps, anaesthesia equipment, patient monitoring systems through to large multi-modal imaging machines and their associated digital imaging processors and storage systems, the clinical engineer requires not only engineering expertise but considerable financial, planning and management skills as well.

Computational modelling: A major contribution of the biomedical engineer is in the application of computational modelling approaches to molecular, cellular and physiological systems. Complex computer models of the cardiovascular system, for example, have led to a better understanding of the physiology of the heart and circulatory system. Computer models of neurons and neural networks provide deeper insight into the functioning of the nervous system. Models of protein structure and the interactions of molecular and genetic circuits are greatly enhancing our knowledge of the relationships between structure and function.

Implants and prosthetics: Biomedical engineers involved in the development, replacement and support of implantable devices need skills ranging from materials science, materials compatibility, mechanical and electronic engineering, as well as a sound understanding of the physiology and chemistry of the human body.

Materials chosen for the construction of implantable devices must be physically and chemically stable, compatible with long-term implantation in the body and mechanically robust. An artificial hip, for example, must be capable of withstanding the rigours of continual movement and widely varying loading with the weight of the body, for many years.

Active implants, such as pacemakers and neural stimulators, require signal detection, processing and stimulation capabilities supported by a power source capable of providing energy to the implant to allow many years of operation between replacements. They also require non-contact communication technologies and software support to allow programming and altering of operational parameters, after implantation, to support the clinical needs of the patient.

Neural engineering: Application of engineering principles and techniques have greatly assisted the study of, and interaction with, the nervous system. Our understanding of hearing, for example, would be greatly hampered were it not for engineering approaches to the study of the cochlear and the auditory system. This includes using mathematical models, computers in the generation of acoustic signals and acquisition of biological signals, and advanced data-processing techniques in preparing and conducting experiments and analysing complex data. The same can be said for a large number of sensory, motor and general nervous system investigations. Cochlear and cochlear nucleus implants are successful examples of advanced engineering applied to deafness. Retinal implants are not far off and computer-brain interfaces are already making a tremendous impact, albeit for only few people.

Regulatory standards: In regulatory or standards-setting organizations, biomedical engineers play a role in bringing together the more traditional bodies of engineering knowledge to set appropriate safety and performance standards and then assess medical devices against those standards prior to a regulator giving marketing approval. In such work, the engineer needs further knowledge of the often complex legal and legislative structure in which those standards and regulations are developed and implemented.

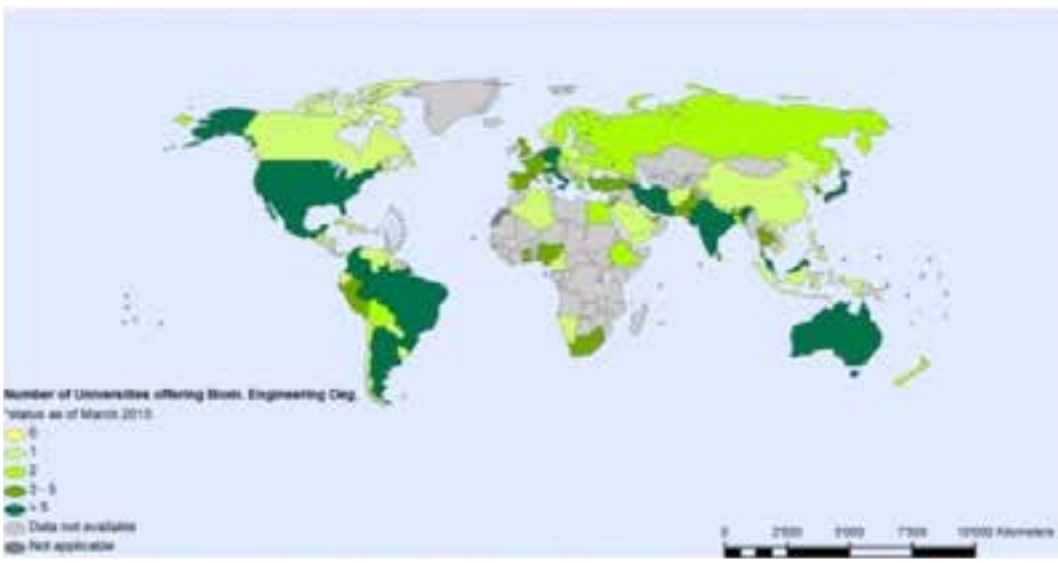
Rehabilitation: Biomedical engineers work closely with clinical personnel (including physical and occupational therapists) to help patients who have suffered injury or disease to achieve normality in their life. They assist by developing diagnostic equipment to analyse a patient's range of movement or motion, and by designing and producing personalized solutions to assist the patient. Rehabilitation engineers work with a wide range of patients and solutions can be as simple as engineering an externally worn knee brace to assist and support a damaged skeletal joint, specifying a wheelchair design for a patient or as complex as designing a complex computer controlled artificial limb to replace a partial or complete amputation, or an exoskeleton that restores mobility to patients with neurological or physical injuries.

Process and systems engineering: In all of these fields of BME, a strong understanding of systems engineering is required to enable the engineer to apply their engineering knowledge and tools of analysis, design and implementation to problem solving within the complex structure of the human body and the equally complex organizational and institutional systems through which health care is provided. Solutions typically involve integrating knowledge of the physiology of the body with engineering knowledge in the many disciplines which we consider to be "conventional" engineering, as well as an extensive range of organizational skills such as project management, process engineering, budgeting, procurement, contracting, IT integration, change management, supply-chain management, performance monitoring and reporting, staff supervision and training, service management, vendor management, disaster preparedness and response and recall management. Depending on organizational resources and maturity, some of these different functions may be assigned to a single person (e.g. maintenance of instrumentation), whereas in other situations, an individual may have responsibility for a wide range functions over an extended geographical region.

2.3 Universities – global data

In line with the objective of disseminating information about BME educational programmes, WHO included educational institutions in the Biomedical Engineering Surveys (2009/2016). Figure 2.1 shows the number of universities that completed the WHO survey.

Figure 2.1 Universities offering biomedical engineering degrees by country



Source: Data from surveys launched by WHO 2009–2015.

2.4 Education and training by region

There follows a summary of the current BME educational programmes on offer worldwide.

2.4.1 Africa

Biomedical engineering education

In Africa, the development of BME education can be traced to the late 1960s. In 1969, the Medical Physics and Bioengineering Department was formed in the University of Cape Town (UCT), South Africa.*(36)* Four years later, UCT's Biomedical Engineering Department was established as a separate entity and postgraduate programmes in BME were introduced. In the early 1970s, the College of Medicine, University of Lagos, Nigeria, established a BME department to train low- and middle-level human resources in BME. In 1976, the Systems and Biomedical Engineering Department was established in the Faculty of Engineering, Cairo University, Egypt, and produced its first graduate in 1980. In the late 1990s and early 2000s, there was a plethora of African academic institutions launching programmes in BME. A list of BME programmes in Africa can be found in Annex 2.

Participants at the "Innovators Summer School for 2012," supported by the United Nations Economic Commission for Africa (ECA), resolved to form an African Biomedical Engineering Consortium (ABEC).*(37)* The mission*(38)* of the ABEC states:

"The African Biomedical Engineering Consortium (ABEC) is a regional platform for promoting innovation and entrepreneurship in health-care infrastructure and technologies for improved health-care outcomes in Africa."

The ABEC in 2016 is composed of 16 organizational members organising an innovation summer school every two years:*(39)*

- Addis Ababa Institute of Technology (Ethiopia)
- Cairo University (Egypt)
- Dar es Salaam Institute of Technology (United Republic of Tanzania)
- Jimma University (Ethiopia)
- Kenyatta University (Kenya)
- Kyambogo University (Uganda)
- Makerere University (Uganda)
- Malawi University of Science and Technology (Malawi)
- Mbarara University of Science and Technology (Uganda)
- Muhimbili University of Health and Allied Sciences (United Republic of Tanzania)
- Technical University of Mombasa (Kenya)
- Uganda Industrial Research Institute (Uganda)
- University of Cape Town (South Africa)
- University of Eldoret (Kenya)
- University of Ibadan (Nigeria)
- University of Lagos (Nigeria).

Biomedical engineering training

Most of the early developmental efforts in African BME have been in the area of training, through short courses, continuing education, professional development or conferences. This is to be expected as this aspect of human resources development can be sponsored and provides channels for individuals making changes in their fields of interest. *(40,41,42,43)*

Initial entrants into the BME profession held degrees and/or certificates in traditional engineering areas such as electrical, mechanical or chemical engineering. These individuals needed to acquire BME skills to be able to manage biomedical equipment. While "formal education" emphasizes the development of knowledge, "training" emphasizes the development of skills that can come in the form of continuing education, continuing professional development or short courses.*(44)*

Attempts at BME training in Africa started even earlier than BME education. Many non-BME institutions have conducted courses. Specifically, in South Africa, even before the University of Cape Town commenced specific BME programmes, it had, in conjunction with other institutions, organized workshops and courses in BME in the 1960s. In Nigeria, in the early 1970s, the Nigerian Association of Health Engineering, based in the BME department of the College of Medicine, University of Lagos, conducted a number of seminars and conferences in BME. Their first conference was held in 1974. After South Africa and Nigeria, sub-Saharan Africa biomedical engineering training (BMET) started in the 1980s at the Mombasa Polytechnic in Kenya (now Technical University of Mombasa) and many sub-Saharan countries now offer BMET training programmes. These programmes lead to advanced certificates, diplomas and advanced diplomas, depending on the national educational systems. BMET courses normally include industrial or clinical placements and sometimes internships to familiarize students/graduates with the reality of their profession.

Biomedical engineering practice

Initiated through the establishment of a handful of educational institutions and professional associations in the 1960s, African BME professional practice is now expanding exponentially in the 21st century. Most BME professionals work in hospitals, medical and health centres or other clinical health-care settings. Among the five career areas of BME – clinical, industry, research/development, academia and government – the clinical setting holds the greatest prospect. As a result, many teaching hospitals and ministries of health have recognized and created separate BME units or departments. Biomedical engineering practice in academia is also improving in Africa. This is understandable given the increase in educational institutions offering BME programmes.

Pure BME research centres are rare in Africa. Those that do exist are in the educational institutions running BME programmes. A handful of ancillary research centres, such as those in cancer research, biotechnology, pharmaceutics/vaccine, agriculture and medical areas, are present. Nigeria, for instance, has the Cancer Research Centre, National Biotechnology Centre, National Vaccine Centre, National Virology Institute and the Nigerian Institute for Medical Research. Consequently, there are biomedical engineers engaged in these research centres. The industry sector suffers most from the paucity of professional practice of BME in Africa. There is some small-scale biomedical equipment manufacturing in Africa, mostly in the production of biomedical accessories and disposables. The African BME industry is based largely on the distribution of finished products and services.

Accreditation

Every African country has its own accreditation bodies and procedures, however, in general, a national accreditation board linked to the ministry of education accredits academic programmes where technical and vocational education and training (TVET) normally accredit training programmes.

2.4.2 Asia-Pacific

Biomedical engineering education

Japan initiated BME education in the Asia-Pacific region by establishing the region's first BME department in 1963. Subsequently, Taiwan, China (1972), China (1977), Republic of Korea (1979), Mongolia (1996), Malaysia (1997), Indonesia (2004), Hong Kong (SAR), China (2005) and Thailand (2006) successively established BME departments (see Annex 2). These efforts have fostered the growth of BME professionals in the region and more and more universities have established departments and/or programmes ranging from undergraduate to doctoral studies.

The areas of expertise for BME education in the Asia-Pacific region are classified as biomedical electronics, biomedical materials, biomechanics, biomedical imaging and biomedical informatics. According to the latest survey in 2015, the majority of graduates have expertise in biomedical electronics, which is in contrast to biomedical informatics (corresponding to the BME lecturers' expertise).

In 2015 Kang-Ping Lin conducted a BME education survey in nine Asia-Pacific countries.*(45)* Graduate schools were surveyed regarding student skills training, course information and graduate employment. Currently, over 300 universities have a BME department with more than 2600 professional lecturers.

Biomedical engineering practice

Regarding careers, over 50% of BME graduates work in BME related fields. These employment opportunities range widely as a result of BME being long established. Examples of positions commonly available include: service or sales engineers in global enterprises for medical devices; engineers in R&D in medical devices companies; educators; and engineers in hospitals responsible for equipment repair, maintenance, procurement and administration. Such wide ranging roles has a tremendous impact on the advancement of maintenance, R&D and medical devices producing and improving medical care quality for patients. The special role biomedical engineers play in the clinical care of patients has gradually developed as an important sub-area of BME expertise; since the 1990s known in hospitals in the Asia-Pacific region as "clinical engineering".

Currently, in the Asia-Pacific region, only hospitals in Japan and China have permanent clinical engineering departments. Other countries are working to achieve this goal, but they are stymied by current policies and regulations for government health-care departments. This affects the role of clinical engineers in hospitals, and, as a result, some medical devices and instrumentation are maintained by nurses instead of clinical engineers. In addition, when problems with, or malfunctions of, medical devices occur, the hospital will often seek assistance from suppliers, because there is lack of trained clinical engineers. This situation is common in hospitals in the Asia-Pacific countries, with notable exceptions in Japan and some areas of China.

Accreditation

Most BME departments in China are accredited via the Washington Accord (see section 2.5). Although BME education in Japan is the oldest in the region, only some of its universities have been accredited according to the Washington Accord. China was preparing for accreditation in 2014. Other Asia-Pacific countries have not yet established the accreditation system of the Washington Accord.

2.4.3 Australia and New Zealand

Kirsner and McKenzie make a convincing case that David Dewhurst is the father of BME in Australia.*(46)* There is little doubt that Australia has made significant advances in the area of BME. The multi-channel cochlear implant is undoubtedly the most successful neural prosthetic developed to date. A recent review of the BME programmes in Australia, however, suggests that improvements in programme offerings could be made.*(47)* Programme data for both Australia and New Zealand can be found in the Annex 2 (WPR).

2.4.4 Europe

European Higher Education Area harmonization

The creation of the European Higher Education Area (EHEA) aims to lead to comparability of degrees, both undergraduate and postgraduate (cycles), across Europe. A major tool applied towards this goal is the establishment of the European Credit Transfer System (ECTS), which allows comparable degrees to be mutually recognized, and facilitates an increased flow of students and teaching staff between universities. However, the ECTS is still only partially implemented. The BME field, belonging to the broader engineering subject area with traditionally five years of studies for graduation, has faced strong opposition to reformation. Today, there are countries in the broader European area that have fully adopted the three plus two years' scheme (first and second cycles), but others are still offering only one five-year cycle for engineers leading directly to a second level degree. Harmonization, therefore, remains a difficult task in such a diverse environment. The Tempus IV joint project "Curricula Reformation and Harmonization in the Field of Biomedical Engineering" (CRH-BME) had, as a main objective, to propose an updated generic curriculum. Our findings on European BME study programmes is mainly based on the results and recommendations of this project. A new Tempus initiative has just been awarded funding from the European Union – the BME-ENA project. This project will implement the previously harmonized standards in the creation of new study programmes in the Eastern Neighbouring Area (ENA) countries, and promote the reform of existing ones.

BME education

The survey of over 300 BME study programmes in Europe carried out within the CRH-BME Tempus project to evaluate the present status and future needs in BME education has shown that second cycle (MSc level) programmes currently dominate (30% BSc, 50% MSc, 20% PhD).*(48)* This is not surprising since the profile of a biomedical engineer is that of an engineer cross-trained and specialized in biomedical application areas. The most straightforward pathway to such a profile is, therefore, to recruit students from the pool of graduates of "classical" engineering disciplines (e.g. electrical, mechanical) or physical sciences (e.g. physics). Only first- and second-cycle degrees (BSc and MSc), as defined by the Bologna Declaration, were considered here. The third-cycle (PhD) programmes are of a much more specialized nature and differ significantly among different European universities. Therefore, studies leading to a doctoral degree are not considered. Concerning the creation of the BME programmes, only 15% were in existence 20 years ago, and 67% have started since 2000. The oldest programme has been running since 1967, and new ones are continuously being planned and implemented. A list of BME programmes in Europe can be found in Annex 2.

There are three distinct generic types of BME programmes in Europe:

- Type 1: First-cycle BME programme (BSc)
- Type 2: Integrated first- and second-cycle BME programme (MSc)
- Type 3: Stand-alone second-cycle BME programme (MSc).

These programmes can be further distinguished into three sub-types according to entry requirements:

- Entry from a first-cycle BME programme
- Entry from a first-cycle engineering (non-BME) or physical sciences programme
- Entry from a first-cycle medical or biological programme.

The majority of BSc programmes (63%) run for six semesters. More than half of the MSc programmes take four semesters, and one third of the MSc programmes are only two semesters long. Concerning doctoral programmes, more than two thirds take a minimum of six semesters, while the remaining one third last from eight to ten semesters. Due to the significant differences between the existing study programmes in terms of total duration (in years) and the organization of the studies (e.g. semesters or trimesters), from the harmonization point of view the programmes are specified in terms of ECTS credits representing student workload. The minimum number of ECTS is prescribed for each programme, but the total number of credits of any combination of first- and second-cycle programmes is at least 300, as required according to the Bologna Declaration, while type 3 programmes must deliver 90 ECTS as a minimum.

Most BSc and MSc programmes in Europe incorporate education in basic engineering and physical sciences (maths, physics, programming, electrical, mechanical and/or chemical engineering) as well as basic biological and biomedical sciences (e.g. cell biology, basic anatomy and physiology). The duration and content of the basic aspects reflect the requirements for prior knowledge and experience of the students enrolled in the programme. All study types include courses that provide the foundations on which the application-oriented courses can build. The programmes commence with education in basic engineering and physical sciences, and basic biological and biomedical sciences. The duration and content of this aspect of programmes depend on the prior knowledge and experience of the students. Students undertaking a first-cycle programme or an integrated first- and second-cycle programme are expected to have very limited knowledge in both basic areas and the time (and ECTS) devoted to basic material should be considerable.

Students entering second-cycle programmes can be expected to have high-level knowledge acquired from their first-cycle degree. The duration of the basic aspects of the programme is correspondingly decreased and tailored to the nature of the student's prior knowledge, e.g. whether it was an engineering or biomedical based degree. There is also recognition of the non-technical competencies and skills needed to practise BME in an academic, industrial or health-care context. Effective communication, both written and verbal, is vital for effective team working – central to many BME activities. Additionally, management skills are essential to obtain the best results from such teamwork. All students must be aware of the ethical context in carrying out and publicizing research, as well as the specific ethical constraints of working within the medical area. These non-technical aspects are either delivered as stand-alone courses, or are integrated within the other programme topics. Students are also expected to carry out research of significant depth to demonstrate their expertise in the application of ideas and techniques. In general, the topics included in BME education in Europe can be grouped into the following areas: basic engineering and physical sciences, engineering and physical sciences focused on BME applications, basic biological and biomedical sciences, general introduction to BME and BME specialization, generic skills, ethics (general, medical, research), management, visits to/from companies or lectures/seminars from staff of relevant institutions and BME research project for thesis.

European core biomedical engineering subjects

The core subjects/topics identified as the basic components of BME programmes of any type are:

- Biomaterials
- Biomechanics
- Biomedical data and signal processing
- Biomedical instrumentation and sensors
- Health technology design, assessment and management
- Information and communication technologies in medicine and health care
- Medical imaging and image processing.

In this context the term subject/topic is generally meant to represent a category broader than a single course. A particular core topic can be covered by more than one course within a BME programme, depending on specific needs. A first- or second-cycle study programme should cover at least four of these core subject/topics in depth in order to be considered as a typical BME programme.

Electives

The purpose of BME elective topics is to cover teaching content not identified as part of core topics and thus allow for the introduction of new and emerging technologies and applications. Elective subjects represent approximately 30% of the overall study programmes but with a lot of variation across Europe. The elective subjects offered depend on the specialization of the departments involved in the BME education, the expertise and specialization of their staff, the level of international collaboration or perceived social, health-care or industrial needs. The most common topics identified in the above-mentioned survey include:

- Anatomy and physiology
- Artificial intelligence and neural networks
- Bioethics, humanities
- Biology and biochemistry
- Biomedical electronics
  - Nanotechnology
  - Ultrasound
- Bionics, biocybernetics and robotics
- Cell and tissue engineering
- Clinical engineering
- Control theory, modelling and simulation
- Diagnostic and therapeutic methods
- Gene and molecular engineering
- Mathematics, statistics and data analysis
- Patient safety, hospital environment
- Physics (acoustics, electricity, mechanics, optics, etc.)
- Quality management, health-care assessment
  - Health-care organization, management and legislation
  - Health-care technology assessment and quality of life
  - Medical technology, marketing and economics
- Rehabilitation engineering
- Research methodology
- Telemedicine and virtual reality.

The exact wording and depth of the elective topics titles may differ from programme to programme.

Internship/cooperative (co-op) education requirements

Internship is also promoted and facilitated. Many universities have agreements with companies or service providers and students may spend between a month and one year in an internship. The recognition placed on this activity as part of the educational process however varies considerably among the different institutions.

Study abroad

Student exchange and mobility is very much promoted in Europe today. Approximately 90% of BME programmes apply the ECTS facilitating study abroad. More than two thirds of programmes accept foreign students, and 70% have bilateral agreements with other universities. English is offered by the majority of programmes as a teaching language, and often two teaching languages are used.

Accreditation

The accreditation of BME programmes in Europe today implies that institutions should have a policy and associated procedures for the assurance of the quality and standards of their programmes. They should also commit themselves explicitly to the development of a culture that recognizes the importance of quality, and quality assurance, in their work.

2.4.5 Latin America

Biomedical engineering education

According to Allende et al, BME "is a multidisciplinary field that integrates various sciences, such as physics, chemistry, biology, mathematics, electronics and informatics, with the aim at developing technology innovations in health-related areas, at improving prevention, diagnostic and pathologies treatments and, thus, at improving the life quality of people."*(50)*

Biomedical engineering in Latin America has a nearly 40-year-old history. The first academic undergraduate programmes in Latin America were established in Mexico and in Colombia in the 1970s and in Argentina in 1985. Subsequently, graduate programmes were created in the Bolivarian Republic of Venezuela, Brazil, Colombia, Cuba, Peru and Uruguay.

The number of BME and bioengineering undergraduate and graduate programmes has increased from 50 to 60 since 2007. *(49,50)* The number of countries and universities that offer these programmes are shown in Table 2.1 and a list of BME programmes in Latin America can be found in Annex 2.

Table 2.1 Latin American countries offering BME and bioengineering programmes

	2007	2015
Latin American countries	23	23
Latin American countries with BME undergraduate education	9	12
Latin American universities with BME and bioengineering programmes	50	117

The early stages of bioengineering and BME education in Latin America was mainly based on electronics and bioinstrumentation, leaving aside biomechanics and biomaterials.*(29,48)* Most of the universities prepared professionals dedicated to installation and maintenance of medical devices. In the last five years, however, this model has evolved with changes in the main regional health needs and the emerging technologies in the fields of bioinformatics, neural engineering telemedicine, therapeutic systems and the new "internet of things" trend in health care that allows patients to monitor their own health data. Among the factors that influenced this change are the increasing rate of chronic conditions and their risk factors that are now the major causes of death, disability and illness in the region. Based on these issues, BME programmes now include new areas of interest to ensure new engineers have sufficient skills to create new designs and develop and improve new medical solutions in order to increase the quality of life of the region's population.

In addition, there is also a field focused on clinical engineering which is important for engineers to acquire the tools to support a hospital with optimal management of medical technology through technology acquisition management and ensure ongoing safety.*(51)*

According to Allende et al, "since the early times of BME as an undergraduate academic programme, a hot debate has arisen as to whether to train generalist engineers or specialist professionals – specialization may prove necessary in developed countries, where a biomedical engineer can work within a predetermined family of medical devices. Nevertheless, by being specialized in some area of interest, the professional loses some global knowledge in other important areas. In particular, in Latin American countries, a biomedical engineer must be proficient enough to adapt themselves and solve very different problems, in health centres as well as in medical device companies. The best conditions arise when an extensive education is given so that it covers a wide range of knowledge with which the engineer can effectively deal with whatever situations arise. This mainly occurs in undergraduate programmes, where the future engineer studies fundamental topics throughout five or six years of education. "If they wish to go on, further specialization is given along with graduate studies, thus increasing their domain of competence."*(51)*

In Latin America the same tendency is observed in the newly created BME programmes. In general, their curricula include the following fields:

- Bioelectricity and biomagnetism
- Bioinformatics and communication theory
- Bioinformatics and computational biology, systems biology, and modelling methodologies
- Bioinstrumentation, biosensors, biomicro/nanotechnologies
- Biomaterials and biomechanics
- Biomathematics, modelling and simulation
- Clinic engineering and hospital safety
- Design and equipment construction
- Electromedicine and bioinstrumentation
- Signal and image processing
- Telemedicine and telesurgery
- Therapeutic systems, devices and technologies, and clinical engineering.

Accreditation

The government in each country has an accreditation programme for their universities. To guarantee standards each academic programme is evaluated by a group of experts nominated by the government, every four or five years in order to get their accreditation renewed. For international accreditation, ABET is the most implemented system, which accredits "college and university programs in the disciplines of applied science, computing, engineering, and engineering technology at the associate, bachelor, and master degree levels, to ensure students, employers, and the society we serve can be confident that a program meets the quality standards that produce graduates prepared to enter a global workforce."

2.4.6 North America (USA and Canada only)

Biomedical engineering education

The maturation of BME programmes in the United States of America is advancing rapidly, producing practitioners who work in academia, industry and in the health-care professions as academics, engineers, physicians and other professionals devoted to knowledge creation, medical device design, and delivery of health care. Very few graduates of undergraduate BME programmes work in industry immediately after obtaining their degrees unless they have had some internship or co-op experience. Industry, for some time, has been insisting on an MSc in BME as the entry-level degree, unless the applicant has had a significant industrial internship or co-op experience. A few BME undergraduates, upon receiving their degree, work in hospitals or shared-service organizations, but they often lack experience in critical clinical environments to be effective immediately. They need additional training to become effective.

There are 97 accredited bioengineering or BME undergraduate programmes in the United States today,*(52)* but no undergraduate programmes offering clinical engineering degrees.*(53)* In fact, there are no MSc clinical engineering degree programmes (although the University of Connecticut offers an MSc in BME with a substantial clinical engineering internship component). In Canada there are 36 universities offering BME degrees,*(54)* but only two offering MSc programmes in clinical engineering.

From 1999 to 2007, the Vanderbilt-Northwestern-Texas-Harvard-MIT (VaNTH) Engineering Research Center in Bioengineering Educational Technologies existed for the purpose of examining BME programmes in the United States of America in order to provide:

- A listing of recommended core content, as opposed to core courses, for BME undergraduate programmes.
- Recommendations for creation of curricula in terms of both content and pedagogy.*(55)*

Biomedical engineering training

There are only eight accredited BME technology programmes in the United States.*(56)* The Biomedical Equipment Maintenance Technician Training Program of the Defence Health Agency provides training for the military.*(57)*

Accreditation

In the United States, accreditation of engineering programmes is done by the Accreditation Board for Engineering and Technology (ABET). Today ABET is a not-for-profit, nongovernmental accrediting agency for programmes in applied science, computing, engineering and engineering technology recognized as an accreditor by the Council for Higher Education Accreditation. By receiving ABET accreditation, college and university programmes are assured of meeting the quality standards of the relevant profession for which the programme prepares graduates. Programmes, not institutions, are accredited and accreditation is voluntary. It provides specialized accreditation for post-secondary programmes within degree-granting institutions already recognized by national or regional institutional accreditation agencies and national education authorities worldwide. To date, approximately 3600 programmes across 700 colleges and universities in 29 countries have received ABET accreditation. Each year around 85 000 students graduate from ABET-accredited programmes, and millions of graduates have received degrees from ABET-accredited programmes since 1932.*(58)*

2.5 International accreditation agreements

In addition to accreditation organizations, a number of important accords have been established.

Washington Accord, 1989

This multinational agreement set in motion the progression toward the mutual recognition of engineering accreditation.

The major aim was to attain the substantial equivalency of accredited engineering degrees among the respective signatory countries. The accrediting bodies of eight countries (Australia, Canada, Hong Kong (SAR) China, Ireland, New Zealand, South Africa, United Kingdom and United States of America) were the original signatories. Numerous additional countries have subsequently been accepted as signatories.

Bologna Declaration, 1999

This European educational reform declaration set forth the Bologna Process, a series of specific action items for creating the EHEA. These measures concern degrees, credits, mobility, quality assurance and "the European dimension" though well-defined masters and doctoral programmes. As an intergovernmental initiative launched by 29 European countries, it affirmed the establishment of three degree levels: bachelors, masters and doctoral. Through promoting this common higher educational dimension, whereby the degree-granting systems of the various countries become reasonably compatible, the Bologna Process aims at making it easier for students to work and study abroad.*(59)*

2.6 List of educational institutions

1050 educational institutions offering BME degrees were identified through the surveys worldwide:

- 52 African Region
- 33 Eastern Mediterranean Region
- 253 European Region
- 360 Region of the Americas
- 119 South-East Asia Region
- 233 Western Pacific Region.

A detailed list of all identified institutions is attached as Annex 2.

Credit: THET/Anna Worm; first meeting of sub-Saharan professional BME associations, Johannesburg, October 2015.

3 Professional associations

3.1 Purpose of professional associations

Professional associations provide a valuable service to the wider society by helping to formalize the evolution and transmission of specialized knowledge through research, training and certification of skills and recognition of excellence which define a given area of professional practice. We live in a world that is continuously evolving, and its dependence on technology for supporting quality of life has never been greater. The acceleration of scientific, technological, economic and political pressures is forcing established professions to become more dynamic and adaptive, and is creating incentives for new professions to form in order to address new societal needs and opportunities.

For the purposes of this chapter, BME will be used in a generic sense to represent a diverse set of interrelated professional bodies of knowledge and practice that contribute to the broad spectrum of expertise required to design, produce, install and manage health-care technologies that are safe, effective and affordable. These disciplines include clinical engineering, biomechanical engineering and biomechanics, nano-engineering, molecular engineering, biomaterials, rehabilitation engineering and other related disciplines.

Health-related services depend significantly on technology to promote healthy behaviour and to manage illness when it occurs, through detection, treatments, monitoring palliative care and rehabilitation. In particular, the demand for and deployment of technology at the point-of-care, where management of patients' conditions and caregivers converge, are rapidly growing. This dependence, along with the limited availability of resources globally, means that strategies and methods are increasingly important for professionalized management of technology throughout its life cycle. The use of organized scientific and technology knowledge, working in multidisciplinary teams, and technical management methodologies, are all competencies that are now recognized as common and necessary elements of the profession, and the list of required capabilities continues to grow as health-care systems become more complex.

Belonging to professional associations can be beneficial, indeed essential, for individuals seeking to enter and to practise in the field, as they strive to understand, adapt to and influence the rapid changes in technology, regulatory and accreditation rules, globalization of markets and rapidly growing dependence of health-care systems on technology for delivery of services. Professional associations typically provide specialized information resources, legal advocacy, professional development workshops, mentoring and supportive career guidance as members proceed along their professional career paths. The professions of BME, clinical engineering, rehabilitation engineering, engineering for medicine and biology and related health technology management (HTM) and health technology assessment, among others, have been developing such resources nationally and internationally for many years. Furnishing this range of services is the main reason that the BME associations are growing rapidly – in number, membership and scope of services offered. These associations also represent their constituents to policy-makers and other associations, as well as to other co-workers who share in the critical mission of managing global health-care delivery systems.

3.2 Global biomedical engineering associations

Globalization of BME activities is underscored by the fact that there are several major professional BME associations currently operational throughout the world. The various countries and continents to have developed concerted "action" groups in BME are Europe, the Americas, Canada and the Far East, including Japan and Australia. The WHO survey documented the following international professional associations:

- International Union for Physical and Engineering Sciences in Medicine (IUPESM)
- International Federation for Medical and Biological Engineering (IFMBE)
- Institute of Electrical and Electronics Engineers - Engineering in Medicine and Biology Society (IEEE - EMBS)
- Commission for the Advancement in Health-care Technology Management in Asia (CAHTMA)
- European Alliance for Medical and Biological Engineering and Science (EAMBES)
- European Society of Engineering and Medicine (ESEM)
- International Council on Medical and Care Compunetics (ICMCC)
- Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)
- Association Francophone des Professionnels des Technologies de Santé (AFPTS)
- Consejo Regional de Ingeniería Biomédica para América Latina (CORAL).

While all organizations share in the common pursuit of promoting BME, national associations are geared to serving the needs of their local memberships. The activities of the major international professional organizations are described below.

3.2.1 International Union for Physical and Engineering Sciences in Medicine

The IUPESM is the international umbrella organization for BME and medical physics. An account of its development, aims and activities was recently presented by Nagel (2007).*(60)* It is a union of two international organizations – the International Federation for Medical and Biological Engineering (IFMBE) founded in 1959, and the International Organization for Medical Physics (IOMP) founded in 1963. Every three years, IUPESM co-hosts, with the IFMBE and IOMP, and two local associations (one BME and one medical physics) a World Congress on Medical Physics and Biomedical Engineering. Further information can be found at: http://www.iupesm.org/

In 1999, IUPESM was acknowledged by the International Council of Science (ICSU) as a scientific organization. Within the IUPESM, the Health Technology Task Group (HTTG) has the mission to promote health and quality through the advancement of application and management of health technology. In pursuit of its mission, the HTTG promotes international cooperation and communication among those engaged in health-care technology. Additional information and educational material can be found at: http://www.iupesm.org/health-technology-tas-group-httg/

3.2.2 International Federation for Medical and Biological Engineering

Founded in 1959, the IFMBE is the principal organization representing biomedical and biological engineers in over 50 nations. The IFMBE comprises 53 national medical and biological engineering associations and six transnational associations. A history of the first 40 years of the IFMBE was published in 1997*(61)* and Launching the IFMBE into the 21st century was published more recently.*(62)* The federation has two divisions: the Clinical Engineering Division (http://cedglobal.org/) and the Health Technology Assessment Division (http://2016.ifmbe.org/organisation-structure/divisions/htad/).

The IFMBE publishes a journal, Medical & Biological Engineering & Computing (MBEC), which celebrated its 50th anniversary in 2013. As of 2016, IFMBE has been an NGO in official relations with WHO for more than 10 years. Further information about the federation can be found at: www.ifmbe.org

3.2.3 Institute of Electrical and Electronics Engineers - Engineering in Medicine and Biology Society

The IEEE (www.ieee.org) is the largest international professional organization in the world and accommodates 37 different associations under its umbrella structure. Of these 37, the EMBS represents the foremost international organization serving the needs of nearly 8000 BME members around the world. The field of interest of EMBS is application of the concepts and methods of the physical and engineering sciences in biology and medicine. Each year, the society sponsors a major international conference while co-sponsoring a number of theme-oriented regional conferences throughout the world. A growing number of EMBS chapters and student clubs globally provide the forum for enhancing local activities supplemented by EMBS's special initiatives that provide faculty and financial subsidies to such programmes through the society's distinguished lecturer programme and its regional conference committee. The EMBS publishes three journals: Transactions on Biomedical Engineering, Transactions on Rehabilitation Engineering and Transactions on Information Technology in Biomedicine and a bi-monthly magazine (IEEE Engineering in Medicine and Biology Magazine). EMBS is a transnational voting member society of the IFMBE. For further information see: http://www.embs.org/

3.3 Professional biomedical associations – global data

In order to understand the status and profile of biomedical engineers globally, WHO integrated data from 2009 to 2016, which are presented in Figure 3.1, documenting the existence of international, national and regional associations, which are key for promoting collaboration between individuals, governing bodies and academic institutions of biomedical engineering. High numbers of active members within these associations encourages collaboration between sectors and rapid development of curriculum. It is important to note that this report does not in any way endorse the work performed by the professional associations listed, but simply serves to compile information on these groups and raise awareness of initiatives in the BME field.

In total, 164 BME professional associations and associations were identified. The Region of the Americas accounts for the greatest number, though it is important to note that the

United States of America accounts for more than half of this number, as it has several subnational associations and associations. In contrast, most of the other countries report only one national BME professional society or association. The complete list of all associations and federations can be found in Annex 3.

Figure 3.1 illustrates the total number of identified biomedical engineering professional associations by region including international associations not specifically classified in any WHO region. In total, 160 biomedical engineering professional associations were identified by compiling all sources of information, though only 25 completed the WHO 2015 survey. It is important to note that Andorra, Armenia, Azerbaijan, Belarus and the Russian Federation reported the presence of BME associations within the country though the name of such associations was not stated and is missing in this report. In contrast, most of the other countries incorporate only one national BME professional association. Figure 3.1 also includes three international associations and organizations.

Figure 3.2 illustrates the percentage of countries with at least one biomedical engineering professional association. In total BME association presence was identified in 86 countries distributed by region as follows; African Region (17 countries), Region of the Americas (11 countries), South-East Asia Region (4 countries), European Region (43 countries), Eastern Mediterranean Region (6 countries) and Western Pacific Region (7 countries).

Figure 3.3 depicts the percentage of countries with BME professional associations by income grouping. This figure underlines disparities between high- and Low income countries. 44% of countries with at least one identified biomedical engineering association are High income countries while only 12% of these countries are grouped as Low income. Low- and lower middle-income countries together only account for 27% of the identified biomedical engineering professional associations. Nevertheless the data for 109 countries is still missing thus further efforts are needed in the future to fill this information gap.

Figure 3.1 Number of biomedical engineering professional associations at global, national and subnational level stratified by WHO region

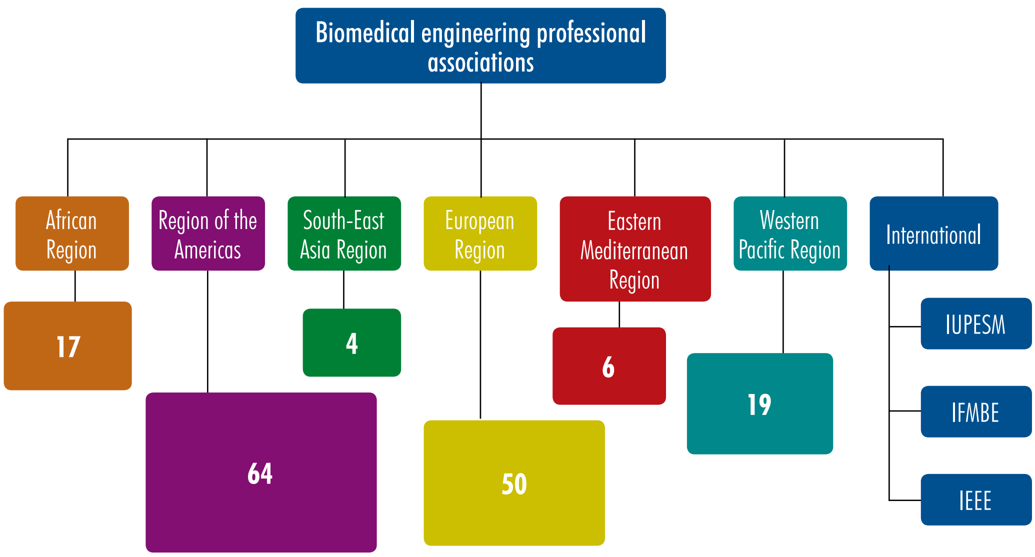
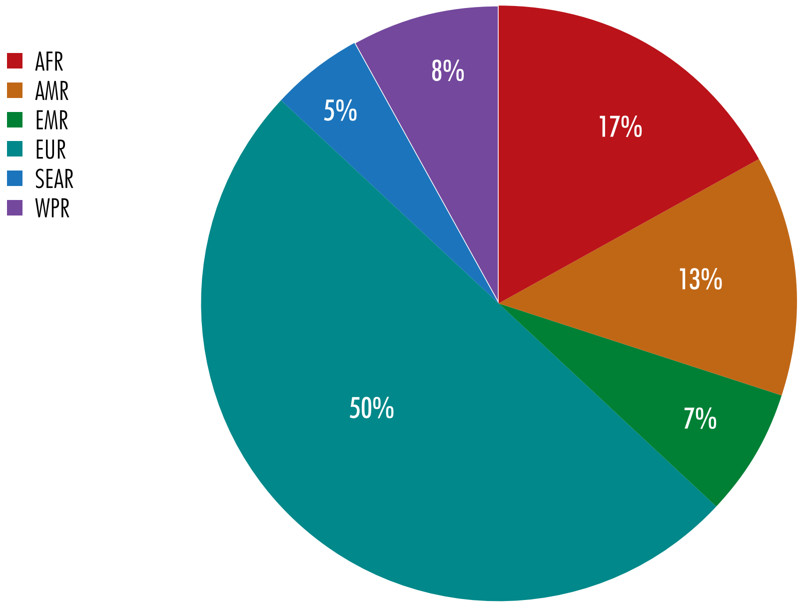
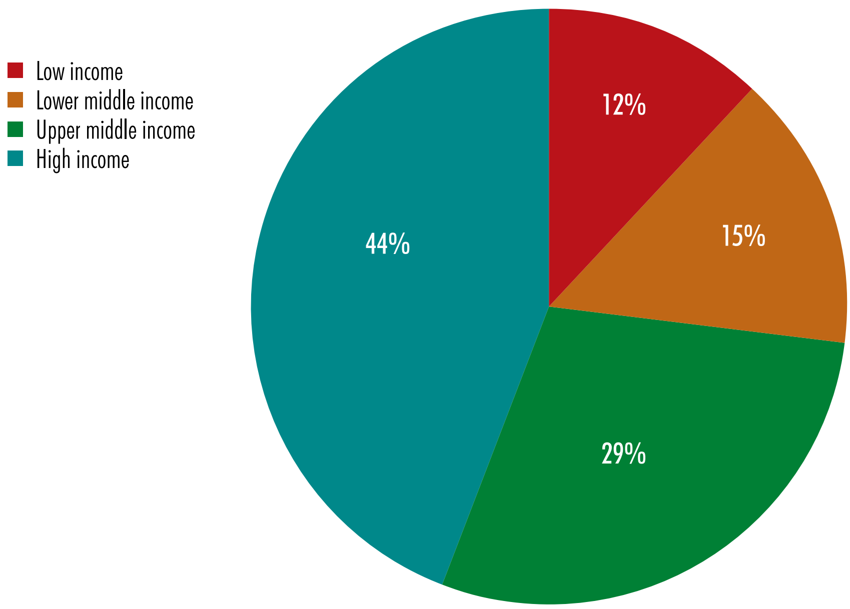


Figure 3.2 Countries with at least one BME professional association by WHO region



Source: Data was reported in surveys launched by WHO from 2009–2015.

Figure 3.3 Countries with at least one BME professional society by income grouping



Source: Data was reported in surveys launched by WHO from 2010–2015.

3.4 Phases of institutional development of a profession

One can determine the stage and status of the professionalization of a social institution by noting the accomplishment of six crucial events:*(63)*

- First training school
- First university school
- First local professional association
- First national professional association
- First state licensing law
- First formal code of ethics.

The early appearances of training schools and university affiliation underscore the importance of the cultivation of a knowledge base. The strategic innovative role of the universities and early teachers lies in linking knowledge to practice and creating a rationale for exclusive jurisdiction. Those practitioners pushing for prescribed training then form a professional association. The association defines the task of the profession: raising the quality of recruits, redefining their function to permit the use of less technically skilled people to perform the more routine, less involved tasks and managing internal and external conflicts. In the process, internal conflict may arise between those committed to established procedures and newcomers committed to change and innovation. At this stage, some form of professional regulation, such as licensing or certification, surfaces because of a belief that it will ensure that minimum standards are met for the profession, enhance its status and protect the layperson in the process.

The last area of professional development is the establishment of a formal code of ethics, which usually includes rules to exclude unqualified and unscrupulous practitioners, reduce internal competition and protect clients and emphasize the ideal of service to society. A code of ethics usually comes at the end of the professionalization process. Efforts to adopt codes of ethics have been seen recently – the BMES in 2004,*(64)* and IFMBE in 2010.*(65,66)*

As health services grow ever more technology intensive and their dependence on that technology increases, the professional characteristics of those engineers who develop and manage this critical environment, and the organizations that guide their career development, promote a commitment to serve human needs ethically, honestly and competently in accordance with highest standards of professional conduct. There are so many challenges facing young biomedical/clinical engineers – whether in coping with work pressures, budgetary constraints, value conflicts or interpersonal communications – that it is essential to have a support system*(67)* that collects and shares experiences in the form of a professional organization, where knowledge, commitment and professional responsibility to those served are explicit pillars of practice.

3.4.1 Institutional maturity of biomedical engineering

In BME, all six critical steps mentioned above have been clearly taken. It has demonstrated the sequence of maturing organizational capabilities required to qualify as a legitimate and credible profession by both historical and societal standards. In April 2015, the European Economic and Social Committee (EESC) drew up its own initiative on promoting the European single market combining BME with the medical and care services industry. In this initiative, the EESC recognizes the role of BME in society, and recommends following the American example and recognize the discipline as a stand-alone science.

Credit: James Wear, Chinese clinical engineering certification exam.

4 Certification

4.1 Defining certification

Professional certification is the process of issuing a certificate formally attesting that the knowledge, know-how, skills and competences acquired by professionals have been assessed and validated by a competent body against predefined standards. Appropriate career paths and opportunities, including professional registration, certification or licensing, should be available to all health professionals for the benefit of public health and patient safety. This chapter describes the introductory information, history, current status and future prospects of professional certification, and gives a number of examples of different national, transnational and global models. Biomedicine and health-care challenges in the 21st century demand regulation of all health professions worldwide, so certification of professionals in the field of BME is among the global priorities.

One of the professional approval processes used in BME is certification; but this term is sometimes confused with related terms like registration, accreditation, credentialing and licensing. To clarify the definitions, similarities and differences between the terms within the professional context is outlined below.
Credentialing: An umbrella term used for different approval processes including accreditation, certification, licensing and registration. "Credential" is defined as an attestation of qualification, competence or authority of professionals issued to individuals by a third party with the authority to do so. Obtained professional credentials demonstrate proficiency in the field of interest and identify individuals as committed to their profession, and provide assessment and recognition of their background, experience and legitimacy to meet predetermined and standardized criteria.

Certification: This is generally a third-party attestation that specified requirements related to persons, products, processes or systems have been fulfilled. In order to apply professional standards, increase the level of practice and protect the public, a professional organization may establish a certification. Professional certification earned by an individual to perform a job or task is often simply called "certification". In this context certification is the process of issuing a certificate – a statement or declaration such as a diploma, degree, title, clearance, etc. – formally attesting that knowledge, know-how, skills and competences acquired by an individual have been assessed and validated by a competent body against predefined standards. Professional certification may further require certain work experience in a related field before certification is awarded, either for a lifetime or as a time-limited recognition of an individual. Certifications are usually earned from professional associations, but also from universities and private certifiers for some specific certifications. Certifications are very common in the health-care sector and are often offered by particular specialisms. An example of such a certification process is a physician who receives certification by a professional specialism board in the practice of, for instance, radiology. The most general type of certification is profession-wide and is intended to be portable to all places a certified professional might work. Certification is a voluntary process and it is based on the premise that there is a right to work. However, it is not a permission to work, but rather a statement of completion or qualification, with the purpose to educate and inform. Certification may be withdrawn at any time by the issuing organization, but this does not stop individuals from working. Licensing and certification are similar in that they both require the achievement of a certain professional level.

Accreditation: A third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. It is a formal process of quality assurance through which accredited status is granted, showing it has been approved by the relevant legislative or professional authorities by having met predetermined standards. Accreditation standards are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organizations. Accreditation is often a voluntary process in which organizations choose to participate, rather than a process required by laws and regulations. It is common in the health-care sector, and an accreditation decision about a specific health-care organization is usually made following a periodic on-site evaluation by a team of peer reviewers, typically conducted every few years. Although the terms "accreditation" and "certification" are used interchangeably, accreditation usually applies only to organizations, while certification may apply to individuals, as well as to organizations. When applied to individual practitioners, certification usually implies that the individual has received additional education and training, and demonstrated competence in a specialist area beyond the minimum requirements set for licensing. When applied to an organization, or part of an organization, such as a laboratory, certification usually implies that the organization has additional services, technology or capacity beyond those found in similar organizations.

Licensing: This is generally a mandatory approval process by which a governmental authority grants time-limited permission (licence) to individuals or organizations, after verifying that they met predetermined and standardized criteria, to perform an activity that is otherwise forbidden, considered hazardous or which requires a high level of expertise. Licensing presumes that engagement in the particular field is a privilege rather than a right, so the given privilege may be withdrawn at any time by the issuing authority. The purpose of licensing is to restrict entry and strictly control a profession or activity by ensuring that the licensee has met eligibility requirements and passed some form of assessment, usually at the state level and required by law. The licence may be renewed periodically through payment of a fee or proof of continuing professional development, by inspection, etc. Licensing is common in medicine, nursing, pharmacy, psychology, social work, engineering, etc., but hardly ever in BME. The main aim of licensing is to protect public health and ensure patient safety. Professional associations are often an important resource and support to those looking to obtain a special level of certification or licence.

Registration: This concerns insertion on an official register organized by a regulatory body, usually by recording or registering certificates. Registration implies standards for training, professional skills, behaviour, health etc., which registrants must meet in order to become registered and must continue to meet in order to maintain their registration or licence. In most cases, the terms "licensing" and "registration" are also used interchangeably.*(68,69,70)*

4.2 International certification of biomedical engineers

There is considerable variety in the ways that different nations manage the certification of BME and related disciplines, including clinical engineers, rehabilitation engineers and biomedical technicians.

The International Federation for Medical Electronics and Biological Engineering was founded in 1959 and eventually shortened its name to the International Federation for Medical and Biological Engineering (IFMBE). Two special divisions are currently part of the organizational structure: Clinical Engineering Division (CED), and Healthcare Technology Assessment Division (HTAD). Originally established as a working group in 1979, the CED attained official division status in 1985.

In 1981, the Agreement on Mutual Recognition of Qualifications for Clinical Engineers was signed by 22 affiliated national associations (ANS) of the IFMBE (Austria, Australia, Belgium, Canada, Denmark, Finland, Federal Republic of Germany, France, German Democratic Republic, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Norway, Spain, South Africa, Sweden, United Kingdom, United States of America and Yugoslavia), mutually agreeing to recognize any holder of IFMBE's Certificate of Registration as a Clinical Engineer, subject only to such additional criteria as might be specified by individual ANS.

Mechanisms of registration were developed and elaborated as follows. The International Registration Board (IRB) is responsible for the registration of clinical engineers. The IRB consists of the chair of the national examining authority (NEA) from each of the ANS party to the agreement, plus representatives of independent international bodies and others as appropriate. Each ANS establishes the NEA in its country, and acts as a communication channel with the IRB. Each NEA recommends individual candidates to the IRB for registration. The CED establishes the constitution and by-laws of the IRB to be approved by the IFMBE Administrative Council. A non-refundable fee for certification covers the cost of processing applications. Each NEA publishes operational guidelines, submits its constitution and by-laws to be approved by the IRB, takes care of funding, participates in IRB's activities through its chair, organizes collection and processing of applications, sets up and conducts examinations for candidates, and recommends actions to the IRB. The exact form of the examination process (written, oral, view, etc.) is left to the individual NEA, but has to satisfy the requirements of the IRB, i.e. has to be meaningful so that successful candidates perform well within the specialism without preventing well qualified individuals from attaining certification.

In order to obtain international registration as a clinical engineer, the agreement defined that a candidate must have successfully completed a basic education in engineering or applied sciences to BSc level and to have more than three years' relevant clinical engineering experience, or, in addition to achieving a BSc, to have a MSc or PhD and/or training in BME and to have more than two years' relevant clinical engineering experience. NEAs may, at their discretion, but with the approval of the IRB, impose additional requirements as dictated by local national practices. Two years' relevant experience counts as one year of training, where experience is offered instead of training.

Formally, this agreement seems still to be in place, but since registration and/or certification have never been made mandatory by national legislation in most of the countries, the agreement has been neglected and the project of international registration and/or certification has actually never been accomplished to a full extent using defined mechanisms, as elaborated above. A possible initial attempt to resolve this appeared via the first issue of an international directory of clinical engineers in 1994, containing names of more than 1200 individuals from 62 countries, with the intention to improve recognition, communication and networking within the global clinical engineering community.*(71)*

Though neither the law nor employers usually require certificates in clinical engineering, there is a significant interest in and need for clinical engineering certification, as shown by the latest global CED survey among clinical engineering professionals and associations. Biomedicine and health-care challenges in the 21st century demand regulation of all health professions worldwide, thus an international umbrella programme for certification in clinical engineering is among the priorities of the global clinical engineering community. Currently an ongoing CED project on international clinical engineering certification is expected to help in finally achieving this goal.

4.3 Certification by region

4.3.1 Certification in Africa

South Africa has a voluntary registration programme of clinical engineers, clinical engineering technologists and clinical engineering technicians, which is based on experience and academic requirements. They also include medical equipment repair personnel. In Zimbabwe the Health Profession Act does not recognize biomedical equipment technicians and engineers under allied health professionals. However, there is a Chief Medical Engineer in the Ministry of Health. The technicians and engineers are in the process of forming a national association to advocate for legal recognition within the act. Once they are recognized, they will be able to participate in the annual review of human capacity needs for the health-care sector. The Zimbabwean situation is a good example of the situation in most sub-Sahara African countries, although at least 17 countries have a registered association.

4.3.2 Certification in the Americas

Canada

Certified biomedical engineering technologists and technicians

A group of biomedical engineering professionals started the discussion of certification in 1976 during a national conference which led to the creation of the Canadian Board of Examiners for Biomedical Engineering Technologists and Technicians in 1981. The board was initially affiliated with the AAMI sponsored International Certification Commission (ICC) until it was replaced by the AAMI Credential Institute (ACI) in 2016.

Certified clinical engineers

By 1980, it was recognized that engineers working in clinical engineering required a distinct but unrecognized body of knowledge to perform their tasks competently. Since there was no licensing process in place specifically for clinical engineering, leaders in Canada decided to establish a certification process that would be administered by competent members of the profession. In order to begin such an effort, discussions were held with colleagues in the United States of America who had undertaken a similar approach under the leadership of AAMI. Canadians with established track records working in the profession were certified (on the grounds of experience), and established the first Canadian Board of Examiners for Clinical Engineering Certification. They developed a written and an oral exam. This process of certification continued for a number of years. However, the initial rush of applicants dwindled and it remained a voluntary activity with limited visibility in the health-care community.

Adding further credibility to the process, the US Board of Examiners is accountable to the Health Technology Certification Commission (HTCC), which oversees the work of the board and ultimately decides on recommendations from the board to certify individuals. Discussions between the Canadian and American boards gained support and encouragement from American colleagues. Under the laws of the Canadian provinces and territories, the use of the title "engineer" in a job description requires that the incumbent be licensed as a professional engineer in that jurisdiction. Canada has always taken the position that to be eligible to seek certification in clinical engineering an applicant must first obtain a licence as a professional engineer. Once a person is licensed as a professional engineer and is working in the field of clinical engineering, then they can apply to the Canadian Board of Examiners for Clinical Engineering Certification. Another main issue of divergence of practice between clinical engineers in the two countries relates to the country specific codes, regulations and standards, an important but relatively small part of the written exam. In discussion, it was agreed that members of the Canadian board would review the American written exam, to identify those questions requiring specific knowledge of American codes, standards and regulations. Canadian candidates are examined through a slightly different but parallel process to their American counterparts.*(72)*

It was agreed that Canadian applicants would register and be administered by the secretariat to the American board, to avoid setting up a parallel office in Canada. Sites are available in Canada to sit for the written exam, which is made available in both countries on a single date and time each year, early in November. All policies and procedures are harmonized and the Canadian board assists the American board in the generation of new written and oral exam questions. Members of the two boards discuss their work on a regular basis, and the chairs of each sit on the HTCC. The harmonized process was established in 2010 and remains in place. There has been good communication between the two boards, and a generally high level of support for the harmonized process.

United States of America

Certified biomedical equipment technicians

Certification in the United States of America in the clinical engineering field began with biomedical equipment technicians. A taskforce was established by the Association for the Advancement of Medical Instrumentation (AAMI) to look at the BMET field and the maintenance of medical equipment in hospitals. The taskforce decided that certification was needed to allow BMETs to demonstrate that they had a minimum level of expertise. A board of examiners was established by AAMI and the first exam set in 1971. Individuals who passed the written exam became certified biomedical equipment technicians (CBETs).

Specialist exams were also developed by AAMI for BMETs who work on laboratory and radiological equipment. These

BMETs do not have to take the general exam since they only work on specialized equipment, but they need certification to demonstrate a minimum level of expertise in their specialism. Individuals who pass these exams become certified radiological equipment specialists (CRES) and clinical laboratory equipment specialists (CLES).

Certified clinical engineers

Individuals must meet the following qualifications to take the certified clinical engineer (CCE) exam: three years of clinical engineering experience plus a professional engineer licence or MSc in engineering or a BSc in engineering plus four years' total engineering experience, or BSc in engineering technology plus eight years' total engineering experience.

The written and oral exams are developed by the board of examiners and are based on the body of knowledge developed by the American College of Clinical Engineering (ACCE).*(73)*

Brazil

In the 1990s, nine Brazilian clinical engineers were certified by the ICC and the Brazilian Board of Examiners for Clinical Engineering Certification was created. However, a certification programme has not yet been developed.*(74)*

Mexico

In 1991, the first Mexican clinical engineer was certified by the ICC and in 1993 the CCE exam was given in Mexico and three more Mexican clinical engineers were certified. In 1994, the Mexican Board of Examiners was approved by the ICC which accepted the affiliation of the Mexican Certification Commission. The recently established Mexican College of Biomedical Engineers will certify biomedical engineers, BMETs and rehabilitation engineers. For further information see: http://www.cib.org.mx/servicios.html.*(75)*

4.3.3 Certification in Asia

Commission for the Advancement of Health-care Technology Management in Asia

The Commission for the Advancement of Health-care Technology Management (CAHTMA) was initiated in 2005 with the endorsement of the Asian Hospital Federation (AHF), which is an international NGO, supported by members from 14 countries in the Asia-Pacific region. CAHTMA is a member of the IFMBE. It was established to provide a platform for health-care professionals to discuss and exchange ideas on health-care technologies and practices. Central to these objectives are the promotion of best technology management practices, the certification of clinical engineering practitioners and health-care professionals, and the dissemination of appropriate management tools through seminars and workshops.

CAHTMA has certified a few clinical practitioners. Technicians are certified as a level one clinical practitioner with a written exam and experience which is similar to the ICC BMET. Engineers are certified as level two clinical practitioners with a written exam and an oral exam and experience which is similar to the HTCC CCE. To encourage more engineers to become certified, CAHTMA is going to use the process of certifying individuals based on credentials similar to the initial programme in the United States of America.

CAHTMA is also the certifying faculty for BME technology programmes which are developing with the increased need for technologists to maintain medical equipment. In 2012, lecturers at one school were tested as assessors and certified by CATHMA with the Certification for Clinical Engineering Assessors. Lecturers who completed five weeks of training and passed the exams were certified by CATHMA with the Certification for Clinical Engineering Trainers.*(76)*

China

In 2005, international clinical engineer certification was introduced in China. The Medical Engineering Division of the Chinese Medical Association hosted the first international clinical engineering certification training courses and certification examination. The written exam is based on the ACCE body of knowledge with some adjustment for the practice of clinical engineering in China. The written exam is in English and is prepared by international senior specialists. Individuals who pass this 100-question multiple choice exam have to then pass an oral exam in English to become certified. The oral exam is given by the international senior specialists. In the seven training sessions since 2005, 760 clinical engineering personnel have attended. Some 252 individuals have passed the two exams and been certified as international clinical engineers. The candidates for certification are mostly senior clinical engineers with more than 10 years' experience. In 2012, the Medical Engineering Division of the Chinese Medical Association carried out Chinese Registered Clinical Engineer Certification (RCEC) training and examination. The candidates were junior engineers in large hospitals or new graduates with majors in medical engineering. This exam is the basic admission exam to the occupational qualification of clinical engineering. The RCEC exam consists of a theoretical exam and practical test. There is a Chinese exam question bank from which the theoretical questions are randomly selected. Candidates then take a practical test including repair, measurement and maintenance of medical devices. A committee of Chinese clinical engineering experts evaluates the ability of the candidates and determines if they are qualified to receive the Registered Clinical Engineer Certification.

China is establishing continuing education for both certifications to maintain and improve the quality of the clinical engineers. The Medical Engineering Division plans to recommend to the government to officially authorize clinical engineer training and certification. *(77)* In Hong Kong (SAR), China, BMETs take the ICC exam used in the United States of America; no Hong Kong board of examiners has been appointed. For CCE they use the American exam process under the HTCC.*(78)*

The Taiwan Society for Biomedical Engineering (TSBME) performs certification in clinical engineering in Taiwan, China. In 2000, TSBME established the Certification Executive Committee for Clinical Engineering certification. The first testing for certification of clinical engineers and technologists of medical equipment was in 2007. The TSBME provides certification for clinical engineers, medical equipment technicians and biomedical engineers. In 2010 they had certified 93 clinical engineers, 132 medical equipment technicians and 224 biomedical engineers. Clinical engineers and medical equipment technicians work in hospitals and biomedical engineers work in the medical device industry. This is the only certification that has a separate certification programme for hospital and industry engineers.*(79)*

Japan

In Japan the government certifies clinical engineering technologists (CET), who must graduate from a clinical engineering training school which can be a university, junior college or training school and pass a national exam to be certified. CETs are also called clinical engineers and are paramedics who specialize in the medical equipment essentials in medical care. About 35% work in haemodialysis and about 20% in maintenance. Others work in respiratory care, operating rooms, intensive care units, heart related, hyperbaric and other areas. In 1987 the clinical engineering system was established by the Clinical Engineers Act. This act created the CET as a professional medical position responsible for the operation and maintenance of life-support systems under the direction of doctors. This act established a national qualification including a 180-question exam in medicine, engineering and medical technology. In 2010 there were about 28 000 certified CETs and about 18 000 currently working in the field. The certification of CETs is most equivalent to the CBET in the ICC system in the United States of America.*(80,81)*

In addition to the CET certification by the government, the Japan Society for Medical and Biological Engineering has a BME certificate programme, which has two classes of certification for biomedical engineers. The first is for experienced clinical engineers and in 2008 the pass rate was 22.2% for 433 applicants. This exam covers basic aspects of medical engineering and medical device related subjects. The second exam is for students or recent graduates of clinical engineering and many take it as preparation for the national CET exam. In 2008 the pass rate for this exam was 29.3% for 1398 applicants.*(82)*

4.3.4 Certification in Europe

In the European Union BME is not a regulated profession; hence there is no centralized, common certification programme that establishes certification standards for all European Union Member States. Further research will be needed to develop a strategy for official acknowledgement and certification for biomedical engineers in this region.

Czech Republic

Since 2004, the Act on Nonmedical Health Service Occupations and related regulations has recognized health service professionals with technical competences (biomedical technicians with a BSc in biomedical technology and biomedical engineers with a MSc in biomedical engineering) and health service specialists with specialized technical competences (clinical technicians with BSc in clinical technology and clinical engineers with a MSc in clinical engineering), in addition to similar legislation that had existed for decades for medical professionals. If workers with technical competences come into contact with patients or if they can directly impact patient health through their professional activities, they are required to have the qualification of either health service professional or health service specialist. There is an established system of both undergraduate and postgraduate, specialized and life-long education, accredited by ministries of education and health, to gain qualifications and appropriate certifications.

The graduates of accredited study programmes and fields get a certificate of qualification to perform health service occupations. Graduates of other BSc or MSc study programmes in electrical engineering can obtain a qualification for health service workers with technical competence if they complete the course in BME (MSc in engineering) or biomedical technology (BSc) accredited by the Ministry of Health. Graduates of other study programmes must complete specialized postgraduate courses in BME. The specialized technical competences for clinical technicians and clinical engineers can be obtained by completing specialized education and training provided by institutions accredited by the Ministry of Health, and by passing an official examination in front of the board appointed by the Ministry of Health. Clinical engineering as specialized education and training for biomedical engineers, and clinical technology for biomedical technicians are types of education organized by the Institute for Postgraduate Education in Health directly controlled by the Ministry of Health.

The Ministry of Health issues the official certificates for biomedical technicians/engineers and clinical technicians/engineers. Then they can apply for registration in the Registry of Health Care Professionals, which is a part of the National Health Care Information System. They receive a certificate that is valid for six years and renewable thereafter under defined criteria.*(83)*

Germany

Germany has developed a certified clinical engineering programme, but it does not require an exam. It is based on experience and academic background. They are also planning to develop a certified BMET programme. In most European countries, there are more engineers than technicians and so the certification of the engineer is more important.

Ireland

In 2003, in anticipation of forthcoming legislation for Statutory Registration of Health and Social Care Professions, the Biomedical Engineering Association of Ireland and Biomedical Engineering Division of Engineers Ireland established the Clinical Engineering Voluntary Registration Board and an associated clinical engineering registration scheme, as a voluntary professional registration plan. The Clinical Engineering Voluntary Registration Board was composed of engineers from academia, practitioners from the public and private sector, and representatives of publically and privately funded hospitals. The plan considered education, clinical engineering experience, ethics, professional standing and continuing professional development (CPD).

The plan is based on achieving Engineers Ireland's professional titles (engineering technician, associate engineer and chartered engineer). Engineers Ireland has statutory responsibility for the title of "chartered engineer" in Ireland. The three protected titles of Engineers Ireland require the achievement of a specified academic standard, a specified minimum number of years of experience, an interview based on a set of published competencies, and an engagement with a code of ethics. Engineers Ireland also has a well-developed plan to support "grandfathering" with a process which recognizes experience in lieu of academic qualifications by assessing candidates' ability with respect to specific competencies. In addition, the plan includes an application form where two recognized practitioners sign-off on the candidates' experience in the clinical engineering field. A voluntary CPD scheme was also developed. Since clinical engineering is a small profession in Ireland, statutory registration will not be implemented for some years. It is thought the Clinical Engineering Voluntary Registration Board plan will meet the short-term requirements for a registration plan.*(84)*

Italy

In Italy, a process of defining common rules for recognizing the activities of biomedical and clinical engineers and for the certification of the skills of engineers is currently in progress. The Territorial Associations of Professional Engineers have the right to set up voluntary certification of skills for their members. Recent Italian laws have explicitly mentioned clinical engineers and clinical engineering services, making the need for a certification procedure more pressing. The laws state that the Territorial Associations of Professional Engineers are responsible for defining a set of rules for certification. The document, being drafted by local BME committees, will identify a metric of evaluation that is based on the verification of the contents of the documents submitted for the recognition of skills, on the interview with the candidate and on the evidence for continuity of professional activity.*(85)*

Poland

In 2002 the programme of specialization in medical engineering for engineers as professionals in clinical environments was introduced by national legislation, under the auspices of the Ministry of Health, the Medical Centre of Postgraduate Education and the national consultant in the field of medical engineering, in a way similar to education and training programmes for medical professionals. The candidates for this specialization must have a MSc in BME, automatics and robotics, electronics and telecommunications, mechanical engineering or computer science, and at least three years' work experience in a clinical environment. The workload of this postgraduate medical engineering specialization programme is 1700 hours over two to three years, with about half filled with lectures and laboratory exercises, and the rest placement in hospitals and clinics with appropriate facilities, equipment and staff for such activity, and being accredited by the State Commission for Accreditation.

At the end of the programme, in order to obtain the title and the certification as a specialist in medical engineering, the candidate has to pass the practical and theoretical parts of the state exam in front of the State Examination Commission. Professional competences gained during postgraduate education, entitles successful individuals to work in clinical environments as a medical engineer. Moreover, a participation of certified specialists in medical engineering in some advanced medical procedures is also required by law, as well as in the positions of national and regional consultants for medical engineering issues.*(86)*

Sweden

The Swedish Society for Medical Engineering and Physics started the Certification of Clinical Engineers in 1994. The certification is performed by an examination at two levels, corresponding approximately to BSc and MSc degrees in engineering, respectively. The BSc in engineering, as the lower level of certification, was chosen because in 1989 a Swedish law came into force, stating that a worker should preferably have at least this level of education to work in clinical engineering. At the time, there were many engineers working in clinical engineering departments in hospitals who did not possess a BSc but rather an older degree from a polytechnic institute. These engineers were accepted for certification if their degree dated 1989 or earlier, but they had to have at least six years' instead of three years' work experience.
Applications for certification are sent to the society twice a year, and are reviewed and judged by a certification committee with the mandate from the society's board. The certification committee consists of a chair (preferably a lawyer from a state health-care organization or a health-care provider), two university professors in BME, and two experienced certified clinical engineers.

The requirements, besides the engineering degree and minimum three years' hospital work experience as a clinical engineer supervised by an experienced and preferably certified clinical engineer, are university/institution/company courses in biomedical or clinical engineering, medicine or related fields corresponding to at least 30 ECTS points assigned and collected under defined criteria. Since 1994, there have been a total of 695 applications, 571 at BSc level and 124 at MSc. Some 391 have been certified (304 BSc and 87 MSc).

A programme that certifies specialists in clinical engineering was developed in 2014. To become a certified specialist in clinical engineering, the engineer should have at least two years' specialist training supervised by an experienced and certified specialist in clinical engineering. The specialist training programme consists of courses corresponding to CPD, which are classified by the certification committee. Specialist training years should equal a minimum of 30 ECTS points. Certification of specialists is also performed at both BSc and MSc level in engineering. To keep specialist certification, clinical engineers should continue with their professional development through ongoing training and education. Different specialist programmes are currently under development: medical imaging, dialysis, intensive care, computers in health care, responsibility and management, etc.*(87)*

United Kingdom

The United Kingdom initially developed a certification for clinical engineers in the 1990s but this programme has been dropped due to lack of interest. Currently there is voluntary registration for clinical scientists and clinical technologists, which includes professionals working in the field of clinical engineering and medical physics.

Credit: Adriana Velazquez; launch of the European Parliament interest group in biomedical engineering, May 2016.

PART II: THE PRACTICE OF BIOMEDICAL ENGINEERING

5 Development of medical devices policy

5.1 Introduction

Only in recent years have biomedical engineers begun moving into senior positions in governments, international organizations, hospitals, academia and the medical devices industry. This chapter presents a profile of their activities, within these different settings, at senior management level and considers the roles biomedical engineers can have in the planning and development of health technology policies and in the implementation of medical devices policies at government and international organization level.

5.2 International organizations

A few international organizations and NGOs with an agenda in public health engage biomedical engineers, including United Nations agencies such as UNICEF and WHO and Doctors Without Borders.

However, according to the January 2015 Global Survey - Professional and Academic Profiles on Biomedical Engineers and Technicians, their numbers are still very limited. Worldwide, Doctors Without Borders currently employs 12 biomedical engineers, UNICEF six and Medics Without Vacations (which contributes to the sustainable improvement of care in African hospitals) only one. Although some biomedical engineers exist in this capacity, many more are needed for a better understanding of, and advocacy for, the exploration of new medical technologies and their role in achieving the aims of these global institutions.

The United Nations family includes various global organizations, but the 2015 survey indicates only the United Nations Population Fund (UNFPA), United Nations Office for Project Services (UNOPS), UNICEF and WHO with staff with a BME profile. Key organizations such as the Word Bank, World Trade Organization and World Intellectual Property Organization, even though all deal with procurement, trade or intellectual property and medical technologies, do not have positions for biomedical engineers. They do have specialists in the area of health products, mainly dedicated to medicines, but are lacking the expertise of biomedical engineers or related fields, to target the medical devices challenges.

An explanation of what biomedical engineers undertake in the different organizations will be presented.

5.2.1 United Nations Population Fund

In support of reproductive health and maternal health programmes and services, UNFPA procures medical devices and medical equipment in the following categories: medical and surgical instruments, diagnostic, laboratory, medical electrical, anaesthetic, sterilization, medical renewable supplies, medical attire and medical utensils. A full list of commodities can be found at: https://www.unfpaprocurement.org/products

In collaboration with partners, UNFPA has developed interagency reproductive health kits for use in crisis situations. These kits have been designed to facilitate the provision of priority reproductive health services to displaced populations without medical facilities, or where medical facilities are disrupted during a crisis. They contain essential medical equipment and supplies and medicines to be used for a limited period of time and a specific number of people. In addition, UNFPA, following input from health-care professionals and other experts, has compiled a number of standardized surgical sets for sexual and reproductive health procedures.

Because quality is crucial to UNFPA, efforts are made to ensure, in line with international standards and guidelines, that the medical devices provided to relevant countries are safe and of good quality. The quality assurance (QA) process is conducted by the team in the QA Cluster in collaboration with the technical division, with assistance from external technical experts where necessary.

5.2.2 United Nations Office for Project Services

This agency is an operational arm of the United Nations, supporting the successful implementation of its partners' peacebuilding, humanitarian and development projects around the world. It provides project management, procurement and infrastructure services to governments, donors and United Nations organizations.

In Latin America and the Caribbean, UNOPS manages health projects from the planning, design, construction and reconstruction of health facilities, to the procurement of medical equipment and medicines, including the analysis and reorganization of the supply chain at national or institutional levels.

In 2015, UNOPS was involved in implementing 28 health projects in Latin America and the Caribbean and created a professional network on health, including 20 biomedical engineers, specialists and professionals related to medical technology. This network is present in 15 countries, promoting the sharing of knowledge, skills and experiences, to support health projects, increasing the effectiveness and efficiency of all those specialized services provided by UNOPS, and optimizing the technical resources inside the organization.

In the medical equipment field, UNOPS supports the equipment of existing or new hospitals, like the Gonaïves Hospital in Haiti, the Dr Alejandro Davila Bolaños Hospital in Nicaragua and the 24 health facilities for the Social Security Institutes in Guatemala and Panama, which it is assisting in building.

In 2014, UNOPS supported the Honduras Ministry of Health in the renegotiation of an existing contract to purchase and maintain medical equipment, generating US$ 47 million in savings. In 2014 and 2015, UNOPS supported the Social Security Institute of Panama to build a national teleradiology network connecting 38 health facilities throughout the country: investment value US$ 89 million, including equipment renewal and radiology information system/picture archiving and communication system (RIS/PACS) implementation. Further information can be found at: https://www.unops.org/english/About/Pages/default.aspx

5.2.3 United Nations Children's Fund

The health technology area in UNICEF's Supply Division in Copenhagen deals with procurement, supply chain of essential products, including medical devices and assistive devices for children in low-resource settings. Biomedical engineers play an essential role within UNICEF, providing medical device expertise along the entire supply chain for essential medical supplies for health programmes and emergency response.

UNICEF works in over 190 countries globally to promote the rights of children and is a major source of health, nutrition, education, water and sanitation and child protection supplies in low-resource settings. In 2014, for example, UNICEF procured US$ 3.3 billion worth of supplies for development programmes and humanitarian emergencies, of which approximately US$ 140 million was medical devices and kits for maternal, newborn and child health (MNCH) interventions.

UNICEF has five health technology managers currently working on medical devices and medical kits. They include two biomedical engineers, two biomedical scientists and one clinician. They work in the technical team within the Medical Devices Unit of the Health Technology Centre, and are responsible for the technical aspects of the selection and procurement of over 800 medical and clinical laboratory devices that form UNICEF's standard product range, which can be seen at: https://supply.unicef.org/unicef_b2c/app/displayApp/(layout=7.0-12_1_66_67_115&carea=%24ROOT)/.do?rf=y

The technical aspects of the work include outlining the need for the devices, developing specifications, ensuring relevant QA standards are met and overseeing how the devices perform technically in the field. Within the Medical Devices Unit, there is also a team of contracting colleagues, who focus on all the commercial aspects of the procurement exercise and are accountable for an understanding of the market for all of the devices in the portfolio.

In the Health Technology Centre more broadly, three additional units oversee the technical and commercial aspects of procurement of injection devices, cold chain equipment, rapid diagnostic tests and bed nets; several of the technical staff in these units are also biomedical engineers by training.

The Medical Devices Unit's technical team is also responsible for developing and managing medical kits for emergency response and health system replenishment, often in coordination with WHO and other United Nations partner agencies. In addition to medical and clinical laboratory devices and medical kits, UNICEF's biomedical engineers are product experts on in vitro diagnostics, personal protective equipment (PPE) used in health emergencies, such as the Ebola response, as well as assistive health technologies (AHTs) for children with disabilities, and training products for health-care workers on essential MNCH interventions.

In addition to managing medical device procurement, the team advises on supply chain management and health technology management in-country, beginning with needs assessments. They also work closely with WHO and other partners to foster product innovation, produce guidance for medical device selection in low-resource settings and harmonize specifications for essential supplies for MNCH. The biomedical engineers also conduct fit for purpose evaluations and market research on essential, strategic devices.

Some examples of current projects the team is managing include: strengthening MNCH services in the Democratic Republic of the Congo through the supply of medical devices to equip 200 hospitals and 1000 health centres nationwide; leading two projects to foster innovation for child wheelchair solutions for use in emergencies and for improved acute respiratory infection diagnosis for children in their communities; and working with partners to evaluate new point of care HIV diagnostics in seven African countries. Their expertise is essential to ensuring quality medical devices are available where they are most needed.

5.2.4 World Health Organization

The primary role of WHO is to direct and coordinate international health within the United Nations system. The main areas of work, are: health systems, promoting health through the life course, noncommunicable and communicable diseases, and preparedness, surveillance and response.

One of the six strategic objectives of WHO is to increase access to health products, which include medical and assistive devices, vaccines and medicines. However, the medical devices work has historically received less resources than medicines and vaccines. And so in 2016, very few staff work in this area; only .05% of the WHO staff have a BME background, which include five staff in headquarters working on: prequalification of in vitro diagnosis; in vitro diagnostic innovation; assistive technologies; and a senior advisor on policies, selection, assessment and procurement of medical devices. Outside headquarters, only one biomedical engineer is engaged as a senior advisor on health technologies – in the EMR region and two in country offices (Iraq and Brazil). Each year, the Medical Devices Unit benefits from around 10 interns from different countries or university programmes and volunteers who work on a range of projects. Not all the interns have a BME background; some are medical doctors, health economists, nurses, international relations, lawyers and other engineers.

The team uses its technical knowledge to provide resources to support the development of medical devices policies, regulation, innovation, health technology assessment and health technology management of medical devices and a diverse range of publications annually. Guidance on how to increase access to safe, effective and affordable and appropriate medical technologies to meet the global needs is the objective. Recent publications include the 18-book *Medical device technical series, the annual Compendium of Innovative Technologies* for Low Resource Settings and numerous technical specifications. The team is currently developing the following Essential Lists of Medical Devices: for reproductive, maternal, newborn and child health; for all stages of cancer care; and for ageing populations. Other key areas in which the team is involved include, medical devices pricing and feasibility tools for local production, PPE and medical devices for emergencies or for outbreak response and preparedness.

The team's wide ranging involvement and contribution demonstrate the need for ongoing interdepartmental and interagency collaboration within international organizations – specifically between researchers, policy-makers and biomedical engineers. This is to ensure that advancements in the understanding of diseases and treatments and WHO recommendations, are in synchrony with the availability of effective, reliable and affordable medical technologies, with which to administer these solutions.

The Medical Devices Unit currently has eight collaborating centres (in Brazil, Canada, China, Colombia, India, Mexico and United States, many of which are led by biomedical engineers) and maintains official relations with 16 NGOs*(88)*, specialized in different fields related to medical devices, like pathology, laboratory, radiology, BME, hospital engineering and medical devices trade associations, among others. Ideally in the future, more BME experts will become staff in regional offices and country offices to incentivize the work around medical devices at country level.

More information on publications and global collaboration can be found at: http://www.who.int/medical_devices/en/

5.3 National organizations

Generally, every ministry of health has an agency, unit or service dealing with health technologies and medical devices with different functions and objectives depending on the country and whether it is a low- or High income nation.

The specialized staff in these units support the formulation, monitoring and evaluation of national health technologies policies within the national health plan. They may also liaise between the national regulatory authority section on medical devices, national reimbursement and procurement units and allocation of resources. They participate in working groups established by the health ministry for sector strategies in cooperation with other ministries for the issues related to health, environment, economy or in case of emergencies and disasters.

There are key units in ministries of health where a biomedical engineer can have a substantive role:

Regulatory agency:

- It is proposed that the medical devices should be analysed by specialized human resources like biomedical engineers who can understand the standards compliance, the parts involved in the equipment or the use the devices will have and the risk level and the importance of quality.
- Management and participation in the process of the adverse event reporting process.
- Preparation of the process of medical device recalls or limitation in their use when incidents related to safety are encountered.
- In the registration of the device for market approval.

Refer also to Chapter 7.

Health technology agency or reimbursement commission or similar:

- To support the assessment of the medical devices, understand not just the cost effectiveness but the relation of the device within the package of interventions that will be supported by a benefits package in the health system.
- To define the "positive list" or "basic/ priority medical devices authorized for public procurement".
- Establishing and updating a standard equipment list in line with the national package of health-care interventions, in the framework of universal health coverage (UHC).

Refer also to Chapter 8.

Health technology management national unit or similar:

- Coordinating medical devices maintenance and put in place planned preventive maintenance (PPM) standard procedures for health technologies.
- Management and participation in the political documents preparation (orders of the minister, policy documents, recommendations and guidelines) regarding the selection, distribution, use, and maintenance of medical devices.

- Preparation and/or approval of medical devices technical specifications, aiming at the best procurement for resource allocations or standardization of health technologies used in public hospitals and increase in quality of care.
- Promoting the use of appropriate medical equipment accordingly to interventions for the established levels of medical care, depending on the population needs.

Refer also to Chapter 9.

Participation in **procurement procedures** when high and sophisticated technology is being procured centrally (CTs, MRIs, etc.) at the ministry of health.

However, the majority of countries aim to establish medical devices management policies and instruments, for a safe, appropriate and efficient use of technology in the national health system.

Traditionally a clinical engineer figure is associated with hospital environments and a biomedical engineer with research and academia; but either profile, combined with extensive expertise and technical knowledge in the field, would allow them to work at senior level in health-care institutions, and at national level, in particular, ministries of health or in international organizations.

5.4 World Health Organization – medical devices

It should be noted that development of national health technology policies requires full expertise in the field and collaboration with colleagues in the ministry of health developing the national health plan. As the WHO *Medical device technical series* demonstrates, it is very important that health technology policies are aligned with the national health policies and plans of the country. This includes all aspects of research and development, selection, use of medical devices according to country needs, available infrastructure and specialized human resources for health delivery. Working at higher levels requires not only knowledge of BME core competencies but additional skills in strategic management, planning, monitoring and prioritization, among others. WHO has requested ministries of health in Member States to nominate a focal point for medical devices retrieval and dissemination of technical information. These designated individuals liaise with the medical devices staff in WHO and are part of an information network to allow global communication to enhance the best use of medical devices globally according to country needs.*(89)*

5.5 Conclusion

The challenges are enormous but the medical technologies require good management at all levels – international, country and health facility – and thus the biomedical engineer and related professions should have the tools and background to further develop this important area of health-care services.

Successful biomedical engineers have become senior managers and leaders, and it is important to promote their role model in any institutions, countries and international organizations that manage, use or advise on health technologies, especially medical devices to target priority health needs in Member States.

Credit: Kelso lab setting, CIGHT @ NU; biomedical engineers demonstrate the simplicity and accuracy of a rapid test for infant HIV developed at the Center for Innovation in Global Health Technologies (CIGHT) at Northwestern University, Chicago.

6 Medical device research and innovation

This chapter offers insights on how biomedical engineers can lead the innovation process in the design of medical devices to respond to health needs, paying particular attention to the roles and responsibilities they may have in different sectors and resource settings.

6.1 Introduction

The world has changed greatly since the 1950s and the dawn of the electronic age when innovators such as Wilson Greatbach, an assistant professor of electrical engineering at the University of Buffalo in the United States of America, built the first cardiac pacemaker in his garage. The regulatory requirements alone could render such a scenario impossible today. And yet there are some similarities with those times 60 years ago. With software now also classified as a medical device, why couldn't a student at any university, say, develop a new mobile phone or tablet app that would have the same impact in terms of health outcomes that Greatbach's invention has achieved globally?

Therein lies the excitement of medical device innovation, attracting some of the brightest talent on the one hand while on the other maintaining a multi-billion dollar global industry, and given the wide range of medical devices, from a syringe to a MRI scanner (there are some 10 000 generic items in the medical device universe) and changing disease patterns globally, there remains a strong demand for investment in medical device innovation, with biomedical engineers in particular playing a central role.

That medical devices (including in vitro diagnostics) play an important role in health care at all levels of health system delivery, and in both well resourced and poorly resourced settings, is widely accepted. Yet there remain many challenges, globally in optimizing the technology mix to ensure optimal efficiencies (both allocative and technical). WHO has been instrumental in helping address these challenges with, inter alia, the publication of a series of technical guides covering many aspects of the health technology/medical device life cycle (*Medical device technical series*). WHO has also played a leading role in examining and supporting the role of medical device innovation, with a particular focus on developing countries.*(90)*

It is worth noting at this point that there are different types of generic innovation, ranging from basic research to incremental (by far the most common type of innovation in the context of medical devices), breakthrough, disruptive and sustaining (see Table 6.1).

The following disclaimer should be noted with regard to this chapter. There are many texts dealing with medical device innovation as well as with the various fields of BME research. This chapter therefore, aims to provide an overview of medical device innovation from the perspective of applied biomedical engineering to underline the importance of the knowledge, skills and competencies of the thousands of individuals and teams that engage themselves in both the art and the science of medical device innovation. Space constraints do not allow for in-depth examination of all the many relevant issues.

Table 6.1 Innovation matrix for biomedical devices

Disease focus	Single disease	Multiple disease							
Component of disease burden addressed	Mortality	Morbidity	Both						
Targeted level of health-care delivery	Individual focus (self-care)	Community-based	Primary	Secondary	Tertiary	Specialized	Combination	All	
Phase of care	Preventive/ promotive	Screening	Diagnose	Treatment	Palliation	Rehabilitation	Assistive	Combination	All
Scope of market	Country	Region	Global						
Target patient group(s)	Infants	Children	Women	Mothers	Disabled	Men (adult)	Adolescents	Combination	All
Type of health technology	Basic (e.g. water)	Medical consumable	Accessory to existing medical device	Medical device (low complexity)	Medical device (medium complexity)	Medical device (high complexity)	Information system	Management/ process intervention	Other
Type of innovation	Basic technology/ cross cutting/ upstream	Product/Device	Process	Financial	Other				
Level of innovation	Incremental	Sustaining	Disruptive	Breakthrough	Game changer	Adapted (tech transfer)			
Anticipated impact	Improved resource utilization	Improved access/ coverage	Improved service delivery	Improved patient safety/quality of care	Improved health outcomes	Combination			
Level of development of targeted market(s)	Low	Medium	High	Combination					
Level of infrastructure needed	None	Low	Medium	High	Combination				
Product cycle	Specification	Development	Commercialization	Manufacturing	Marketing/ distribution	Adoption/ incorporation	Utilization/ support	Discontinuation/ disposal	
Innovation functional areas	Needs assessment	Research and Development	Cross-functional management	Legal/IP	Regulatory	Quality	Clinical	Manufacturing	Financial (incl. reimbursement)
Stakeholders	Individuals	Communities	Health professionals	Health technology regulators/ standards bodies	Health-care providers	Government/ policy-makers	NGOs	Private sector/ industry	Medical insurance companies/health-care funders

6.2 The field of medical device innovation

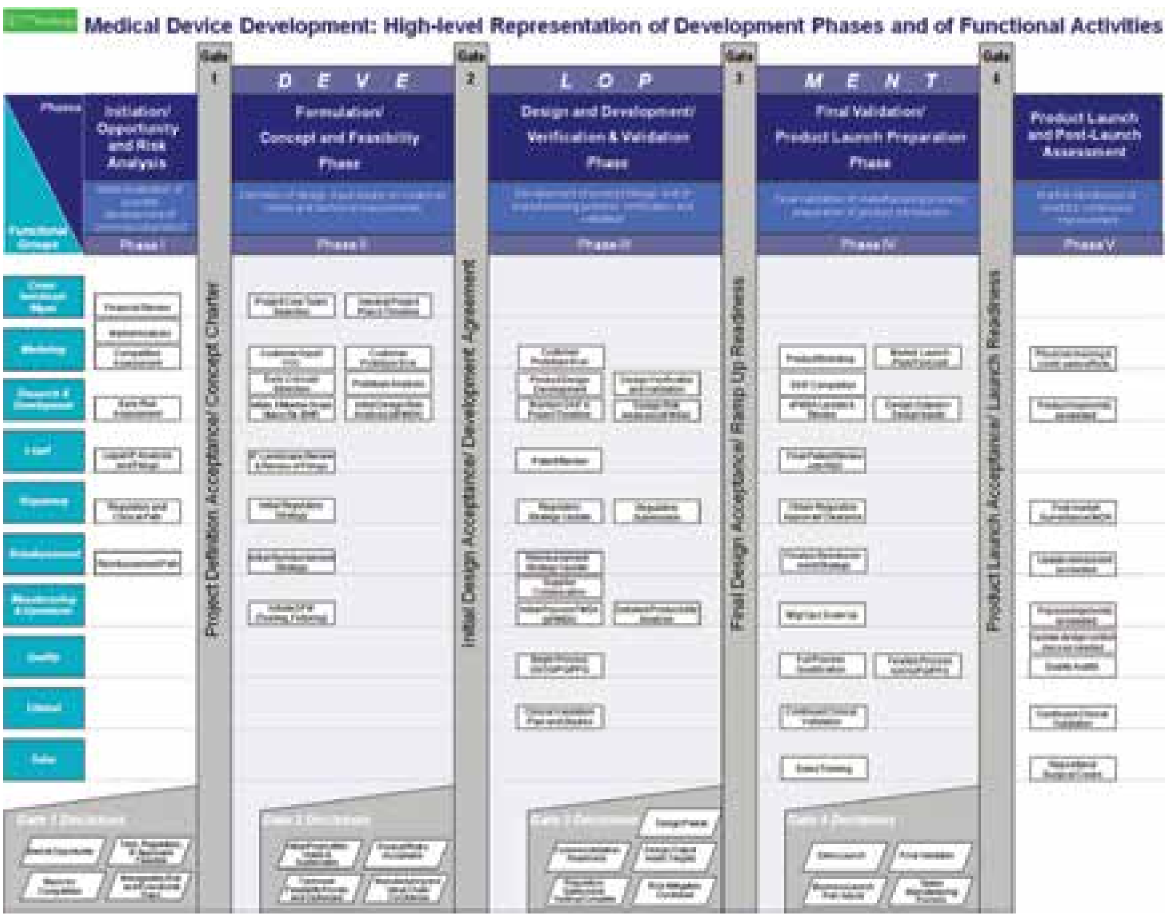
Table 6.1 shows the multiple dimensions and layers associated with medical device innovation; it is worth noting that each cell in the matrix – assuming all others remain unchanged – could be associated with any number of innovations and, by extension, BME practitioners with very different skills sets.

There are many models to support the medical device innovation process and, as mentioned earlier, it is not the intention here to dwell on these. The United Kingdom's Design Council in 2005 defined a four-stage innovation process (Figure 6.1): discover, define, develop, deliver.*(91)* Such (generic) expressions of best-practice design are brought to fruition when the principles of people-centred research and inclusive (universal) design are combined, coupled with collaboration between engineers, clinicians and other members of the innovation teams.*(92)*

6.3 Innovation competencies

Some of the core competencies biomedical engineers will need for innovation in high-resource settings are illustrated in the "stage-gate process model" developed at Stanford University, as unpacked below ((Figure 6.1).*(93)* They include, among others: academic and corporate R&D, device prototyping, clinical trials, manufacturing processes, regulatory

Figure 6.1 Biodesign model (innovation phases) (functional groups and activities)



Source: Pietzsch JB et al (2009). Stage-gate process for the development of medical devices. *Journal of Medical Devices.*

requirements, intellectual property law, cross-functional management, reimbursement policy, facility operations, quality controls, clinical practices, marketing and sales. The model identifies five phases of development, with four decision gates to evaluate whether to proceed with the innovation effort. The phases involve coordination of multidisciplinary fact-finding, consultations and evidence-based reviews that assess the readiness of the innovation to move to the next phase.

While such models increase the chances of success, they are not of themselves determinants of success. The importance of people with the requisite skills and teams with the right balance of skills are key.

6.4 Skills requirements

The previous section suggests that a wide range of skills are required as part of the medical device innovation process and related activities. Even if we were to focus on the roles of biomedical engineers, skills requirements at a particular step in the innovation process for a specific technology would typically require the collective and complementary skills of a number of individuals, each on their own skills development trajectory*(94)* and career path (the important role of teams is addressed in the next section). The skill sets would also differ depending on whether the biomedical engineers were in an academic, health-care or industry setting. Since academic and health-care settings are covered elsewhere in this publication, the focus here will be on industry.

Increasingly dynamic environments also require industrial firms to focus on: (a) building market-driven, technological and integration competencies, not a stream of product improvements; and (b) decoupling these competencies from current products in order to create and exploit new opportunities.*(95)* Given that a product-centred perspective provides little insight or guidance about the process by which a firm's strategy can contribute to its future success, the distinction between a firm's products and the underlying competencies used to create its products has led to increased exploration of how competencies are developed over time. In environments characterized by rapid change, accelerating product life cycles and technological discontinuities, traditional product-centred strategies provide little long-term strategic advantage.*(96)* These realities have led to renewed efforts to understand how firms can develop dynamic capabilities that enable them to adapt, integrate and reconfigure their skills and competencies. Cascaded down to individual level, it becomes clear that biomedical engineers working in such settings should remain tapped into such trends and adapt/adjust their own competencies as needed.

This applies also to the medical device sector, be it in developed or developing country settings. In the case of the former, the medical device industry has conducted situational analyses to help ensure that the capacity development pipeline continues to provide the skills in the mixes and numbers required. As an example, a 2007 Australian report*(97)* identified skills shortages and skills gaps existing for product R&D engineers, business development and project management personnel, and regulatory affairs specialists, amongst others, with the greatest needs concentrated at the pre-manufacturing start-up level. An Irish report*(98)* highlighted the need – based on evidence from study visits to America – to increase entrepreneurial activity in order to develop new businesses, whether stand-alone businesses or within existing companies. The report also saw great potential for developing opportunities related to deepening technological convergence in the area of medical devices. This convergence will impact on skills requirements in a number of ways: it will broaden the range of disciplines that are core to the medical devices sector, from mechanical engineering, BME, materials engineering and medicine, to also include biological sciences, electronic engineering, pharmacology and chemistry. Technologies that will emerge that are core to areas of convergence will have to be understood by significant numbers of people from different disciplines.

6.5 Innovation and teams

Health professionals (most often as users), health-care experts, patients and their advocates seek technologies to meet health needs. Innovators – be they engineers, material scientists, systems specialists, biologists and others – seek beneficial use for their technologies. The challenge lies in exploring potential matches between these two camps. In some cases, one person completely bridges the two but more often the task, nowadays, requires organized teams.*(99)*

The importance of team composition is highlighted by the Stanford University Biodesign Program leadership in their review of the first 12 years of the programme.*(100)* While ranking dedicated mentorship as the most critical component of the programme, they emphasize the importance of having more than just a mix of different engineering and medical backgrounds and suggest four main profiles of "innovation personalities":

- The *builder,* well-versed in design and prototyping.
- The *organizer,* with the skills to keep the team on track.
- The *researcher,* who will extract maximum value from the existing body of clinical, engineering and business literature.
- The *clinician,* who understands the complex issues associated with introducing a new technology into clinical practice.

In their view, "individual team members may be more than one of these phenotypes, but all four need to be represented in the team for it to be highly functional". The reviewers also highlight the importance of managing interpersonal dynamics and communication within a multidisciplinary team, and the need to learn to navigate potential conflict.

The important roles of stakeholders impacting on the medical device innovation and diffusion processes, including users, patients (and their advocates), health economists, government officials, health-care managers, insurers and regulators must also be recognized.*(101)* These increasingly contribute to identifying needs and demands for new technologies as well as determining which of these will be integrated into mainstream care, how they will be used, distributed, paid for, evaluated and monitored. As such, they are significant determinants of successful innovation; and innovators need to develop the skills to manage the many interaction/engagement interfaces.

6.6 The innovation process and its increasing scope

Although the stage-gate model, unpacked in Figure 6.1 provides a detailed overview of the medical device innovation process, significant opportunities for innovation lie both upstream and downstream of the process as indicated.

Upstream, forecasting the cost implications of a new technology early in the innovation process *(102)* is being increasingly accepted as a valuable contribution to ensuring affordable implementation (often linked to reimbursement) and therefore greater likelihood of successful adoption and utilization; this is closely linked to what is known as early stage health technology assessment. HTA, in its own right, currently plays an important role in decisions relating to adoption of health-care interventions and related technologies and devices.*(103)*

Downstream opportunities include (adding value through provision of product-related services, i.e. viewing the product sale as a way to open the door for provision of future services. In many industries today, the sale of a product accounts for only a small portion of overall revenues. *(104)* The spectrum of downstream opportunities includes embedded services and/or comprehensive services, integrated solutions and distribution control. Particularly in resource-scarce settings, where medical devices are often donated, downstream innovations linked to user training, technical support and maintenance, calibration and testing, etc. present significant opportunities for innovation. In this context, medical devices should be seen as part of an integrated technology package, rather than as isolated products.

6.7 Medical device innovation for low-resource settings

It is widely recognized that many diseases affecting millions of poor people in low-resource settings are not being addressed by the pharmaceutical industry since the demand for drugs that would address this component of the global diseases burden is driven by the ability of consumers/ beneficiaries to pay.*(105)* In some instances, as has been the case with the waiving of patents for HIV-related drugs by select multinationals in order for these to be made available affordably, stakeholders are able to agree on more appropriate business models, at least in terms of incentives relating to supply and demand. Even so, distribution of these much-needed interventions is hampered by weak health systems.

Much the same also applies to medical devices, given that almost 80% of medical devices in Low income countries (LICs) are acquired by donation,*(106)* and given the absence of technical support capability in many low-resource settings, these countries continue to rely on donations to replace devices and equipment that cannot be maintained or repaired. Non-governmental organizations such as Engineering World Health (EWH) have established a niche in filling the gap with regard to technical support in some LICs, although needs continue to far outstrip the supply of adequate capability.

In addition to donations, medical devices are also acquired through technology transfer: local production of devices that resemble technology designed for use in High income countries (HICs) or the low-cost sale of older models of devices originally designed for use in HICs.*(107)* However, use of medical devices in LICs that were originally designed for use in HICs is not entirely successful; one study noted that 40% of medical devices were dysfunctional in LICs versus less than 1% in HICs.(*104,108)* In LICs, constraints including unreliable energy supply and water, limited distribution and infrastructure, inadequate or untrained workforces, lack of spare parts, required consumables, and high costs affect the availability and acceptability of many devices.*(109)* A more recent and emerging practice is for medical devices multinationals to establish a presence in selected LICs to design and manufacture devices that are appropriate for local needs and conditions, and therefore perform better and are more sustainable than devices acquired through other means; General Electric's Healthymagination and related activities in India is a case in point.*(110)* Such initiatives will significantly promote the development of BME capability that is best suited to respond to local needs through appropriate innovations.

The limited availability of highly trained health providers presents another extraordinary challenge in providing universal quality care. For instance, while Africa bears more than 24% of the global burden of disease, it only has access to 2% of the global supply of physicians;*(111)* 47% of the WHO Member States reported having less than one physician per 1000 population.*(112)* The mismatch reported between the number of commercially available medical devices and the projected global burden of disease, as well as the limited number of available devices designed for use in primary health-care facilities by lay health workers (30 out of 358 medical devices) will challenge policy-makers and the global health community to provide intellectual, financial and regulatory support in order to develop the necessary technology in a timely manner. *(113)* Although it is not possible to separate the effects of medical devices from the effects of social, political, economic and health-care measures on mortality in LICs,(*106)* availability and accessibility of medical devices are important and, if part of a comprehensive solution, can positively impact global mortality and morbidity trends.

This poses a design challenge on how to develop medical devices that are simple enough to use that lay health providers can deliver or perform some of the more common and urgent health services and tasks previously undertaken only by highly trained health providers. This can have a tremendous implication for both developing and developed countries. Such, presumably task shifting, medical devices may benefit low-resource settings that have limited access to highly trained physicians, and high-resource settings by informing the design and development of easy to use medical devices that may be suitable for home-based health-care services, or for lower cost hospital services.

WHO has been instrumental in supporting the innovation of medical devices for low-resource settings, particularly through initiatives such as its *Compendium of innovative health technologies for low-resource settings: Assistive devices, eHealth solutions, medical devices* published in 2014. The objective of the compendium series is to provide a neutral platform for technologies which are likely to be suitable for use in low-resource settings. It presents a snapshot of several health technologies which might have the potential to improve health outcomes and the quality of life, or to offer a solution to an unmet medical/health technology need. It celebrates notable success stories while raising awareness of the pressing need for appropriate and affordable design solutions and to encourage more innovative efforts in the field. This effort also aims to encourage greater interaction among ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics and the general public, to ensure greater investment in health technology and to move towards universal access to essential health technologies.

Resources such as the WHO compendium serve as effective stimulants of further R&D and innovation of medical devices for low-resource settings, as well as supporting the development of local and regional capabilities. The constraints typical of low-resource settings also present opportunities for innovation by encouraging the design of devices that are adaptable to the realities of health care in these settings, such as unreliable power supplies, the lack of user training and technical support and low budgets to procure consumables/ disposable.*(114)* Innovators wishing to be successful in bridging the significant resource gap between developed and developing nations need to immerse themselves in resource-scarce settings to fully understand the solutions they need to deliver, and how.

The importance of human factors is a determinant of "user-friendliness" and therefore greater likelihood of correct and safe operation of devices. While consideration of human factors is important for devices intended for any setting,*(115,116)* it is particularly relevant to low-resource settings where users may have received less exposure to technologies generally and medical devices specifically, and little or no user support is available (this is very common for equipment donations, with medical devices and their accessories and consumables often sourced from different manufacturers, making it practically impossible to standardize). Increasing attention is also being focused on the concept of *jugaad* innovation – cost-effective technologies developed for low-resource settings – and emerging market needs being taken to developed country settings and markets.*(117,118)*

Lastly, medical device innovations should be seen – through an integrating lens – as part of a broader set of health-related technology innovations since the needs of communities in low-resource settings are multiple and multifaceted, and similar approaches and tools can be used to address them. Importantly, devices or technologies alone are not enough – they need to be combined with innovations in processes and health systems strengthening as well as matching interventions in other sectors*(119)* to have the optimal effect. *(120)* This is turn will require new sets of skills for biomedical engineers and their peers and counterparts.

6.8 Conclusion

This chapter has provided some snapshots of where we stand currently with regard to medical device innovation and some pointers to what the future holds. As the principles of lean design converge with, on the one hand ageing societies in the developed north and younger emerging societies in the developing south, and leap-frogging technologies such as the smartphone on the other, it is expected that ever greater proportions of health technology innovations that align with the imperatives of universal health access and coverage – underpinned by the complementary drivers of equity and cost-effectiveness – will emerge with innovative BME practitioners playing important catalytic roles. How appropriate, the adage that "the best way to predict the future is to create it". With needs (in both well-resourced and low-resourced settings) as the driver, biomedical engineers and their peers as innovators – enabled and supported by the quadruple helix of government, private sector/industry, academia and the NGO sector – the vision of better health for all through, inter alia, improved access to medical devices at all phases and levels of health-care delivery seems more achievable than ever before.

Credit: Adriana Velazquez; regulations of medical devices meeting in Saudi Arabia, coordinated by Dr Adham Ismail, April 2016.

7 Role of biomedical engineers in the regulation of medical devices

7.1 Introduction

There is growing demand for access to affordable, appropriate, safe and high quality medical devices around the world. The constant integration of new medical devices and treatments into coherent health-care programmes is requiring more comprehensive professional skill sets and organizational capabilities and biomedical engineers are actively involved in meeting these challenges on many fronts.

The medical devices industry is growing rapidly as a tide of technological innovations floods the world market. Medical device technologies require developers and regulators to have a strong scientific background and knowledge to ensure that efficient verifications and marketing approvals assure safety, quality, effectiveness and performance of the technologies according to the intended purpose of the device. Regulation must occur in reasonable time to allow patients and health-care providers access to the most advanced medical technology.

In addition to ensuring safe performance of medical equipment in the operational settings of health-care facilities, biomedical engineers may play a crucial role in the design and evaluation of medical devices. In their regulatory roles, biomedical engineers evaluate information technically and scientifically for the purpose of obtaining marketing authorization provided by the industry to regulatory authorities.

Three international experts in medical device regulation, with extensive experience in regulatory authorities, industry and academia, participated in developing this chapter, shedding light on the many issues related to medical device regulation, from both regulatory authority and industry perspectives. Among the subjects addressed in this chapter are:

- Identifying the need to regulate medical devices
- Examining interactions of medical devices with information technology systems
- Investigating the research, development and management aspects of medical devices
- Pre-market assessment and approval phase to post-market surveillance
- Different registration standards for medical devices
- Role of biomedical engineers in regulating medical devices
- Skill sets of biomedical engineers involved with regulating medical devices
- Interactions of medical device industry regulatory specialists with other professionals.

In 2012, data from the United States Bureau of Labor Statistics and other governmental agencies ranked BME as the second best profession based on five criteria: physical demand, work environment, income, stress and hiring prospects. This analysis indicates BME is a rewarding profession from both financial and moral standpoints.

7.2 Need for biomedical engineers in regulatory affairs

Worldwide shifts in the global burden of disease, ageing populations, increasing prosperity, spreading economic development and increasing access to information are driving global societal demand for access to medical device technology. Users (government agencies, hospitals, doctors and nurses, insurers and patients) all demand technologies that are appropriate for their context of use and are accessible, affordable and available to intended users and stakeholders of health-care systems. Users also expect that medical devices, including in vitro diagnostic medical devices, are reasonably safe when used as intended, perform as specified, achieve their diagnostic or therapeutic purposes, and are of appropriate quality. Manufacturers are primarily responsible for fulfilling users' expectations, in addition to all parties in the supply chain from the purchaser to end user. Medical personnel and users also share in those responsibilities.*(121)*

In many, but not all, countries, laws and regulations have been established to protect the public from unsafe and ineffective medical devices. One or more regulatory authorities and/or conformity assessment bodies typically ensure manufacturers fulfil safety responsibilities and comply with regulatory controls throughout the product life cycle. Regulatory authorities and assessment bodies may also regulate device use, clinical investigations and promotional activities as well as conduct post-marketing surveillance of user experience with medical devices. For some or all devices, the regulatory authority or assessment body may use controls including pre-market review of manufacturers' evidence of device safety and performance, evaluation and risk assessments. Authorities may conduct audits of manufacturers' facilities and quality management systems pre- and post-marketing. In some countries, manufacturers are required to inform the regulatory authority promptly of adverse events associated with post-market use of medical devices. Such systems may complement alternate systems, either voluntary or mandatory, required by professionals or lay users for reporting adverse events.

The regulatory authority may have a system for registering active medical device manufacturers, importers and distributors in their territory. The authority may also require listing devices that are placed on the market within the authority's jurisdiction. These systems facilitate authority surveillance of the market, oversight of promotional activities, identification of adverse event trends, and enforcement action as necessary. Systems also serve as the basis for international cooperation and exchanging information on adverse events and post-marketing manufacturer field safety and corrective actions.

In some countries, the regulatory process for medical devices is identical to, or based upon, that for medicines. In other countries, a separate process specific to medical devices has been established. Regulatory processes specific to medical devices more appropriately reflects the fundamental differences in technologies, modes of action in or on the human body, product life cycles, and methods of use between product sectors. A medical device regulatory system should also reflect the varying levels of risk associated with different product categories (e.g. tongue depressors or simple dressings compared with artificial heart valves), with corresponding regulatory controls proportionate to relative risks.

In all countries, compliance with relevant regulatory requirements is an essential part of a manufacturer's civic duties, reputation and public trust. Such compliance is "the price of admission" that manufacturers pay to compete in the marketplace.

7.3 Medical devices regulation – scope and function in different countries

Medical device regulations define requirements in the design, development and manufacture to ensure that the public receives safe, efficient and effective products.

There are different regulatory bodies worldwide; however, the Global Health Task Force (GHTF) strived towards global uniformity in the industrialized nations. GHTF was set up in 1992 by a group of representatives from regulatory authorities and industry in Australia, Canada, Japan, the European Union and the United States of America, with the purpose of harmonizing medical device regulation in order to standardize the quality of medical devices worldwide and to facilitate international trade.

In 2011, a voluntary group of medical device regulators formed an International Medical Device Regulators Forum (IMDRF) based on the foundational work done by the GHTF, in order to accelerate international harmonization and convergence on regulations.

Medical device regulations do not exist in all countries, especially those with resource-poor settings. However, most industrialized nations have medical device directives. The European Union has directives for approval of devices for the European market, and the United States Food and Drug Administration (FDA) has separate and distinct requirements for the attributes of medical devices being introduced into its market.*(122)*

Regulations should specify that all medical devices, whether imported or locally produced, must meet international norms and standards in order to bring public health benefits without harming patients, health-care workers or the community.

7.4 Professionals in the field of medical devices regulation

The work of medical device regulation is dynamic and diverse, requiring professionals from a variety of backgrounds to interact with each other as they deal with the various technical, scientific and medical aspects of a device, from its development to commercialization, utilization, and monitoring performance feedback during the operational phase. Thus a regulatory professional in industry may deal with others from R&D, production, marketing and sales.

Medical device regulatory activities occur throughout the whole life cycle of a medical device: from pre-market to the post-market phases and even in the market placement. The pre-market phase starts with conception and design of the product and encompasses manufacturing and packaging and labelling. The post-market phase deals with the actual use and disposal and re-use of the product, while advertising and sale is the commercial phase of the product life cycle.

- Regulatory professionals are not only in demand in the manufacturing sector, in government agencies, clinics and hospitals, and consultancies but also in universities and clinical research organizations. So, what are the backgrounds of professionals involved in this field? They may have a background in R&D, life cycle management and regulation of products and also in clinical professions.
- A biomedical engineer can take an active part in the field of regulation, from the pre-market phase until

the product is on sale. With their background and special skills, biomedical engineers can play a crucial role in the medical device industry, which is increasingly changing into a technology-driven field, in activities including:

- Acting as an advisor on legal and scientific requirements
- Actively participating in design and development
- Participating in developing appropriate pre-clinical and clinical plans to evaluate safety and effectiveness
- Collecting, collating and evaluating scientific data
- Actively participating in preparation of registration documents for regulatory agencies or bodies
- Being involved in the negotiations necessary to obtain and maintain marketing authorization of the product
- Acting as technical advisor
- Ensuring that proper reporting and input is given to the commercial development of the product
- Being involved in the recall process
- Supporting development of standards.

7.5 Biomedical engineers as regulatory specialists in industry

Medical device manufacturers' compliance with all relevant laws and regulations begins with an in-depth understanding of regulatory requirements at both the working and strategic levels. For all but the most basic, low-risk class of devices and basic regulatory requirements, effective compliance will require manufacturers to follow adequate and dedicated specialized technical resources and be qualified through both training and experience. Board members and senior level managers must have a broad understanding of regulatory system requirements and recognize how requirements influence both product development strategies and the current and future business climate. Through their words and actions, board members and executive managers set a precedent for compliance within the company.

Background, training and expertise of government and industry regulatory specialists for medicines differ (or should differ) from regulatory specialist qualifications for medical devices. Knowledge of engineering (i.e. mechanical, electrical or software) and materials science is essential, and direct experience using medical devices in a hospital clinical laboratory or BME department will serve as valuable background.

As medical device technology continues to advance, developers will focus more on "combination products" to address unmet diagnostic and therapeutic needs. Combination products contain elements that, standing alone, would typically be regulated as medicines, medical devices or biologics. By combining product elements, significant new regulatory questions will arise, requiring cross-sectoral and multidisciplinary expertise.

Within a medical device development and/or manufacturing company, the biomedical engineer who has regulatory specialization typically takes the lead in developing required submission plans for any relevant regulatory authorities and/or conformity assessment bodies. Submissions may support product pre-marketing authorization applications (usually required for higher risk class devices) or notifying changes to products already authorized for marketing. Regulatory professionals are generally responsible for drafting, compiling, verifying and submitting applications and handling all follow-up questions and requests from the authoritative body. In some organizations, regulatory professionals are also responsible for writing post-marketing reports of adverse events or field safety corrective actions, whereas in other organizations, quality assurance groups assume these responsibilities.

In fulfilling regulatory roles, the specialists will typically collaborate with colleagues in other functional areas of the company.

7.6 Professional functions fulfilled by biomedical engineers in the regulatory domain

There is an extensive range of issues and questions that biomedical engineers may be called upon to address in the regulatory domain.

7.6.1 New product planning

- What is the claimed intended use(s) for a new device?
- What regulatory requirements will apply to proposed new products?
- What evidence will be required to demonstrate conformity to those requirements (e.g. will a *de novo* clinical investigation be required)?
- How long will it take to develop that evidence?
- Are similar products already in the market and what was their regulatory pathway?
- Does a proposed new product target new intended uses or users?
- Will regulatory determinations on new pathways or policies have to be made by the authority?
- Does inclusion of a new technology (or one not previously used in medical devices) raise important new questions of regulatory requirements?
- How do those considerations affect project costs, timelines, risks and returns on investment?

7.6.2 Research and development

- What are the relevant international and national standards that may apply?
- What detailed technical information will be required, and at what stages of the development process, for inclusion in a pre-marketing conformity assessment dossier, if required?
- What information should be developed and retained in the product summary technical file (to support a submission and/or be held for future product audits)?
- What elements of a device design may require clarification of regulatory requirements?
- What are the requirements for interfaces between a product and other products with which it may reasonably be foreseen to be combined in a new "system"?
- Beyond the requirements of the medical device regulator, are there other regulatory regimes to be considered, e.g. telecommunications or radio compatibility or environmental regulations?
- Are there regulatory requirements or standards for human factors evaluation for safe use by the intended user(s)?
- How will required labelling and instructions for use be incorporated in the product design?
- How will regulatory requirements for risk management be incorporated in the product development process and timeline?

7.6.3 Clinical research

- What existing clinical evidence, e.g. from similar previous products and/or published literature, may be used to demonstrate clinical safety and performance?

- How relevant is it to a new product?
- Is new clinical evidence required?
- Will that evidence require a new clinical investigation?
- What are the appropriate clinical investigation designs to generate evidence required for regulatory purposes? In what form?
- Will the statistical design of a study be sufficient for regulatory purposes?
- Does the proposed clinical investigation fulfil all relevant ethical requirements and standards?
- Does the study design and implementation fulfil all relevant regulatory requirements, e.g. for investigator qualifications, recordkeeping and monitoring?

7.6.4 Quality management systems and manufacturing operations

- Are there any specific regulatory requirements for design verification and validation, manufacturing, acceptance or certification of a product?
- Are there any relevant international or national standards that apply to the operations? What QMS and manufacturing information must be prepared for the product summary technical file, for possible submission and/or future auditing?
- What are the documentation and recordkeeping requirements? What are the requirements for training and certification of personnel?
- How will regulatory requirements for risk management be incorporated in the product manufacturing planning process?
- When does a change in specifications or manufacturing process require a notification to the regulatory authority or conformity assessment body?
- What are the requirements, and how can the manufacturer be prepared, for external audits of the QMS?
- What is required to comply with regulatory requirements for post-marketing surveillance, complaint handling and adverse event or vigilance reporting?

7.6.5 Marketing and sales

- For what intended use(s) does the manufacturer wish to promote the medical device?
- Are there any specific regulatory requirements or limitations on such claims?
- What technical and clinical evidence will be required to support such claimed intended uses?
- What intended uses are claimed by similar devices?
- What has been the regulatory pathway for competitive devices?
- Who are the intended users of the device?
- What are the regulatory requirements and international standards (including symbols) for labels, labelling, and instructions for the device?
- Are there regulatory requirements for user testing and validation of instructions for use?
- What languages are required in labelling?
- Is labelling in alternative media such as via the internet or on CD-ROM permitted?
- When must proposed labelling be available for inclusion in a pre-marketing regulatory submission?
- When does a change in labelling require notification of, and review by, the regulatory authority?
- What are the regulatory requirements for, and constraints upon, advertising and promotional materials?
- Does the regulator require specific user training as a condition of marketing the device?

7.6.6 Technical writing

- Does safe use of the device over its life cycle require detailed instructions for use and/or technical service manuals?
- Is it intended that the user or medical institution will maintain or calibrate the device?
- What are the regulatory requirements for such instruction materials?

7.6.7 Health economics and health technology assessment

A small but growing number of countries face the hurdle of marketing authorization by regulatory authorities prior to bringing a new medical device to market. Health-care systems may require evidence of clinical utility, cost effectiveness of a device, associated therapy or diagnostic tests as conditions of payment or reimbursement.

- How would the regulatory affairs professional work with health economists and others to fulfil those requirements, as well as to assure consistency between clinical evidence and claimed intended use for regulatory purposes and HTA purposes?

7.6.8 Standards and standardization bodies

In many jurisdictions, evidence of a device's or manufacturer's conformity with recognized international or national standards is deemed to be evidence of compliance with relevant regulatory requirements.

- What standards apply to a device?
- How are internal product specifications kept up-to-date as those standards are revised?
- How should the manufacturer demonstrate conformity with standards requirements?
- Where relevant recognized international or international standards do not exist, are there other standards acceptable for regulatory purposes, e.g. industry standards?
- What are the opportunities for the manufacturer's technical experts to participate in the development of standards? Can those experts support government experts in standardization work?

7.7 Industry and government affairs

Regulatory requirements and practices are important factors in determining whether a country's policy environment is conducive to investing in research and developing accessible, appropriate, affordable and available medical technologies. The regulatory affairs professional may be called upon to advise industry groups or company government affairs staff on how regulations may be improved. When regulatory authorities publish proposed regulations for public input, regulatory professionals may analyse proposals and submit comments, either directly or through industry groups.

The complexity of these issues grows with the nature of the device, its degree of novelty, risk classification, diversity of product range, the number of countries/regions in which the manufacturer plans to offer a medical device, and the comprehensiveness and sophistication of national regulatory systems. The experience and training of, and resources available to, the regulatory affairs professional, must reflect the degree of complexity. The role is not, and should not be seen as, a purely administrative position.

7.8 Education and experience of industry regulatory affairs professionals

The 2012 Scope of Practice and Compensation Report for the Regulatory Profession by the Regulatory Affairs

Professionals Society (RAPS) is based on a survey of nearly 3000 regulatory affairs professionals in 58 countries. *(123)* The report provides information on the most recent data from 22 years of surveys examining the scope of work and compensation of regulatory affairs professionals from industry and regulatory authorities, as well as consultancies, academic institutions, basic and clinical research organizations, and care delivery settings. As such, the report may be the most comprehensive and systematic profile of the international regulatory affairs profession.

Though not exclusive to medical devices, report findings indicated:

- Approximately 65% of survey respondents work with medical devices or in vitro diagnostic medical devices.
- More than 98% hold a university degree, and 70% have pursued postgraduate education; 20% hold doctorates and 40% masters degrees.
- 90% hold university degrees in the sciences, clinical disciplines and engineering and/or technical sciences including chemistry and physics. 13% of professionals, and 20% of those with five or fewer years of regulatory experience, participated in postgraduate certificate or graduate degree programmes in regulatory affairs or regulatory science, in order to transition into regulatory positions.
- Overall, 14% of regulatory professionals also hold degrees in business, with 12% holding masters in business administration.
- The vast majority of regulatory professionals (96%) did not begin their careers in a regulatory position. Most regulators transitioned through one or more areas of work before moving into regulatory positions. On average, regulatory professionals accrue eight years of "other" professional experience prior to moving into a regulatory position. Immediately prior to transitioning to regulatory positions, 83% of professionals worked in positions closely aligned with research, product development, clinical research, manufacturing or quality of clinical care. Prior experience would include biomedical engineers previously practising in health-care and academic settings.

To help regulatory affairs professionals attain and maintain requisite regulatory knowledge, some academic institutions offer courses in regulatory science. Additionally, RAPS offers reference materials, training conferences and online remote learning programmes, many of which specific to medical devices, to regulatory professionals. Some courses may lead to certificates, including the Regulatory Affairs Certification (RAC) *(124)* – a professional certification for medical device regulation earned by passing an examination administered by an accredited third-party testing provider. The RAC requires re-certification every three years by acquiring credits from regulatory-oriented activities. Other bodies, including the World Medical Device Organization (WMDO),*(125)* also offer online learning tools focused on medical devices.

7.9 Conclusion

A biomedical engineer may perform many different roles in the regulatory process, depending on what stage of a product's journey to market and beyond is involved. The medical device industry is an evolving field demanding various types of expertise from engineers, not only in research, project management, analytics, interpretation and negotiation, but also skills in business and communication.

Biomedical engineers, in addition to their engineering education, need training in management and regulation of medical devices. Furthermore, regulatory professionals have to deal with increasing globalization of health-care products, the changing needs of the public and patients, differing marketing and post-marketing approval surveillance requirements of different regions. They may coordinate scientific design with regulatory demands throughout the life cycle of the product, to ensure that innovations deliver the maximum benefit to all stakeholders.

Experienced biomedical engineers may find rewarding professions in the field of regulatory affairs. The quality of advice and work products, analytical and strategic thinking, and relationships management by the regulatory affairs professional are important in determining whether a "breakthrough" medical device technology is successfully brought from the laboratory bench to the clinical bedside – and ultimately contributes to better health outcomes.

Through country-specific policies and international collaboration, national governments should develop a robust regulatory capacity by educating and retaining skilled professional work forces in industry, academia and government. Increasing regulatory capacity ultimately contributes to improving timely public access to appropriate, affordable and available medical technologies.

Credit: Jitendar Kumar; 6th HTA fellowship, School of Public Health,
Postgraduate Institute of Medical Education & Research, Punjab, India, January 2016.

8 Role of biomedical engineers in the assessment of medical devices

8.1 Introduction

Health technology assessment is used to inform policy- and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies. The assessment is conducted by interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies.

With WHO's drive to achieve UHC as outlined in Sustainable Development Goal (SDG) 3, the need to choose and effectively manage technologies to be adopted within countries' health systems, particularly in a context of limited resources, is a critically important undertaking. Countries are called on to consider establishing national systems of health intervention and technology assessment and encourage the systematic and transparent utilization of independent health intervention and technology review evidence. Developing and strengthening national capacity will have to build on established best practices, information exchange and collaborative approaches to make the best use of limited resources and yield robust scientific assessments.*(126)*

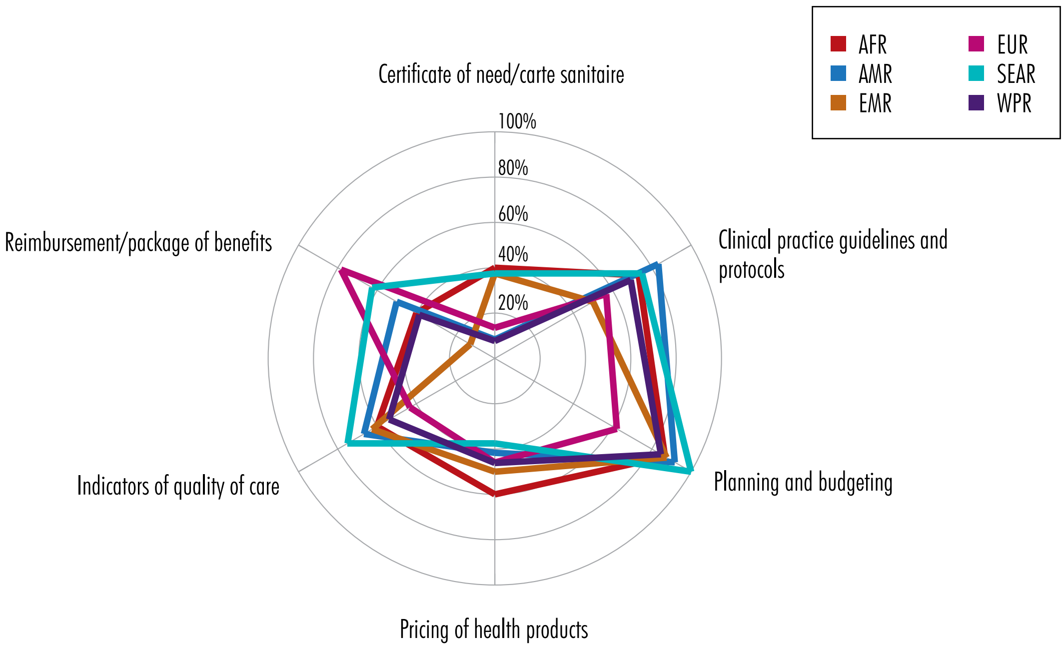
The WHO 2015 Global Survey on Health Technology Assessment by National Authorities,*(127)* conducted as recommended by World Health Assembly resolution WHA 67.23 on health intervention and technology assessment in support of universal health coverage,*(128)* indicates (as shown in Figure 8.1):

- All Low income countries surveyed and 85% of middle-income use HTA for planning and budgeting.
- Middle-income countries used HTA to inform clinical practice guidelines and protocols (85%).
- High income countries use HTA for determining service reimbursement or inclusion on a benefits package.

In the specific case of medical devices, HTA has emerged as an important tool for supporting the core functions of effective and sustainable health systems and defining prioritization, incorporation and selection of medical devices. *Health technology assessment of medical devices,* part of the WHO's *Medical device technical series*, provides an overview of HTA.*(130)* It presents how health technology regulations, health technology management and HTA are all important in the medical devices life cycle; these are interrelated and complementary, but distinct functions. All these issues are addressed in the present publication (see chapters 7 and 9). All three (regulation, health technology assessment and management) are needed for better health care and population health in a country. Along with other professionals, biomedical engineers have different functions in these three areas as indicated in Figure 8.2.*(131)*

As indicated in World Health Assembly resolution WHA 60.29 on health technologies the term "health technologies" includes not only medical devices, but also pharmaceuticals, interventions and other forms of application of organized knowledge and skills.*(132)* However, not all assessments or evaluations of technologies should be

Figure 8.1 Purpose of undertaking health technology assessment by region and country income*(129)*



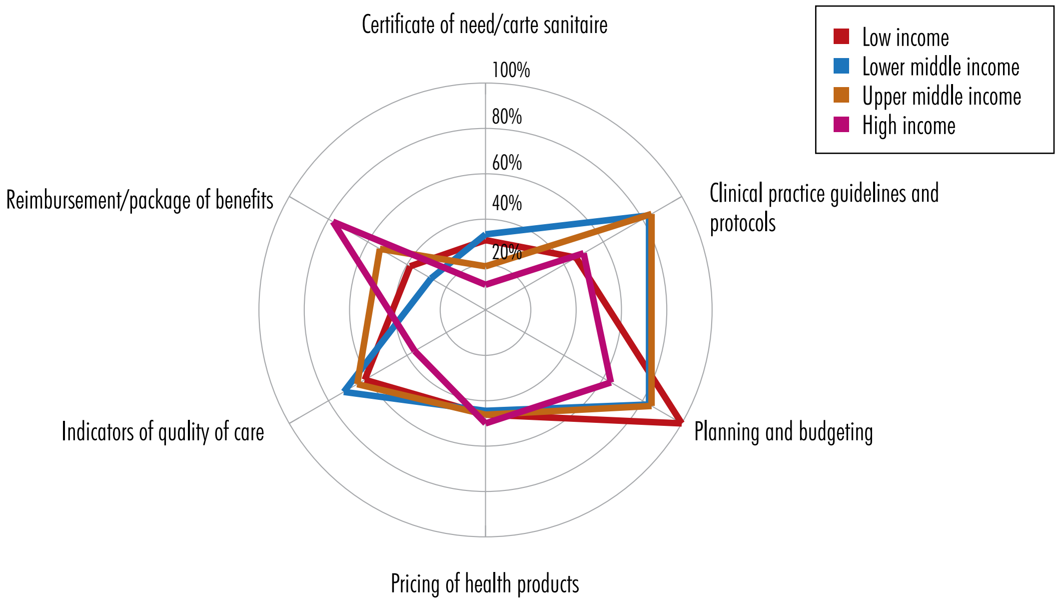


Figure 8.2 Domains of health technology processes

called HTA. HTA "refers specifically to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an HTA assessment is to inform policy decision-making."*(133)*

8.1.1 From performance to use in health care

Figure 8.3 represents the stages and values of HTA and their relationship to regulatory processes.*(134)* There is a lack of emphasis on organizational impact, equity, ethical issues, feasibility considerations and acceptability to patients and health-care providers. Value for money is similarly neglected unless the device forms part of a vertical programme that needs to be assessed – even then the individual device may not always be considered; shared use devices are rarely evaluated.

It is important to note that, partial assessments focusing "only" on clinical or technical or economic dimensions are not considered full HTA if they are not run systematically and in multidisciplinary perspective.*(135)*

Technical and economic evaluations are important primary studies and the knowledge synthesis that is key to full HTA. Without such primary studies by biomedical engineers, clinicians, epidemiologists, economists, social scientists, ethicists and other researchers and evaluators, it is impossible to do comprehensive HTA. Effective HTA mobilizes the scientific knowledge of stakeholders, including clinicians, administrators and patients to inform decision-making processes.*(136)*

The important contribution of biomedical engineers in HTA goes beyond producing primary evidence to be included in HTA, especially regarding medical devices. They have an essential part to play in the comprehensive HTA process for medical devices as they have specific knowledge and background to analyse and review technical characteristics, clinical use and

Figure 8.3 Stages and values of HTA and their relationship to regulatory process

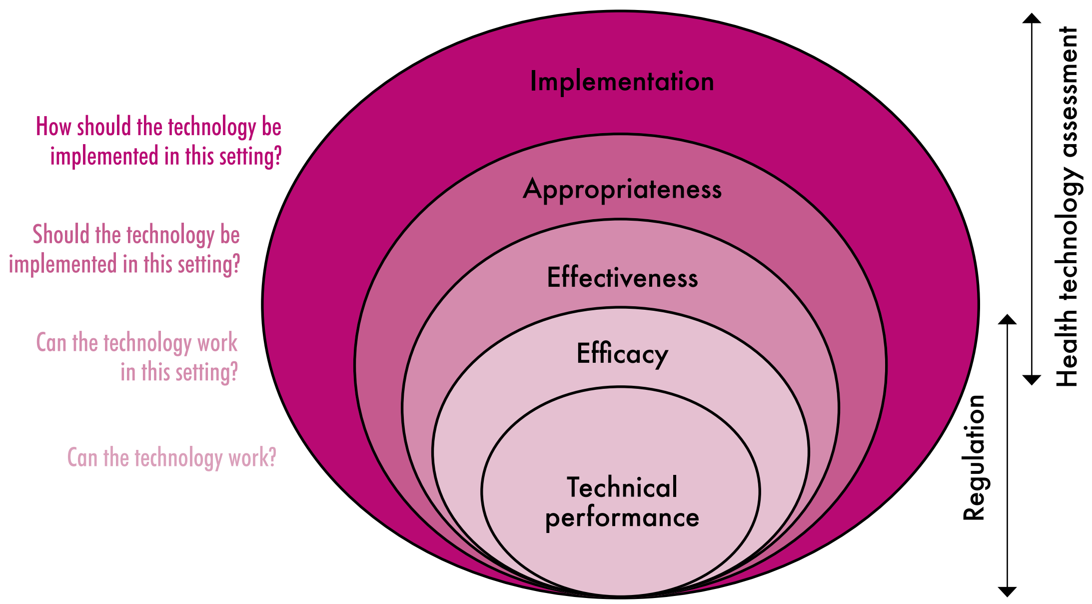
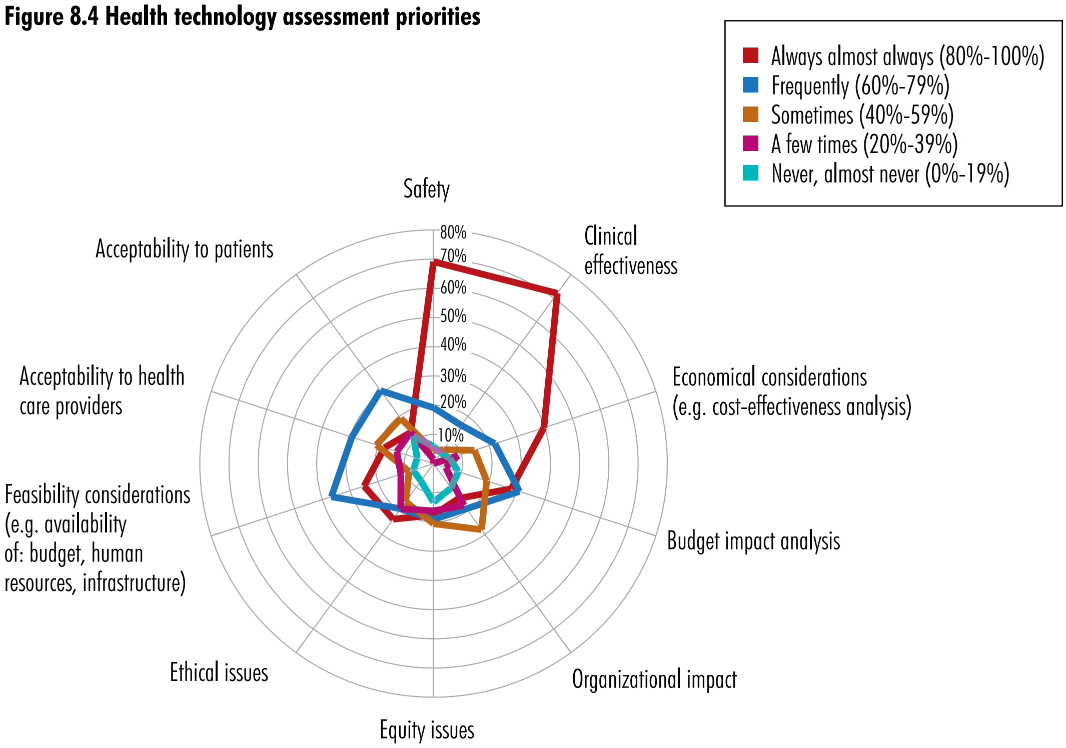


Figure 8.4 Health technology assessment priorities



quality and safety issues, pricing and comparison with similar technologies.

The purpose of this chapter is to describe the current and potential role of biomedical engineers in HTA in national agencies. It should be noted that HTA can be developed at various levels:

- Global or national to enhance policy decision-making.
- Meso- and micro-level, e.g. in hospital-based HTA which directly support decision-making in hospitals, where biomedical engineers play a fundamental role in the interdisciplinary analysis on medical devices to be used in the institution.

Biomedical engineers typically work in hospitals but an increasing number is moving into national policy positions related to the HTA process.

8.2 Methods of health technology assessment

Worldwide there are various methods, degrees of detail and scope of practice of HTA reports. Nevertheless, HTAs systematically examine various combinations of the following dimensions: the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organizational implications, social consequences, and legal and ethical implications of the application of a health technology. A HTA report is based on sound evidence and not only contains investigations on all aspects that influence the technology but also those aspects that the technology influences. The choice of the different dimensions for an assessment report depends on the specific context of the policy question – one can concentrate on safety, clinical efficacy and effectiveness and cost as in the pre-marketing phase*(137,138,139)* or more on organizational issues as in the hospital-based HTA.*(140)*

A HTA report starts with the policy question. A policy question is raised either by the decision-makers or by the institution itself. If the policy question is not properly defined, then the first step is to formulate it. One framework proposed by the European Collaboration on HTA*(141)* contains the following steps: submission of an assessment request, followed by prioritization and commissioning, conducting the particular assessment, and then dissemination. The assessment process itself comprises of defining the policy question, a preliminary protocol, collection of background information, definition of the research questions, data search pertaining to the different dimensions, draft report which is reviewed externally and, finally, publication.

An alternative programme of HTA*(142)* may go through identification and specification of assessment topics, evidence retrieval and collection of appropriate data, appraisal and integration of evidence followed by report generation and dissemination. However, not all agencies or Institutions follow all the steps or as a matter of fact in a chronological order.

There are numerous materials on the methodology of conducting HTA, e.g. the handbook on HTA published by the Danish Centre for Health Technology Assessment, which gives a sound overview on the methodologies.*(143)*

8.3 Different disciplines in health technology assessment

By definition, HTA is a multidisciplinary field of policy analysis. The three most common disciplines involved in HTA are evidence-based medicine, economic evaluation in health care, and population and public health ethics.*(144)* Currently, the discipline of BME is less represented in HTA agencies, than in other areas like R&D, regulation or health technology management. One of the reasons could be that national agencies do not have specific teams of procedures for HTA of medical devices.*(145)* Conversely, the increasing application of HTA to inform decisions around medical devices and the shift in health-care costs towards medical devices will require biomedical engineers to play a greater role in HTA than they have in the past.

For example, a recent study on medical device prioritization in Gambia and Romania revealed a lack of biomedical engineers across both countries; where present biomedical engineers were not invited to take part in HTA or resource allocation decisions, instead they were only consulted on maintenance and servicing issues. Should biomedical engineers be consulted and empowered to play a role in HTA, it is reasonable to assume both settings would see considerable improvements in medical devices management and use.*(146)*

8.4 Core competencies required for health technology assessment

A pre-workshop on capacity building for an efficient and effective HTA agency was conducted at the Health Technology Assessment international conference in Washington (DC), USA in June 2014. The objective of this workshop was to provide a preliminary exploratory discussion on the skills needed for HTA. The results of the workshop showed certain skills (both "hard" and "soft") or competencies needed to practise or use HTA (see Table 8.1).*(147)*

8.4.1 Interdisciplinary teams

In 2008, a survey of international HTA organizations revealed that the majority of the participating organizations had "clinical specialists" (71.1%) in their organizations followed by "economists" (68.4%) and "information specialists" (65.8%) (Table 8.2). In addition to the

Table 8.1 Competencies needed to practise HTA

Skill sets	Specific skills	
"Hard" scientific skills	Literature search	Health-care policy
	Critical appraisal of literature	Statistics
	Evidence-based medicine	Ethics
	Mathematical modelling (e.g. Markov models)	Priority setting in HTA
	Health economics	Formulating recommendations
	Economic analysis	CPGs evaluation AGREE instrument
	Epidemiology	Horizon scanning
	Clinical effectiveness	Multi-criteria decision analysis
"Soft" consensus-building and communication skills	Team building	Understanding culture, local context
	Working in (and communicating with) a multidisciplinary team	Report writing – catering to different audiences
	Coordinating and managing HTA project and project team including stakeholders	How to "read" a report
	Way to communicate to patient and public	Consensus-building skills
	Communication between different organizational structures that are involved	
	Know-how to adapt reports to local context	

Table 8.2 Background of the professionals in HTA organizations*(149)*

	HTA organisations according to number of staff				
			None*	1-5*	>5*
Background	N**	Median (range)	N (%)	N (%)	N (%)
Clinical specialist	38	1 (0-8)	11 (28.9)	23 (60.5)	4 (10.6)
Economist	38	1.5 (0-11)	12 (31.6)	20 (52.6)	6 (15.8)
Information specialist	38	1 (0-12)	13 (34.2)	23 (60.5)	2 (5.3)
Social scientist	38	1 (0-10)	18 (47.4)	17 (44.7)	3 (7.9)
Health service researcher	38	1.5 (0-43)	18 (47.4)	13 (34.2)	7 (18.4)
Public Health specialist	38	0.5 (0-12)	19 (50.0)	15 (39.5)	4 (10.5)
Epidemiologist	37	0 (0-9)	19 (51.4)	16 (43.2)	2 (5.4)
Statistician	38	0 (0-7)	20 (52.6)	17 (44.7)	1 (2.7)
Nurses/nursing scientist	37	0 (0-29)	22 (59.5)	12 (32.4)	3 (8.1)
General practitioner	37	0 (0-8)	23 (62.2)	13 (35.1)	1 (2.7)
Media professional	37	0 (0-28)	24 (64.9)	11 (29.7)	2 (5.4)
Psychologist	37	0 (0-6)	28 (75.7)	8 (21.6)	1 (2.7)

Notes: *None: Number of HTA agencies with no specialist professional working in the organization; 1–5: number of HTA agencies with 1 to 5 specialist professionals; >5: number of HTA agencies that had more than 5 specialist professionals.
** Number of respondents replying to each category.

other professionals listed in Table 8.2, biomedical engineers were mentioned in an additional category of content specific experts such as dentists, pharmacists, physiotherapists, lawyers, chemists and nutritionists.*(148)*

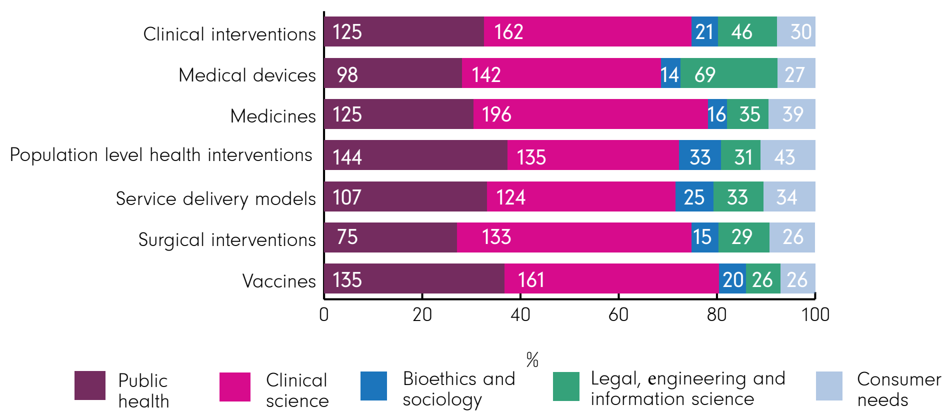
The WHO 2015 Global Survey on Health Technology Assessment by National Authorities documented that legal, engineering and information professionals are involved in the assessment of medical devices, as can be seen in Figure 8.5.

As shown in Figure 8.5,*(150)* the number of engineers increased when the objective of HTA was medical devices. Individuals from these professions have knowledge and skills in the areas of clinical epidemiology, evidence-based medicine, clinical trials, health services research, meta-analysis, economic (cost-effectiveness) analysis, consensus conferences, technology management, decision-making, policy-making/analysis, priority setting, legal, social and ethical aspects.*(151)* The specific roles of these professions vary across HTA organizations, but they are all likely to be involved in the collection and synthesis of clinical and/or economic data, which form the basis for evidence-based decision-making. HTA specialists should be able to perform literature searches, assessing and avoiding the several types of bias (e.g. publication bias, language bias, retrieval bias, reporting bias), synthesizing the evidence (may be qualitative, quantitative [meta-analysis] or formal decision-analysis) and publishing the results (both paper and electronic versions).*(152)*

8.5 Survey of biomedical engineers involved in health technology assessment

A survey was developed in 2013 by Holmes, Banken and Muller, to gather information for this section and it showed that the involvement of biomedical

Figure 8.5 Professionals involved in assessment of medical devices



engineers in HTA varies internationally, though few HTA organizations report having individuals with these credentials on their staff. In saying this, most HTA organizations noted that biomedical engineers may have a growing role to play in the future. Similarly, international HTA experts and policy-makers recognize the vital role biomedical engineers play in HTA and medical devices selection, prioritization and management more generally.*(153)*

Biomedical engineers are not commonly found in most HTA organizations, and where they do work, they usually perform the same role as other members of an HTA team; their role is not specific to their training as a biomedical engineer. However, a few exceptions exist in Europe. For instance, in the United Kingdom, one of the 23 members of the National Institute for Health and Care Excellence Medical Technologies Advisory Committee is a biomedical engineer while in Italy the national agency for public procurement in health employs five biomedical engineers and several hospital HTA units are headed by biomedical engineers (e.g. Ospedales Pediatrico Bambino Gesù, Rome and Azienda Sanitaria Locale, Benevento). In the HTA unit in CEDIT, for Paris public Hospitals, the unit comprises biomedical engineers, physicians and methodologists.*(154)*

HTA is a core topic in the majority of European BME courses. In 2010, it was included among the core topics of BME.*(155)*

In Latin America*(156)* there are more biomedical engineers working in HTA agencies, as can be found in the National Center for Health Technology Excellence in the Ministry of Health in Mexico (CENETEC).*(157)*

Conversely, the situation is much more fragmented in Asia. For instance, a respondent from Singapore notes: "We do not have any assessment processes that require a biomedical engineer specifically. Our staff who have biomedical engineering background function as HTA researchers and would carry out the same assessment processes as any other staff performing that role."

Likewise, in the Republic of Korea: "They are involved with an overall process of HTA including synthesizing evidences [sic] through systematic reviews. We train them exactly [the] same as other staffs [sic], many with [a] clinical background."

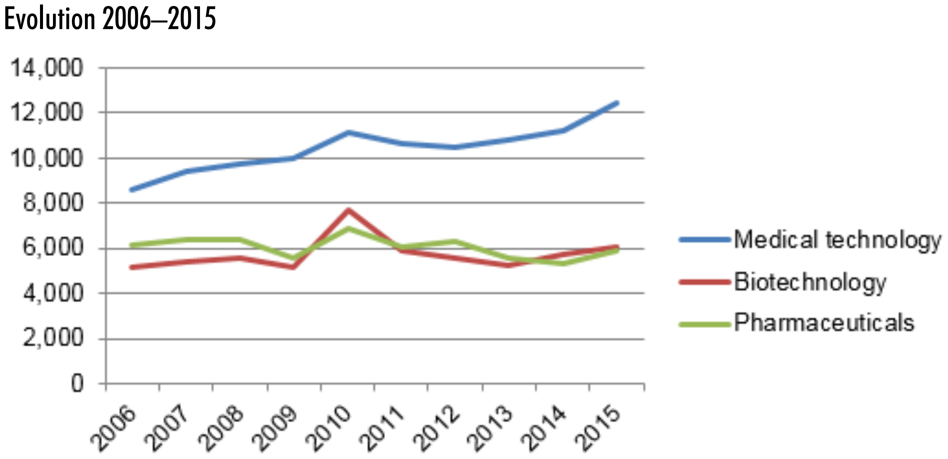
The HTA division of IFMBE states that "the role of biomedical engineers is peculiar … as their activities go from the medical devices research, design, development, utilization, management and assessment."*(158)* Further on, they mention that due to their background biomedical engineers "may play a very important role in early stage HTA."*(159)*

In organizations where they are employed or consulted specifically for their biomedical expertise, it is customary to provide advice around the technical characteristics, usability and safety of devices, particularly when the evidence base traditionally used for HTA is limited.

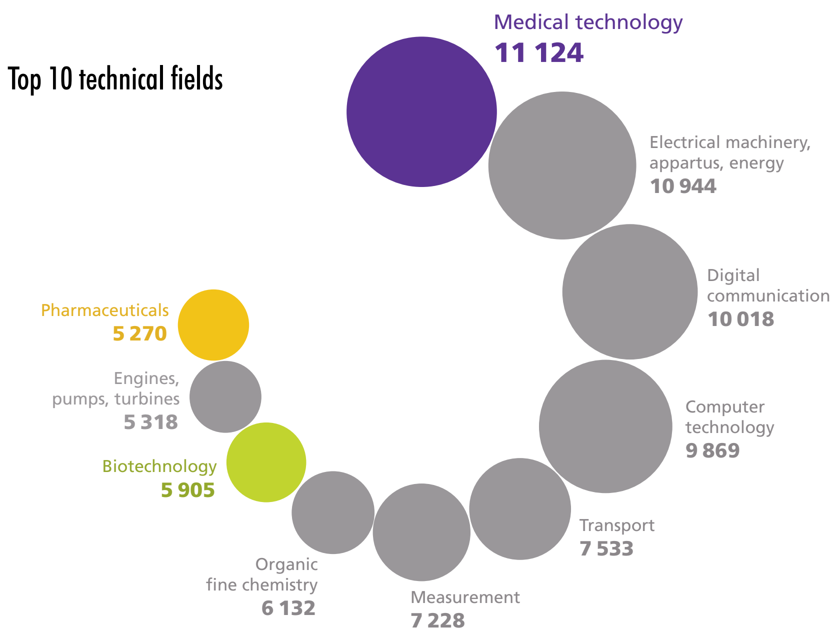
Some HTA agencies do not usually have job descriptions specific to biomedical engineers – rather the same skills are required as for any other member of the HTA team. However, one of the agencies stated that they specifically hire biomedical engineers in their unit in order for them to contribute and share their expertise "on the technical aspects of medical devices and procedures".

The few agencies*(160)* that have job descriptions specifically for biomedical engineers, request a postgraduate

Figure 8.6 European patent applications



Evolution 2006-2015 and Top 10 technical fields



qualification in BME in addition to the standard skills needed for HTA.

8.6 The developing role of biomedical engineers

The findings from the 2013 survey are consistent with the conclusions drawn in the 1990s by Menon:*(161)*

- Their expertise should be part of the interdisciplinary work of HTA directly informing decision-making at different levels in health systems.
- It is imperative that proper educational programmes be developed to prepare engineers for a broader role in health care, and, more specifically, the principles and concepts of HTA.

As discussed above, the important contribution of biomedical engineers in HTA goes beyond producing primary evidence to be included in HTAs, especially regarding medical devices. They have an essential part to play in the HTA process especially considering that the focus of health-care innovations is shifting from drugs towards medical devices. In fact, in the past 10 years, the number of medical technologies patented each year has doubled compared with that for drugs and biotechnologies – in 2014, for example, medical technologies ranked first in intellectual property applications in Europe.

This implies that over the next years, thousands of new medical devices will be available for adoption, causing a significant shift in health-care costs from drugs to devices, and a growing request for HTA studies focusing on devices. To cope with this huge change, the European legislation on medical devices is currently under revision and, according to first drafts, will require device assessment as a prerequisite for market admission. This is a huge challenge for HTA as, different from drugs, there is a well-recognized lack of methods and tools to support HTA for medical devices,*(162)* especially in pre-market phases,*(163,164)* which many authors tend not to consider relevant for HTA field.

This shift will require a reinforcement of BME contribution in HTA studies, which has already been recognized by the BME international community; though this will take a few years to work through to national HTA entities. For the first time HTA was introduced as a core topic for biomedical engineers in 2009;*(165)* since 2012 all the IFMBE conferences*(166)* have had sessions on HTA*(167)* and since 2015 a whole dedicated track, which in IFMBE conferences is a pool of invited and proposed sessions chaired by one or two experts and often resulting in special issues on relevant BME journals; and for the first time there was an invited keynote talk at the 2015 World Congress of BME on HTA;*(168,169)* in August 2016 the first IFMBE HTA Division content management system was published;*(170)* November 2016 the first IFMBE eLearning platform was developed and since then, more than 20 hours of training material on HTA have been uploaded.*(171,172,173)*

8.7 Professional societies and international collaboration in health technology assessment

Is global collaboration in HTA necessary? Global collaboration can facilitate the exchange of know-how (between limited resource countries and developing countries, between individuals, agencies, and industry and policy-makers), lessons learned and global/regional/national work. This section will consider the different activities and goals of international organizations dealing with HTA and also some of the regional networks that have emerged in the Americas, Europe and Asia.*(174)*

Depending upon the background and interest of the individuals – whether they are users, producers and those interested in HTA – they could become members in one or more of the organizations, societies or networks mentioned below.

One of the strengths in using HTA as a tool in decision-making is that it involves a multidisciplinary team in which biomedical engineers have an important role to play to play.

8.7.1 Health Technology Assessment international

Health Technology Assessment international (HTAi) is an interdisciplinary global scientific and professional society with a focus in HTA.*(175)* Its members come from academic institutions, health service producers, industry, business, government, patients and consumers from all continents and it acts as a neutral forum for collaboration, sharing of expertise and information.

The objectives of the society are:

- To collaborate actively with WHO, various networks and regionally based HTA societies to increase the application of HTA in health policy-making
- Support the HTAi policy forum by fostering open debates on issues involving HTA related to health policy matters both in the public and private sectors
- Conduct annual international meetings, which serve as meeting points for all stakeholders and address the interests and needs of the members
- To develop its work with interest subgroups and facilitate information exchange in specific focus areas
- To support the publication and diffusion of the International *Journal of Technology Assessment in Health Care.*

8.7.2 International Network of Agencies in HTA

The International Network of Agencies in HTA (INAHTA), which was established in 1993, has 57 member agencies from six continents. All members are non-profit making organizations linked to regional and national government, which produce HTA reports. The members meet face-to-face once a year in conjunction with the HTAi conference. Additionally, INAHTA provides networking opportunities throughout the year as a member of the various community of practices. It serves as a platform to share information and provides opportunities for cooperation internationally and regionally. It also facilitates information exchange between members through Listserv.

The INAHTA website plays an important part in facilitating communication between the members and includes information on HTA reports and ongoing activities. The *Brief series* of INAHTA encourages member agencies to present their overviews on recently published reports, with some indication of impacts on decisions made by governments at regional, national or international level. Furthermore, the website encourages member agencies and/or individuals to take a consistent and transparent approach to HTA.*(176)*

8.7.3 EuroScan International Network

The International Information Network on New and Emerging Health Technologies (EuroScan International Network) is a collaborative network of member agencies for the exchange of information on emerging new drugs, devices, procedures, programmes and settings in health care.*(177)*

The members of the network strive to:

- Establish a system of sharing skills and experiences in early awareness and alert activities.
- Develop applied methods for early identification and assessment.
- Exchange and disseminate information on new and emerging technologies.

8.7.4 HTAsiaLink

HTAsiaLink was established in 2010. The aim of the network is to strengthen individual and institutional capacity in the field of HTA and enhance the integration of evidence into policy decisions. The network facilitates information exchange (not only between members but also other networks and organizations), joint research projects, annual regional conference and other activities.*(178)*

8.7.5 La Red de Evaluación de Tecnologías Sanitarias de las Américas

RedETSA was formally launched in 2011 and has currently members from 25 institutions and 13 countries from the region. Initially it was funded by PAHO (Pan American Health Organization) and ANVISA (Agência Nacional de Vigilância Sanitária), Brazil. The aim of the network is to promote and strengthen HTA as a tool to support decision-making through regional exchange relating to the introduction, dissemination and use of the technologies and by adopting common methodologies, and capacity building measures through cooperation.*(179)*

8.7.6 European Network for HTA

The European Network for HTA (EUnetHTA) has evolved into an international collaboration among HTA researchers and policy-makers in European countries. It was established in 2008 to create an effective and sustainable network and has developed and implemented practical tools, after careful piloting, to provide reliable, timely, transparent and transferable information to contribute to varied HTA research in member states.*(180)* EUnetHTA coordinates the efforts of 39 institutions from 30 countries.

8.7.7 Eastern Mediterranean Regional Network in HTA

A regional network has been setup and hosted by WHO EMR to provide a platform for members to pose queries, exchange news and resources, and request advice. The members come from 22 countries and comprise HTA advocates, champions and international experts.*(181)*

Key progress has been made in the area of HTA in EMR through two intercountry meetings aimed at technically supporting the Member States in the development of their own national HTA programmes within existing health systems. Both meetings resulted in the introduction of a regional network that includes over 100 experts as well as national and regional champions. The network has grown and now includes countries from WHO SEAR and WPR as well. In order to seek the political and financial commitment needed to establish/strengthen national HTA programmes, Member States were alerted to the importance of building their HTA technical capacities during the regional committee meeting conducted in Kuwait in October 2015. The presentation was well received and resulted in several official requests from Member States such as Egypt, Iran (Islamic Republic of), Oman, Qatar, Saudi Arabia, Sudan and Tunisia.

8.7.8 Health Care Technology Assessment Division (IFMBE)

The IFMBE was established in 1959 when a group of medical engineers, physicists and physicians met in Paris to create the international scientific society of biomedical engineers. The IFMBE is a United Nations recognized NGO holding a seat in all the UN agencies (e.g. WHO) and is part of a global system working to improve health worldwide. Being a federation of scientific societies, IFMBE is not open to individuals, but rather national and regional societies. In 2016, it represented 54 national societies, seven transnational associations (e.g. IEEE-EMBES), accounting for about 120 000 members from six continents. It has two divisions:

- Clinical Engineering Division (CED), mainly focused on the management of health-care technology.
- Healthcare Technology Assessment Division (HTAD), focused only on HTA. The goal of HTAD is to promote HTA within the biomedical and clinical engineering community.*(182)*

The specific activities covered by HTAD include:

- To increase the knowledge of HTA among biomedical engineers, supporting the introduction of HTA related content at BSc, MSc, PhD and continuous education levels, and developing learning resources. Here, the division has produced more than 100 hours of eLearning content on basic concepts, methods, tools and case studies, which are freely accessible to the IFMBE associates through their member societies' websites. Moreover, a summer school on HTA, specifically conceived for biomedical engineers and medical physicists was launched in 2015 and will run every two years.*(183)*
- Encouraging basic and applied research in HTA; an open access journal is being launched,*(184)* and increasing space has been devoted to HTA in IFMBE conferences since 2012.
- Stimulating cooperation and promotion of worldwide collaboration between different societies involved in HTA.
- To support guidelines and case studies of particular relevance (e.g. HTA of medical devices, guidelines for multi-criteria decision analysis for HTA of medical devices, early stage HTA).
- Reinforcing the dialogue between medical device researchers and policy-makers, through HTA. HTAD coordinated the organization of the first European Parliament Interest Group on BME, launched the 31 May 2016 at the European Parliament. This group of six Members of the European Parliament from five countries, will meet twice a year, supporting action regarding HTA of medical devices in European regulations (e.g. the regulation on medical devices, currently under revision).*(185)*

8.8 Conclusion

In quite a few HTA agencies biomedical engineers are part of multidisciplinary teams. However, they are still not automatically involved when health technologies, particularly for medical devices, are assessed. HTA of medical devices seems to be the area in which the contribution of biomedical engineers to the HTA process will grow significantly, together with early stage HTA.

The Sustainable Development Goals published in 2015, include universal health coverage, under Goal 3. This implies that decisions on coverage will have to be made on the selection, prioritization, and reimbursement of medical technologies. Decisions are required to select priority clinical interventions for prevention, screening, diagnostic, treatment, rehabilitation and palliative care. When medical technologies are being assessed it is important to consider the competencies of the biomedical engineer. Therefore, HTA agencies should consider including this profession in their multidisciplinary HTA teams developing assessments and providing information for better policy decision-making, especially involving medical technologies.

In settings with few resources in HTA, where it may not be possible to hire biomedical engineers, strong links could be developed with BME departments in hospitals and universities, to share knowledge and resources. By improving the contribution of biomedical engineers to the HTA process, the necessary links between innovation, regulation, HTA and HTM of medical technologies will be strengthened and the contribution of HTA to sustainable health systems will be enhanced.*(186)*

Credit: James Goh; biomedical engineers in surgery room in China.

9 Role of biomedical engineers in the management of medical devices

9.1 Introduction

The professional figure typically assigned to manage medical devices in health-care facilities is the biomedical engineer, although in some countries, they are called clinical engineers or medical engineers. Clinical – or biomedical engineers (as referred to here) – are generally considered a specialization of work in BME. Whereas in some countries BME is practised primarily in academic institutions, the research laboratory or manufacturing, "clinical engineering" is practised in hospitals and other environments where medical device technologies are used.*(187)* However, some countries have BME departments in hospitals and health-care services, responsible for the management of all medical technology. There is no definitive definition of a clinical engineer but over the years several societies have attempted to provide an appropriate definition:

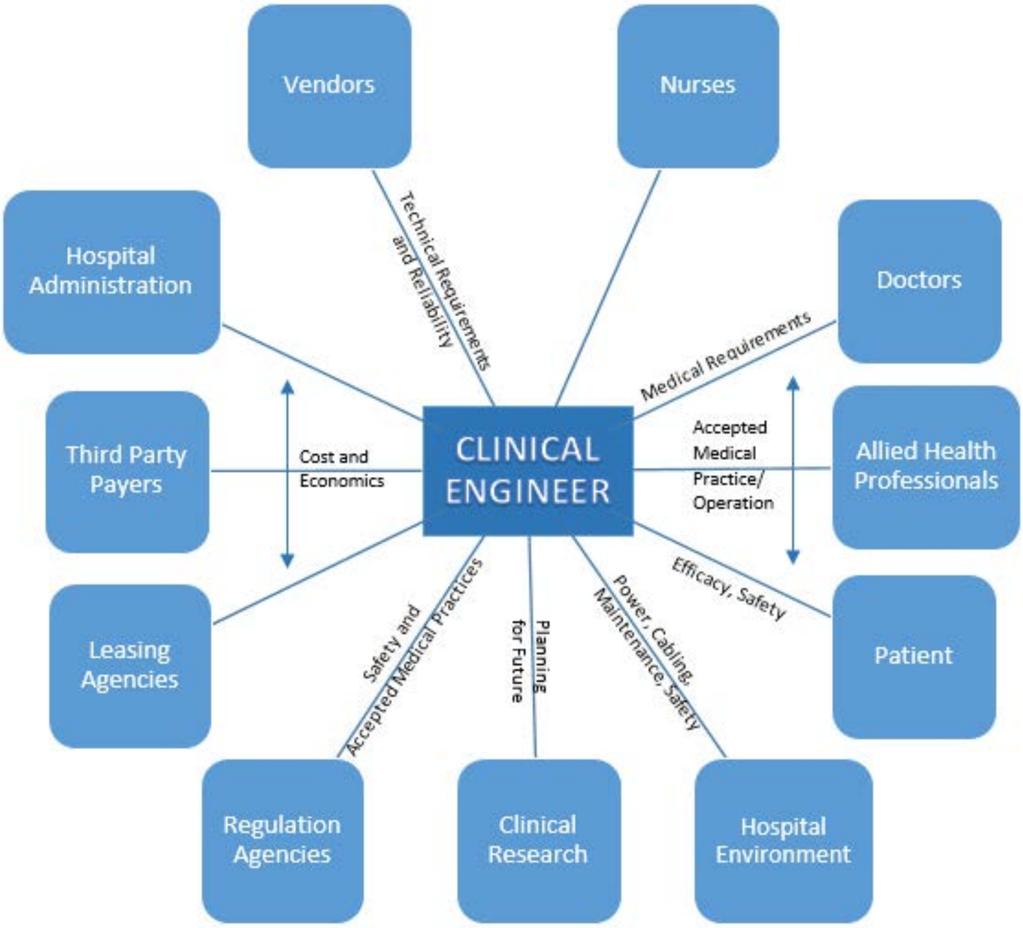
- ACCE: A professional who supports and advances patient care by applying engineering and managerial skills to health-care technology.*(188)*
- AAMI: A professional who brings to health-care facilities a level of education, experience, and accomplishment which will enable him to responsibly, effectively, and safely manage and interface with medical devices, instruments, and systems and the user thereof during patient care.*(189)*

However, today these definitions are obsolete and need redefining to reflect the new role of the biomedical engineer in health-care systems as a health-care professional who supports and promotes patient care by applying engineering, economic, communication and managerial skills to health technologies. As clinical medicine has become increasingly dependent on more sophisticated technologies and the complex equipment associated with it, the biomedical engineer, as the name implies, has become the bridge between modern medicine and equally modern engineering, supplemented with a combination of education in life sciences, human factors, systems analysis, medical terminology, measurements, communication systems and instrumentation. Such cross-disciplinary knowledge and skill plays an increasingly vital role in ensuring the safe and effective integration and interoperability of many medical devices and innovations with existing IT systems, business systems and organizational processes.

Biomedical engineers take care of medical devices throughout their life cycle within health-care facilities, managing not only medical equipment, but also implantable medical devices, in order to safeguard patients' lives. Biomedical engineers may also train clinicians, nurses and other professionals operating in health-care facilities for the best and safe use of medical devices.

Biomedical engineers work in different levels of health-care facilities. Biomedical engineers should participate in the planning of areas or new units of hospitals as well as in the planning of health-care facilities, to support the decision-making of medical technologies requirements depending on the clinical interventions that would take place responding to the population needs.

Figure 9.1 A biomedical (or clinical) engineer's interactions



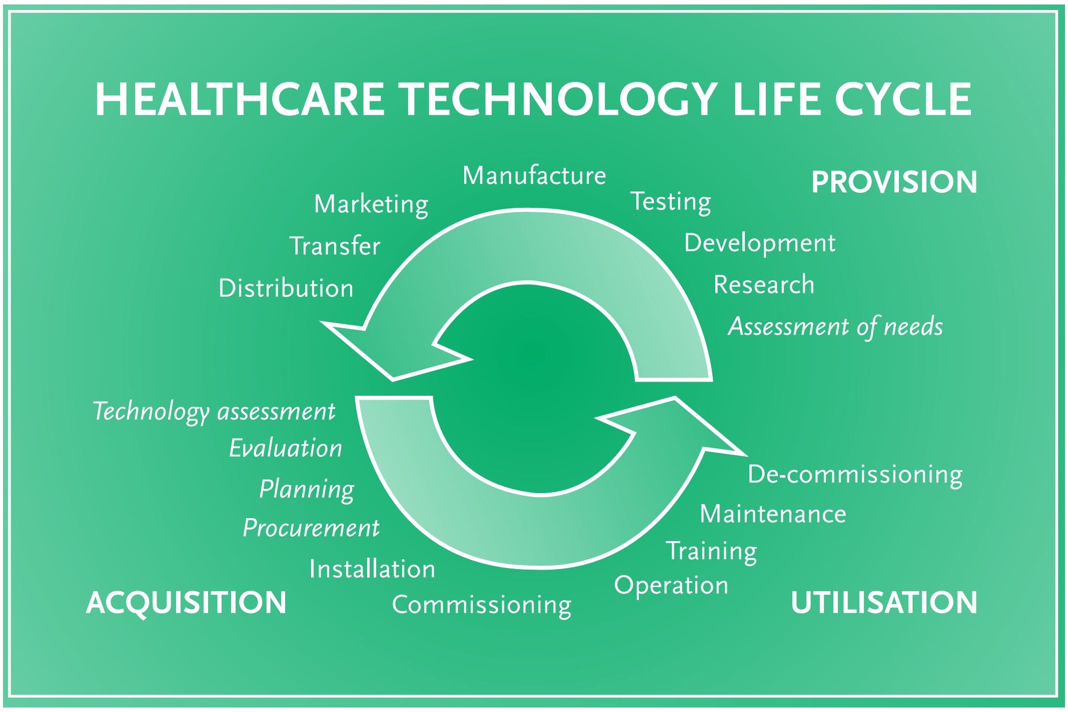
While working in hospitals, where they directly interface with medical devices, clinical staff and operations personnel, biomedical engineers may also work in higher levels of health care, such as ministries of health and international organizations.

9.2 Biomedical engineering activities through the life cycle of devices and systems

A biomedical engineer at the hospital level is responsible for managing health technologies from assessment and introduction within the hospital to decommissioning. The WHO health technology life cycle (Figure 9.2) describes all the phases of health technology.

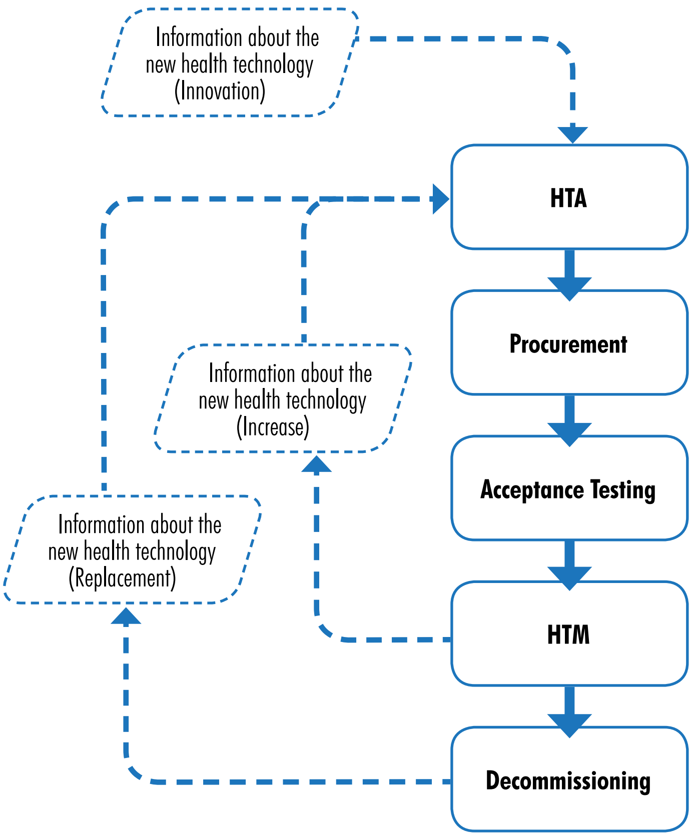
Biomedical engineers not only manage day-to-day operations to ensure that the medical device infrastructure is performing reliably, but they are also responsible for understanding and managing the longer term issues of technology assessment, installation, integration with IT systems, managing hazard alerts and recalls, upgrades and developing transition strategies for replacement technologies.

Figure 9.2 Health-care technology life cycle



Source: Medical device regulations: Global overview and guiding principles (http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf).

Figure 9.3 Major life cycle functions for medical devices



9.2.1 Health technology assessment

Biomedical engineers are sometimes involved in HTA committees in order to evaluate efficacy, safety and effectiveness of health technologies. The HTA process focuses on different technology aspects (such as clinical, technical, economic, ethical and legal). Biomedical engineers contribute to the process with their technical knowledge and capacity to interact with different fields professionals. Further details on HTA can be found in Chapter 8.

9.2.2 Procurement

Procurement is the process of obtaining planned requirements according to transparency and anti-corruption rules. Biomedical engineers work with procurement departments in the acquisition of planned health technologies planned. According to Bailey's "five rights",*(190)* to obtain the right product or service, a generic description within a clear specification is required. Biomedical engineers are in charge of assessing the technical specifications of different manufacturers' bids, and recommending the best overall solution.

9.2.3 Health risk management

Health risk management (HRM) is defined as the combination of strategic activities used to prevent, or reduce to a minimum, adverse events. Risks in health-care facilities are various: clinical, financial, strategic, legal, etc. Risk assessment requires the joint participation of different stakeholders within the organization. Biomedical engineers are an essential component of multidisciplinary HRM teams operating within health-care facilities, analysing accidents involving medical devices which have caused – or contributed to produce – severe injuries to patients or health workers. They are often the only professionals available who possess a broad span of health technology knowledge that allows them to analyse deeply the operation of medical devices and to identify causes of errors (e.g. wrong maintenance, design deficiencies, human-machine interaction deficiencies, inappropriate use, etc.).*(191)*

9.2.4 Health information technology

Health information technology (HIT) involves the exchange of health information in an electronic environment. Widespread use of HIT within health-care facilities will improve the quality of health care, prevent medical errors, reduce health-care costs, increase administrative efficiencies, decrease paperwork and expand access to affordable health care. It is imperative that the privacy and security of electronic health information be ensured as this information is maintained and transmitted electronically.

Biomedical engineers, as health technology experts, are involved in HIT in diverse ways within hospitals. Their expertise concerns the knowledge of certification procedures of software in medical devices, and standards, such as IEC 80001-1, concerning best practice for IT-networks incorporating medical devices. As with other health technologies, staff training and comprehensive service agreements are essential for effective installation and use of software.

In some hospital settings, biomedical engineers may be involved in the management of the hospital information system (HIS), which is a comprehensive, integrated information system used to manage data flow in hospitals. As more and more devices become networked, dedicated expertise is needed to ensure these devices are integrated into the IT network infrastructure, which data models are compatible, and that coordinated change management is built into the working relationships between the biomedical and IT departments and staff.

HIS is not the only information system within the hospital. Other systems include cardiology information system (CIS), laboratory information system (LIS), PACS and RIS. These systems are totally independent even if they could interact and exchange information. More information can be found in Chapter 10.

9.2.5 Health technology management

Traditionally, the core activities of a biomedical engineer concern HTM, and include all management activities relating to medical devices within the hospital. In HTM activities a biomedical engineer is often supported by a biomedical equipment technician who is in charge of detailed technical activities. The most important tool for HTM is the medical devices inventory, which provides a technical assessment of the technology on hand, giving details of the type and quantity of equipment, and the current operating status. Furthermore, when linked to standard equipment lists and an appropriate nomenclature, it provides the basis for effective asset management, including facilitating scheduling and tracking of preventive maintenance, repairs, alerts and recalls.*(192)*

Key elements of the HTM life cycle are:

- **Acceptance testing:** The act of accepting a new medical device in a hospital, checking it is safe and functional.
- **Maintenance:** Keeping a medical device in safe and functional condition by regular checks and repair as necessary.
- **Decommissioning:** Permanent removal of a medical device from use in a hospital, for obsolescence or other reasons.

Acceptance testing

This process checks that a medical device meets safety standards, clinical requirements and the procurement requirements of the hospital from the day it arrives. The safety of the medical device must be guaranteed and verified in order to protect patients and health-care workers. Generally, an acceptance form is filled out for this process (see sample acceptance test log sheet for equipment). *(193)* The acceptance test includes:

- Correspondence check of medical device purchased with that delivered
- Visual inspection
- Functional check
- Electrical safety check
- Calibration and measurement (for specific medical devices).

Each acceptance test should be recorded as "pass/fail" or not applicable (n/a). Once all the regulatory criteria for acceptance have been satisfied, the device can be labelled with an asset number, and then formally handed over to the user.*(194)*

Maintenance

These activities represent an essential segment of HTM activities. There are two types of maintenance activities: corrective and preventive. Corrective maintenance involves activities aimed at fixing a medical device following a breakdown. The biomedical engineer's role is to identify a breakdown and its causes and to manage all activities, technical, organizational and logistic, which allow re-establishing medical device functionality. Preventive maintenance or planned preventive maintenance (ppm) is identified as the set of maintenance activities carried out at pre-set intervals or according to predetermined criteria. This kind of maintenance is necessary to reduce breakdown likelihood, to maintain medical equipment functionality, and to prevent possible damage for patients and health-care workers. The biomedical engineer should plan a real maintenance policy, established and discussed within the hospital, in order to ensure the permanence of safety and efficacy, and the replacement of older equipment.

Decommissioning

This process is the well considered, final phase of the health technology life cycle. The aim of the process is to guarantee the appropriateness of the whole health technology asset, and to permit permanence in activity only for those health technologies that are safe, useful and economically sound, and accord with applicable standards. A biomedical engineer is the health professional able to manage the whole decommissioning process appropriately, from the identification of decommissioning processes to the definition of appropriate criteria to assess if the identified health technologies may be decommissioned. In this process, a biomedical engineer may collaborate with other health professionals (doctors, nurses, etc.) in order to understand all the factors involved.

9.2.6 Education and user training

This activity is fundamental to a biomedical engineer's work. Indeed, education and user training could reduce damage both for users and patients. Biomedical engineers' interdisciplinary knowledge allows them to organize lectures, workshops and courses aimed at different health professionals. In these events they teach how to use medical devices, what the technology can offer the patient, but also the cost and organizational problems that need to be considered. In this way health professionals acquire awareness of the importance of the best use of technology and which behaviours to avoid. Biomedical engineers can also provide in-service training for BME personnel, e.g. biomedical equipment technicians, regarding electrical safety and maintenance. Finally, they may give advice to consumer representative groups on the availability of technology, the effective and safe use of resources, and the significance of new developments.

9.2.7 Ethics committee

An ethics committee is a body consisting of health-care professionals and nonmedical members, whose responsibility is to protect the rights, safety and well-being of human subjects involved in a clinical trial. The committee also provides public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.*(195)* Ethics committees' competences concern, in addition to clinical trials on medicinal products for human use, issues on medicines, medical devices, and on the use of clinical and surgical procedures. Biomedical engineers' are essential members of ethics committees, because they are medical devices experts, and they have the knowledge of the technological and organizational hospital context.

9.3 Organizational models of biomedical engineering services

In a health-care facility there is no single organizational model for BME services. The managers and others responsible for the BME service can consider a variety of options and their ramifications – including cost considerations – in order to arrive at the best decision for their environment. *(196,197)* However, it is possible to identify three basic models.

9.3.1 In-house personnel model

In this model all biomedical equipment maintenance activities (consultations, safety verifications, etc.) are executed by in-house personnel located in the hospital, including the management of

Figure 9.4 In-house personnel model – main activities

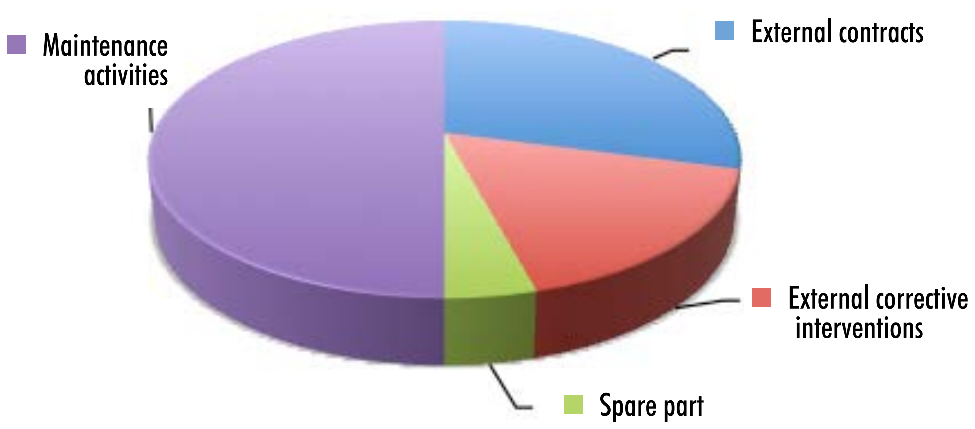


Figure 9.5 Mixed model

supplying spare parts and contracts with manufacturers.*(10)*

9.3.2 Mixed model

In this model the hospital stipulates contracts regarding servicing the maintenance of biomedical equipment. BME department managers should decide if this service should be performed by the original equipment manufacturer (OEM), by a third party such as an independent service organization (ISO) or a mix of the two.*(11,198)* The management of the contracts with manufacturers and the provisioning of spare parts and other high-level activities are carried out by in-house personnel.

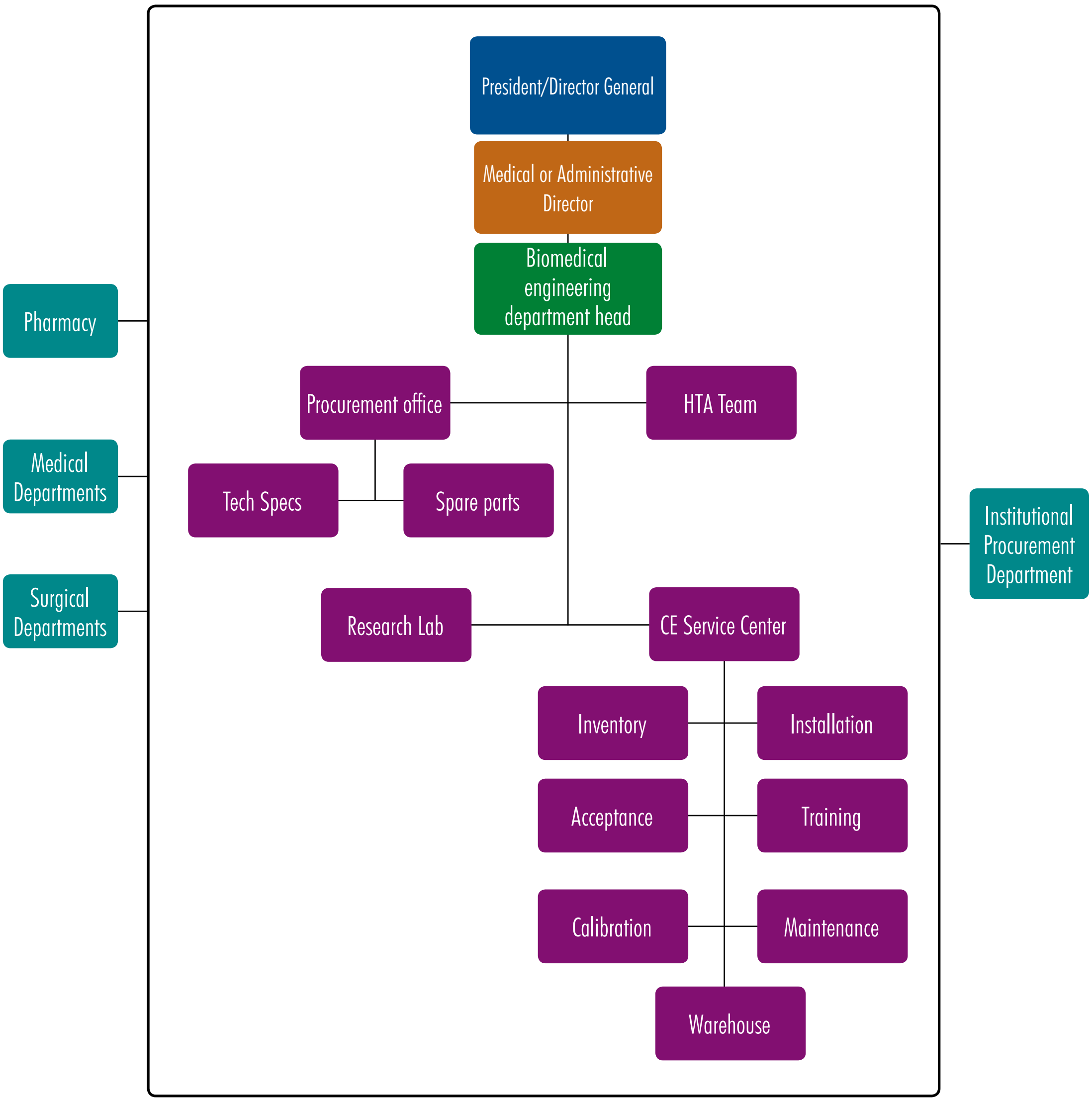
9.3.3 Third-party multi-vendor service model

In this model the hospital stipulates a contract to service the full-risk maintenance activity and for other BME services with an ISO.*(11)* In this way the health-care facility does not need to be concerned with the management of biomedical (test) equipment and medical devices.

9.3.4 Biomedical engineering departmental structures within hospitals

The BME department or service is an internal structure within hospitals. It is specific for each health-care facility and can vary in its composition between health-care providers and from country to country. However, it is possible to describe a generic BME department – see Figure 9.6. Generally, it comes under the medical department director. This position is strong evidence that biomedical engineers cover a key health-care role within hospitals and health-care facilities. Furthermore, BME departments liaise with other departments, interacting with all the different professionals within a health-care facility: physicians, nurses, pharmacists, economists etc.

Figure 9.6 Typical BME department in a hospital



Source: Fred Hosea, 2016.

9.3.5 Key roles in a biomedical engineering department

These functions would differ depending on the type of health facility, the organization, the needs and the resources available.

- **Biomedical engineering director/ manager:** The biomedical engineering director acts as a manager and technical director of the BME department or service. Their typical background will be a MSc in BME or equivalent programme and three years' minimum experience as a biomedical engineer. Furthermore, they must have some business knowledge and management skills that enable them to participate in budgeting, cost accounting and personnel management.*(1)*

9.4 Biomedical engineering around the world

engineer will have a BSc in BME and (depending on the position) four to five years' hospital experience in: conducting research; leading procurement processes; organizing and supervising service centre activities; and supervising technicians, students.

- **Biomedical engineering technician:** A biomedical equipment technician is an engineering technician or other technical equipment specialist "trained to maintain instruments biomedical equipment used in hospitals, laboratories and other clinical areas".*(199)* They perform troubleshooting, corrective and preventive maintenance, electrical safety tests and calibration of a wide variety of medical devices, medical equipment and in vitro diagnostics devices.

African Region: Gambia

Distribution of biomedical engineers: No data
BME societies: Early stage
Main BME activities: HTM (maintenance)

Gambia does not possess a programme for general training on medical devices maintenance that would provide the fundamental qualifications to work safely as a biomedical technician in hospitals and other health-care facilities. Generally, maintenance staff working on medical devices in all health-care facilities only had prior professional training in electrical/electronic technologies. However, the Medical Research Council Unit, in Gambia has, by contrast, a quite successful BME department. In 2015, the department consisted of a biomedical engineer, one senior BMET, three BMETs, two assistant BMETs and two local trade students. The department now supports almost 99% of biomedical technologies "in-house" and performs regularly with measurable indicators.

African Region: Zambia

Distribution of biomedical engineers: No data
BME societies: Early stage
Main BME activities: HTM (installation, maintenance, decommissioning)

The acceptance of BME in the health system is improving because the failure of a single item of equipment has the potential to bring service delivery to a standstill and serious suffering to patients. The main difficulties faced are the absence of strong financial support and a safety standards system within the health-care system. There is a need for the government to introduce schools to train engineers in this discipline and to develop specific policies to help improve the situation.

Eastern Mediterranean Region: Jordan

Distribution of biomedical engineers: Medium (90 for 30 ministry of health hospitals and 1200 health-care medical centres)
BME societies: Absent
Main BME activities: HTM, procurement

Jordanian BME experience is the only one in the EMR. It belongs to the Directorate of Biomedical Engineering (DBE), officially established in 2001 to be the technical arm for the Jordanian Ministry of Health and to overcome all the challenges and difficulties related to medical equipment. Nowadays DBE has become a unique establishment covering all issues and activities related to medical devices and equipment life cycle, with fully automated, web-based, paperless software as an integrated comprehensive solution. All HTM system components and procedures are automated, locally developing and implementing a unique technical management software system, within DBE according to DBE needs.

The complete web-based system includes a powerful software package designed on an Oracle base and implemented on a network covering different locations of the DBE. The core of the system is a fully paperless computerized maintenance management system where all maintenance operations are performed fully paperless, including spare orders management. The system also includes a powerful reporting module capable of producing all types of standard and customized reports about all activities and information related to any medical equipment such as inventory information, life cycle cost and including any other information such as staff productivity, travel hours, performance, training etc. The main lesson learned was that every country or health organization needs a HTM system developed to meet local requirements. Copying systems from more developed countries may not necessarily work. This system presents a unique model in terms of setup, cost and performance. It contributes to better quality patient care.

Region of the Americas: United States of America

Distribution of biomedical engineers: High
BME societies: ACCE, 50 state and regional societies
Main BME activities: HIT, HRM, HTM, procurement, ethics committee

The main challenge currently is to transform the health-care system into an interoperable health-care system. Medical device interoperability refers to the ability of medical devices to exchange information with each other and with patient data repositories such as electronic health records (EHRs). In the context of device and EHR interoperability, it refers to information sharing from one device to another or between devices and EHRs.

European Region: Croatia

Distribution of biomedical engineers: Medium (about 1 per million population)
BME societies: Croatian Medical and Biological Engineering Society (1984–2015) renamed Croatian Biomedical Engineering and Medical Physics Society (2015 onwards)
Main BME activities: HIT (HIS – rarely, PACS, RIS, LIS – occasionally), HTM (acceptance testing – occasionally, corrective maintenance – rarely, preventive maintenance – rarely, electrical safety test – never, decommissioning – occasionally, user training – rarely), procurement (technical specifications – occasionally, selection – rarely).

European Region: Italy

Distribution of biomedical engineers: High
BME societies: Associazione italiana ingegneri clinici – Italian Association Clinical Engineers (AIIC)
Main BME activities: HIT, HRM, HTM, ethics committee, procurement

In Italy there is great mobilization concerning biomedical engineer recognition as health-care professionals. In 2014 the government approved the undertaking to accord biomedical engineers as national health system health-care professionals. If biomedical engineers' activities mainly concerned medical equipment in the past, nowadays they extend to medical devices. For this reason, medical devices will be the main topic of the 15th AIIC national congress.

South-East Asia Region: India

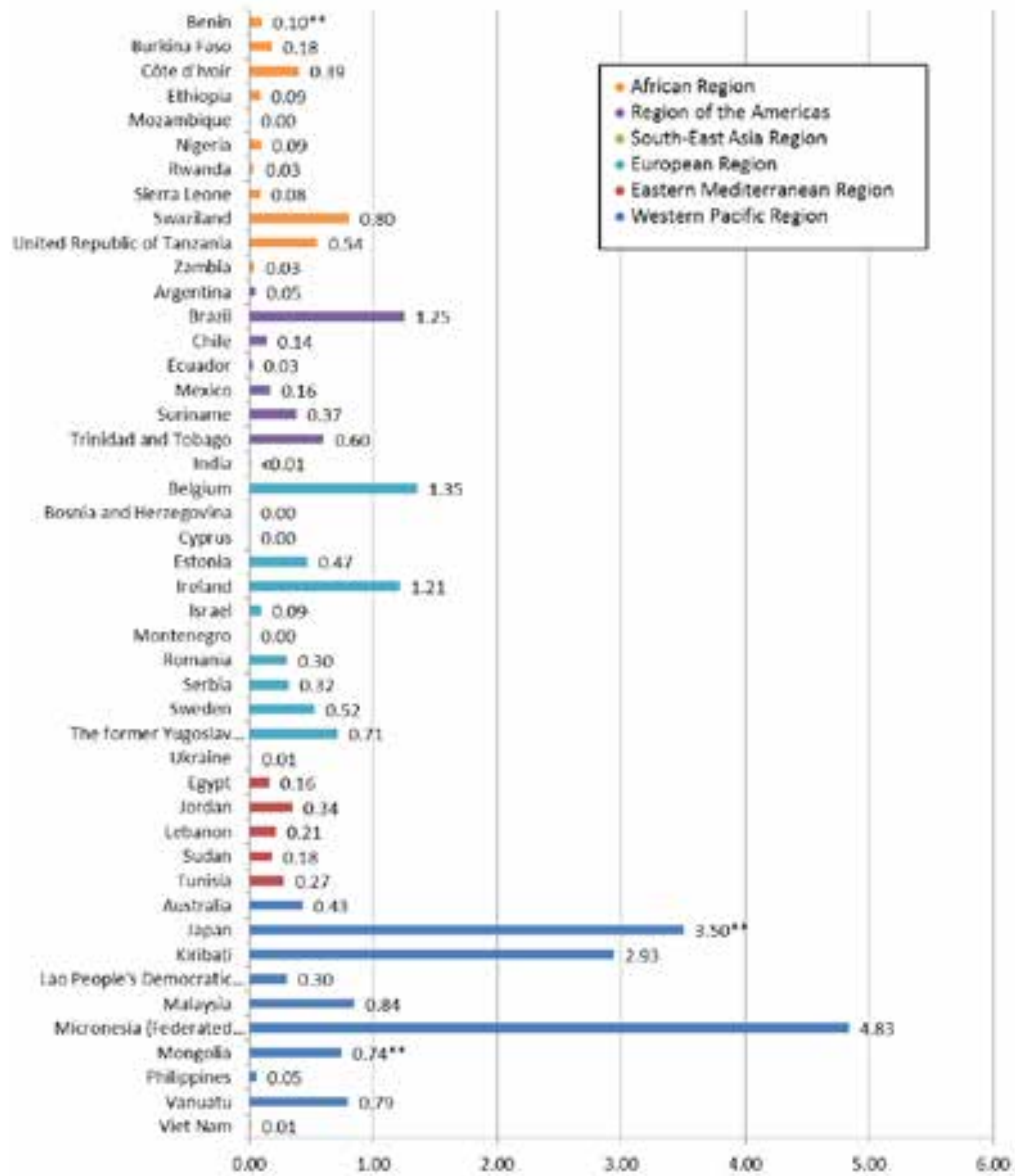
Distribution of biomedical engineers: Low (1500 estimated for 16 000 health-care facilities)
BME societies: Biomedical Engineering Society of India, Clinical Engineering Society of India has been in existence for a couple of decades
Main BME activities: HTM (focusing on corrective maintenance), procurement

Leaders of health-care systems in India are well aware that use of modern medical technology is essential for providing advanced diagnostic and therapeutic services to patients. In recent years, there has been a great influx of modern, sophisticated and expensive equipment into all types of hospitals. However, an understanding that well qualified, highly trained and certified biomedical engineers are equally essential within the system for effectively and safely managing this advanced technology, has been lacking. This has been one major factor for causing suboptimal development of the BME profession in India. Absence of a formal state recognized nationwide programme for certification of biomedical engineers is another hurdle in correctly projecting the importance of this profession to other health-care professionals and to the society at large. Though recent efforts have managed to make some progress in attracting the attention of health-care system leaders and policy-makers towards these lacunae, much more effort is needed to bring about the required strengthening of the BME profession in India.

9.4.1 Global survey of biomedical engineering

The January 2015 Global Survey - Professional and Academic Profiles on Biomedical Engineers and Technicians, conducted by WHO, investigated the number of hospitals with BME departments/service worldwide. Table 9.1 depicts the density of hospitals with a BME department per 100 000 population. This indicator was not reported by every country reporting BME professionals. However, it provides a tangible comparison of the level of involvement of biomedcal engineers in country health systems, and it shows the disparity not only between Member States, but also between regions. Currently, no data have been provided for SEAR, where further information is needd In order to increase the relevance of the indicator.

Table 9.1 Density of hospitals with BME service per 100 000 population by WHO region



* Most data in this graph need to be validated by national authorities.
** Validated data

9.5 Conclusion

This chapter presents a general overview of BME in hospitals. It could be useful for those health-care facilities considering introducing a BME service, as well as for those who wish to improve their department.

Activities performed inside a BME service are diverse, but all are related to medical devices and health technologies. The most important is undoubtedly HTM, which is the core of BME. Nevertheless, HTA, research, procurement, planning of health facilities and other activities are performed with the same aims of HTM: patient safety, proper use of health technologies and cost minimization of health-care services.

It is important to underline that the figure of the biomedical engineer is the only one assigned to the management of medical devices, encompassing both hardware and software functions. Biomedical engineers could be considered as health-care professionals in parallel with physicians and nurses. For this reason, it is important that they become more involved in health-care delivery systems, with countries recognizing the biomedical engineer as an essential professional for 21st-century health-care.

WHO encourages all biomedical engineers to dedicate substantial time during their academic preparations in hospital settings (via internships, fellowships, practicals) to understanding health technologies for the widest contexts and uses.

This recognition of biomedical engineers as essential health-care figures is very important for WHO, IFMBE and other national BME associations globally. Today, these organizations are making great efforts to increase the availability of biomedical engineers worldwide in order to support health service delivery. It is therefore important to advocate for the inclusion of the biomedical engineer (and clinical engineer) in the national and regional classifications of occupations as well as in the International Classification of Occupations published by ILO.*(200)*

Credit: IFMBE; clinical engineering in hospital setting, Brazil.

10 Role of biomedical engineers in the evolution of health-care systems

10.1 Biomedical engineering for 21st-century health-care systems

The world of medical devices is going through economical, technological, and globalization revolutions simultaneously, which are radically changing the health-care processes and relevant professional skills that biomedical engineers need to develop and manage medical devices, along multi-year and multi-decade product life cycles. This is particularly true for BME professionals working in hospital systems who must ensure that hundreds of medical device types work harmoniously in the complex ecosystems of IT, business systems and organizational processes. These changes are putting unprecedented technical, financial, societal and political pressure on all health-care systems, regardless of size or wealth; but these changes also create new opportunities for better, safer and more universally accessible care, if the appropriate professional capabilities are established in hospitals, academia, professional associations, government and industry.

BME professionals need new skills and education so they can fill a larger and more complex role as subject matter experts and as advocates for systemic intelligence across the various stakeholders in complex health-care systems. Those new skills will allow them to shape how these new challenges and opportunities are understood and managed at varied local, regional, national and international levels. The specific professional competencies needed will depend on each organization's level of resources and complexity, the kinds of services being offered, and the fiscal, organizational and technical maturity of the organization. The biomedical engineer's skill sets are in the process of being expanded, re-focused and refined to meet the organization's goals, in order to ensure that technologies are appropriately designed, evaluated, chosen, installed, integrated with IT systems and efficiently maintained over their life cycle to deliver the safest, most effective, affordable care.

10.2 Revolutions impacting biomedical engineering

Table 10.1 presents a partial snapshot of the revolutions that are re-defining BME, requiring changes in organizational strategy for clinical services and expansion of the training of biomedical engineers as caretakers of systemic intelligence and capabilities across multiple clinical domains. As science and innovations are advancing, biomedical engineers will need to broaden their professional horizons as well to incorporate changes constructively rather than reactively. For example, the fields of molecular and nano-technological engineering are yielding new sensors and actuators that allow tools that can operate at the atomic and molecular level. Other revolutionary factors are:

Table 10.1 New developments and innovations impacting biomedical engineering

Miniaturization	Devices are being made dramatically smaller, enabling portable monitoring and decentralized management of care.
Implantation	Devices that used to require external power, controls and maintenance can be implanted for long periods of time, with mobile power sources and controls.
Smart device	Multicore processors and increased memory capacity enable medical devices to execute a much wider range of functions, including self-monitoring and reporting, remote management, process controls, embedded security and stand-alone functions when disconnected from the network.
Hybridization	Devices can synthesize multiple functions previously requiring several devices, servers and databases, expanding to include monitoring, diagnostic and treatment capabilities.
Networking	Devices can connect to other devices and wired/wireless networks, disseminating data to aggregators, monitoring stations, mobile devices, specialized servers, EMRs and exercising new safety controls.
Informatics standard	Devices now must produce data in formats that are compatible with national standards that cross organizational and sectoral boundaries.
Clinical process re-engineering	Devices will play an increasing role in controlling compliance with built-in safety "guardrails" and best clinical processes.
Molecular and nano-technical engineering	The granularity and scale of what constitutes a medical device is becoming increasingly refined to molecular and nano-scale structures and processes, creating radically new levels of specificity for detection, diagnosis, monitoring and treatment.
Virtualization of care away from hospital	Models of care are expanding beyond the hospital to include retail sites, business locations, other community-based locations such as gyms, shops, schools, monitoring and advice centres, and to include new providers and services.
Point-of-care labs on a chip	Micro-diagnostic technologies will enable rapid and decentralized laboratory services, extending care into new locations and populations.
Materials science	New materials will enable devices to be used in novel ways, swallowed as pills, implanted as dissolvable devices, materials with bonding specificity that pairs with imaging and ultrasound technologies to target diagnosis and therapies more precisely.
Interoperability	Multiple devices and information systems may need to interact with each other in order to monitor and adjust care in real-time. Timing synchronization, data models and control language will require standardization.
Clinical decision support	Devices will play a stronger role in providing clinicians with decision support at the point of care and remotely. Device reliability will be crucial to reliable decision support.
Telehealth and wellness models of care	New devices will come into use as consumers and providers move to adopt more preventive, mobile models of "care anywhere."
New research methods based on new sources of data	New methods and disciplines will be needed to take advantage of cloud- and crowd-sourced health data derived from multiple new sources and device types.
Design and performance analytic	Biomedical and clinical engineers will need to take a more active role in shaping the design of medical devices, and evaluating competing alternatives in terms of the overall system life cycle of costs, benefits and operational requirements.
Software evolution	Increasingly, devices will be defined by changeable software capabilities that will enable more rapid upgrading and evolution of medical devices, requiring significant skills in configuration, change management and ongoing IT partnerships.
Personalized medicine	New devices, analytics and procedures will enable health care to be delivered in ways that are specific to individual genetic and personal circumstances.

Interdependencies	Device performance and safety characteristics are becoming interdependent with other devices and/or information systems. e.g. self-adjusting medication infusion may be controlled by one or more physiological monitoring systems and/or central clinical decision support software.
Wireless and mobility	Devices are expected to function without wires that limit deployment flexibility or that can themselves introduce hazards into the clinical environment.
Wearable technologies	Devices can be worn by the patient, which has some of the benefits of implantation but exposes the device to additional environmental risks and risks of interruptions in wireless communication.
Cybersecurity	Smart, networked medical devices are now being hacked and attacked, creating novel safety and performance threats which may be hidden from easy detection.
Heterogeneous integration of multi-vendor, multi-modality devices	Devices are being combined in novel ways that challenge traditional detection or assignment of "fault".

10.3 Other contextual factors driving change in health-care systems

In addition to the technological and clinical changes identified in Table 10.1, there are numerous socioeconomic factors that both inspire and constrain change, including:

- Supply-chain problems that obstruct the economic and timely flow of parts and services needed to keep medical devices in proper running condition, affordably.
- Aggressive plans for modernization of obsolete national health-care infrastructures.
- Embedded traditions of business and political corruption, institutional and professional rigidity, and outmoded bureaucratic practices that impede adoption of more effective, affordable health-care practices.
- New ethical questions about eligibility for care, end-of-life care, and prioritization of care under conditions of limited resources.
- Increasing numbers of well-educated health-care professionals are capable and motivated to create 21st-century health-care systems, but they often must work against historical, political and economic obstacles.

Taken together, these forces lay out a challenging landscape that both experienced and novice biomedical engineers need to consider, understand and respond to with critical thinking, study, formal education, interdisciplinary discussions with health-care colleagues, life-long learning and a spirit of innovation that attempts to envision more effective health-care, not just in terms of devices, but also in terms of processes, multiple interacting systems and systems-of-systems.

10.4 Biomedical engineers work in many sectors

Because of how critical medical devices are in all health-care programmes, biomedical engineers have evolved diverse career paths to ensure that appropriate engineering and clinical expertise is applied along the entire strategic and operational life cycle of medical devices and the systems they interact with.

These practitioners may have similar academic preparation, but eventually develop specialized skills as they move between sectors. These careers may evolve in different directions over time depending on personal motives, abilities, training, certification and organizational policies on human resources. This diversity of professional practice is a manifestation of the growing need for "horizontal intelligence" to cut across health-care sectors and create devices and clinical capabilities that work harmoniously with IT and electronic medical record systems, business systems and the wider system of standards, policy and accreditation.

All of these careers will likely be affected by the rapid, sometimes disruptive, changes and transformations of the underlying health and wellness sciences, engineering, technologies, clinical practices, policies and business strategies.

There are three major domains and institutional complexes where BME expertise is needed to create and manage safe and effective medical devices and services – institutional foundations, innovation and management and operations. These domains present a wide range of career opportunities for biomedical engineers, and also demonstrate where BME expertise is needed in every institution and sector that is involved in the science, technology, policy, funding, design, testing, market development, service strategy and operational management of medical devices. This chapter provides some basic conceptual frameworks and guidance for biomedical engineers in many widely varied settings, including academic and training centres, hospitals and clinics, ministries of health, health-care innovation centres and manufacturers.

Being trained as a biomedical engineer can lead to employment in a wide range of sectors, with a variety of job titles (Figure 10.1).

Figure 10.1 Diversity of job fields and titles

Professional job family title	**Biomedical technician (BMET)**	**Biomedical engineer (BME)**	**Clinical engineer (CE)**	**Clinical systems engineer (CSE)**
	May be employed as:			
Employment titles	• Technician • Supervisor	• Technician • Supervisor • Project manager • Manager • Trainer, instructor, professor • Account representative • Programme director • Scientific investigator • Inventor • Consultant • Executive, CEO, CTO, CIO, CFO	• Clinical engineer • Project manager • Manager • Service/programme director • Scientific investigator • Inventor • Account executive • Trainer, instructor, professor • Consultant • Policy-maker • Executive, CEO, CTO, CIO, CFO	• Clinical engineer • Biomedical engineer • Project manager • Manager • Systems engineer • Service/Programme director • Scientific investigator • Inventor • Account executive • Instructor, professor • Consultant • Policy-maker • Executive, CEO, CTO, CIO, CFO

Source: Fred Hosea, 2016.

10.4.1 Evolution in biomedical engineering career paths

Traditional BME responsibilities typically have included:

- Evaluation of the existing device infrastructure
- Identification and evaluation of emerging technologies in terms of cost, effectiveness, efficiency, safety and fit with clinical interventions
- Procurement and contracting of new devices, support services, rentals and parts
- Installation of new technologies
- Planning of health facilities
- Integration of medical technologies with electronic medical records and other IT systems
- Training of health-care workers
- Ongoing maintenance and repairs
- Documentation required for hospital accreditation
- Analysis of failure trends and costs, in order to identify need for replacements
- Management of hazard alerts and recalls
- Forensic investigation of product-related failures, injuries and deaths
- Retirement or cascading re-use of ageing devices.

Many of these traditional responsibilities will undergo significant transformation and growth in coming years as a consequence of the numerous changes in technology, government policy and models of care.

10.5 Evolution of modern medical devices

Modern medical devices are evolving to be smarter and more complex – more interconnected, integrated, interoperable and interdependent. They are increasingly being designed with software/firmware features and control capabilities that are critical to their interactive role with informatics systems, electronic medical records, clinical decision support systems, and both patients and caregivers. Stand-alone devices, single-purpose devices, and/or hardware-defined devices are quickly becoming obsolete or marginalized to narrow roles. Most devices use embedded microprocessors, data storage and communication chips that allow them to be networked to deliver sophisticated new functions. New safety and clinical features are emerging through local and distributed-intelligence capabilities, remote software and data access, configurability, and sharing and functional interoperability with other devices and systems. Today's software-based devices are configurable to provide customized or optimized functions and features throughout their life cycle. Such devices need to be understood both as evolving, adaptive technologies and as components or subsystems within larger clinical systems of systems (SoS), not merely as static, fixed machines. This evolutionary SoS framework adds a significant, highly dynamic dimension to the BME career that calls for constant learning, research, collaborative design intelligence and troubleshooting, and leadership skills for working in wider institutional contexts. This new expertise can help inform and guide the health-care strategy of provider organizations, regulators, insurers and manufacturers.

10.5.1 Telehealth and telemedicine

Technological innovations in telehealth and telemedicine are expanding the physical and social dimensions of health care, and the range of services, beyond the traditional hospital setting, with increasing emphasis on prevention, wellness, real-time monitoring and use of social media. This expanded scope involves wider groups of health "partnerships," data strategies and service models that go far beyond the traditional roles and market mechanisms that have defined health care for decades. Health coaches, health advocates, advice nurses, gym staff, social media, family members and support groups may all play a role in the complex mix of voluntary, everyday activities (diet, exercise, education, support) and evidence-based clinical care plans. These new dimensions of care will require sophisticated advances in workflow design, clinical and ethnographic research, service management, service strategies and systems integration. These systems challenges are a central component of the BME career. Biomedical engineers need to be prepared to lead, collaborate with and support these innovative engineering efforts. Designing, planning and managing these clinical devices, processes and systems will require engineering skills – and nimble organizations – that are dynamic beyond anything currently in existence. Tomorrow's devices will have to be more agile and responsive to real-time – or near real-time – clinical and/or environmental patient needs. To avoid premature obsolescence, these devices must also be able to adapt over time to changes in clinical practice and informatics requirements. This built-in "developmental headroom" in devices will be essential to more efficient and affordable adoption of clinical innovations.

10.5.2 More sophisticated organizational and IT requirements

In addition to traditional operational skills required for managing deployments, recalls, maintenance and repairs, BME staff will need a dynamic range of new knowledge and organizational skills related to computer architecture and performance, network technology, data modelling and database management, troubleshooting, telecommunications and software programming/configuration skills. They will also need appropriate project management skills for the software and system development life cycle (SDLC), continuous quality management capability, the ability to supervise technical staff with appropriate skills, and the ability to communicate effectively with clinical and technical experts from related disciplines.

10.6 Mission critical: Systems engineering and systems of systems engineering

Medical device functions are still critical success factors in the detection, diagnosis and treatment of most medical conditions. However, as information and communication technology becomes a ubiquitous and pervasive part of health care, the devices themselves are only part of the overall system of care. At the same time, numerous technologies that support wellness, fitness and medical care are reaching into the home and may be worn or carried by individuals during everyday activities. Health, wellness and medical care are therefore weaving linked systems of medical devices and information systems into a flexible and extensible fabric of health and wellness. Ensuring that health-care services perform continuously at the place and time of need will be more cost effective than waiting for crises and hospitalization; but understanding and managing multiple distributed medical devices in such a fabric represents a complex systems of systems engineering (SoSE) challenge that will require upgrading the traditional model of health-care professions across the board. Understanding the complex and extended nature of health-care technology systems, and the interaction and interdependence of innovative systems of systems, will be essential to the effective practice of BME, whether in urban centres, small towns or remote rural clinics.

The International Council on Systems Engineering (INCOSE) provides networking and training resources to support formal education in the emerging SoSE field. Because the language and focus of INCOSE's community is generalized for many different industrial fields, the biomedical engineer will need to adapt it to the health-care paradigm. Given the enormous importance and cost of health-care systems, it may become a societal imperative to develop health-care systems engineering as a profession of importance equivalent to that of engineers who design outer-space systems, large metropolitan settlements, and national security infrastructures.

Biomedical engineers could explore the V-model of system verification and validation (V&V) that has been described by INCOSE and others instructive for managing SoSE projects. Also, writings by Barry Boehm *(201)* on the "spiral model" of project management may assist in mapping traditional "waterfall" and newer "agile" and "extreme" project management methods into longer term, multi-year projects such as hospital or health system modernization.

10.7 Elements of an ideal, integrated health and information technology system

Health-care systems of all kinds are evolving through several stages of maturity to achieve higher levels of clinical quality and wider extension of their services. Because biomedical engineers may work for years in hospitals or regional service networks, they often have extensive experience with the numerous performance issues affecting clinical services, not just related to devices but to the wider "performance ecosystem" of manufacturers, third party service providers, physical materials and replacement parts, ergonomic design, supply-chain weaknesses, facility infrastructure needs, weaknesses in the managerial and leadership levels, end-user training, vulnerabilities to variations in IT system performance, etc.

Because of this wider, "end-to-end" systems perspective, biomedical engineers often understand the bigger picture better than many of the administrative, financial and IT specialists who may be making important decisions with incomplete understanding or historical experience. Biomedical engineers may be better prepared to work in the planning and budgeting discussions, to ensure that their systemic experience informs the decision-making process.

Working upward from the most basic level of services (from family homes and schools to village outposts and clinics to hospitals, regional systems, national systems and international systems), health-care planners and biomedical engineers can use tools such as WHO's OneHealth *(202)* software, "to link strategic objectives and targets of disease control and prevention programmes to the required investments in health systems. The tool provides planners with a single framework for scenario analysis, costing, health impact analysis, budgeting and financing of strategies for all major diseases and health system components. It is thus primarily intended to inform sector wide national strategic health plans and policies".

Within this strategic framework, representatives from the various jurisdictions can begin to coordinate their plans and staffing models to provide the desired capabilities. All medical devices must be understood in terms of the medical services they support, and the contextual factors impacting those services. As medical devices evolve, so do those services. Each medical device may be surrounded by a complex network of connective factors that must be studied and closely managed – e.g. organizational and infrastructural changes, logging accurate clinical metrics for grants and research projects; secure data and network transactions; supply-chain needs; pharmaceuticals; training requirements; IT connectivity requirements; changes in network security and access precautions; surges of displaced persons from epidemics, climate change or political persecution that require additional organizational capabilities, clinical skills and security precautions; upgrades, recalls and hazard alerts that must all work together harmoniously to provide safe, effective and affordable health care.

While most other professionals in the health-care system are organized around specialized "vertical" expertise, experienced biomedical engineers can often provide unique "horizontal" perspectives on the complex end-to-end operational factors that are involved in translating plans into successful clinical services over the lifetime of the medical devices they are responsible for. Biomedical engineers may participate in, or manage, clinical technology committees that bring together doctors, nurses, and financial stakeholders to evaluate and prioritize replacement technologies. Biomedical engineers may participate in regular quality improvement meetings, to identify defects in device performance or clinical processes, and recommend new requirements for replacement technologies and related warranty terms and contract specifications. Biomedical engineers will increasingly devote time working with researchers and manufacturers to improve medical device design and to re-engineer clinical processes and services related to new device capabilities and increasingly stringent requirements of clinical practice guidelines.

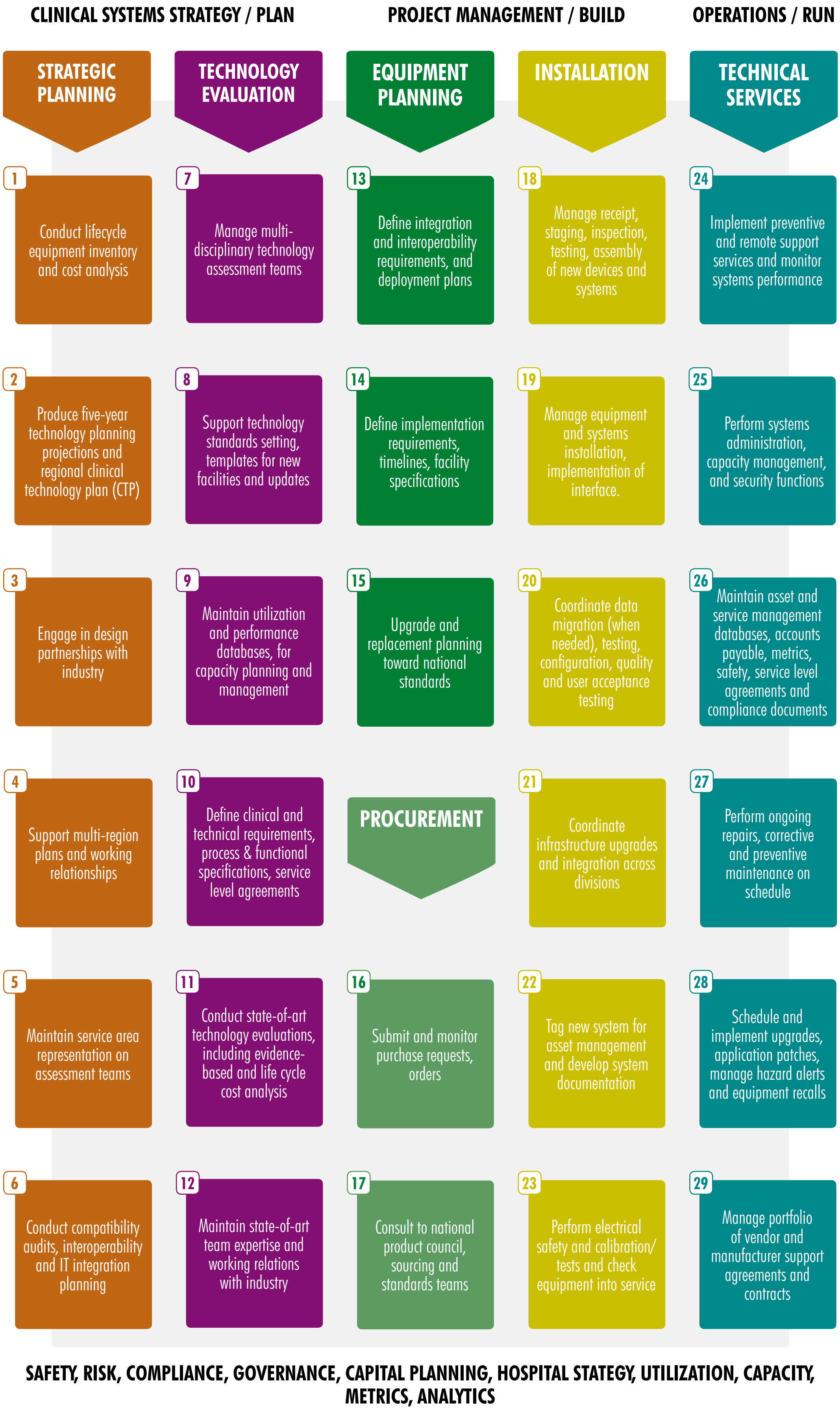
10.8 Establishing a comprehensive biomedical engineering value proposition

In order to ensure that the full range of professional responsibilities is clearly assigned to biomedical engineers – encompassing all health and information technologies – the field requires clear and comprehensive written definitions that can be considered at the policy level of ministries of health, regulatory bodies, professional associations, hospitals and health-care systems. These definitions allow development of statements of vision, mission and goals, and help argue for appropriate institutional resources needed to fulfil those duties.

Three crucial dimensions of the BME responsibilities in a hospital system are:

- **Enterprise strategy:** Biomedical engineers can contribute to a cost-focused strategy for the enterprise by providing expert technical and business consultations to the organization's standards bodies, to supply-chain and contracting stakeholders, to national and international standards bodies, regulatory agencies and professional associations, and by facilitating expert design relationships with manufacturers.
- **Clinical strategy:** Biomedical engineers can manage innovation and integration activities along the life cycle of all clinical technology devices and systems in the health-care system, facilitating clinician-led research design, technology assessment, integration and deployment of emerging technologies, in support of rapidly evolving clinical priorities and operational needs.

Figure 10.2 Clinical system life cycle



Source: Fred Hosea, 2016.

- **Operational excellence:** Biomedical engineers can deliver or manage timely, professional field services around the clock, to satisfy legal, regulatory and compliance standards for accreditation readiness through rigorous maintenance, repair and quality assurance procedures. Biomedical engineers can ensure highly professionalized teamwork with enterprise partners in the technical integration and project management of emerging clinical technology systems.

The scope of professional capabilities outlined in this value proposition is ambitious but essential for hospital systems which want to gain greater control over the growing "grey" areas that are currently not part of anyone's job description, but which can increase medical risk, cost significant time and money and lead to inefficiency when they are not professionally understood and addressed.

For one example of how a large, multi-hospital system organizes clinical systems engineering functions for its 10 million members, see Figure 10.2.

10.9 Build competencies in strategic, clinical and operational domains

At the hospital level, an effective clinical technology programme could be staffed to provide a dynamic range of strategic, clinical and operational services. Historically, most hospital-based biomedical engineers have been originally assigned to operational duties of managing, planning, maintaining, training on use of medical devices; but there are significant new "grey" areas in the design and management of future health-care systems that are going to require a more comprehensive skill set beyond the traditional ones.

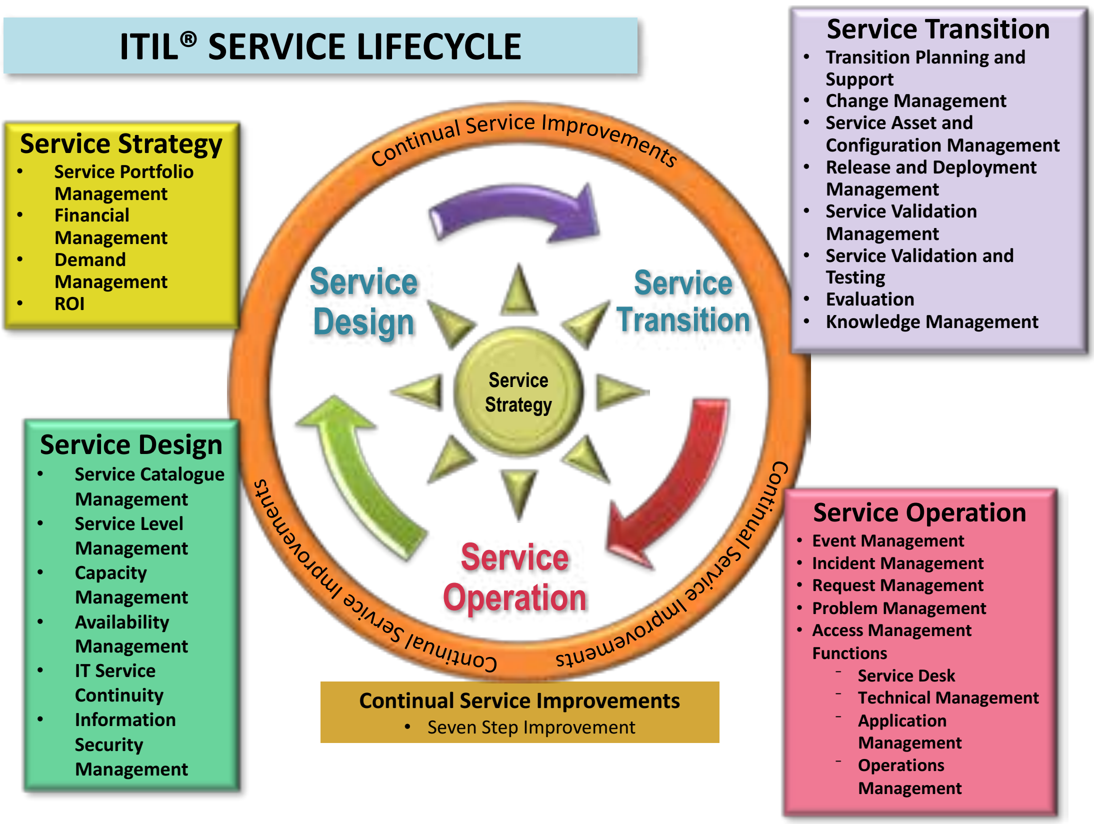
Strategic services: These are concerned with issues three to five years in the future, including standards development, regulatory policies, device design, R&D alliances, academic partnerships, market development, professional scopes of practice, professional training, credentialing and continuing education. A long-term strategic overview is needed in order to determine how best to divide up the new responsibilities between IT, biomedical, clinical and other facility staff. The strategic clinical services that biomedical engineers provide could include the capacity to design and evaluate clinical research, design and evaluate new clinical practices, and consult with clinicians and all system life cycle stakeholders to develop coherent models of care. New operational skills will be needed to troubleshoot complex networked and virtualized environments of care, to manage the constant updating and upgrading of medical devices, and to provide ongoing feedback to organizational planners regarding the performance of the existing device infrastructure.

Convergence: Devices and information systems will continue to converge, making separation of one from the other harder and harder. Although skill specialization may often be valued, cross-training and collaborative team problem solving may be equally important. New skills will be needed by these BME managers, because the stakeholders they work with span such a large number of disciplines and professions. Their skills should be situationally and contextually appropriate, flexible and adaptable for communications between learning teams, coaches, mentors leaders, partners, and providers.

IT systems alignment and integration: Biomedical engineers, clinical engineers and biomedical equipment technicians will need more than a casual understanding of core IT infrastructure components and skills, including topics like software, networks, databases, security management, change management, user interface design and configuration, decision support systems and wireless communication systems. Many, perhaps most, devices will have one or more of these IT components embedded, and the selection, safe deployment, and ongoing maintenance and repair will require competent IT troubleshooting with IT peers, and coordinated repair processes. Further, because most devices will likely be interconnected with one or more electronic medical record systems (EMR or EHR) and since those systems may themselves introduce significant patient safety risks and challenges, clinical technology management staff will likely need EMR/EHR support skills in order to perform point-to-point or device-to-device or device-to-system safety and performance validation and verification.

The ITIL framework: The Information Technology Infrastructure Library (ITIL) provides an indispensable model for aligning mission-critical services, business processes, data models and activities between IT and biomedical systems. The criticality of aligning these dynamic service functions cannot be overstated, as IT and biomedical systems become more interoperable and interdependent. Biomedical engineers are urged to receive formal training in the ITIL model and participate in ongoing efforts to architect the organizational capabilities needed to enable IT and biomedical

Figure 10.3 The ITIL service life cycle



systems to interact and co-evolve in a rational, mutually supportive fashion. The ITIL service life cycle identifies essential business processes that IT and biomedical functions must align in a constant and systematic fashion.*(203)*

10.10 Dimensions of career development in biomedical engineering

One major difference between a job and a professional career is the presence in the profession of a sustained trajectory of personal aspiration, commitment, learning and fulfilment that will span decades of professional life. Careers in BME could provide opportunities for continuing growth, responsibility and creativity that give engineers a vital and authentic investment in improving the well-being of their society, their organizations and of the patients they serve. Biomedical engineering must be understood and valued as an expansive career of life-long learning, personal growth and creativity. This growth dimension must be valued not only by biomedical engineers themselves, but also by employers and social institutions invested in health-care, through the support of:

- Regular release time and financial support for continuing education
- Attendance at conferences
- Membership and activity in professional associations
- Allocation of a suitable portion of the BME job description to participation in "horizontal", cross-functional committees, quality improvement projects and innovation initiatives.

10.10.1 A biomedical engineer's career anchor considerations

Edgar Schein identified eight generic "career anchors" that affect personal competence and fulfilment over time. *(204)* These frameworks can be useful in anticipating the kinds of personal needs and motives that affect professional engagement and development. The anchors Schein identified are:

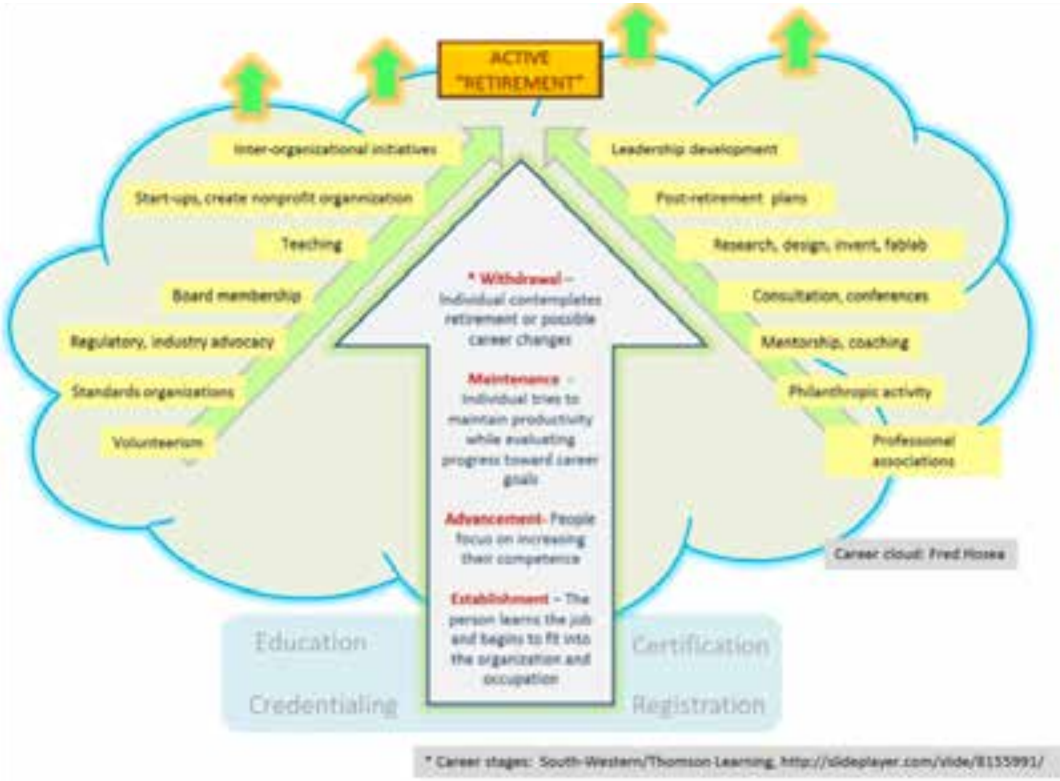
1. Technical/functional competence
2. General managerial competence
3. Autonomy/independence
4. Security/stability
5. Entrepreneurial creativity
6. Service/dedication to a cause
7. Pure challenge
8. Lifestyle.

Anchors 2 and 5 focus attention and skills on both leadership and management for biomedical engineers. As Joel Nobel, founder of the Emergency Care Rescue Institute (ECRI), often posited, there is a difference between leading people and managing things. The leadership side of a biomedical engineer's career includes intra- and inter-organizational skills, including coaching subordinates, trainees and interns, and incorporating human and contextually oriented elements of listening, observing and constructive dialogue that must be communicated upwards to supervisors and senior managers as well as laterally to peers. To be successful, these skills may need to span one or more enterprises, countries, cultures or languages. Management skills that biomedical engineers may need to develop include, but are not limited to: effective written and oral communication, general and ICT technology project management (including system and software development) and business or government policy management.

10.10.2 Biomedical engineering career stages

Individuals and organizations are urged to envision career paths that anticipate personal and professional needs across the life span of a career, in order to provide sustained and evolving career paths that keep people involved and growing, in tempo with technological and

Figure 10.4 Internal and external career paths



clinical changes. Biomedical engineers will need to pursue activities outside of their primary employing organization to build knowledge, connections and experience that will nurture their career possibilities. These "external" professional development activities not only improve career potential as an employee; they also lay the foundation for meaningful professional service after retirement.

In addition to the "internal" career stages typical of professional employment, Figure 10.4 identifies other external disciplines, institutions and initiatives where biomedical and clinical engineers can become fruitfully involved. These "outside" activities can be indispensable not only for the aspiring professional personally, but for the wider society as well, because they create considerable value-added in social capital – in knowledge, creativity and alignment of professional resources that are typically not addressed, or paid for, in the daily job descriptions that govern formal work life.

In view of the increasing speed of change, complexity of devices and processes, and the interdependencies of systems, biomedical engineers will need to have very dynamic, life-long learning approaches to their professional life, and organizations are urged to provide routine support for this learning process.

10.10.3 Key emerging biomedical engineering competency opportunities

The following trends are re-defining the realities that biomedical engineers will need to understand, to provide new value-added competencies:

- **Convergence of technologies:** This will accelerate novel decision support tools (IBM's emerging Watson programme is an example) using many artificial intelligence methods. New skills will be needed for design, implementation, management, disaster/business continuity planning and support. Also, as mentioned above, novel SoSE skills and tools will be essential.

- **Human-computer interaction of all stakeholders:** This will be a weak point that must be considered and incorporated in HR skill development. e.g. interview and related written and oral communication skills may become more crucial. Biomedical engineers might lead or participate in process re-engineering, ethnographic studies, human factors analysis and user experience design.
- **Risk and project management:** This will continue to require larger and larger matrices of interdependencies. Skills and tools for identifying, mapping and managing risk need to be developed. Planning and change management will remain crucial, but the complexity will increase. As business and clinical processes become increasingly complex, there will be increasing need for process automation software skills, where biomedical engineers might excel because of their experiences with the system life cycles of many devices, with clinicians and with operations stakeholders.
- **Diverse economic settings:** The biomedical engineer's skill requirements will vary significantly between high-, medium- and low-resource settings and countries. Clinical strategy and resource planning could be staged so that each stage lays a coherent foundation for each subsequent stage, with a minimum of obsolescence and disruption, unless the disruption is well understood and carefully planned. Each jurisdiction needs to conduct a formal self-assessment and plot its plans on the basis of a "capability maturity model" appropriate to its resources and economic prospects.

10.11 Training topics

Depending on the economic circumstances and existing infrastructure of the health-care system, other topics for professional development may be important to consider:

- Requirements engineering
- Epidemiology
- Clinical process modelling, process re-engineering
- Public health
- Electronic medical record
- Personal health record
- Telehealth
- Telemedicine
- Medical tourism
- Clinical decision support
- Medical anthropology
- Ethnography
- Clinical trials
- Patient care services
- Continuity of care
- Consumer health education
- Human factors analysis
- General systems theory
- Project management
- Six Sigma and lean manufacturing
- Innovation methodology (e.g. IDEO)
- IT life cycle management models (e.g. comprehensive delivery process)
- Root-cause analysis
- Wireless spectrum management
- Use-case development
- Developing technical requirements and specifications
- Testing and certification
- Translational research methodology
- Process modelling, mapping and automation
- IPv6
- Rapid prototyping methodology
- Scenario methodology

- Legal and regulatory definitions of medical devices and medical information systems
- Hospital accreditation procedures.

10.12 Conclusion

Biomedical engineering is growing into dramatically new areas of professional knowledge and responsibility, which will need to be cultivated and organized through ongoing efforts outside the primary employment location of the engineer. Individual hospitals or departments are unlikely to have sufficient staffing levels, budgets or infrastructures to understand or manage these emerging complexities; so it will be necessary to address these needs through a variety of inter-organizational efforts involving professional associations, provider consortia, academic liaisons, innovation centres and partnerships, national research programmes funded by government agencies or philanthropies, and industry consortia. Organizations employing biomedical engineers must understand and support the value of such "outside" activities through release time, conference expenses and outside committee work.

Because biomedical engineers may possess substantive historical knowledge that spans multiple device types, departments, hospital stakeholder groups and manufacturers, they are often the best prepared people to provide the "horizontal intelligence" that will be increasingly needed to ensure that the various "vertical" professions of the health-care system actually cohere and deliver the best care for the lowest cost. Hospitals, payers, government and professional sectors must understand the critical value-added of 21st-century BME, to ensure that appropriate resources, job families and organizational frameworks are created to support its evolution in coming years.

10.13 Further reading

Articles

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Websites

ANSI Health Information Technology Standards Panel Useful Clinical Engineering standards include: Interoperability Standard (IS-77): Remote Patient Monitoring and the Technical Note (TN-905): General Medical Device Interoperability: http://www.HITSP.org

CED Global: www.CEDGlobal.org

IHE Patient Care Device Domain, including the multi-vendor, multi-modality IHE Rosetta Terminology Mapping System Project: https://www.ihe.net/Patient_Care_Devices/

International Council on Systems Engineering (INCOSE): http://www.incose.org/

World Health Organization (Medical devices): http://www.who.int/medical_devices/en/

World Health Organization (Biomedical engineering global resources): http://www.who.int/medical_devices/support/en/

World Health Organization (Publications and other resources): http://www.who.int/medical_devices/links/en/

Credit: Adriana Velazquez; policy-makers at the Ethiopian Ministry of Health, November 2016.

11 Conclusions and recommendations

The Sustainable Development Goals, approved in September 2015, include Goal 3 "Ensure healthy lives and promote well-being for all at all ages", which specifically lists the need for universal health coverage. In order to support the achievement of this goal, it is required that biomedical engineers play a role in health-care systems and therefore consider in their academic programmes and professional development: both innovations in science and technology, and global health priorities and economic challenges, while aiming to increase access to medical devices that are of good quality and that can be safe, affordable, acceptable, appropriate and available to the final users.

At the same time that new technologies are extending diagnostic and therapeutic capabilities down to nano-and molecular scales, health-care services in many countries are expanding dramatically outward, beyond the traditional hospital-centric model into outpatient specialized clinics, homes and emergency settings, and wearable personal sensors, as well as via mobile phones, tablets, mobile clinics, teleconsultations and portable diagnostic devices for remote and low-resource regions. This veritable flood of innovations poses significant, often destabilizing, challenges for health-care systems worldwide, because public expectations escalate easily and most hospitals and health authorities are not well equipped to track, evaluate and incorporate changes of such magnitude, complexity, cost and functional interdependency.

The current innovation revolutions range across areas as diverse as biomimetic engineering, electronic medical records, telehealth technologies, crowd-sourced pandemic tracking, big data, telemedicine, robotics, 3D printing of prosthetics and organ tissue to nano- and molecular engineering, miniaturization of lab analytics, disaster management, microbiomes and epigenetics. These innovations put considerable change pressures on all health-care systems, organizationally and personally – from national to local levels – requiring increased attention to the design, regulation and assessment of medical devices, and to the multiple interdependencies that will exist between medical devices, clinical and IT processes, business systems, accreditation standards, staffing models, scopes of professional practice, and expanding service models oriented toward wellness promotion.

The purpose of the BME profession is to understand, manage and improve the life cycle of operational complexities of medical devices, systems and services in a disciplined and skilled manner, building on core competencies that are augmented over time with specialized training and project work with diverse stakeholders spanning the health-care sectors. Biomedical engineers increasingly work across the entire spectrum of employment sectors to improve the design of medical devices, verify their quality and safety through regulatory processes, define in which clinical interventions they are useful, improve standards and policies, bring practical clinical experience into BME projects in academic and R&D settings, and provide ongoing expertise in the integration of health-care innovations in hospitals, clinics and decentralized services worldwide.

Through evidence-based understanding of the "system life cycle" of medical technology innovations, biomedical engineers can help integrate the vertical intelligences of the various sectors in an integrated, holistic manner according to population needs. As is shown in the present publication, the role of biomedical engineers spans national policy, regulation, technical standards, professional education, academic and industry R&D, device and service design, prototyping, clinical research and trials, technology assessment, contracting, supply chain and service strategy, deployment, integration with IT and business systems, operational monitoring, process re-engineering, device maintenance and repairs, hazard alerts and recalls, inventory analysis and replacement planning. This "life cycle" intelligence is an essential professional resource for any 21st-century health-care innovator, manufacturer, planner, care provider or relevant government agency; and should, therefore, be considered as such along with other members of the health workforce.

11.1 Future role of biomedical engineers in low- and middle-income countries

In order to support the Sustainable Development Goals and the universal health coverage included in Goal 3 (Health), it is necessary that medical devices are safe, of good quality and accessible to health-care providers. The biomedical engineer can play an important role in this, especially in LMICs, as described in this publication.

Beyond the ongoing health-care burdens of population growth, political and economic instability, disease management, disasters, millions of refugees, accidents, terror attacks and routine medical services, our world's health-care systems are facing enormous organizational challenges to manage the transition into 21st-century care. The relentless flood of scientific and technological innovation is radically redefining the nature of health care in virtually every dimension, from nano-engineered theranostics at the molecular level to telehealth and telemedicine at the national and global level. The challenge of achieving universal health coverage implies having appropriate health technologies, in particular, medical devices, to support health interventions from prevention to early diagnostics, screening when possible, effective treatment, and palliative care. There are many challenges in this respect: the availability of the technology (medical devices), the availability and training of health-care workers and the affordability of interventions. Most health-care systems are not adequately staffed to comprehend or manage these forces of change. Most systems are structured around vertically expert professions (doctors, nurses, administrators) and annual plans, and most lack the expertise that biomedical engineers can provide, to understand and manage the complex life cycles of medical devices and processes.

Low- and middle-income countries, especially, face a double challenge of selectively "catching up" with developed countries (in terms of infrastructure and human resources), at the same time that developed countries themselves are re-defining their models of care, beyond hospital-centric "ill care" to include wellness promotion, remote monitoring and decentralized, point-of-care technologies that enable "care anywhere". Biomedical engineers can play vital roles in all sectors of this transformation, as guarantors that new medical devices and related processes are intelligently designed and managed from the outset with careful understanding of all performance requirements at each stage of the life cycle of medical services. This expertise will be of critical value in low-resource settings, where there is no room for waste or inefficiency.

As the Ebola crisis demonstrated, multidisciplinary team expertise and collaboration are keys to success; yet most professional training ignores these "horizontal" dimensions of competency and success. The effective health workforce of the 21st century will consist of more than individual physicians, nurses and administrators. Medical devices play a growing role in creating new clinical services that are dramatically more effective, timely and less costly. In academia, government and industry, we find teams of biomedical engineers and design innovators who integrate knowledge of standards, science, technology, regulations and clinical strategy to create new clinical tools that save lives and money. In hospitals, we find biomedical engineers who ensure the proper acquisition, installation and operation of devices and systems. With the increasing role of technology in health care, professional comprehension and design expertise for the entire span of the technology life cycle – across systems and sectors – will be critical to ensuring the best outcomes clinically, economically and operationally.

Based on the these needs, there should be a higher investment in the education of biomedical engineers and technicians, to respond to demand, and create funded positions in the health-care sector, particularly in LMICs, following the mandates of the Global Strategy on Human Resources for Health and the UN ComHEEG.

11.2 Reclassification of biomedical engineers and technicians

The continuous advances in science and technology for health, require that health delivery systems include the biomedical engineer in the selection, and best use of medical devices globally, according to specific settings and depending on local needs.

The activities developed by these specialized human resources for health are related to medical devices and medical technology, from development to use, in all contexts. Although the ILO counts them as part of the health workforce this category of engineers do not have a classification of their own, which makes it difficult to track the statistical trends and pinpoint their availability in Member States. Therefore, it is proposed that a specific classification is made in the ISCO for biomedical engineers, considering their importance in providing support for medical technologies to support universal health coverage to reach the Sustainable Development Goals.

There is an immediate priority to upgrade the professional standing of biomedical engineers worldwide. The classification as a distinct professional group within engineering professionals, will help validate the essential role that biomedical engineers should play in health-care systems, and support the various institutional initiatives (policy, training, certification, staffing, budgets, operational infrastructure, etc.) that will be needed to establish and maintain high global standards for health-care services.

Considering all the information presented in this publication, a proposal to change to the profile of the biomedical engineer and technician has been developed, from that currently outlined in the ISCO, dating from 2008. This proposal, for consideration by national, regional and global organizations, to facilitate a specific classification of biomedical engineers and technicians, can be found in Annex 7.*(205)*

11.3 Final statement

Recalling the WHO resolutions on medical devices, the SDGs, the WHO Global Strategy on Human Resources for Health, and ComHEEG, this book on human resources for medical devices raises awareness of the role of biomedical engineers in health sector provision to ensure appropriate medical technologies are used depending on local settings and needs to comply with universal health coverage.

The book Human resources for medical devices, the role of biomedical engineers is part of the WHO Medical device technical series and it comprehensively presents the different roles biomedical engineers perform in the development, innovation, regulation, assessment, supply and use of medical devices in the health-care sector. The biomedical engineer needs to interact with many other professionals in engineering, economic, political and clinical spheres. Most users of medical technologies are health-care workers with medical and clinical background.

It is important to note that the studies, surveys and review of published material clearly show there are biomedical engineers and biomedical technicians in more than 100 Member States of WHO, including LMICs, across the six WHO regions. The data presented in this publication were compiled from 2009 to 2015, and demonstrate the growing initiatives in education at professional and technical level and theincreasing uptake of biomedical engineers in the health-care sector in more than 100 countries. These numbers express only a head count and some data on certification, accreditation of programmes and roles in the health-care sector. A priority for the near future is that data should be compiled and classified to include biomedical engineers within National Health Workforce Accounts, so as to be able to adequately monitor their workforce situation to achieve universal health coverage, define gaps and suggest ways to address them locally.

This publication demonstrates the availability and the different areas of work of biomedical engineers. However, specifically in LMICs, it will be important to increase: academic programmes, demand within the health-care sector, availability, and funded positions in health-care services, at national level for policy-making and at local level (particularly in secondary and tertiary level hospitals) and ensure cadres are developed locally to meet local needs, in line with the WHO Global Strategy on Human Resources for Health.

This book is a contribution to the evolution of the profession itself, and serves as a call to institutional leaders to look to BME to expand the professional capabilities that health-care systems worldwide need as they grapple with the often overwhelming complexities and questions that no one seems adequately prepared to answer. Biomedical engineering is and most certainly will be part of the solution to providing better health care to those in need in order to achieve the Sustainable Development Goals.

Credit: Shauna Mullally; University Teaching Hospital, Zambia

Annex 1 Biomedical engineers by country and relevant demographic indicators

Country	Code	Population (2015)	Income grouping	Reported number of biomedical engineers	Number of biomedical engineers per 10 000 (2015)
African Region					
Algeria	DZA	39 666 519	Upper middle-income	1	0.000252102
Benin	BEN	10 879 829	Low income	16	0.014706113
Botswana	BWA	2 262 485	Upper middle-income	52	0.229835778
Burkina Faso	BFA	18 105 570	Low income	7	0.003866214
Cameroon	CMR	23 344 179	Lower middle-income	19	0.008139074
Chad	TCD	14 037 472	Low income	12	0.008548548
Côte d'Ivoire	CIV	22 701 556	Lower middle-income	50	0.022024922
Democratic Republic of the Congo	COD	7 726 6814	Low income	20	0.002588433
Ethiopia	ETH	99 390 750	Low income	150	0.015091948
Gambia	GMB	1 990 924	Low income	17	0.085387488
Ghana	GHA	27 409 893	Lower middle-income	4	0.001459327
Guinea	GIN	12 608 590	Low income	0	0
Kenya	KEN	46 050 302	Lower middle income	20	0.004343077
Liberia	LBR	4 503 438	Low income	0	0
Mozambique	MOZ	27 977 863	Low income	0	0
Namibia	NAM	2 458 830	Upper middle-income	1	0.004066975
Nigeria	NGA	182 201 962	Lower middle-income	280	0.015367562
Rwanda	RWA	11 609 666	Low income	5	0.004306756
Senegal	SEN	15 129 273	Lower middle-income	23	0.015202317
Sierra Leone	SLE	6 453 184	Low income	1	0.001549623
South Africa	ZAF	54 490 406	Upper middle-income	300	0.055055563
Swaziland	SWZ	1 286 970	Lower middle-income	1	0.007770189
Uganda	UGA	39 032 383	Low income	49	0.012553679
United Republic of Tanzania	TZA	53 470 420	Low income	4	0.000748077
Zambia	ZMB	16 211 767	Lower middle-income	46	0.028374452

Country	Code	Population (2015)	Income grouping	Reported number of biomedical engineers	Number of biomedical engineers per 10 000 (2015)
Americas Region					
Argentina	ARG	43 416 755	Upper middle-income	1500	0.34548874
Barbados	BRB	284 215	High income	1	0.035184631
Belize	BLZ	359 287	Upper middle-income	1	0.027832902
Bolivia (Plurinational State of)	BOL	10 724 705	Lower middle-income	45	0.041959196
Brazil	BRA	207 847 528	Upper middle-income	250	0.012028048
Canada	CAN	35 939 927	High income	642	0.178631415
Chile	CHL	17 948 141	High income	650	0.362154498
Colombia	COL	48 228 704	Upper middle-income	300	0.06220362
Cuba	CUB	11 389 562	Upper middle-income	59	0.051801816
Dominican Republic	DOM	10 528 391	Upper middle-income	100	0.094981275
Ecuador	ECU	16 144 363	Upper middle-income	30	0.018582337
El Salvador	SLV	6 126 583	Lower middle-income	190	0.31012393
Grenada	GRD	106 825	Upper middle-income	1	0.093611046
Guatemala	GTM	16 342 897	Lower middle-income	1	0.000611887
Guyana	GUY	767 085	Lower middle-income	1	0.013036365
Haiti	HTI	10 711 067	Low income	2	0.001867228
Honduras	HND	8 075 060	Lower middle-income	1	0.001238381
Jamaica	JAM	2 793 335	Upper middle-income	1	0.00357995
Mexico	MEX	127 017 224	Upper middle-income	3000	0.23618844
Panama	PAN	3 929 141	Upper middle-income	325	0.827152805
Paraguay	PRY	6 639 123	Lower middle-income	35	0.052717806
Peru	PER	31 376 670	Upper middle-income	360	0.114734929
Suriname	SUR	542 975	Upper middle-income	5	0.092085271
Trinidad and Tobago	TTO	1 360 088	High income	40	0.294098617

Country	Code	Population (2015)	Income grouping	Reported number of biomedical engineers	Number of biomedical engineers per 10 000 (2015)
United States of America	USA	321 773 631	High income	15700	0.487920653
Uruguay	URY	3 431 555	High income	10	0.029141308
Venezuela (Bolivarian Republic of)	VEN	31 108 083	Upper middle-income	60	0.019287592
Eastern Mediterranean Region					
Afghanistan	AFG	32 526 562	Low income	1	0.000307441
Bahrain	BHR	1 377 237	High income	2	0.014521829
Djibouti	DJI	887 861	Lower middle-income	1	0.011263024
Egypt	EGY	91 508 084	Lower middle-income	1000	0.109279963
Jordan	JOR	7 594 547	Upper middle-income	500	0.658367115
Lebanon	LBN	5 850 743	Upper middle-income	750	1.281888471
Pakistan	PAK	188 924 874	Lower middle-income	360	0.019055193
Saudi Arabia	SAU	31 540 372	High income	300	0.095116189
Sudan	SDN	40 234 882	Lower middle-income	365	0.090717303
Tunisia	TUN	11 253 554	Upper middle-income	20	0.017772163
United Arab Emirates	ARE	9 156 963	High income	3	0.003276195
Yemen	YEM	26 832 215	Lower middle-income	1	0.000372686
European Region					
Albania	ALB	2 896 679	Upper middle-income	53	0.182968151
Austria	AUT	8 544 586	High income	800	0.936265373
Belgium	BEL	11 299 192	High income	980	0.867318654
Bosnia and Herzegovina	BIH	3 810 416	Upper middle-income	5	0.013121927
Bulgaria	BGR	7 149 787	Upper middle-income	35	0.048952507
Croatia	HRV	4 240 317	High income	200	0.47166285
Cyprus	CYP	1 165 300	High income	15	0.128722217
Denmark	DNK	5 669 081	High income	450	0.79377945
Estonia	EST	1 312 558	High income	60	0.457122657
Finland	FIN	5 503 457	High income	1500	2.725559589
France	FRA	64 395 345	High income	600	0.093174437

Country	Code	Population (2015)	Income grouping	Reported number of biomedical engineers	Number of biomedical engineers per 10 000 (2015)
Georgia	GEO	3 999 812	Lower middle-income	250	0.625029376
Germany	DEU	80 688 545	High income	2050	0.254063325
Greece	GRC	10 954 617	High income	300	0.273857133
Hungary	HUN	9 855 023	Upper middle-income	400	0.40588439
Iceland	ISL	329 425	High income	56	1.699931699
Ireland	IRL	4 688 465	High income	330	0.7038551
Israel	ISR	8 064 036	High income	2000	2.480147658
Italy	ITA	59 797 685	High income	1366	0.228436937
Kyrgyzstan	KGZ	5 939 962	Lower middle-income	3	0.005050537
Latvia	LVA	1 970 503	High income	350	1.77619623
Lithuania	LTU	28 78 405	High income	250	0.868536568
Montenegro	MNE	625 781	Upper middle-income	15	0.23970047
Netherlands	NLD	16 924 929	High income	500	0.295422214
Norway	NOR	5 210 967	High income	1	0.00191903
Poland	POL	38 611 794	High income	163	0.042215081
Portugal	PRT	10 349 803	High income	94	0.090822985
Republic of Moldova	MDA	4 068 897	Lower middle-income	1	0.002457669
Romania	ROU	19 511 324	Upper middle-income	1250	0.640653602
Russian Federation	RUS	143 456 918	High income	2	0.000139415
Serbia	SRB	8 850 975	Upper middle-income	300	0.338945709
Slovakia	SVK	5 426 258	High income	63	0.116102109
Slovenia	SVN	2 067 526	High income	174	0.841585547
Spain	ESP	46 121 699	High income	1000	0.216817685
Sweden	SWE	9 779 426	High income	850	0.869171667
Switzerland	CHE	8 298 663	High income	120	0.144601606
The former Yugoslav Republic of Macedonia	MKD	2 078 453	Upper middle-income	5	0.024056353
Turkey	TUR	78 665 830	Upper middle-income	960	0.122035196
Ukraine	UKR	44 823 765	Lower middle-income	350	0.078083579
United Kingdom	GBR	64 715 810	High income	469	0.072470699

Country	Code	Population (2015)	Income grouping	Reported number of biomedical engineers	Number of biomedical engineers per 10 000 (2015)
South East Asia Region					
Bangladesh	BGD	160 995 642	Low income	2	0.000124227
Bhutan	BTN	774 830	Lower middle-income	6	0.077436341
India	IND	1 311 050 527	Lower middle-income	40000	0.305098844
Indonesia	IDN	257 563 815	Lower middle-income	1	3.88253E-05
Maldives	MDV	363 657	Upper middle-income	1	0.027498439
Myanmar	MMR	53 897 154	Low income	1	0.000185539
Nepal	NPL	28 513 700	Low income	1	0.000350709
Sri Lanka	LKA	20 715 010	Lower middle-income	3	0.001448225
Thailand	THA	67 959 359	Upper middle-income	5	0.000735734
Timor-Leste	TLS	1 184 765	Lower middle-income	1	0.008440492
Western Pacific Region					
Japan	JPN	126 573 481	High income	20001	1.580188823
Malaysia	MYS	30 331 007	Upper middle-income	2500	0.824239037
Mongolia	MNG	2 959 134	Lower middle-income	240	0.811048097
Kiribati	KIR	112 423	Lower middle-income	3	0.26684931
Australia	AUS	23 968 973	High income	320	0.133505929
Viet Nam	VNM	93 447 601	Lower middle-income	1000	0.107011843
New Zealand	NZL	4 528 526	High income	26	0.057413825
Micronesia (Federated States of)	FSM	526 344	Lower middle-income	2	0.037997963
Vanuatu	VUT	264 652	Lower middle-income	1	0.037785469
China	CHN	1 376 048 943	Upper middle-income	4497	0.032680524
Fiji	FJI	892 145	Upper middle-income	1	0.01120894
Lao People's Democratic Republic	LAO	6 802 023	Lower middle-income	7	0.010291056
Philippines	PHL	100 699 395	Lower middle-income	50	0.004965273
Republic of Korea	KOR	50 293 439	High income	5	0.000994165
Singapore	SGP	5 603 740	High income	320	0.57104

Annex 2 Educational institutions with biomedical engineering programmes

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
African Region								
Algeria	Upper middle	University of Tlemcen	Tlemcen					
Benin	Low	Ecole Polytechnique Abomey Calavi part of Université Abomey Calavi	Cotonou	Département de Maintenance Biomédicale et Hospitalière				X
Burkina Faso	Low	Ecole Superieur des Techniques Avancees	Ouagadougou	Génie Biomédical				X
Burkina								
Faso	Low	Institut Superieur de Technologies IST	Ouaga-dougou	Génie Biomédical				X
Cameroon	Lower middle	Lycée Technique de Garoua						
Cameroon	Lower middle	Universite de Yaoundé	Yaoundé	Biomedical Equipment Maintenance	X			
Cameroon	Lower middle	Université des Montagnes	Bangangte	Ingénierie Biomédicale				X
Cameroon	Lower middle	Université des Montagnes	Bangangte	Génie Biomédical		X		
Cameroon	Lower middle	Université des Montagnes Filère Instrumentation et Maintenance Biomédicale	Bangangté	Ingénierie Biomédicale		X		X
Democratic Republic of Congo	Low	Institut Supérieur des Techniques Appliquées	Kinshasa	Maintenance de Matériel Médical				
Ethiopia	Low	Addis Abba University	Addis Ababa	Biomedical Engineering	X	X		
Ethiopia	Low	Comcbocha College	Comc-bocha	BMT				X
Ethiopia	Low	Debere Markos College	Debre Markos	BMT				X
Ethiopia	Low	Jimma Institue of Technology and Engineering	Jimma	Biomedical Engineering	X			
Ethiopia	Low	Tegbare-ID College		BMT				X
Ghana	Lower middle	All Nations University	Koforidua	Biomedical Engineering	X			
Ghana	Lower middle	Kwame Nkrumah University of Science and Technology,	Kumasi					
Ghana	Lower middle	University of Ghana	Accra	Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Ghana	Lower middle	Valley View University	Adentan	Bio-Medical Equipment Technology				X
Kenya	Lower middle	Kenya Medical Training College	Nyeri	Medical Engineering				X
Kenya	Lower middle	Kenya Medical Training College (KMTC)	Eldoret, Loitokitok, Nairobi	Medical Engineering				X
Kenya	Lower middle	Technical University Mombasa (fomerly Mombasa Polytechnic)	Mombasa	Medical Engineering Services				X
Madagascar	Low	Institut Superieur de Technologies (IST)	Antananarivo	Génie Biomédical	X			X
Malawi	Low	Malawi University of Science and Technology	Blantyre	BME	X			
Malawi	Low	The Malawi Polytechnic	Blantyre	BME	X			
Mozambique	Low	Centro Regional de Desenvolvimento Sanitário (CRDS)	Maputo	Health Maintenance Technology				X
Namibia	Low	Polytechnic of Namibia	Windhoek					
Nigeria	Lower middle	Ahmadu Bellon University Teaching Hospital	Zaria	Biomedical Engineering Technologist (BMET)				X
Nigeria	Lower middle	Bells University of Technology	Ota	Biomedical Engineering	X			
Nigeria	Lower middle	Federal University of Technology, Akura	Akure	Biomedical Engineering	X			
Nigeria	Lower middle	Federal University of Technology, Owerri	Owerri	Biomedical Engineering	X			
Nigeria	Lower middle	School of BME, Ahmadu Bellon University Teaching Hospital	Zaria	BMET				X
Nigeria	Lower middle	School of BME, University of Benin Teaching Hospital		Biomedical Engineering Technology				X
Nigeria	Lower middle	School of BME, University of Maiduguri Teaching Hospital		BME				X
Nigeria	Lower middle	University of Benin Teaching Hospital	Benin City	Biomedical Engineering Technology				X
Nigeria	Lower middle	University of Ilorin	Ilorin	Biomedical Engineering	X			
Nigeria	Lower middle	University of Lagos	Lagos	Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Nigeria	Lower middle	University of Maiduguri Teaching Hospital	Maiduguri	Biomedical Engineering				X
Nigeria	Lower middle	University of Port Harcourt	Port Harcourt	Biomedical Engineering	X			
Rwanda	Low	IPRC	Kigali	Biomedical Equipment Technology (BMET)				X
Senegal	Lower middle	Centre National de Formation de Techniciens en Maintenance Hospitalière (CNFTMH)	Diourbel	Hospital Maintenance				X
South Africa	Upper middle	Tshwane University of Technology	Pretoria	Clinical Engineering	X	X	X	
South Africa	Upper middle	University de Stellanbosch	Stellenbosch	Biomedical Engineering		X	X	
South Africa	Upper middle	University of Cape Town	Cape Town	Biomedical Engineering		X	X	
South Africa	Upper middle	University of Witwatersrand	Johannesburg	Biomedical Engineering	X			
Uganda	Low	Ernest Cook Ultrasound Research and Education Institute	Kampala					
Uganda	Low	Kyambogo University	Kampala	Biomedical Engineering				X
Uganda	Low	Makere University	Kampala	Biomedical Engineering	X			
United Republic of Tanzania	Low	Arusha technical College	Arusha					X
United Republic of Tanzania	Low	Dar es Salaam Institute of Technology	Dar es Salaam					X
Zambia	Lower middle	Northern Technical College	Ndola	Biomedical Engineering Technologist (BMET)				X
Eastern Mediterranean Region								
Afghanistan	Low	American University of Afghanistan	Kabul					
Bahrain	High	Kingdom University	Manama					
Bahrain	High	University of Bahrain	Manama					
Egypt	Lower middle	Ain Shams University	Cairo					
Egypt	Lower middle	University of Wisconsin System	Madison					
Iran (Islamic Republic of)	Upper middle	Amirkabir University (Tehran Polytechnic)	Tehran	Biomedical Faculty	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Iran (Islamic Republic of)	Upper middle	Iran University of Science and Technology Bioelectrics	Tehran	Biomechanics	X	X	X	
Iran (Islamic Republic of)	Upper middle	Isfahan University of Technology	Isfahan					
Iran (Islamic Republic of)	Upper middle	K.N. Toosi University of Technology	Tehran	Bioelectrics		X		
Iran (Islamic Republic of)	Upper middle	Shahid Beheshti University	Tehran	Bioelectrics			X	
Iran (Islamic Republic of)	Upper middle	Sharif University	Tehran	Bioelectrics	X	X		
Iran (Islamic Republic of)	Upper middle	Tabriz Modares University Biomaterials	Tehran	Bioelectrics	X	X		
Iran (Islamic Republic of)	Upper middle	University of Isfahan Biomaterials	Tehran	Biomechanics	X	X		
Iran (Islamic Republic of)	Upper middle	University of Tehran Bioelectrics	Tehran	Biomechanics				
Jordan	Upper middle	Al-Ahliyya Amman University Biomaterials	Amman		X			
Jordan	Upper middle	German Jordan University	Amman					
Jordan	Upper middle	Hashemite University	Zarqa					
Jordan	Upper middle	Institute of Biomedical Technology/Royal Medical Services	Amman					
Jordan	Upper middle	Jordan University of Science and Technology	Irbid					
Jordan	Upper middle	Yarmouk University	Irbid					
Lebanon	Upper middle	American University of Beirut	Beirut					
Oman	High	College of Engineering at Sultan Qaboos University (SQU)	Muscat					
Pakistan	Lower middle	Aga Khan University Hospital, Nairobi	Karachi					
Pakistan	Lower middle	Hamdard University	Karachi					
Pakistan	Lower middle	Mehran University	Jamshoro					
Pakistan	Lower middle	NED University of Engineering and Technology	Karachi					
Pakistan	Lower middle	Sir Syed University of Engineering and Technology	Karachi					

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Saudi Arabia	High	King Faisal University, College of Engineering Nasha	Ashaa					
United Arab Emirates	High	Ajman University of Science and Technology	Ajman					
United Arab Emirates	High	American University of Sharjah	Sharjah					
United Arab Emirates	High	Higher Colleges of Technology	Abu Dhabi					
United Arab Emirates	High	Khalifa University	Sharjah					
Yemen	Lower middle	Lebanese International University	Yemen					
European Region								
Armenia	Lower middle	State Engineering University of Armenia		Biomedical Engineering	X	X		
Armenia	Lower middle	UNESCO Chair in Life Sciences - Life Science International Postgraduate Educational Center		Biomedical Engineering		X	X	
Austria	High	Fachhochschule Technikum Wien	Vienna	Biomedical Engineering	X	X		
Austria	High	Fachhochschule Technikum Wien	Vienna	Healthcare and Rehabilitation Technology		X		
Austria	High	Medical University of Vienna	Vienna					
Austria	High	Technische Universität Graz	Graz	Biomedical Engineering	X	X		
Austria	High	Technische Universität Graz	Graz	Electrical and Biomedical Engineering			X	
Austria	High	Technische Universität Graz	Graz	Molecular Bioengineering		X		
Austria	High	UMIT	Österreich					
Austria	High	Upper Austria University of Applied Sciences	Linz	Medical Engineering	X	X		
Azerbaijan	Upper middle	Khazar University		Biomedicine	X	X		
Belarus	Upper middle	Belarussian National Technical University		Biotechnical and medical apparatus and systems	X	X		
Belarus	Upper middle	Belarussian National Technical University		Instruments and articles for medical purposes			X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Belarus	Upper middle	Belarussian State University of Informatics and Radioelectronics		Medical Electronics	X	X	X	
Belgium	High	IBiTECH Universiteit Gent	Gent					
Belgium	High	Katholieke Hogeschool Limburg - Radiation Protection	Diepenbeek					
Belgium	High	Katholieke Universiteit Leuven	Heverlee	Biomedical and Clinical Engineering/ Biomedical Technology		X		
Belgium	High	Université Catholique de Louvain	Louvain	Biomedical Engineering		X	X	
Belgium	High	Vrije Universiteit Brussel and Ghent University	Brussels	Biomedical Engineering		X		
Belgium	High	Université Libre de Bruxelles	Brussels	Civil Biomedical Engineering	X	X		
Bulgaria	Upper middle	Technical University of Sofia - Branch Plovdiv	Plovdiv	Electronics	X			
Bulgaria	Upper middle	Technical University of Varna		Medical Electronics		X	X	
Croatia	High	University of Zagreb	Zagreb	Medical Construction Design		X		
Croatia	High	University of Applied Sciences Varaždin		Biomedical Electronics	X			
Czech Republic	High	Brno University of Technology	Brno	Biomedical Technology and Bioinformatics	X			
Czech Republic	High	Brno University of Technology	Brno	Biomedical and Environmental Engineering		X		
Czech Republic	High	Czech Technical University	Prague	Biomedical and Clinical Technology	X	X	X	
Czech Republic	High	Czech Technical University	Prague	Radiological Technology	X	X	X	
Czech Republic	High	Czech Technical University	Prague	Devices and Methods in Biomedicine/ Biomedical and Rehabilitation Engineering		X		
Czech Republic	High	Czech Technical University	Prague	Artificial Intelligence and Biocybernetics/ Biomechanics			X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Czech Republic	High	Technical University Ostrava		Biomedical Technology	X			
Denmark	High	Aalborg University		Biomedical Science and Engineering			X	
Denmark	High	Aalborg University		Biomedical Engineering and Informatics		X		
Denmark	High	Technical University of Denmark		Medicine and Technology	X	X		
Denmark	High	Aarhus University		Biomedical Engineering/ Cardiovascular Technology		X		
Estonia	High	Tallinn Technical University	Tallinn	Biomedical Engineering and Medical Physics		X	X	
Estonia	High	University of Tartu		Medical Technology		X		
Estonia	High	University of Tartu		Medical Physics and Biomedical Engineering			X	
Finland	High	Helsinki University of Technology (Aalto University)	Espoo	Biomedical Engineering as a Major in Technical Physics and Mathematics		X		
Finland	High	University of Oulu	Oulu	Medical Technology/ Biophysics in the technology of medicine	X	X	X	
Finland	High	University of Turku		Biomedical Engineering as a Minor for Electrical and Information Technology		X		
Finland	High	Tampere University of Technology		Biomedical Engineering		X	X	
Finland	High	University of Kuopio		Medical Physics and Engineering		X		
France	High	L'Université de Franche-Comté	Besançon					
France	High	Université Claude Bernard Lyon 1	Lyon					
France	High	Université de la Méditerranée	Marseille	Bioinstrumentation/ Biomedical Engineering		X		
France	High	Université de Technologie de Compiègne	Compiègne					
France	High	ESEO Group		Biomedical Technology		X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
France	High	Ecole Centrale Paris		Engineering of Medical Research Biotechnological Data		X		
France	High	Groupe des Ecoles des Mines, Graduate School of Nancy/ Saint-Etienne		Biomedical engineering			X	
France	High	University Joseph Fourier, Grenoble and Grenoble Institute of Technology		Health and Medical Engineering		X		
Germany	High	Aachen University of Applied Sciences	Jülich	Biomedical Engineering	X	X		
Germany	High	Anhalt University of Applied Sciences	Köthen	Biomedical Engineering	X	X		
Germany	High	Ansbach University of Applied Sciences	Ansbach	Biomedical Engineering	X			
Germany	High	Bautzen University of Cooperative Education	Bautzen	Medical Engineering				
Germany	High	Chemnitz University of Technology	Chemnitz	Medical Engineering	X	X		
Germany	High	Dresden University of Technology	Dresden					
Germany	High	Hamburg University of Applied Sciences	Hamburg	Biomedical Engineering	X	X		
Germany	High	Hamm-Lippstadt University of Applied Sciences	Hamm	Biomedical Engineering	X	X		
Germany	High	Heidelberg University	Heidelberg	Biomedical Engineering		X		
Germany	High	Hochschule Furtwangen University	Furtwangen	Biomedical Engineering		X		
Germany	High	Hochschule Furtwangen University	Furtwangen	Medical Engineering	X			
Germany	High	Ilmenau University of Technology	Ilmenau	Biomedical Engineering	X	X		
Germany	High	Jade University of Applied Sciences	Wilhelmshaven	Biomedical Engineering	X			
Germany	High	Koblenz University of Applied Sciences	Remagen	Medical Engineering	X			
Germany	High	Landshut University of Applied Sciences	Landshut	Biomedical Engineering	X			
Germany	High	Leibniz University of Hanover	Hannover	Biomedical Engineering		X		
Germany	High	Mannheim University of Applied Sciences	Mannheim	Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Germany	High	Münster University of Applied Sciences	Steinfurt	Biomedical Engineering		X		
Germany	High	Otto-von-Guericke University Magdeburg	Magdeburg	Medical Engineering	X			
Germany	High	Otto-von-Guericke University Magdeburg	Magdeburg	Medical Systems Engineering		X		
Germany	High	Pforzheim University of Applied Sciences	Pforzheim	Medical Engineering	X			
Germany	High	Ruhr-University Bochum	Bochum					
Germany	High	RWTH Aachen University	Aachen	Biomedical Engineering		X		
Germany	High	Saarland University of Applied Sciences	Saarbrücken	Biomedical Engineering	X	X		
Germany	High	South Westphalia University of Applied Sciences	Hagen, Lüdenscheid	Medical Engineering	X			
Germany	High	Technical University of Hamburg	Hamburg	Medical Engineering		X		
Germany	High	Technical University of Darmstadt	Darmstadt					
Germany	High	Technical University of Berlin	Berlin	Biomedical Engineering		X		
Germany	High	Technical University of München	Garching	Medical Technology and Engineering		X		
Germany	High	Technische Hochschule Nürnberg/Nuremberg Tech	Nürnberg	Electronical Medical Engineering	X			
Germany	High	Trier University of Applied Sciences	Trier	Medical Engineering	X			
Germany	High	Ulm University of Applied Sciences	Ulm	Medical Engineering	X	X		
Germany	High	University of Applied Sciences Bremerhaven	Bremerhaven	Medical Engineering	X			
Germany	High	University of Applied Sciences Amberg-Weiden	Amberg-Weiden	Medical Engineering	X	X		
Germany	High	University of Applied Sciences Jena	Jena	Medical Engineering	X	X		
Germany	High	University of Applied Sciences Lübeck	Lübeck	Biomedical Engineering	X			
Germany	High	University of Applied Sciences Lübeck & University of Lübeck	Lübeck	Biomedical Engineering		X		
Germany	High	University of Applied Sciences Mittelhessen	Giessen	Biomedical Engineering	X	X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Germany	High	University of Applied Sciences Offenburg	Offenburg	Medical Engineering	X	X		
Germany	High	University of Applied Sciences Stralsund	Stralsund	Medizinisches Informations management/ eHealth	X			
Germany	High	University of Applied Sciences Stralsund	Stralsund	Medizintechnische Systeme		X		
Germany	High	University of Applied Sciences Würzburg-Schweinfurt	Schweinfurt					
Germany	High	University of Duisburg-Essen	Duisburg, Essen	Medical Engineering	X	X		
Germany	High	University of Erlangen-Nuremberg	Erlangen	Medical Engineering	X	X		
Germany	High	University of Lübeck	Lübeck	Medical Engineering Science	X	X		
Germany	High	University of Rostock	Rostock	Biomedical Engineering	X	X		
Germany	High	University of Stuttgart	Stuttgart	Medical Engineering	X	X	X	
Germany	High	University of Tübingen	Tübingen	Biomedical Technologies	X	X		
Germany	High	West Saxon University of Applied Sciences of Zwickau	Zwickau					
Germany	High	Westphalian University of Applied Sciences	Gelsenkirchen	Mikrotechnology and Medical Engineering		X		
Greece	High	National Technical University of Athens	Athens					
Greece	High	University of Patras	Patras	Biomedical Engineering		X	X	
Greece	High	Aristotle University of Thessaloniki	Thessaloniki	Medical Informatics		X	X	
Hungary	Upper middle	Budapest University of Technology and Economics	Budapest	Biomedical Engineering		X		
Iceland	High	Reykjavik University		Biomedical Engineering	X			
Ireland	High	Dublin Institute of Technology	Dublin	Signal Processing Engineering with Biomedical and Advanced Image Processing		X		
Ireland	High	Trinity College	Dublin	Bioengineering/ Clinical Engineering		X		
Ireland	High	University of Limerick		Biomedical Engineering		X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Israel	High	Ben-Gurion University	Beer Sheva	Biomedical Engineering	X	X	X	
Israel	High	Jerusalem College of Technology	Jerusalem					
Israel	High	Hebrew University		Biomedical Engineering			X	
Israel	High	Tel-Aviv Academic College of Engineering	Tel Aviv	Biomedical Engineering	X	X	X	
Israel	High	Israel institute of Technology (Technion)		Biomedical Engineering	X	X	X	
Italy	High	Università degli Studi di Bologna	Bologna	Biomedical Engineering			X	
Italy	High	Università degli Studi di Bologna	Bologna	Post-MSc (II lev) Master Course in Clinical Engineering				X
Italy	High	Università degli Studi di Bologna	Cesena	Biomedical Engineering	X	X		
Italy	High	Università Politecnica delle Marche	Ancona	Biomedical Engineering	X			
Italy	High	Università degli Studi di Cagliari	Cagliari	Biomedical Engineering	X			
Italy	High	Università degli Studi "Magna Graecia" di Catanzaro	Catanzaro	Biomedical and IT Engineering	X			
Italy	High	Università degli Studi di Firenze	Firenze	Biomedical Engineering		X		
Italy	High	Università degli Studi di Firenze	Firenze	Post-Bachelor (I lev) Master Course in Clinical Engineering				X
Italy	High	Università degli Studi di Firenze	Firenze	Post-Bachelor (II lev) Master Course in Healthcare Engineering and HTA				X
Italy	High	Università degli Studi di Genova	Genova	Biomedical Engineering	X	X		
Italy	High	Università degli Studi di Genova	Genova	Bioengineering			X	
Italy	High	Politecnico di Milano	Milano	Biomedical Engineering	X	X		
Italy	High	Politecnico di Milano	Milano	Bioengineering			X	
Italy	High	Università degli Studi di Napoli "Federico II"	Napoli	Biomedical Engineering	X	X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Italy	High	Università degli Studi di Napoli "Parthenope"	Napoli	Biomedical and ICT Engineering	X			
Italy	High	Università degli Studi di Padova	Padova	Biomedical Engineering	X	X		
Italy	High	Università di Pisa	Pisa	Biomedical Engineering	X	X		
Italy	High	Università di Pisa	Pisa	Automation, Robotics and Bioengineering			X	
Italy	High	Politecnico di Torino	Torino	Biomedical Engineering	X	X	X	
Italy	High	Università degli Studi di Roma "La Sapienza"	Roma	Clinical Engineering	X			
Italy	High	Università degli Studi di Roma "La Sapienza"	Roma	Biomedical Engineering		X		
Italy	High	Università degli Studi di Roma "La Sapienza"	Roma	Automation and Bioengineering			X	
Italy	High	Università degli Studi di Roma "Tor Vergata"	Roma	Medical Engineering		X		
Italy	High	Università degli Studi "Roma Tre"	Roma	Electronic/ Biomedical Engineering		X	X	
Italy	High	Università "Campus Bio-Medico"	Roma	Biomedical Engineering		X		
Italy	High	Università degli Studi di Pavia	Pavia	Bioengineering	X	X		
Italy	High	Università degli Studi di Pavia	Pavia	Bioengineering and Bioinformatics			X	
Italy	High	Università degli Studi di Trieste	Trieste	Clinical Engineering		X		
Italy	High	Università degli Studi di Trieste	Trieste	Information Engineering			X	
Italy	High	Università degli Studi di Trento	Trento	Tissue-materials Interactions			X	
Italy	High	Università degli Studi di Trieste	Trieste	Post-Bachelor (I lev) Master Course in Clinical Engineering				X
Italy	High	Università degli Studi di Trieste	Trieste	Post-MSc (II lev) Master Course in Clinical Engineering				X
Italy	High	Università degli Studi di Pavia	Pavia	Post-MSc (II lev) Master Course in Clinical Engineering				X

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Latvia	High	Biomedical Engineering and Nanotechnologies Institute						
Latvia	High	Riga Technical University	Riga	Biomedical Engineering and Medical Physics	X	X	X	
Latvia	High	Riga Technical University	Riga	Biomaterials and Biomechanics			X	
Latvia	High	University of Latvia		Biomedical Optics		X		
Lithuania	High	Vilnius Gediminas Technical University						
Lithuania	High	Kaunas University of Technology		Biomedical Engineering		X		
Malta	High	University of Malta		Biomedical Engineering		X		
Moldova	Lower middle	Technical University of Moldova		Biomedical Systems Engineering	X	X		
Netherlands	High	Delft University of Technology	Delft	Biomedical Engineering		X	X	
Netherlands	High	Technical University Eindhoven	Eindhoven	Biomedical Engineering	X	X	X	
Netherlands	High	Technical University Twente	Enschede	Biomedical Engineering		X		
Netherlands	High	University of Groningen	Groningen	Biomedical Engineering		X		
Norway	High	Stavanger Universitetssjukehus	Stavanger					
Norway	High	Norwegian University of Science and Technology	Trondheim	Medical Technology		X		
Poland	High	AGH-University of Science and Technology	Krakow	Biomedical Engineering	X	X	X	
Poland	High	Politechnika Gdańska	Gdansk					
Portugal	High	Universidade Católica Portuguesa	Rio de Mouro					
Portugal	High	Universidade de Lisboa	Lisboa	Bioengineering		X		
Portugal	High	Universidade de Lisboa	Lisboa	Biological and Medical Imaging			X	
Portugal	High	Universidade de Coimbra		Biomedical Engineering	X	X		
Romania	Upper middle	"Gr.T.Popa" University of Medicine and Pharmacy	Lasi					

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Romania	Upper middle	University "Politehnica" of Bucharest	Bucharest	Bioinformatics/ Medical and Clinical Engineering/ Biomaterials		X		
Russian Federation	High	Kursk State Technical University	Kursk					
Russian Federation	High	Ryazan State Radio Engineering University	Ryazan					
Russian Federation	High	Tomsk Polytechnic University	Tomsk	Biomedical Engineering	X			
Russian Federation	High	Nizhny Novgorod State Technical University	Nizhny Novgorod	Biomedical Engineering	X			
Russian Federation	High	Vladimir State University		Bio-Technical and Medical Apparatuses and Systems/ Engineering in Medical-Biological Practice	X			
Serbia	Upper middle	University of Novi Sad	Novi Sad					
Serbia	Upper middle	University of Belgrade	Belgrade	Biomedical Engineering and Technologies			X	
Slovakia	High	The Technical University of Košice	Kosice	Prosthetics and Orthotics	X			
Slovakia	High	The Technical University of Košice	Kosice	Bionics and Biomechanics			X	
Slovakia	High	University of Zilina		Biomedical Engineering	X	X		
Slovakia	High	Slovak University of Technology in Bratislava	Bratislava	Radioelectronics, specialization Biomedical Technology		X		
Slovenia	High	University of Maribor		Biomedical Technology			X	
Spain	High	Universidad de Navarra	Pamplona	Biomedical Engineering		X	X	
Spain	High	Universidad de Valencia/Universidad Politécnica de Valencia	Valencia	Biomedical Engineering		X	X	
Spain	High	Universidad Politecnica de Madrid, E.T.S.I. de Telecomunicacion	Madrid	Bioengineering and Telemedicine		X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Spain	High	Universitat de Barcelona/ Universitat Politècnica de Catalunya	Barcelona	Biomedical Engineering		X	X	
Spain	High	Universidad de Zaragoza	Zaragoza	Biomedical Engineering		X	X	
Sweden	High	Chalmers University of Technology	Goteborg	Biomedical Engineering		X		
Sweden	High	Linköping University	Linköping	Biomedical Engineering		X		
Sweden	High	Luleå University of Technology	Luleå	Biomedical Engineering and Physics				
Sweden	High	Royal Institute of Technology (KTH)	Stockholm	Medical Engineering	X			
Sweden	High	Umeå University	Umeå	Radiation Physics and Biomedical Engineering			X	
Sweden	High	University of Borås	Borås	Electrical/ Biomedical Engineering		X		
Switzerland	High	Bern University of Applied Sciences	Bern	Biomedical Engineering		X	X	
Switzerland	High	Interstaatliche Fachhochschule für Technik Buchs	Buchs					
Switzerland	High	Swiss Federal Institute of Technology	Zurich	Biomedical Engineering		X		
Turkey	Upper middle	Afyon Kocatepe University						
Turkey	Upper middle	Akdeniz University						
Turkey	Upper middle	Ankara University						
Turkey	Upper middle	Bahçeşehir University						
Turkey	Upper middle	Başkent University	Ankara	Biomedical Engineering	X			
Turkey	Upper middle	Biruni University						
Turkey	Upper middle	Boğaziçi University		Biomedical Engineering		X	X	
Turkey	Upper middle	Bülent Ecevit University						
Turkey	Upper middle	Çukurova University						
Turkey	Upper middle	Düzce University						
Turkey	Upper middle	Erciyes University						
Turkey	Upper middle	Fatih Sultan Mehmet Vakif University						
Turkey	Upper middle	Fatih University		Genetics and Bioengineering	X	X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Turkey	Upper middle	Gediz University						
Turkey	Upper middle	Işik University						
Turkey	Upper middle	İstanbul Arel University						
Turkey	Upper middle	İstanbul Medeniyet University						
Turkey	Upper middle	İstanbul Medipol University						
Turkey	Upper middle	İstanbul Technical University						
Turkey	Upper middle	İstanbul University						
Turkey	Upper middle	İzmir Katip Çelebi University		Biotechnology, Bioengineering		X		
Turkey	Upper middle	Karabük University						
Turkey	Upper middle	Kocaeli University						
Turkey	Upper middle	Middle East Technical University		Bioelectric Engineering/ Biomaterials/ Biomechanics/ Biomolecular Engineering		X		
Turkey	Upper middle	Namik Kemal University						
Turkey	Upper middle	Near East University						
Turkey	Upper middle	Pamukkale University						
Turkey	Upper middle	Sabanci University	Istanbul	Biological Sciences and Bioengineering	X	X	X	
Turkey	Upper middle	Süleyman Demirel University						
Turkey	Upper middle	Tobb University of Economics and Technology						
Turkey	Upper middle	Yeditepe University		Biomedical Engineering	X			
Turkey	Upper middle	Yeditepe University		Genetics and Bioengineering		X		
Turkey	Upper middle	Yeni Yüzyil University						
Ukraine	Lower middle	Kharkov National University of Radio and Electronics	Kharkov	Biomedical engineering	X			
Ukraine	Lower middle	Kharkov National University of Radio and Electronics	Kharkov	Biotechnical and Medical Apparatus and Systems/ Biomedical Electronics		X		
Ukraine	Lower middle	National Technical University of Ukraine	Kiev	Medical Equipment and Systems	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Ukraine	Lower middle	The International Solomon University		Biotechnical and Medical Devices and Systems	X	X		
Ukraine	Lower middle	Sumy State University	Sumy Oblast					
United Kingdom	High	Cardiff University	Cardiff	Clinical Engineering		X		
United Kingdom	High	Durham University	Durham					
United Kingdom	High	Imperial College London	London	Biomedical Engineering		X		
United Kingdom	High	Keele University		Biomedical Engineering/ Cell and Tissue engineering		X		
United Kingdom	High	King's College London	London	Medical Engineering and Physics	X	X		
United Kingdom	High	Queen Mary, University of London	London	Biomedical Engineering		X		
United Kingdom	High	Queen Mary, University of London	London	Biomedical Materials Science	X			
United Kingdom	High	University College	London	Biomaterials and Tissue Engineering/ Engineering in Medicine		X		
United Kingdom	High	University College	London	Biomedical Engineering			X	
United Kingdom	High	University of Aberdeen	Aberdeen	Biomedical Engineering		X		
United Kingdom	High	University of Birmingham		Biomaterials		X		
United Kingdom	High	University of Birmingham		Biomedical and Microengineering			X	
United Kingdom	High	The University of Bradford	Bradford	Medical Engineering		X		
United Kingdom	High	The University of Bradford	Bradford	Clinical Technology	X			
United Kingdom	High	The University of Edinburgh		Medical Physics and Medical Engineering			X	
United Kingdom	High	The University of Manchester		Medicine and Engineering/Tissue Engineering		X		
United Kingdom	High	University of Oxford	Oxford	Biomedical Engineering		X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United Kingdom	High	University of Strathclyde	Glasgow	Biomedical Engineering/ Medical Technology		X		
United Kingdom	High	University of Surrey	Surrey	Biomedical Engineering		X		
Region of the Americas								
Argentina	Upper middle	Instituto Tecnológico de Buenos Aires	Buenos Aires	Bioengineering	X			
Argentina	Upper middle	Universidad de Buenos Aires	Buenos Aires	Biotechnology		X		
Argentina	Upper middle	Universidad de Maimonides	Buenos Aires	Bioengineering and Biomedical Engineering	X			
Argentina	Upper middle	Universidad de Mendoza	Mendoza	Bioengineering and Biomedical Engineering	X			
Argentina	Upper middle	Universidad del Mar del Plata	Mar del Plata					
Argentina	Upper middle	Universidad Favaloro	Buenos Aires	Biomedical Engineering	X			
Argentina	Upper middle	Universidad Nacional Arturo Jauretche	Buenos Aires	Bioengineering	X			
Argentina	Upper middle	Universidad Nacional de Córdoba	Córdoba	Biomedical Engineering	X			
Argentina	Upper middle	Universidad Nacional de Entre Ríos	Entre Ríos	Bioengineering and Biomedical Engineering	X			X
Argentina	Upper middle	Universidad Nacional de San Juan	San Juan	Bioengineering	X			
Argentina	Upper middle	Universidad Nacional de Tucumán	San Miguel de Tucumán	Bioengineering and Biomedical Engineering	X			
Argentina	Upper middle	Universidad Nacional de Villa Mercedes	San Luis	Bioengineering	X			
Argentina	Upper middle	Universidad Tecnológica Nacional	Mar del Plata					
Bahamas	High	The College of the Bahamas	Nassau					
Barbados	High	University of the West Indies	Cave Hill					
Belize	Upper middle	Universidad de Concepción						
Belize	Upper middle	University of Belize	Belmopan					
Bolivia (Plurinational State of)	Lower middle	Universidad Católica Boliviana San Pablo		Biomedical Engineering	X			
Bolivia (Plurinational State of)	Lower middle	Universidad del Valle		Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Bolivia (Plurinational State of)	Lower middle	Universidad Católica Boliviana “San Pablo”	La Paz					
Bolivia (Plurinational State of)	Lower middle	Universidad Privada del Valle	Cochabamba					
Brazil	Upper middle	Centro de Engenharia Biomédica						
Brazil	Upper middle	Escola de Engenharia da Universidade Federal do Rio Grande do Sul	Porto Alegre					
Brazil	Upper middle	Federal University of São João Del-Rei	São José dos Campos	Biosystems Engineering	X			
Brazil	Upper middle	Instituto de Engenharia de Sistemas e Tecnologia de Informação						
Brazil	Upper middle	Pontifícia Universidade Católica de Chile	São Paulo					
Brazil	Upper middle	Pontifícia Universidade Católica do Paraná	Curitiba					
Brazil	Upper middle	Pontifícia Universidade Católica do Rio Grande do Sul	Porto Alegre					
Brazil	Upper middle	Universidad de Valparaiso	Porto Alegre					
Brazil	Upper middle	Universidade Católica de Pelotas	Pelotas	Biotechnology	X			
Brazil	Upper middle	Universidade de Mogi das Cruzes	Mogi das Cruzes	Biotechnology		X	X	
Brazil	Upper middle	Universidade de São Paulo	São Paulo	Bioengineering		X	X	
Brazil	Upper middle	Universidade do Vale do Paraíba	São José dos Campos					
Brazil	Upper middle	Universidade Estácio de Sá	Rio de Janeiro					
Brazil	Upper middle	Universidade Federal da Paraíba	São Paulo	Biotechnology	X			
Brazil	Upper middle	Universidade Federal de Itajubá	Itajubá	Bioprocesses Engineering	X			
Brazil	Upper middle	Universidade Federal de Pernambuco	São Paulo	Biomedical Engineering	X			
Brazil	Upper middle	Universidade Federal de Santa Catarina	Santa Catarina					

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Brazil	Upper middle	Universidade Federal de São Paulo	São Paulo					
Brazil	Upper middle	Universidade Federal de Uberlândia	São Paulo	Biomedical Engineering	X	X		
Brazil	Upper middle	Universidade Federal do Rio de Janeiro	Rio de Janeiro	Bioprocesses Engineering	X	X	X	
Brazil	Upper middle	Universidade Tecnológica Federal do Paraná	Guarapuava	Biotechnology Engineering	X			
Canada	High	British Columbia Institute of Technology	Vancouver	Biomedical Engineering				X
Canada	High	Carleton University	Ottawa	Biomedical, Elec, Mech. Engineering and MEng Clinical Engineering	X	X	X	X
Canada	High	College of The North Atlantic	Station Seal Cove	Electronics Engineering Technology (Biomedical)				X
Canada	High	Concordia University	Montreal					
Canada	High	Dalhousie University	Halifax	Biomedical Engineering		X	X	
Canada	High	Durham College	Oshawa	Biomedical Engineering Technology				X
Canada	High	École Polytechnique Montréal	Montreal	Biomedical Technology - Electronic Instrumentation				X
Canada	High	McGill University	Montreal	Biological and Biomedical Engineering		X	X	
Canada	High	McMaster University	Hamilton	Biomedical Engineering	X	X	X	
Canada	High	Memorial University of Newfoundland	St. Johns	Biomedical Engineering Program	X	X	X	
Canada	High	Northern Alberta Institute of Technology	Edmonton	Biomedical Engineering Technology				X
Canada	High	Queen's University	Kingston	Biomedical Engineering		X	X	
Canada	High	Ryerson University	Toronto	Biomedical Engineering	X	X	X	
Canada	High	Simon Fraser University	Burnaby	Biomedical Engineering	X	X	X	
Canada	High	St. Clair College		Biomedical Engineering Technology				X

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Canada	High	Université de Moncton	Moncton					
Canada	High	Université de Montréal	Montreal					
Canada	High	Université de Sherbrooke	Quebec					
Canada	High	Université du Québec À Trois-Rivières	Trois Rivieres					
Canada	High	Université Laval	Laval					
Canada	High	University of Alberta	Edmonton	Biomedical Engineering		X	X	X
Canada	High	University of British Columbia	Vancouver	Biomedical Engineering		X	X	
Canada	High	University of Calgary	Calgary	Biomedical Engineering	X	X	X	
Canada	High	University of Guelph	Guelph					
Canada	High	University of Manitoba	Winnipeg	Biomedical Engineering		X	X	
Canada	High	University of New Brunswick	Fredericton	Biomedical Engineering Program	X			
Canada	High	University of Ottawa	Ottawa	Biomed Mech Eng, Biomedical Eng, MEng Clinical Eng.	X	X	X	X
Canada	High	University of Prince Edward Island	Charlotte town					
Canada	High	University of Saskatchewan	Regina	Biomedical Engineering		X	X	
Canada	High	University of Toronto	Toronto	Biomedical Engineering and Clinical Engineering	X	X	X	
Canada	High	University of Victoria	Victoria	Biomedical Engineering	X			
Canada	High	University of Waterloo	Waterloo	Biomedical Engineering	X			
Canada	High	University of Western Ontario	London					
Canada	High	University of Windsor	Windsor					
Chile	High	Universidad de Concepción	Concepcíon	Civil Biomedical Engineering	X			
Chile	High	Universidad de Valparaíso	Viña del Mar	Civil Biomedical Engineering	X	X		
Colombia	Upper middle	Escuela Colombiana de Ingeniería Julio Garavito / Universidad del Rosario		Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Colombia	Upper middle	Escuela de Ingeniería de Antioquia	Medellín	Biomedical Engineering	X			
Colombia	Upper middle	Instituto Tecnológico Metropolitano	Medellín					
Colombia	Upper middle	Pontificia Universidad Javeriana	Bogotá	Bioengineering	X			
Colombia	Upper middle	Universidad Antonio Nariño	Bogotá	Biomedical Engineering	X			
Colombia	Upper middle	Universidad Autónoma de Manizales	Manizales	Biomedical Engineering	X			
Colombia	Upper middle	Universidad Autónoma del Caribe Cebi						
Colombia	Upper middle	Universidad Autónoma Occidente de Cali	Cali	Biomedical Engineering	X			
Colombia	Upper middle	Universidad CES (convenio)	Medellín					
Colombia	Upper middle	Universidad de Antioquia		Bioengineering	X			
Colombia	Upper middle	Universidad de la Sabana	Bogotá	Bioscience Doctorate			X	
Colombia	Upper middle	Universidad de los Andes		Biomedical Engineering	X	X		
Colombia	Upper middle	Universidad Manuela Beltrán	Bogotá	Biomedical Engineering	X			
Colombia	Upper middle	Universidad Pontificia Bolivariana	Medellín					
Colombia	Upper middle	Universidad Santiago de Cali	Cali	Bioengineering	X			
Cuba	Upper middle	Instituto Superior Politécnico José Antonio Echeverría	Havana	Biomedical Engineering	X	X	X	
Cuba	Upper middle	Universidad "Martha Abreu"	Las Villas	Signal processing and Systems		X	X	
Cuba	Upper middle	Universidad de Oriente	Santiago de Cuba	Biomedical Engineering	X	X	X	
Dominica	Upper middle	Dominica State College, Escuela de Salud Pública						
Dominican Republic	Upper middle	Universidad Autónoma de Santo Domingo	Santo Domingo					
Ecuador	Upper middle	Universidad Central del Ecuador						
El Salvador	Lower middle	Don Bosco University	San Salvador	Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
El Salvador	Lower middle	Universidad Cristiana Latinoamericana	El Salvador					
Grenada	Upper middle	St. George's University	St. George					
Guatemala	Lower middle	Universidad de San Carlos de Guatemala	Guatemala					
Guyana	Lower middle	University of Guyana	Greater Georgetown					
Haiti	Low	Université Quisqueya	Port-au-Prince					
Honduras	Lower middle	UNITEC Academic Head of Electromechanical Engineering	Tegucigalpa					
Honduras	Lower middle	Universidad Nacional Autónoma de Honduras	Tegucigalpa					
Jamaica	Upper middle	University of the West Indies	Jamaica					
Mexico	Upper middle	Centro de Investigación y de Estudios Avanzados	Mexico City	Master of Science in Bioelectronics		X	X	
Mexico	Upper middle	Instituto Politécnico Nacional	Mexico City	Biomedical Engineering	X			
Mexico	Upper middle	Instituto Tecnológico de Hermosillo	Hermosillo	Biomedical Engineering	X			
Mexico	Upper middle	Instituto Tecnológico de Mérida	Mérida	Biomedical Engineering	X			
Mexico	Upper middle	Instituto Tecnológico de Tijuana	Tijuana	Biomedical Engineering	X			
Mexico	Upper middle	Instituto Tecnológico y de Estudios Superiores de Monterrey	Monterrey	Biomedical Engineering/ Biotechnology	X		X	
Mexico	Upper middle	Tecnológico de Monterrey Campus Aguascalientes	Aguas calientes	Biomedical Engineering	X			
Mexico	Upper middle	Tecnológico de Monterrey Campus Chihuahua	Chihuahua	Biotechnology	X			
Mexico	Upper middle	Tecnológico de Monterrey Campus Ciudad de México	Mexico City	Biomedical Engineering	X			
Mexico	Upper middle	Tecnológico de Monterrey Campus Guadalajara	Guadalajara	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Anáhuac Campus Norte	Mexico City	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Autónoma Chihuahua	Chihuahua	Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Mexico	Upper middle	Universidad Autónoma de Aguascalientes	Aguas calientes	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Autónoma de Baja California	Tijuana	Bioengineering	X			
Mexico	Upper middle	Universidad Autónoma Metropolitana	Mexico City	Biomedical Engineering	X	X	X	
Mexico	Upper middle	Universidad Autónoma de Querétaro	Querétaro	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Autónoma de Querétaro	Querétaro	Biosystems Engineering			X	
Mexico	Upper middle	Universidad Autónoma de San Luis Potosí	San Luis Potosí	Biomedical Engineering	X			
Mexico	Upper middle	Universidad de Celaya	Celaya	Biomedical Engineering	X			
Mexico	Upper middle	Universidad de Guadalajara	Guadalajara	Biomedical Engineering	X			
Mexico	Upper middle	Universidad de Guanajuato	León	Biomedical Engineering	X			
Mexico	Upper middle	Universidad de la Salle	Mexico City	Biomedical Engineering	X			
Mexico	Upper middle	Universidad de las Américas	Puebla	Biomedical Engineering	X			
Mexico	Upper middle	Universidad de Monterrey	Monterrey	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Iberoamericana	Mexico City	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Nacional Autónoma de México	Mexico City	Biomedical Systems Engineering	X			
Mexico	Upper middle	Universidad Politécnica Bicentenario	Guanajuato	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Politécnica de Chiapas	Chiapas	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Politécnica de Pachuca	Pachuca	Biomedical Engineering	X			
Mexico	Upper middle	Universidad Politécnica de Sinaloa	Sinaloa	Biomedical Engineering	X			
Panama	Upper middle	Universidad Especial de las Américas	Panamá City	Biomedical Engineering with specialization in Electromedicine	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Panama	Upper middle	Universidad Latina de Panamá	Panamá City	Biomedical Engineering	X			
Paraguay	Lower middle	Universidad Nacional de Asunción						
Peru	Upper middle	Peruvian Engineering College	Lima					
Peru	Upper middle	Pontificia Universidad Catolica del Peru	Lima	Biomedical Engineering		X		
Peru	Upper middle	Universidad Nacional de Ingenieria	Lima					
Peru	Upper middle	Universidad Nacional Mayor de San Marcos	Lima					
Peru	Upper middle	Universidad Tecnólogica del Peru	Lima	Biomedical Engineering	X			
Trinidad and Tobago	High	University of Trinidad and Tobago		Biomedical Engineering	X			
United States of America	High	Albany Technical College	Albany, New York					
United States of America	High	Arizona State University	Tempe, Arizona	Biomedical Engineering	X	X	X	
United States of America	High	Binghamton University, State University of New York	Binghamton, New York	Bioengineering	X	X	X	
United States of America	High	Boston University	Boston, Massachusetts	Biomedical Engineering	X	X	X	
United States of America	High	Brown University	Providence, Rhode Island	Biomedical Engineering	X	X	X	
United States of America	High	Bucknell University	Lewisburg Pennsylvania	Biomedical Engineering	X			
United States of America	High	California Institute of Technology	Pasadena, California	Bioengineering	X		X	
United States of America	High	California Polytechnic State University, San Luis Obispo	San Luis Obispo, California	Biomedical Engineering	X	X		
United States of America	High	Carnegie Mellon University	Pittsburgh, Pennsylvania	Biomedical Engineering	X	X	X	
United States of America	High	Case Western Reserve University	Cleveland, Ohio	Biomedical Engineering	X	X	X	
United States of America	High	Catholic University of America	Washington (DC)	Biomedical Engineering	X	X	X	
United States of America	High	Cedar Crest College	Allentown, Pennsylvania					
United States of America	High	Cincinnati State Technical and Community College	Cincinnati, Ohio	Biomedical Equipment and Information Systems Technology (BMET)				X

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	City College of New York	New York, New York	Biomedical Engineering	X	X	X	
United States of America	High	City University of New York	New York, New York	Biomedical Engineering	X	X	X	
United States of America	High	Clemson University	Clemson, South Carolina	Bioengineering	X	X	X	
United States of America	High	Colorado State University	Fort Collins, Colorado	Bioengineering		X	X	
United States of America	High	Colorado State University	Fort Collins, Colorado	Biomedical Engineering		X		
United States of America	High	Colorado State University	Pueblo, Colorado	Biomedical Engineering/ Chemical and Biological Engineering	X			
United States of America	High	Colorado State University	Pueblo	Bioengineering		X	X	
United States of America	High	Columbia University	New York, New York	Biomedical Engineering	X	X	X	
United States of America	High	Cornell University	New York, New York	Biomedical Engineering		X	X	
United States of America	High	Cornell University	New York, New York	Biological Engineering	X	X	X	
United States of America	High	Cuyahoga Community College	Cleveland, Ohio	Electrical/ Electronic Engineering Technology-Bio-Medical (BMET)				X
United States of America	High	Devry Institute of Technology and Keller Graduate School of Management, New York	Rego Park, New York					
United States of America	High	Devry University, Arizona	Phoenix, Arizona	Biomedical Engineering Technology	X			
United States of America	High	Devry University, California	Pomona, California	Biomedical Engineering Technology	X			
United States of America	High	Devry University, Colorado	Colorado Springs, Colorado					
United States of America	High	Devry University, Florida	Hollywood, Florida	Biomedical Engineering Technology	X			
United States of America	High	Devry University, Georgia	Decatur, Georgia	Biomedical Engineering Technology	X			
United States of America	High	Devry University, Illinois	Downers Grove, Illinois	Biomedical Engineering Technology	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	Devry University, Missouri	Kansas City, Missouri					
United States of America	High	Devry University, New Jersey	North Brunswick Township, New Jersey	Biomedical Engineering Technology	X			
United States of America	High	Devry University, Ohio	Columbus, Ohio	Biomedical Engineering Technology	X			
United States of America	High	Devry University, Pennsylvania	Fort Washington, Pennsylvania	Biomedical Engineering Technology	X			
United States of America	High	Devry University, Texas	Austin, Irving and Mesquite, Texas	Biomedical Engineering Technology	X			
United States of America	High	Devry University, Washington	Federal Way					
United States of America	High	Drexel University	Philadelphia, Pennsylvania	Biomedical Engineering	X	X	X	
United States of America	High	Duke University	Durham, North Carolina	Biomedical Engineering	X	X	X	
United States of America	High	East Tennessee State University	Johnson City, Tennessee	Biomedical Engineering Technology				X
United States of America	High	Florida Agricultural and Mechanical University	Tallahassee, Florida	Biological and Agricultural Systems Engineering	X			
United States of America	High	Florida Gulf Coast University	Fort Myers, Florida	Bioengineering	X			
United States of America	High	Florida State University	Tallahassee, Florida	Biomedical Engineering	X	X	X	
United States of America	High	Florida International University	Miami, Florida	Biomedical Engineering	X	X	X	
United States of America	High	Fox Valley Technical College	Appleton, Wisconsin					
United States of America	High	Gannon University	Erie, Pennsylvania	Biomedical Engineering	X			
United States of America	High	George Mason University	Fairfax, Virginia	Bioengineering	X	X	X	
United States of America	High	Georgia Institute of Technology/Emory University	Atlanta, Georgia	Biomedical Engineering; Bioengineering	X	X	X	
United States of America	High	Harvard University	Cambridge, Massachusetts	Biomedical Engineering	X	X	X	
United States of America	High	Hi-Tech School of Miami	Miami, Florida					
United States of America	High	Howard Community College	Columbia, Maryland					
United States of America	High	Illinois Institute of Technology	Chicago, Illinois	Biological Engineering		X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	Illinois Institute of Technology	Chicago, Illinois	Biomedical Engineering	X	X	X	
United States of America	High	Indiana Institute of Technology	Fort Wayne, Indiana	Biomedical Engineering	X			
United States of America	High	Indiana University	Bloomington, Indiana	Biomedical Engineering	X	X	X	
United States of America	High	Indiana University - Purdue University Indianapolis	Indianapolis, Indiana	Biomedical Engineering	X	X	X	
United States of America	High	Indiana University - Purdue University Indianapolis	Indianapolis, Indiana	Biomedical Engineering Technology	X			
United States of America	High	Iowa State University	Ames, Iowa	Biological Systems Engineering	X	X	X	X
United States of America	High	Johns Hopkins University	Baltimore, Maryland	Biomedical Engineering	X	X	X	
United States of America	High	Johns Hopkins University	Baltimore, Maryland	Bioengineering Innovation and Design		X		
United States of America	High	Johnson College	Scranton, Pennsylvania					
United States of America	High	Kansas State University	Manhattan, Kansas	Biological Systems Engineering	X	X	X	
United States of America	High	Lawrence Technological University	Southfield, Michigan	Biomedical Engineering	X			
United States of America	High	Lehigh University	Bethlehem, Pennsylvania	Bioengineering	X	X	X	
United States of America	High	Louisiana Tech University	Ruston, Louisiana	Biomedical Engineering	X	X	X	
United States of America	High	Louisiana State University and A&M College	Ruston, Louisiana	Biological Engineering	X	X	X	
United States of America	High	Manhattan College	New York, New York					
United States of America	High	Marquette University	Milwaukee, Wisconsin	Bioengineering	X	X	X	
United States of America	High	Massachusetts Institute of Technology	Cambridge, Massachusetts	Biological Engineering	X	X	X	
United States of America	High	Massachusetts Institute of Technology	Cambridge, Massachusetts	Biomedical Engineering		X		
United States of America	High	Mayo Graduate School	Rochester, Minnesota					
United States of America	High	Mercer University	Atlanta, Georgia	Biomedical Engineering	X	X		
United States of America	High	Miami University	Oxford, Ohio	Bioengineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	Michigan State University	East Lansing, Michigan	Biomedical Engineering	X	X	X	
United States of America	High	Michigan Technological University	Houghton, Michigan	Biomedical Engineering	X	X	X	
United States of America	High	Milwaukee School of Engineering	Milwaukee, Wisconsin	Bioengineering	X			
United States of America	High	Mississippi State University	Starkville, Mississippi	Biological Engineering	X	X	X	
United States of America	High	Mississippi State University	Starkville, Mississippi	Biomedical Engineering		X	X	
United States of America	High	New Jersey Institute of Technology	Newark, New Jersey	Biomedical Engineering	X	X	X	
United States of America	High	New York University Polytechnic School of Engineering	New York, New York	Biomedical Engineering		X	X	
United States of America	High	Normandale Community College	Bloomington, Minnesota					
United States of America	High	North Carolina Agricultural and Technical State University	Greensboro, North Carolina	Bioengineering	X	X	X	
United States of America	High	North Carolina Agricultural and Technical State University	Greensboro, North Carolina	Biological Engineering	X	X		
United States of America	High	North Carolina State University at Raleigh/University of North Carolina, Chapel Hill	Raleigh/ Chapel Hill, North Carolina	Biological Engineering	X	X	X	
United States of America	High	North Carolina State University at Raleigh/University of North Carolina, Chapel Hill	Raleigh/ Chapel Hill, North Carolina	Biological Engineering	X	X	X	
United States of America	High	North Dakota State University	Fargo, North Dakota	Agricultural and Biosystems Engineering	X	X	X	
United States of America	High	North Seattle Community College	Seattle, Washington					
United States of America	High	Northwestern University	Evanston, Illinois	Biomedical Engineering	X	X	X	
United States of America	High	Ohio State University	Columbus, Ohio	Biomedical Engineering	X	X	X	
United States of America	High	Oklahoma State University	Stillwater, Oklahoma	Biomedical Engineering	X			
United States of America	High	Oral Roberts University	Tulsa, Oklahoma					
United States of America	High	Oregon State University	Corvallis, Oregon	Bioengineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	Pennsylvania State University	University Park, Pennsylvania	Bioengineering		X	X	
United States of America	High	Pennsylvania State University	University Park, Pennsylvania	Biomedical Engineering	X			
United States of America	High	Pennsylvania State University	University Park, Pennsylvania	Biological Engineering	X	X	X	
United States of America	High	Pennsylvania State University	New Kensington, Pennsylvania	Biomedical Engineering Technology (BET)				X
United States of America	High	Portland Community College	Portland, Oregon					
United States of America	High	Purdue University	Lafayette, Indiana	Biomedical Engineering; Biological Engineering	X	X	X	
United States of America	High	Rensselaer Polytechnic Institute	Troy, New York	Biomedical Engineering; Chemical and Biological Engineering	X	X	X	
United States of America	High	Rice University	Houston, Texas	Bioengineering	X	X	X	
United States of America	High	Rose-Hulman Institute of Technology	Terre Haute, Indiana	Biomedical Engineering	X	X	X	
United States of America	High	Rutgers University - Cook College	New Brunswick, New Jersey	Biomedical Engineering	X	X	X	
United States of America	High	Saint Augustine College	Raleigh, North Carolina					
United States of America	High	Saint Louis Community College-Florissant Valley	St. Louis, Missouri	Biomedical Engineering Technology				X
United States of America	High	Saint Louis University	St. Louis, Missouri	Biomedical Engineering	X	X	X	
United States of America	High	Snead State Community College	Boaz, Alabama					
United States of America	High	Southwest Georgia Technical College	Thomasville, Georgia					
United States of America	High	Stanford University	Stanford, California	Bioengineering	X	X	X	
United States of America	High	Stevens Institute of Technology	Hoboken, New Jersey	Biomedical Engineering	X	X	X	
United States of America	High	Stony Brook University	Stony Brook, New York	Biomedical Engineering	X	X	X	
United States of America	High	Syracuse University	Syracuse, New York	Bioengineering	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	State Technical College of Missouri	Linn, Missouri	Electronics Engineering Technology - Biomedical Engineering Technology Option				X
United States of America	High	Temple University	Philadelphia, Pennsylvania	Bioengineering	X	X	X	
United States of America	High	Texas A & M University	College Station, Texas	Biological and Agricultural Engineering	X	X	X	
United States of America	High	Texas A & M University	College Station, Texas	Biomedical Engineering	X	X	X	
United States of America	High	Texas State Technical College-Harlingen	Harlingen, Texas	Biomedical Equipment Technology				X
United States of America	High	The College of New Jersey	Trenton, New Jersey	Biomedical Engineering	X			
United States of America	High	The George Washington University	Washington (DC)	Biomedical Engineering	X	X	X	
United States of America	High	Trinity College	Hartford, Connecticut	Engineering with a concentration in Biomedical Engineering	X			
United States of America	High	Trinity University	San Antonio, Texas					
United States of America	High	Tufts University	Medford, Massachusetts	Biomedical Engineering	X	X	X	
United States of America	High	Tufts University	Medford, Massachusetts	Bioengineering		X	X	
United States of America	High	Tufts University	Medford, Massachusetts	Chemical and Biological Engineering		X	X	
United States of America	High	Tulane University	New Orleans, Louisiana	Biomedical Engineering	X	X	X	
United States of America	High	Union College	Schenectady, New York	Bioengineering	X	X	X	
United States of America	High	University at Buffalo, State University of New York	Buffalo, New York	Biomedical Engineering	X	X	X	
United States of America	High	University at Buffalo, State University of New York	Buffalo, New York	Chemical and Biological Engineering				
United States of America	High	University of Akron	Akron, Ohio	Biomedical Engineering	X	X	X	
United States of America	High	University of Alabama at Birmingham	Birmingham, Alabama	Biomedical Engineering	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	University of Arizona	Tucson, Arizona	Biosystems Engineering; Biomedical Engineering	X	X	X	
United States of America	High	University of Arkansas	Fayetteville, Arkansas	Biological and Biomedical Engineering	X	X	X	
United States of America	High	University of California - Berkeley	Berkeley, California	Bioengineering; Translational Medicine	X	X	X	
United States of America	High	University of California - Davis	Davis, California	Biomedical Engineering; Biological Systems Engineering	X	X	X	
United States of America	High	University of California - Irvine	Irvine, California	Biomedical Engineering	X	X	X	
United States of America	High	University of California - Los Angeles	Los Angeles, California	Bioengineering	X	X	X	
United States of America	High	University of California - Riverside	Riverside, California	Bioengineering	X	X	X	
United States of America	High	University of California - San Diego	La Jolla, California	Bioengineering	X	X	X	
United States of America	High	University of California - San Diego	La Jolla, California	Biotechnology; Bioinformatics; BioSystems	X			
United States of America	High	University of Central Florida	Orlando, Florida	Bioengineering (minor)				X
United States of America	High	University of Central Oklahoma	Edmond, Oklahoma	Biomedical Engineering	X			
United States of America	High	University of Cincinnati	Cincinnati, Ohio	Biomedical Engineering	X	X	X	
United States of America	High	University of Colorado	Boulder, Colorado	Chemical and Biological Engineering	X	X		
United States of America	High	University of Connecticut	Hartford, Connecticut	Biomedical Engineering (Clinical Engineering)		X		
United States of America	High	University of Connecticut	Storrs, Connecticut	Biomedical Engineering	X	X	X	
United States of America	High	University of Delaware	Newark, Delaware	Biomedical Engineering	X	X	X	
United States of America	High	University of Florida	Gainesville Florida	Agricultural and Biological Engineering	X	X	X	
United States of America	High	University of Florida	Gainesville Florida	Biomedical Engineering	X	X	X	
United States of America	High	University of Georgia	Athens, Georgia	Biological Engineering	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	University of Hartford	West Hartford, Connecticut	Biomedical Engineering	X	X	X	
United States of America	High	University of Hawaii at Manoa	Honolulu, Hawaii	Biological Engineering	X	X		
United States of America	High	University of Hawaii at Manoa	Honolulu, Hawaii	Molecular Biosciences and Bioengineering		X	X	
United States of America	High	University of Houston	Houston, Texas	Biomedical Engineering	X	X	X	
United States of America	High	University of Idaho	Moscow, Idaho	Biological Engineering	X	X	X	X
United States of America	High	University of Illinois at Chicago	Chicago, Illinois	Bioengineering	X	X	X	
United States of America	High	University of Illinois at Urbana-Champaign	Urbana Illinois	Agricultural and Biological Engineering	X	X	X	
United States of America	High	University of Illinois at Urbana-Champaign	Champaign, Illinois	Bioengineering	X	X	X	
United States of America	High	University of Iowa	Iowa City, Iowa	Biomedical Engineering	X	X	X	
United States of America	High	University of Kansas	Lawrence, Kansas	Bioengineering		X	X	
United States of America	High	University of Louisville	Louisville, Kentucky	Bioengineering	X	X		
United States of America	High	University of Maine Graduate School of Biomedical Sciences (GSBS)	Orono, Maine	Biological Engineering		X		
United States of America	High	University of Maine	Orono, Maine	Bioengineering	X			
United States of America	High	University of Maryland	College Park, Maryland	Bioengineering	X	X	X	X
United States of America	High	University of Memphis	Memphis, Tennessee	Biomedical Engineering	X	X	X	
United States of America	High	University of Miami	Coral Gables, Florida	Biomedical Engineering	X	X	X	
United States of America	High	University of Michigan	Ann Arbor, Michigan	Biomedical engineering	X	X	X	
United States of America	High	University of Minnesota	Minneapolis, Minnesota	Biomedical Engineering	X	X	X	
United States of America	High	University of Minnesota	Minneapolis, Minnesota	Bioproducts and Biosystems Engineering	X	X	X	
United States of America	High	University of Missouri - Columbia	Columbia, Missouri	Biological Engineering	X	X	X	
United States of America	High	University of Nebraska at Lincoln	Lincoln, Nebraska	Biological Systems Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	University of North Carolina at Chapel Hill	Chapel Hill, North Carolina	Biomedical and Health Sciences Engineering;	X	X	X	
United States of America	High	University of Oklahoma	Norman, Oklahoma	Biomedical Engineering	X	X	X	
United States of America	High	University of the Pacific	Stockton, California	Bioengineering	X			
United States of America	High	University of Pennsylvania	Philadelphia, Pennsylvania	Bioengineering	X	X	X	
United States of America	High	University of Pittsburgh	Pittsburgh, Pennsylvania	Bioengineering	X	X	X	
United States of America	High	University of Rhode Island	Kingston, Rhode Island	Biomedical Engineering	X			
United States of America	High	University of Rochester	Rochester, New York	Biomedical Engineering	X	X	X	
United States of America	High	University of South Carolina	Columbia, South Carolina	Biomedical Engineering	X	X	X	
United States of America	High	University of South Florida	Tampa, Florida	Biomedical Engineering	X	X	X	
United States of America	High	University of Southern California	Los Angeles, California	Biomedical Engineering	X	X	X	
United States of America	High	University of Southern California	Los Angeles, California	Neuroengineering; Medical Imaging; Medical device Engineering		X		
United States of America	High	University of Tennessee	Knoxville, Tennessee	Biomedical Engineering	X	X	X	
United States of America	High	University of Texas at Arlington	Arlington,Texas	Biomedical Engineering	X	X	X	
United States of America	High	University of Texas at Austin	Austin, Texas	Biomedical Engineering	X	X	X	
United States of America	High	University of Texas at El Paso	El Paso, Texas	Biomedical Engineering	X	X	X	
United States of America	High	University of Texas at San Antonio	San Antonio, Texas	Biomedical Engineering	X	X	X	
United States of America	High	University of Toledo	Toledo, Ohio	Bioengineering	X	X		
United States of America	High	University of Toledo	Toledo, Ohio	Biomedical Engineering			X	
United States of America	High	University of Utah	Salt Lake City, Utah	Biomedical Engineering	X	X	X	
United States of America	High	University of Virginia	Charlottesville, Virginia	Biomedical Engineering	X	X	X	
United States of America	High	University of Washington	Seattle, Washington	Bioengineering	X	X	X	
United States of America	High	University of Wisconsin	Madison, Wisconsin	Bioengineering; Biological Systems Engineering	X			
United States of America	High	University of Wyoming	Laramie, Wyoming					

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
United States of America	High	Utah State University	Logan, Utah	Biological Engineering	X	X	X	
United States of America	High	Vanderbilt University	Nashville, Tennessee	Biomedical Engineering	X	X	X	
United States of America	High	Vermont Technical College	Randolph Center, Vermont					
United States of America	High	Virginia Commonwealth University	Richmond, Virginia	Biomedical Engineering	X	X	X	
United States of America	High	Virginia Polytechnic Institute and State University with Wake Forest University	Blacksburg, Virginia	Biological Systems Engineering/ Biomedical Engineering	X			
United States of America	High	Walla Walla College	College Place, Washington	Bioengineering	X			
United States of America	High	Washington State University	Pullman, Washington	Bioengineering	X			
United States of America	High	Washington State University	Pullman, Washington	Biological Systems Engineering		X	X	
United States of America	High	Washington University in St. Louis	St. Louis, Missouri	Biomedical Engineering	X	X	X	
United States of America	High	Wayne State University	Detroit, Michigan	Biomedical Engineering	X	X	X	
United States of America	High	Western New England University	Springfield, Massachusetts	Biomedical Engineering	X	X		X
United States of America	High	Wichita State University	Wichita, Kansas	Biomedical Engineering	X			
United States of America	High	Worcester Polytechnic Institute	Worcester, Massachusetts	Biomedical Engineering	X	X	X	
United States of America	High	Wright State University	Dayton, Ohio	Biomedical Engineering	X	X		
United States of America	High	Wright State University	Dayton, Ohio	Medical and Biological Systems			X	
United States of America	High	Yale University	New Haven, Connecticut	Biomedical Engineering	X	X	X	
Uruguay	High	Universidad de la República Oriental del Uruguay	Montevideo	Biological Engineering				X
Venezuela (Bolivarian Republic of)	Upper middle	Universidad de los Andes	Mérida	Biomedical Engineering		X		
Venezuela (Bolivarian Republic of)	Upper middle	Universidad Experimental Francisco de Miranda	Táchira	Biomedical Engineering	X			
Venezuela (Bolivarian Republic of)	Upper middle	Universidad Simón Bolivar	Caracas	Biomedical Engineering		X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
South-East Asia Region								
Bangladesh	Low	Bangladesh University of Engineering and Technology	Dhaka					
Bangladesh	Low	University of Dhaka	Dhaka					
Bhutan	Lower middle	Royal Technical Institute						
Democratic People's Republic of Korea	Low	Pyongyang University of Science and Technology	Pyongyang					
India	Lower middle	Aarupadai Veedu Institute of Technology						
India	Lower middle	ACS College of Engineering	Bangalore					
India	Lower middle	Adesh Institute of Engineering and Technology						
India	Lower middle	Adhiyamaan College of Engineering						
India	Lower middle	All India Institute of Medical Sciences	New Delhi					
India	Lower middle	Alpha Institute of Engineering and Technology						
India	Lower middle	Anna University	Chennai					
India	Lower middle	Avinashilingam Deemed University for Women						
India	Lower middle	Avinashilingam Institute for Home Science and Higher Education for Women	Coimbatore					
India	Lower middle	Banaras Hindu University Institute of Technology	Varanasi					
India	Lower middle	Bapuji Institute of Engineering and Technology						
India	Lower middle	Bhagwant Institute of Technology for Women						
India	Lower middle	Bharath Institute of Science and Technology						
India	Lower middle	Bharati Vidyapeeths College of Engineering						

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
India	Lower middle	Bharat-Ratna Indira Gandhi College of Engineering						
India	Lower middle	BMS College of Engineering						
India	Lower middle	C.R. State College of Engineering, Murthal						
India	Lower middle	C.U. Shah College of Engineering and Technology						
India	Lower middle	College of Engineering						
India	Lower middle	College of Engineering and Technology	Bhubeneswar					
India	Lower middle	Dayanand Sagar College of Engineering						
India	Lower middle	Deenbandhu Chhotu Ram University of Science and Technology Murthal	Murthal					
India	Lower middle	Dhanlakshmi Srinivasan Engineering College Perambalur						
India	Lower middle	Dr Ambedkar Institute of Technology						
India	Lower middle	Dr B.R. Ambedkar Center for Biomedical Research	New Delhi					
India	Lower middle	Dr Bhausaheb Nandurkar College of Engineering						
India	Lower middle	Dronacharya College of Engineering						
India	Lower middle	Dwarkadas J. Sanghvi College of Engineering	Mumbai					
India	Lower middle	Eastern Academy of Science and Technology						
India	Lower middle	Gayatri Vidya Parishad College of Engineering for Women						
India	Lower middle	Godavari Institute of Engineering and Technology						

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
India	Lower middle	Gokaraju Rangaraju Institute of Engineering and Technology	Telengana					
India	Lower middle	Government Engineering College, Gandhinagar	Gandhinagar					
India	Lower middle	Gujarat University						
India	Lower middle	Guru Jambheshwar University						
India	Lower middle	Indian Institute of Technology, Bombay	Mumbai					
India	Lower middle	Indian Institute of Technology, Delhi	Delhi					
India	Lower middle	Indian Institute of Technology, Kharagpur	Kharagpur					
India	Lower middle	Indian Institute of Technology, Madras	Madras					
India	Lower middle	Institute of Engineering and Technology Bundelkhand University						
India	Lower middle	Institute of Technology, Banaras Hindu University						
India	Lower middle	J.B. Institute of Engineering and Technology						
India	Lower middle	Jadavpur University						
India	Lower middle	Jawaharlal Nehru Technological University	Telengana					
India	Lower middle	Jerusalem College of Engineering						
India	Lower middle	K.L.E. Society College of Engineering and Technology						
India	Lower middle	Karunya Deemed University						
India	Lower middle	Khaja Banda Nawaz College of Engineering						
India	Lower middle	L.D. Engineering College, Ahmedabad						
India	Lower middle	Mahatma Gandhi Mission College of Engineering and Technology						

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
India	Lower middle	Mahavir Institute of Engineering and Technology						
India	Lower middle	Manipal Institute of Technology						
India	Lower middle	Manipal University						
India	Lower middle	Model Engineering College						
India	Lower middle	Ms Ramaiah Institute of Technology						
India	Lower middle	Mvj College of Engineering						
India	Lower middle	Nagaji Institute of Technology and Management						
India	Lower middle	National Institute of Technology (N.I.T.)						
India	Lower middle	Netaji Subhash Engineering College	Kolkata					
India	Lower middle	Nimt Institute of Engineering and Technolgy Riico Industrial Area						
India	Lower middle	Noorul Islam College of Engineering						
India	Lower middle	Northern India Engineering College						
India	Lower middle	Odaiyappa College of Engineering and Technology Theni						
India	Lower middle	Osmania University						
India	Lower middle	P.D. Memorial College of Engineering						
India	Lower middle	P.S.G. College of Technology						
India	Lower middle	Padmashree Dr D.Y. Patil University						
India	Lower middle	Padmasri Dr B.V. Raju Institute of Technology						
India	Lower middle	P.D.M. College of Engineering						
India	Lower middle	P.S.N.A. College of Engineering and Technology						
India	Lower middle	Rajalakshmi Engineering College						

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
India	Lower middle	Rajiv Gandhi College of Engineering and Technology						
India	Lower middle	Rayat and Bahra Institute of Engineering and Bio-Technology						
India	Lower middle	Region of the Americasita School of Biotechnology						
India	Lower middle	Region of the Americasita University						
India	Lower middle	Sahrdaya College of Engineering and Technology						
India	Lower middle	Saroj Institute of Technology						
India	Lower middle	School of Chemical and Biotechnology						
India	Lower middle	Sengunthar College of Engineering for Women						
India	Lower middle	Shobhit University						
India	Lower middle	Shree Motilal Kanhaiyalal Fomra Institute of Technology						
India	Lower middle	Shri Govindram Seksaria Institute of Technology and Science						
India	Lower middle	Sree Chitra Tirunal Institute for Medical Sciences and Technology						
India	Lower middle	Sri Belimatha Mahasamasthana Institute of Technology						
India	Lower middle	Sri Krishna Institute of Technology						
India	Lower middle	Sri Ramakrishna Engineering College						
India	Lower middle	Sri Siddartha Institute of Technology						
India	Lower middle	Sri Sivasubramaniya Nadar College of Engineering						

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
India	Lower middle	St Ashok Technological Institute						
India	Lower middle	St. Peter's Engineering College						
India	Lower middle	Sun College of Engineering and Technology						
India	Lower middle	Thadomal Shahani Engineering College						
India	Lower middle	Thangal Kanju Musaliar Institute of Technology						
India	Lower middle	Trident Academy of Technology						
India	Lower middle	U.V. Patel College of Engineering						
India	Lower middle	Udaya School of Engineering						
India	Lower middle	University College of Engineering						
India	Lower middle	Velalar College of Engineering and Technology						
India	Lower middle	Veltech Multi Tech Dr Rangarajan Dr Sakunthala Engineering College						
India	Lower middle	Vidyalankar Institute of Technology						
India	Lower middle	Vinayaka Mission's Kirupananda Variyar Engineering College						
India	Lower middle	Watumal Institute of Electronics Engineering and Computer Technology						
India	Lower middle	Yadavrao Tasgonkar institute of Engineering and Technology						
Indonesia	Lower middle	Institut Teknologi Bandung	Bandung	Biomedical Engineering	X	X	X	
Indonesia	Lower middle	Universitas Indonesia	Jakarta	Biomedical Engineering		X		
Indonesia	Lower middle	Universitas Gadjah Mada	Yogyakarta	Biomedical Engineering		X		
Indonesia	Lower middle	Universitas Airlangga	Surabaya	Biomedical Engineering	X	X		
Indonesia	Lower middle	Institut Teknologi Sepuluh Nopember	Surabaya	Biomedical Engineering	X	X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Indonesia	Upper middle	Swiss-German University	Jakarta	Biomedical Engineering	X			
Thailand	Upper middle	Chiang Mai University	Chiang Mai					
Thailand	Upper middle	Chulalongkorn University						
Thailand	Upper middle	King Mongkut's University of Technology	Thonburi					
Thailand	Upper middle	Mahidol University	Salaya					
Thailand	Upper middle	Prince of Songkla University	Songkla					
Timor-Leste	Lower middle	National University of East Timor						
Western Pacific Region								
Australia	High	Flinders University of South Australia	Adelaide	Biomedical Engineering; Biomedical Engineering Technology	X	X		
Australia	High	Griffith University	Nathan QLD	Electronic and Biomedical Engineering; Sport and Biomedical Engineering	X	X	X	
Australia	High	La Trobe University	Melbourne	Biomedical Engineering		X	X	
Australia	High	Monash University	Clayton					
Australia	High	Murdoch University	Murdoch					
Australia	High	Queensland University of Technology	Brisbane	Medical Engineering and Information Technology; Medical Engineering and Mathematics	X			
Australia	High	RMIT University	Melbourne	Biomedical Engineering	X			
Australia	High	Swinburne University of Technology	Hawthorn	Biomedical Engineering	X			
Australia	High	University of Adelaide	Adelaide					
Australia	High	University of Melbourne	Parkville, Melbourne	Biomedical Engineering		X		
Australia	High	University of New South Wales	Sydney	Biomedical Engineering with or without Materials or Engineering Science	X	X	X	X
Australia	High	University of Sydney	Sydney	Biomedical Engineering	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	Academy of Military Medical Sciences	Beijing			X	X	
China	Upper middle	Anhui Medical University	Hefei		X	X	X	
China	Upper middle	Anhui University of Chinese	Hefei		X			
China	Upper middle	Anhui University of Science	Hefei			X	X	
China	Upper middle	Beijing Institute of Technology	Beijing		X	X	X	
China	Upper middle	Beijing Jiaotong University	Beijing		X	X	X	
China	Upper middle	Beijing Union University	Beijing		X			
China	Upper middle	Beijing University of Aeronautics and Astronautics	Beijing	Biomedical Engineering	X	X	X	
China	Upper middle	Beijing University of Aeronautics and Astronautics	Beijing		X	X	X	
China	Upper middle	Beijing University of Chemical Technology	Beijing	Biomedical Engineering	X	X	X	
China	Upper middle	Beijing University of Posts and Telecommunications	Chongqing			X	X	
China	Upper middle	Beijing University of Technology	Beijing	Biomedical Engineering	X	X	X	
China	Upper middle	Capital Medical University	Beijing	Biomedical Engineering	X	X	X	
China	Upper middle	Central South University	Changsha	Biomedical Engineering	X	X	X	
China	Upper middle	Changchun University of Science and Technology	Changchun		X	X	X	
China	Upper middle	Changzhi Medical College	Changzhi	Biomedical Engineering	X			
China	Upper middle	Chengde Medical University	Chengde		X			
China	Upper middle	Chengdu Medical College	Chengdu		X			
China	Upper middle	Chengdu University of Information Technology	Chengdu		X			
China	Upper middle	Chengdu University of TCM	Chengdu		X			
China	Upper middle	China Jiliang University	Hangzhou		X			
China	Upper middle	China Medical University	Shenyang	Biomedical Engineering	X	X		

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	China Medical University	Shenyang		X	X	X	
China	Upper middle	China Pharmaceutical University	Nanjing			X	X	
China	Upper middle	Chinese University of Hong Kong	Hong Kong	Biomedical Engineering	X	X	X	
China	Upper middle	Chongqing Medical University	Chongqing	Biomedical Engineering	X	X	X	
China	Upper middle	Chongqing University	Chongqing	Biomedical Engineering	X	X	X	
China	Upper middle	Chongqing University of Posts and Telecommunications	Chongqing		X	X	X	
China	Upper middle	Chongqing University of Technology	Chongqing	Biomedical Engineering	X	X		
China	Upper middle	Chung Yuan Christian University	Chung Li, Taiwan	Biomedical Engineering	X	X	X	
China	Upper middle	Dali University	Dali	Biomedical Engineering	X			
China	Upper middle	Dalian Medical University	Dalian		X			
China	Upper middle	Dalian Ocean University	Dalian	Biomedical Engineering	X	X		
China	Upper middle	Dalian University of Technology	Dalian		X	X	X	
China	Upper middle	Donghua University	Shanghai	Biomedical Engineering	X	X	X	
China	Upper middle	East China Normal University	Shanghai			X	X	
China	Upper middle	East China University of Science and Technology	Shanghai		X	X	X	
China	Upper middle	Fourth Military Medical University	Xian	Biomedical Engineering	X	X	X	
China	Upper middle	Fudan University	Shanghai	Biomedical Engineering	X	X	X	
China	Upper middle	Fujian Journal of Traditional Chinese Medicine	Fuzhou		X			
China	Upper middle	Fujian Normal University	Fuzhou			X	X	
China	Upper middle	Fuzhou University	Fuzhou			X	X	
China	Upper middle	Gannan Medical University	Ganzhou	Biomedical Engineering	X			
China	Upper middle	Guangdong Medical University	Guangzhou		X			
China	Upper middle	Guangdong Pharmaceutical University	Guangzhou		X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	Guangxi Medical University	Nanning		X	X	X	
China	Upper middle	Guangxi University of Chinese Medicine	Nanning		X			
China	Upper middle	Guangzhou Medical University	Guangzhou		X			
China	Upper middle	Guilin University of Electronic University	Guilin	Biomedical Engineering	X			
China	Upper middle	Guizhou Medical University	Guiyang	Biomedical Engineering	X			
China	Upper middle	Hangzhou Dianzi University	Hangzhou		X	X	X	
China	Upper middle	Harbin Institute of Technology	Harbin	Biomedical Engineering	X	X	X	
China	Upper middle	Harbin Medical University	Harbin	Biomedical Engineering	X	X	X	
China	Upper middle	He University	Shenyang		X			
China	Upper middle	Hebei University	Baoding		X			
China	Upper middle	Hebei University of Science	Shijiazhuang		X			
China	Upper middle	Hebei University of Technology	Tianjin		X	X		
China	Upper middle	Hebei University of Technology	Shijiazhuang		X			
China	Upper middle	Hefei University of Technology	Hefei	Biomedical Engineering	X			
China	Upper middle	Henan University of Science and Technology	Luoyang	Biomedical Engineering	X			
China	Upper middle	Huazhong University of Science and Technology	Wuhan	Biomedical Engineering	X	X	X	
China	Upper middle	Hubei University of Science and Technology	Xianning	Biomedical Engineering	X			
China	Upper middle	Hubei University of Technology	Wuhan		X			
China	Upper middle	Hunan University	Changsha	Biomedical Engineering	X	X	X	
China	Upper middle	Hunan University of Technology	Zhuzhou			X	X	
China	Upper middle	Inner Mongolia Medical University	Hohhot		X			
China	Upper middle	Jiamusi University	Jiamusi		X			
China	Upper middle	Jiangsu University	Zhenjiang	Biomedical Engineering	X	X	X	
China	Upper middle	Jiangxi University of Traditional Chinese Medicine	Nanchang	Biomedical Engineering	X			

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	Jilin Medical College	Jilin		X			
China	Upper middle	Jilin University	Changchun	Biomedical Engineering	X	X	X	
China	Upper middle	Jinan University	Guangzhou	Biomedical Engineering	X	X	X	X
China	Upper middle	Jinggangshan University	Ji'an	Biomedical Engineering	X			
China	Upper middle	Jining Medical University	Jining		X			
China	Upper middle	Kunming University of Science and Technology	Kunming	Biomedical Engineering	X			
China	Upper middle	Kunming University of Science and Technology	Kunming		X			
China	Upper middle	Lanzhou University	Lanzhou	Biomedical Engineering	X	X	X	
China	Upper middle	Macao Polytechnic Institute	Macau	Science in Biomedical Technology	X			
China	Upper middle	Medical School of Chinese PLA	Beijing	Biomedical Engineering	X	X		
China	Upper middle	Mudanjiang Medical University	Mudan-jiang		X			
China	Upper middle	Nanchang Hangkong University	Nanchang	Biomedical Engineering	X	X	X	
China	Upper middle	Nanchang University	Nanchang		X	X	X	
China	Upper middle	Nanjing Medical University	Nanjing		X	X	X	
China	Upper middle	Nanjing University	Nanjing	Biomedical Engineering	X	X	X	
China	Upper middle	Nanjing University of Aeronautics and Astronautics	Nanjing	Biomedical Engineering	X	X	X	
China	Upper middle	Nanjing University of Posts and Telecommunications	Nanjing	Biomedical Engineering	X			
China	Upper middle	Nanjing University of Science and Technology	Nanjing			X	X	
China	Upper middle	Nankai University	Tianjin	Biomedical Engineering	X	X		
China	Upper middle	Nantong University	Nantong		X	X	X	
China	Upper middle	National Cheng Kung University	Tainan, Taiwan	Biomechanics, Biomedical Electronics, Biomaterials, Medical information and Rehabilitation technologies	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	National Chiao Tung University	Hsinchu, Taiwan	Molecular Medicine and Bioengineering	X	X	X	
China	Upper middle	National Taiwan University	Taipei, Taiwan	Biomaterials, Biomechanical Engineering, Bioelectronics, Clinical Engineering, and Biomedical informatics	X	X	X	
China	Upper middle	National University of Defense Technology	Changsha			X	X	
China	Upper middle	North Sichuan Medical College	Chengdu		X			
China	Upper middle	North University of China	Taiyuan	Biomedical Engineering	X	X		
China	Upper middle	North University of China	Taiyuan		X	X	X	
China	Upper middle	Northeast Petroleum University	Daqin		X			
China	Upper middle	Northeastern University	Shenyang	Biomedical Engineering	X	X	X	
China	Upper middle	Northeastern University	Changchun		X	X	X	
China	Upper middle	Northwestern Polytechnical University	Xi'an	Biomedical Engineering	X	X	X	
China	Upper middle	Peking Union Medical College	Beijing	Biomedical Engineering	X	X	X	
China	Upper middle	Peking University	Beijing	Biomedical Engineering	X	X	X	
China	Upper middle	Putian University	Putian		X			
China	Upper middle	Qiqihar Medical University	Qiqihar		X			
China	Upper middle	Shaanxi Normal University	Xi'an			X	X	
China	Upper middle	Shandong University	Jinan	Biomedical Engineering	X	X		
China	Upper middle	Shandong University	Tsingtao		X	X	X	
China	Upper middle	Shandong University of Science and Technology	Qingdao		X			
China	Upper middle	Shandong University of Traditional Chinese Medicine	Jinan		X	X	X	
China	Upper middle	Shanghai Jiao Tong University	Shanghai	Biomedical Engineering	X	X	X	
China	Upper middle	Shanghai university	Shanghai	Biomedical Engineering	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	Shanghai University of medical and Health Science	Shanghai		X			
China	Upper middle	Shanghai University of Traditional Chinese Medicine	Shanghai		X			
China	Upper middle	Shenyang Pharmaceutical University	Shenyang	Biomedical Engineering	X			
China	Upper middle	Shenyang University of Technology	Shenyang	Biomedical Engineering	X	X	X	
China	Upper middle	Shenzhen University	Shenzhen		X	X	X	
China	Upper middle	Sichuan Agriculture University	Chengdu		X			
China	Upper middle	Sichuan Medical University	Chengdu		X			
China	Upper middle	Sichuan University	Chengdu	Biomedical Engineering	X	X	X	
China	Upper middle	Sichuan University of Science and Engineering	Zigong		X			
China	Upper middle	Soochow University	Soochow			X	X	
China	Upper middle	South China University of Technology	Guangzhou	Biomedical Engineering	X	X	X	
China	Upper middle	South University of Science and Technology of China	Shenzhen		X			
China	Upper middle	South-central University for Nationalities	Wuhan	Biomedical Engineering	X	X		
China	Upper middle	South-central University of Technology	Wuhan		X	X	X	
China	Upper middle	Southeast University	Nanjing	Biomedical Engineering	X	X	X	
China	Upper middle	Southern Medical University	Guangzhou	Biomedical Engineering	X	X	X	
China	Upper middle	Southwest Jiaotong University	Chengdu	Biomedical Engineering	X	X	X	
China	Upper middle	Southwest University of Science and Technology	Mianyang	Biomedical Engineering	X			
China	Upper middle	Sun Yat-sen University, SYSU	Guangzhou	Biomedical Engineering	X	X	X	
China	Upper middle	Taishan Medical University	Taishan		X			
China	Upper middle	Taiyuan University of Technology	Taiyuan	Biomedical Engineering	X	X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	The fourth Military Medical University	Xi'an		X	X	X	
China	Upper middle	The Hong Kong Polytechnic University	Hong Kong	Biomedical Engineering	X	X	X	
China	Upper middle	The Second Military Medical University	Shanghai	Biomedical Engineering	X	X		
China	Upper middle	The University of Macau	Macau	Biomedical Instrumentation Design; Biomedical Imaging; Bioinformatics	X	X	X	
China	Upper middle	Third Military Medical University	Chongqing	Biomedical Engineering	X	X	X	
China	Upper middle	Tianjin Medical University	Tianjin	Biomedical Engineering	X	X	X	
China	Upper middle	Tianjin Polytechnic University	Tianjin		X	X	X	
China	Upper middle	Tianjin University	Tianjin	Biomedical Engineering	X	X	X	
China	Upper middle	Tianjin University of Traditional Chinese Medicine	Tianjing			X	X	
China	Upper middle	Tongji University	Shanghai	Biomedical Engineering	X	X	X	
China	Upper middle	Tsinghua University	Beijing	Biomedical Engineering	X	X	X	
China	Upper middle	University of Chinese Academy of Sciences	Beijing			X	X	
China	Upper middle	University of Electronic Science and Technology of China	Chengdu	Biomedical Engineering	X	X	X	
China	Upper middle	University of Science and Technology of China	Hefei			X	X	
China	Upper middle	University of Shanghai for Science and Technology	Shanghai	Biomedical Engineering	X	X	X	
China	Upper middle	Wannan Medical College	Qianghu		X			
China	Upper middle	Weifang Medical University	Weifang		X			
China	Upper middle	Wenzhou Medical College	Wenzhou		X	X		
China	Upper middle	Wenzhou Medical University	Wenzhou	Biomedical Engineering	X	X		
China	Upper middle	Wuhan University	Wuhan	Biomedical Engineering	X	X		
China	Upper middle	Wuhan University of Technology	Wuhan			X	X	

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
China	Upper middle	Xi`an International University	Xi'an		X			
China	Upper middle	Xi`an Technological University	Xi'an		X			
China	Upper middle	Xi'an Jiaotong University	Xi'an	Biomedical Engineering	X	X	X	
China	Upper middle	Xiamen University	Xiamen	Biomedical Engineering	X	X		
China	Upper middle	Xi'an Jiaotong University	Xi'an		X	X	X	
China	Upper middle	Xidian University	Xi'an	Biomedical Engineering	X	X		
China	Upper middle	Xinxiang Medical University	Xinxiang	Biomedical Engineering	X	X	X	
China	Upper middle	Xuzhou Medical University	Xuzhou		X			
China	Upper middle	Yancheng Teachers University	Yancheng		X			
China	Upper middle	Yangtze Normal University	Chongqing		X			
China	Upper middle	Yanshan University	Qinhuangdao	Biomedical Engineering	X	X	X	
China	Upper middle	Yunnan University	Yunnan			X	X	
China	Upper middle	Zhejiang Chinese Medical University	Hangzhou		X			
China	Upper middle	Zhejiang Gongshang University	Hangzhou		X			
China	Upper middle	Zhejiang University	Hangzhou	Biomedical Engineering	X	X	X	
China	Upper middle	Zhejiang University of Technology	Hangzhou		X			
China	Upper middle	Zhengzhou University	Zhengzhou	Biomedical Engineering	X			
Japan	High	Chiba Institute of Science	Chiba					
Japan	High	Chubu University College of Medical Technology	Nagoya					
Japan	High	Fujita Health University	Toyoake					
Japan	High	Hokkaido Institute of Technology	Hokkaido					
Japan	High	Kanazawa University	Kanazawa					
Japan	High	Kawasaki University of Medical Welfare	Kurashiki					
Japan	High	Kitasato University	Sagamihara					

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Japan	High	Kumamoto Institute of General Medical Welfare	Kumamoto					
Japan	High	Kyoto College of Health and Hygiene	Kyoto					
Japan	High	Nagasaki Institute of Applied Sciences	Nagasaki					
Japan	High	Nippon Buri University Medical College	Oita					
Japan	High	Okayama University of Science	Okayama					
Japan	High	Osaka College of High Technology	Osaka					
Japan	High	Osaka Electro-Communication University	Osaka					
Japan	High	Ota College of Medical Technology	Ota					
Japan	High	Saitama Medical University	Saitama					
Japan	High	Suzuka University of Medical Science	Suzuka					
Japan	High	Tenri School of Medical Technology	Tenri					
Japan	Upper middle	Toin University of Yokohama	Yokohama					
Japan	High	Tokai University	Numazu					
Japan	High	University of East Asia	Shimonoseki					
Japan	High	Yomiuri Institute of Technology	Tokyo					
Malaysia	Upper middle	Cyberjaya University College of Medical Sciences	Selangor					
Malaysia	Upper middle	HELP University	Kuala Lumpur					
Malaysia	Upper middle	International Islamic University Malaysia (IIUM)	Kuala Lumpur					
Malaysia	Upper middle	MAHSA University	Kuala Lumpur					
Malaysia	Upper middle	Politeknik Shah Alam	Selangor					
Malaysia	Upper middle	Politeknik Sultan Salahuddin Abdul Aziz Shah	Selangor					
Malaysia	Upper middle	Universiti Malaysia Perlis	Perlis					
Malaysia	Upper middle	Universiti Putra Malaysia (UPM)	Selangor					

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Malaysia	Upper middle	Universiti Teknologi Malaysia (UTM)	Johor					
Malaysia	Upper middle	Universiti Teknologi PETRONAS (UTP)	Perak					
Malaysia	Upper middle	Universiti Tunku Abdul Rahman (UTAR)	Selangor					
Malaysia	Upper middle	University Kuala Lumpur - British Malaysian Institute						
Malaysia	Upper middle	University of Malaya	Kuala Lumpur	Biomedical Engineering	X	X		
Malaysia	Upper middle	University of Malaya	Kuala Lumpur	Biomedical Engineering (Prosthetics and Orthotics)	X			
Malaysia	Upper middle	University of Southampton (Malaysia Campus)	Iskandar Puteri, Johor					
Marshall Islands	Upper middle	Kolej Kemahiran Tinggi Mara Ledang (KKTM)	Ledang, Johor					
New Zealand	High	University of Auckland	Auckland	Biomedical Engineering	X			
New Zealand	High	University of Otago	Dunedin	Bioengineering		X		
Philippines	Lower middle	De La Salle University	Manila					
Republic of Korea	High	Hanyang University	Seoul					
Republic of Korea	High	Kyung Hee University	Wonju					
Republic of Korea	High	Sangji University	Seoul					
Republic of Korea	High	Seoul National University	Suwon					
Republic of Korea	High	Sungkyunkwan University	Seoul					
Singapore	High	Nanyang Polytechnic	Singapore	Biomedical Engineering				X
Singapore	High	National University of Singapore	Singapore	Biomedical Engineering	X			
Singapore	High	Ngee Ann Polytechnic	Singapore	Biomedical Engineering				X
Singapore	High	Republic Polytechnic	Singapore	Biomedical Electronics				X
Singapore	High	SIM University	Singapore	Biomedical Engineering	X			X
Singapore	High	Singapore Polytechnic	Singapore	Bioengineering				X

Country	Income group	Educational institution	City	Programme	Level			
					BSc	MSc	PhD	Other
Singapore	High	Temasek Polytechnic	Singapore	Biomedical Engineering				X
Viet Nam	Lower middle	International University of Vietnam National Universities	Ho Chi Minh City					

Annex 3 National and international professional biomedical engineering associations

Country	Name of society	Acronym	Reported number of members	Income grouping
African Region				
Burkina Faso	L'ASSOCIATION BURKINABE DES TECHNICIENS ET INGENIEURS BIOMEDICAUX	ATBIB	...	Low income
Burundi	ASSOCIATION BURUNDAISE DE L'INGENIERE BIOMEDICALE ET HOSPITALIERE	ABIB	...	Low income
Cameroon	CAMEROONIAN ASSOCIATION OF PROFESSIONAL BIOMEDICAL ENGINEERING	CAP-BME	...	Lower middle income
Côte d'Ivoire	SYNDICAT NATIONAL DES BIOMEDICAUX DE COTE D'IVOIRE	SYNABIOCI	...	Lower middle income
Democratic Republic of the Congo	ASSOCIATION DES INGENIEURS ET TECHNICIENS BIOMEDICAUX		...	Low income
Ethiopia	ETHIOPIAN BIOMEDICAL ENGINEERING ASSOCIATION	EBEA	80	Low income
Gambia (The)	GAMBIA BIOMEDICAL ENGINEERING TECHNOLOGISTS ASSOCIATION	GAMbeta	...	Low income
Ghana	GHANA SOCIETY OF BIOMEDICAL ENGINEERS		...	Lower middle income
Kenya	ASSOCIATION OF MEDICAL ENGINEERING OF KENYA	AMEK	...	Lower middle income
Nigeria	NIGERIAN INSTITUTE FOR BIOMEDICAL ENGINEERING	NIBE	...	Lower middle income
Rwanda	RWANDA MEDICAL ENGINEERING ASSOCIATION	RMEA		Low income
South Africa	BIOMEDICAL ENGINEERING SOCIETY OF SOUTH AFRICA	...	...	Upper middle income
South Africa	CLINICAL ENGINEERING ASSOCIATION SOUTH AFRICA	CEASA	...	Upper middle income
Uganda	UGANDA NATIONAL ASSOCIATION FOR MEDICAL AND HOSPITAL ENGINEERING	UNAMHE	49	Low income
United Republic of Tanzania	ASSOCIATION OF MEDICAL ENGINEERS AND TECHNICIANS TANZANIA	AMETT		Low income
Zambia	BIOMEDICAL ENGINEERING ASSOCIATION ZAMBIA			Lower middle income
Eastern Mediterranean Region				
Iran (Islamic Republic of)	IRANIAN SOCIETY FOR BIOMEDICAL ENGINEERING	ISBME	...	Upper middle income
Jordan	JORDAN BIOMEDICAL ENGINEERING SOCIETY	JBMES	...	Upper middle income

Source: January 2015 Global Survey - Professional and Academic Profiles on Biomedical Engineers and Technicians, WHO.

Country	Name of society	Acronym	Reported number of members	Income grouping
Kuwait	KUWAIT ASSOCIATION OF BIOMEDICAL ENGINEERS	KABME	...	High income
Libya	LIBYAN SOCIETY OF BIOMEDICAL ENGINEERS	LSBE	...	Upper middle income
Saudi Arabia	SAUDI SCIENTIFIC SOCIETY FOR BIOMEDICAL ENGINEERING	SSSBE	300	High income
United Arab Emirates	SOCIETY OF ENGINEERS UNITED ARAB EMIRATES	SOEUAE	...	High income
European Region				
Austria	AUSTRIAN SOCIETY FOR BIOMEDICAL ENGINEERING	OEGBMT	...	High income
Belgium	BELGIAN SOCIETY FOR MEDICAL AND BIOLOGICAL ENGEINEERING AND COMPUTING	...	...	High income
Bulgaria	BULGARIAN SOCIETY OF BIOMEDICAL PHYSICS & ENGINEERING	BSBPE	28	Upper middle income
Croatia	CROATIAN MEDICAL & BIOLOGICAL ENGINEERING SOCIETY	CROMBES	136	High income
Cyprus	CYPRUS ASSOCIATION OF MEDICAL PHYSICS & BIOMEDICAL ENGINEERING	CAMPBE	...	High income
Czech Republic	CZECH SOCIETY FOR BIOMEDICAL ENGINEERING & MEDICAL INFORMATICS	SBMILI	...	High income
Denmark	DANISH SOCIETY FOR BIOMEDICAL ENGINEERING	DMTS	...	High income
Estonia	ESTONIAN SOCIETY FOR BIOMEDICAL ENGINEERING & MEDICAL PHYSICS	...	...	High income
Finland	FINNISH SOCIETY FOR MEDICAL PHYSICS & BIOMEDICAL ENGINEERING	...	...	High income
France	SOCIETE DES ELECTRICIEN ET DES ELECTRONICIENS	...	...	High income
France	SOCIETE FRANCAISE DE GENIE BIOLOGIQUE ET MEDICAL	SFGBM	...	High income
Germany	DEUTSCHE GESELLSCHAFT FUR BIOMEDIZINISCHE TECHNIK E.V.	DGBMT	...	High income
Greece	GREEK SOCIETY FOR BIOMEDICAL ENGINEERING	...	...	High income
Hungary	SOCIETY OF MEASUREMENT & AUTOMATION SECTION BIOMEDICAL ENGINEERING	...	...	Upper middle income
Iceland	ICELANDIC SOCIETY FOR BIOMEDICAL ENGINEERING	...	...	High income
Ireland	BIOMEDICAL ENGINEERING ASSOCIATION OF IRELAND	BEAI	...	High income
Israel	ISRAEL SOCIETY FOR MEDICAL & BIOLOGICAL ENGINEERING	ISMBE	...	High income
Italy	ASSOCIAZIONE ITALIANA DI INGEGNARIA MEDICA E BIOLOGICA	AIIMB	...	High income
Italy	ITALIAN ASSOCIATION OF CLINICAL ENGINEERS	AIIC	1366	High income
Latvia	LATVIAN MEDICAL ENGINEERING AND PHYSICS SOCIETY	...	...	High income

Country	Name of society	Acronym	Reported number of members	Income grouping
Lithuania	LITHUANIAN SOCIETY FOR BIOMEDICAL ENGINERING	LBID	...	High income
Montenegro	THE SOCIETY OF BIOMEDICAL ENGINEERING AND MEDICAL PHYSICS, SERBIA AND MONTENEGRO	...	...	Upper middle income
Netherlands	THE NETHERLANDS SOCIETY FOR BIOPHYSICS AND BIOMEDICAL TECHNOLOGY	BIOPM	...	High income
Norway	NORWEGIAN SOCIETY FOR BIOMEDICAL ENGINEERING	...	...	High income
Poland	POLISH SOCIETY FOR BIOMEDICAL ENGINEERING	PTIB	...	High income
Poland	POLISH SCIENTIFIC AND TECHNICAL COMMITTEE FOR BIOMEDICAL ENGINEERING OF SEP	...	...	High income
Portugal	SOCIEDADE PORTUGUESA DE EGENHARIA BIOMEDICA	SPEB	65	High income
Romania	SOCIETATEA NATIONALA DE INGINERIE MEDICALA SI TECHNOLOGIE BIOLOGICA	SNIMTB	...	Upper middle income
Slovakia	SLOVAK SOCIETY OF BIOMEDICAL ENGINEERING AND MEDICAL INFORMATICS	SBIMI	...	High income
Slovenia	SLOVENE SOCIETY FOR MEDICAL & BIOLOGICAL ENGINEERING	DMBTS	...	High income
Spain	SPANISH SOCIETY OF BIOMEDICAL ENGINEERING	SEIB	...	High income
Sweden	SWEDISH SOCIETY FOR MEDICAL ENGINEERING & PHYSICS	MTF	...	High income
Switzerland	SWISS SOCIETY FOR BIOMEDICAL ENGINEERING	SSBE	...	High income
Turkey	BIOMEDICAL ENGINEERS ASSOCIATION	BIYOMED	95	Upper middle income
Ukraine	INSTITUTE OF MEDICAL ENGINEERING AND CLINICS	...	...	Lower middle income
United Kingdom	INSTITUTION OF PHYSICS AND ENGINEERING IN MEDICINE	IPEM	...	High income
Region of the Americas				
Argentina	SOCIEDAD ARGENTINA DE BIOINGENIERA	SABI	...	Upper middle income
Brazil	SOCIEDADE BRASILEIRA DE ENGENHARIA BIOMÉDICA	SBEB	250	Upper middle income
Canada	CANADIAN MEDICAL & BIOLOGICAL ENGINEERING SOCIETY	CMBES	...	High income
Chile	SOCIEDAD CHILENA DE INGENIERIA BIOMEDICA	SOCHIB	65	Upper middle income
Colombia	COLOMBIAN ASSOCIATION OF BIOENGINEERING AND MEDICAL ELECTRONICS	...	...	Upper middle income
Costa Rica	ASOCIACION COSTARRICENSE DE BIOINGENIERIA Y ELECTROMEDICINA	ACOBEM	...	Upper middle income
Cuba	SOCIEDAD CUBANA DE BIOINGENIERIA	SOCBIO	...	Upper middle income

Country	Name of society	Acronym	Reported number of members	Income grouping
Mexico	COLEGIO DE INGENIEROS BIOMEDICOS	CIB	105	Upper middle income
Mexico	SOCIEDAD MEXICANA DE INGENIERÍA BIOMÉDICA	SOMIB	...	Upper middle income
Peru	ASOCIACION PERUANA DE BIOINGENERIA	APBIO	...	Upper middle income
United Republic of Tanzania	ASSOCIATION OF MEDICAL ENGINEERS AND TECHNICIANS TANZANIA	AMETT	...	Low income
United States of America	AMERICAN INSTITUTE FOR MEDICAL & BIOLOGICAL ENGINEERING	AIMBE	...	High income
Venezuela (Bolivarian Republic of)	BIOENGINEERING VENEZUELAN SOCIETY	SOVEB	...	Upper middle income
South-East Asia Region				
India	BIOMEDICAL ENGINEERING SOCIETY OF INDIA	BMESI	...	Lower middle income
Western Pacific Region				
Australia	AUSTRALIAN FEDERATION FOR MEDICAL & BIOLOGICAL ENGINEERING	SMBE	...	High income
Australia	COLLEGE OF BIOMEDICAL ENGINEERS, ENGINEERS AUSTRALIA	...	...	High income
China	CHINESE SOCIETY FOR BIOMEDICAL ENGINEERING	CSBME	...	Upper middle income
China	MACAU SOCIETY OF BIOMEDICAL ENGINEERING	...	...	Upper middle income
China	HONG KONG INSTITUTION OF ENGINEERS	HKIE	...	Upper middle income
China	TAIWANESE SOCIETY OF BIOMEDICAL ENGINEERING	BMES	660	Upper middle income
Japan	JAPAN SOCIETY OF MEDICAL & BIOLOGICAL ENGINEERING	JSMBE	...	High income
Japan	JAPAN ASSOCIATION FOR CLINICAL ENGINEERS	JACE	15719	High income
Malaysia	MALAYSIAN SOCIETY OF MEDICAL AND BIOLOGICAL ENGINEERING	MSMBE	...	Upper middle income
Malaysia	MALAYSIA MEDICAL DEVICE ASSOCIATION	MMDA	...	Upper middle income
Malaysia	ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES	AMMI	...	Upper middle income
Malaysia	BIOMEDICAL ENGINEERING ASSOCIATION MALAYSIA	BEAM	...	Upper middle income
Malaysia	ASSOCIATION OF PRIVATE HOSPITALS OF MALAYSIA	APHM	...	Upper middle income
Malaysia	FEDERATION OF MALAYSIA MANUFACTURERS	FMM	...	Upper middle income
Mongolia	MONGOLIAN SOCIETY OF BIOMEDICAL ENGINEERING	...	...	Lower middle income
Republic of Korea	KOREAN SOCIETY OF MEDICAL & BIOLOGICAL ENGINEERING	KOSOMBE	...	High income

Country	Name of society	Acronym	Reported number of members	Income grouping
Singapore	BIOMEDICAL ENGINEERING SOCIETY (SINGAPORE)	BES	...	High income
International societies (includes national societies with international membership)				
International	AMERICAN COLLEGE OF CLINICAL ENGINEERING	ACCE	300	N/A
International	COMMISSION FOR THE ADVANCEMENT OF HEALTHCARE TECHNOLOGY MANAGEMENT IN ASIA	CAHTMA	28	N/A
International	EUROPEAN ALLIANCE FOR MEDICAL AND BIOLOGICAL ENGINEERING & SCIENCE	EAMBES	8000	N/A
International	EUROPEAN SOCIETY FOR ENGINEERING AND MEDICINE	ESEM	...	N/A
International	IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY	EMBS	10000	N/A
International	INTERNATIONAL COUNCIL ON MEDICAL AND CARE COMPUNETICS	ICMCC	...	N/A
International	INTERNATIONAL FEDERATION FOR MEDICAL AND BIOLOGICAL ENGINEERING	IFMBE	27538	N/A
International	INTERNATIONAL UNION FOR PHYSICAL AND ENGINEERING SCIENCES IN MEDICINE	IUPESM	40000	N/A
International	ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION	AAMI	7000	N/A
International	AUSTRALASIAN COLLEGE OF PHYSICAL SCIENTISTS AND ENGINEERS IN MEDICINE	ACPSEM	649	N/A
International	ASSOCIATION FRANCOPHONE DES PROFESSIONNELS DE TECHNOLOGIES DE SANTE©	AFPTS-RD CONGO	20	N/A

Annex 4 Survey respondents

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Toronto, Canada (Centre for Global eHealth Innovation, Toronto General Hospital)	Tony Easty
Osteba, Osasun Teknologien Ebaluazioaren Zerbitzua/ Basque Office for HTA	Iñaki Gutiérrez-Ibarluzea
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CEDIT, Comité d´Evaluation et de Diffusion des Innovations Technologiques, France	Alexandre Barna
IETS – Instituto de Evaluación Tecnológica en Salud, Colombia	Aurelio Mejía
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CGATS Departamento de Ciência e Tecnologia, Brazil	Eduardo Coura Assis (translated from Portuguese)
ASERNIP-S – Australian Safety and Efficacy Register of New Interventional Procedures – Surgical	Alun Cameron, Senior Research Officer
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Annex 5 Global Strategy on Human Resources for Health: Workforce 2030 – summary

Vision

Accelerate progress towards universal health coverage and the UN Sustainable Development Goals by ensuring equitable access to health workers within strengthened health systems.

Overall goal

To improve health, social and economic development outcomes by ensuring universal availability, accessibility, acceptability, coverage and quality of the health workforce through adequate investments to strengthen health systems, and the implementation of effective policies at national, a regional and global levels.

Principles

- Promote the right to the enjoyment of the highest attainable standard of health.
- Provide integrated, people-centred health services devoid of stigma and discrimination.
- Foster empowered and engaged communities.
- Uphold the personal, employment and professional rights of all health workers, including safe and decent working environments and freedom from all kinds of discrimination, coercion and violence.
- Eliminate gender-based violence, discrimination and harassment.
- Promote international collaboration and solidarity in alignment with national priorities.
- Ensure ethical recruitment practices in conformity with the provisions of the WHO Global Code of Practice on the International Recruitment of Health Personnel.
- Mobilize and sustain political and financial commitment and foster inclusiveness and collaboration across sectors and constituencies.
- Promote innovation and the use of evidence.

Objectives

1. To optimize performance, quality and impact of the health workforce through evidence informed policies on human resources for health, contributing to healthy lives and well-being, effective universal health coverage, resilience and strengthened health systems at all levels.
2. To align investment in human resources for health with the current and future needs of the population and of health systems, taking account of labour market dynamics and education policies; to address shortages and improve distribution of health workers, so as to enable maximum improvements in health outcomes, social welfare, employment creation and economic growth.
3. To build the capacity of institutions at sub-national, national, regional and global levels for effective public policy stewardship, leadership and governance of actions on human resources for health.

4. To strengthen data on human resources for health, for monitoring and ensuring accountability for the implementation of national and regional strategies, and the Global Strategy.

Global milestones (by 2020)

- All countries have inclusive institutional mechanisms in place to coordinate an intersectoral health workforce agenda.
- All countries have a human resources for health unit with responsibility for development and monitoring of policies and plans.
- All countries have regulatory mechanisms to promote patient safety and adequate oversight of the private sector.
- All countries have established accreditation mechanisms for health training institutions.
- All countries are making progress on health workforce registries to track health workforce stock, education, distribution, flows, demand, capacity and remuneration.
- All countries are making progress on sharing data on human resources for health through national health workforce accounts and submit core indicators to the WHO Secretariat annually.
- All bilateral and multilateral agencies are strengthening health workforce assessment and information exchange.

Global milestones (by 2030)

- All countries are making progress towards halving inequalities in access to a health worker.
- All countries are making progress towards improving the course completion rates in medical, nursing and allied health professionals training institutions.
- All countries are making progress towards halving their dependency on foreign-trained health professionals, implementing the WHO Global Code of Practice.
- All bilateral and multilateral agencies are increasing synergies in official development assistance for education, employment, gender and health, in support of national health employment and economic growth priorities.
- As partners in the UN Sustainable Development Goals, to reduce barriers in access to health services by working to create, fill and sustain at least 10 million additional full-time jobs in health- and social care sectors to address the needs of underserved populations.
- As partners in the United Nations Sustainable Development Goals, to make progress on Goal 3c to increase health financing and the recruitment, development, training and retention of the health workforce.

Core WHO secretariat activities in support of implementation of the Global Strategy on Human Resources for Health: Workforce 2030

Develop normative guidance; set the agenda for operations research to identify evidence-based policy options; facilitate the sharing of best practices; and provide technical cooperation on – health workforce education, optimizing the scope of practice of different cadres, evidence-based deployment and retention strategies, gender mainstreaming, availability, accessibility, acceptability, coverage, quality control and performance enhancement approaches, including the strengthening of public regulation.

Provide normative guidance and technical cooperation, and facilitate the sharing of best practices on health workforce planning and projections, health system needs, education policies, health labour market analyses, and costing of national strategies on human resources for health. Strengthen evidence on, and the adoption of, macroeconomic and funding policies conducive to greater and more strategically targeted investments in human resources for health.

Provide technical cooperation and capacity building to develop core competency in policy, planning and management of human resources for health focused on health system needs. Foster effective coordination, alignment and accountability of the global agenda on human resources for health by facilitating a network of international stakeholders. Systematically assess the health workforce implications resulting from technical or policy recommendations presented at the World Health Assembly and regional committees. Provide technical cooperation to develop health system capacities and workforce competency, including to manage the risks of emergencies and disasters.

Review the utility of, and support the development, strengthening and update of tools, guidelines and databases relating to data and evidence on human resources for health for routine and emergency settings. Facilitate yearly reporting by countries to the WHO Secretariat on a minimum set of core indicators of human resources for health, for monitoring and accountability for the Global Strategy. Support countries to establish and strengthen a standard for the quality and completeness of national health workforce data. Streamline and integrate all requirements for reporting on human resources for health by WHO Member States. Adapt, integrate and link the monitoring of targets in the Global Strategy to the emerging accountability framework of the UN Sustainable Development Goals. Develop mechanisms to enable collection of data to prepare and submit a report on the protection of health workers, which compiles and analyses the experiences of Member States and presents recommendations for action to be taken by relevant stakeholders, including appropriate preventive measures.

For further information, see: http://apps.who.int/iris/bitstream/10665/250368/1/9789 241511131-eng.pdf?ua=1

Annex 6 UN High-Level Commission on Health Employment and Economic Growth

10 recommendations to strengthen health and social protection systems and to meet the targets of the SDGs

1. JOB CREATION
Stimulate investments in creating decent health sector jobs, particularly for women and youth, with the right skills, in the right numbers and in the right places.

2. GENDER AND WOMEN'S RIGHTS
Maximize women's economic participation and foster their empowerment through institutionalizing their leadership, addressing gender biases and inequities in education and the health labour market, and tackling gender concerns in health reform processes.

3. EDUCATION, TRAINING AND SKILLS
Scale up transformative, high-quality education and lifelong learning so that all health workers have skills that match the health needs of populations and can work to their full potential.

4. HEALTH SERVICE DELIVERY AND ORGANIZATION
Reform service models concentrated on hospital care and focus instead on prevention and on the efficient provision of high-quality, affordable, integrated, community-based, people-centred primary and ambulatory care, paying special attention to underserved areas.

5. TECHNOLOGY
Harness the power of cost-effective information and communication technologies to enhance health education, people-centred health services and health information system

6. CRISES AND HUMANITARIAN SETTINGS
Ensure investment in the International Health Regulations core capacities, including skills development of national and international health workers in humanitarian settings and public health emergencies, both acute and protracted. Ensure the protection and security of all health workers and health facilities in all settings.

7. FINANCING AND FISCAL SPACE
Raise adequate funding from domestic and international sources, public and private where appropriate, and consider broad-based health financing reform where needed, to invest in the right skills, decent working conditions and an appropriate number of health workers.

8. PARTNERSHIP AND COOPERATION
Promote intersectoral collaboration at national, regional and international levels; engage civil society, unions and other health workers' organizations and the private sector; and align international cooperation to support investments in the health workforce, as part of national health and education strategies and plans.

9. INTERNATIONAL MIGRATION
Advance international recognition of health workers' qualifications to optimize skills use, increase the benefits from and reduce the negative effects of health worker migration, and safeguard migrants' rights.

10. DATA, INFORMATION AND ACCOUNTABILITY
Undertake robust research and analysis of health labour markets, using harmonized metrics and methodologies, to strengthen evidence, accountability and action.

Annex 7 Current and proposed profiles for biomedical engineers and biomedical engineering technicians (*206*)

Current profile for biomedical engineers	Proposed profile for biomedical engineers
ISCO 08 Code Unit group 2149 Engineering professionals not elsewhere classified This unit group covers engineering professionals not classified elsewhere in Minor group 214, Engineering Professionals (excluding electrotechnology) and 215: Electrotechnology engineers. For instance, the group includes those who conduct research, advise on or develop engineering procedures and solutions concerning workplace safety, biomedical engineering; optics; materials; nuclear power generation and explosives. In such cases tasks would include: a) applying knowledge of engineering to the design, development, and evaluation of biological and health systems and products, such as artificial organs, prostheses, and instrumentation; b) designing devices used in various medical procedures, imaging systems such as magnetic resonance imaging (MRI), and devices for automating insulin injections or controlling body functions; c designing components of optical instruments such as lenses, microscopes, telescopes, lasers, optical disc systems and other equipment that utilize the properties of light; d) designing, testing, and coordinating the development of explosive ordnance material to meet military procurement specifications; e) designing and overseeing construction and operation of nuclear reactors and power plants and nuclear fuels reprocessing and reclamation systems; f) designing and developing nuclear equipment such as reactor cores, radiation shielding, and associated instrumentation and control mechanisms; g) assessing damage and providing calculations for marine salvage operations; h) studying and advising on engineering aspects of particular manufacturing processes, such as those related to glass, ceramics, textiles, leather products, wood, and printing; i) identifying potential hazards and introducing safety procedures and devices. **Included occupations** Examples of the occupations classified here: - Biomedical engineer - Explosive ordnance engineer	ISCO 08 Code Unit group NEW NUMBER Biomedical engineers This unit group covers engineering professionals that apply knowledge of engineering and medical field to health-care systems to optimize and promote safer, higher quality, effective, affordable, accessible, appropriate, available, and socially acceptable health technology to populations. In such cases tasks would include: a) Conducting research, advise or development of medical devices for prevention, diagnosis, treatment, rehabilitation and palliative care across all levels of the health-care delivery; b) Innovating, designing, developing, regulating, managing, assessing, installing, and maintaining such medical devices or health technologies. c) Applying engineering principles and design concepts to medicine and biology for the pursuit of new knowledge and understanding at all biological scales; d) Designing medical devices, software, processes and techniques to be used in health care, including consumables, artificial organs, diagnostic and therapeutic instrumentation and related systems such as magnetic resonance imaging, and devices for automating insulin injections or controlling body functions; e) Designing, developing, evaluating and managing technologies used to promote and support life quality and longevity, including assistive products and technologies for monitoring or rehabilitating activities of daily living; such as wheelchairs, prosthesis leg, hearing aid and personal emergency response systems; f) Designing, developing and managing medical technologies for focus disease areas such as reproductive, maternal, neonatal and child health; infectious and noncommunicable diseases; g) Designing, developing and managing systems for optimal sustained healthcare operations in both resource-scarce and well-resourced settings as well as during challenging events such as disasters and emergencies; h) Designing, developing and applying safety programme methodologies to mitigate risks when dealing with medical devices throughout their life cycle. Including biosafety, patient and health-care worker safety and personal protection;

- Marine salvage engineer - Materials engineer - Optical engineer - Safety engineer **Excluded occupations** Some related occupations classified elsewhere: - Industrial and production engineer - 2141 - Environmental engineer - 2143 - Surveyor - 2165 Note: it should be noted that, while they are appropriately classified in this unit group with other engineering professionals, biomedical engineers are considered to be an integral part of the health workforce alongside those occupations classified in Sub-major Group 22: Health Professionals, and others classified in a number of other unit groups in Major Group 2: professionals.	i) Supporting and training health-care workers on the appropriate and safe use of medical technologies; j) supporting the design of health-care facilities. Examples of the occupations classified here: - Biomedical engineer - Electro medical engineer - Clinical engineer - Medical engineer **Excluded occupations** Some related occupations classified elsewhere: - Industrial and production engineer - 2141 - Environmental engineer - 2143 - Surveyor - 2165 Note: it should be noted that, while they are appropriately classified in this unit group with other engineering professionals, biomedical engineers are considered to be an integral part of the health workforce alongside those occupations classified in Sub-major Group 22: Health Professionals, and others classified in a number of other unit groups in Major Group 2: professionals.
Current profile for ILO for biomedical engineering technician	**Proposed profile for ILO for biomedical engineering technician**
Unit Group 3119. Physical and engineering science technicians not elsewhere classified (considering information from Unit Group 3111 to 3119).	Unit Group 311X Biomedical engineering technicians Biomedical engineering science technicians perform technical tasks to aid in research, design, manufacture, assembly, operation, maintenance and repair of medical equipment, and in the development of medical applications of research results; Organizing maintenance and performing repairs of medical equipment; Assisting engineers in testing, designing and maintaining medical equipment; Preparing and revising technical manuals dealing with assembly, installation, operation, maintenance and repair of medical equipment that has electronic, optical or mechanical components; Assisting biomedical engineers and monitoring technical aspects of manufacturing, use, maintenance and repair or mechanical, optical or electronic equipment used for patient care; Assisting health-care workers in the appropriate use of medical technologies.

Annex 8 Declaration of interests

All collaborators provided conflict of interest statements, which were reviewed in accordance with WHO requirements. The declared interests are listed in the table below.

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7. http://www.who.int/medical_devices/publications/med_dev_donations/en/
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